National Nuclear Security Administration

Department of Energy
National Nuclear Security Administration
Service Center
P. O. Box 5400
Albuquerque, NM 87185

AUG - 2 2007

CERTIFIED MAIL – RESTRICTED DELIVERY – RETURN RECEIPT REQUESTED

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

Dear Mr. Hammond:

This is in final response to your Freedom of Information Act (FOIA) request dated March 14, 2006 for a copy of ***"all minutes of all meetings of the Lawrence Livermore National Laboratory (LLNL) Institutional Biosafety Committee (IBC) since 1 May 2003."***

I contacted the Livermore Site Office who has oversight for the LLNL. LLNL conducted a search for the records you requested and they are enclosed. Please note that information has been removed from portions of these documents, pursuant to Title 5, United States Code, Section 552(b)(2)(Exemption 2 of the FOIA) and (b)(6)(Exemption 6 of the FOIA).

Exemption 2 of the FOIA protects information "related solely to the internal personnel rules and practices of an agency." The courts have interpreted the exemption to encompass two distinct categories of information: 1) internal matters of a relatively trivial nature, often referred to as "low 2" information; and 2) more substantial internal matters, such as critical infrastructure information, the disclosure of which would risk either circumvention of a legal requirement or disruption of a critical operation/activity—often referred to as "high 2" information. As described below, portions of the document are being withheld pursuant to Exemption "high 2."

The Exemption 2 information that was deleted from these documents pertains to infrastructure information. It is believed that if any of the information described above was released, it could benefit adversaries by helping them identify possible program impacts and vulnerabilities, as well as provide them the opportunity to target these facilities. This information is predominantly internal and has not been released to the public. Disclosure of this information could possibly expose this department, as well as other departments/organizations, to a "significant risk of circumvention of agency regulations or statutes."

The purpose of Exemption 6 is to protect "individuals from the injury and embarrassment that can result from the unnecessary disclosure of personal information." To determine whether disclosure would constitute a clearly unwarranted invasion of personal privacy, the public interest in disclosure, if any, must be balanced against the privacy interests that would be invaded by disclosure of the information.

Release of this information pertaining to personalities within the intelligence community will cause inevitable harassment and unwarranted solicitation. Since its release will not reveal anything of significance to the public, the interest in protecting against the invasion of privacy, which would result to the individuals in question, far outweighs the public interest in such disclosure.

The Department of Energy (DOE) regulations provide that documents exempt from mandatory disclosure under the FOIA shall be released regardless of their exempt status, unless the DOE determines that disclosure is contrary to public interest. For the reasons described above, I have determined that release of the information described above is not in the public interest.

Pursuant to 10 CFR, Section 1004.7(b)(2), Ms. Tracy Loughead is the individual responsible for the withholding of information pursuant to Exemptions 2 and 6 of the FOIA.

Pursuant to 10 CFR, Section 1004.8, the denial of a FOIA request may be appealed, in writing, within 30 days after receipt of a letter denying any portion of the request, to the Director, Office of Hearings and Appeals, Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585. The written appeal, including envelope, must clearly indicate that a Freedom of Information appeal is being made, and the appeal must contain all other elements required by 10 CFR, Section 1004.8. Judicial review will thereafter be available to you in the District of Columbia or in the district where: (1) you reside, (2) you have your principal place of business, or (3) the Department's records are situated.

There are no charges to you as the charges are within the amount you receive free – two hours or search and 100 pages.

If you have any questions, please contact Ms. Shirley L. Peterson by telephone at (505) 845-6393, by email at speterson@doeal.gov, or write to the address on the first page. Please reference Control Number FOIA 06-048-P in your communication.

Sincerely,

Carolyn A. Becknell
Freedom of Information Act Officer
Office of Public Affairs

Tracy Loughead
Manager
Office of Public Affairs
Denying Official

Enclosures

University of California
Lawrence Livermore
National Laboratory

Institutional Biosafety Committee
Biology and Biotechnology Research Program
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June 10, 2003

IBC Meeting Minutes
June 10, 2003– 10:30am
Building 361, Room 1155

Attendees:
IBC Members:
Nancy Wrigley (IBC Secretary), Mort Mendelsohn (Chair), Emilio Garcia, Al Jin, Patsy Gilbert, Tricia DiFalco, Alan Casamajor, Rod Balhorn (Co-Chair), Karolyn Burkhart-Schultz, Kris Montgomery, Bree Klotter (Staff)
Guests:
Starlyne Thompson, Christine Little, Maurice Pitesky, Rick Kelly

I.Announcements/Administrative

Bree Klotter is now on-board to help write an IBC Charter and work on developing an IBC website, including guidelines and updating of application forms.

II. Old Business

February minutes were approved on a motion by Al Jin seconded by Alan Casamajor .

Emilio Garcia still does not have a room to do his work. A meeting is scheduled tomorrow with Bert Weinstein (AD for BBRP)to decide. Meanwhile, Emilio's applications to IBC are on hold until decision(s) are made.

RENEWALS:
Christa Prange, IBC 95-004B. Integrated Molecular Analysis of Gene Expression (IMAGE) Consortium.
Turteltaub, IBC 2001-01, · Exemption 2 in cattle: Determination of the median lethal dose for cattle and the detection of the toxin in milk by standard techniques, with a change of PI to Karen Dingley...

Since the last meeting, Kimothy Smith, Mary McBride, Sandy McCutchen-Maloney and Rich Langlois's applications have been amended and approved.

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III.Review of New Applications:

Maurice Pitesky: Mass spectral signature development of avirulent *Mycobacterium tuberculosis* (H37Ra) using bio aerosol mass spectrometry (BAMS)

Discussion

Kathleen Noonan raised concerns about protective health measures for our employees. She was reassured by the actions already advised by Bill Pereira for this project. She requested that in general it would help greatly to modify the standard form covering the agreement of the PI so that it included following medical requirements. In this case, the application should also indicate that after the trip to Cincinnati, everyone needs to go back through Health Services to be checked out (within 3 months).

(Where it is written that the PI is to be responsible for training, Kathleen would like to have it state 'and medical requirements'.)

An offsite IWS needs to be submitted, according to Rick Kelly.

Alan Casamajor motioned to accept the application pending the above changes. Karolyn Burkhart-Schultz seconds the motion. All approve.

Pamala Coker: Isolation of Exemption 2 from environmental samples.

Discussion

Environmental samples (soil, hay, wood) previously collected by Pamala were shipped here from Louisiana where she previously worked. They were shipped with the proper precautions according to Patsy Gilbert.

For future samples to be delivered here a new USDA permit and an amended IBC application will be required.

Does Pamala need to get her own USDA permit to work on these specimens? The answer depends on the current USDA permit. Kris Montgomery will check in the file, but Kris thinks it has Paula McCready's name on it. If so, it would be prudent to have Paula's name added to the application.

The Select Agent Permit is okay for this project according to Alan Casamajor, the RO for LLNL. However, once a sample is determined to be positive for a select agent, Exemption 2 then CDC must be notified rapidly.

The work for this project will be done off hours using 4 gram-sized samples. Al Jin recommended minor changes in wording about disposal and the precise use of household bleach, and Karolyn Burkhart-Schultz did the same about personal protective equipment, reference to the IWS, and accidental release. Similarly Patsy Gilbert simplified the entry for

animal use.

Pamala will be separating the spores and autoclaving the waste before disposing in to regular garbage.

Al Jin motioned for acceptance pending the revised changes. Future shipments of samples will require a USDA soil import permit and a fresh IBC review. Pamala sent a paragraph to Mort via email stating where the samples are from. Pamala will include this in her revision of this application.

Patsy seconded Al Jin's motion and it was unanimously approved.

IV. OTHER ACTIONS:

A memorandum is needed appointing Alan Casamajor to the IBC committee.

Nancy needs to update application form to include her name and remove old Administrators name.

IV New Business

The permit for Select Agents is being resubmitted according to Alan Casamajor. He hopes it will be approved in a few weeks.

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July 11, 2003

IBC Meeting Minutes
July 9, 2003 10:30-11:30
Building 361, Room 1155

Attendees:
IBC Members:
Nancy Wrigley (IBC Secretary), Mort Mendelsohn (Chair), Emilio Garcia, Al Jin, Patsy Gilbert, Rod Balhorn (Co-Chair), Karolyn Burkhart-Schultz, Kris Montgomery, Bree Klotter (Staff), Peter Agron, Exemption 6 Bill Periera
Guests:
Christine Little

Discussion:
Minutes from last meeting, June 10, 2003, are about to be completed and distributed.

Bree Klotter is continuing to help with the IBC charter, website, and administrative procedures.

Pamala Coker's revised written application was approved by Al and Mort, and the laboratory passed inspection by Al. The inspection report and approval are on file.

The permit with CDC for Select Agents has yet to be signed so no shipments of select agents can come in or out of LLNL at this time. We have until November 12, 2003.

Other Business:
Exemption 6 still on committee? Yes, but he had a conflict this past semester because he was teaching a class on Wednesday mornings. He should be able to attend our next meeting. Kimothy Smith is still on the committee but was unable to attend this meeting.

New Application from Emilio Garcia:
The role of unique genomic Exemption 2 **in pathogenesis**

This project is NIH funded since 2002. Vladimir Motin was the original PI, but after he left LLNL the PI shifted to Emilio. The project will study the mechanisms of pathogenesis Exemption 2

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Exemption 2

. The animal studies will not be done at LLNL but probably at Fort Collins. The studies are already approved by the LLNL IACUC. Shalini Mabery is now in Fort Collins, Colorado being trained for handling virulent Exemption 2

Emilio was recently assigned space in Exemption 2 However, laboratory inspection and actual work on the project cannot be done until a new hood is in place.

Action Items for the Application:

- Remove Vladmir Motin's name from first page of the application – he is no longer an LLNL employee, but is a subcontractor/ collaborator at the University of Texas.

- An autoclave and a biosafety cabinet still needs to be installed in Exemption 2 Patsy Gilbert. The room will become a multi-use facility, but no one is sharing as yet. Once we know who will share the room it will add it to the application.

- Page 3. The entry for various Exemption 2 was made in anticipation that Emilio will soon be receiving other Exemption 2 from the republic of Georgia in Russia.

- BR1003 class has been taken by all workers listed on the application.

- Page 7, Item #2. Put Doc .13.1 (Health and Safety Manual, Chapter 30). Also on page 7, insert statement about waste disposal.

- Page 8 – Fourth reference: add ES&H Manual. Second to the last reference – NIH Guidelines April 2002 needs to be added.

- Reference on FSP dates are incorrect. Patsy to get him the correct dates.

- An IWS is under preparation. Unfortunately this version of the application form is missing the entry section for IWS information. Under Safety Office, Emilio should enter the FSP the work is being done under – 360 and 360.01. The date of each document must be cited. On the same page, there is a box for the Assurance Manager's signature. Disregard the signature per Patsy Gilbert.

- Also indicate on the front page that the funding is through 2005.

- Project Duration is ongoing – Emilio to change this.

- Medical surveillance should be added to the first page as well. Also add a bullet on Page 7.

- The principal investigator statement needs to be signed. The text should be modified as per the Minutes of the June 10, 2003 meeting. Thus the second sentence of the second paragraph should read: "I agree to accept responsibility for overseeing the training and medical requirements of all laboratory workers involved in this project." This change should apply to all future IBC applications.

- Remove the statement under IBC that requires 12 copies to be given to the IBC office. Everything is done electronically now.

- Patsy moves to approve this application as long as the proper CDC permits and Lab inspections are done.

- Kris and Bill second. All vote to approve.

Meeting adjourned – 11:10am

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January 13, 2004

IBC Meeting
December 12, 2003
8:30-10:30am
B361, Room 1155

IBC Members:
Nancy Wrigley (IBC Secretary), Mort Mendelsohn (Chair), Al Jin, Patsy Gilbert, Manny Lateiner, Ron Lehman. Alan Casamajor, Kimothy Smith, Kathleen Noonan, Kris Montgomery, Exemption 6 Rod Balhorn, Joanne Horn, Ron Lehman, Karolyn Burkhart-Schultz, Peter Agron

Guests:
Tricia DiFalco, Ed Ballard, Christine Little, Rick Kelly, Garrett Keating, Bree Klotter, and Wendy Wilson

Committee Discussions:

Mort opened the meeting with an extended discussion of recent changes in the operation of the IBC. The details will not be repeated here, but they covered 1) the soon to be unveiled new IBC Website, 2) new interactive application forms based on the concept of 2 levels of approval by Registration or full committee review. Registration projects involving microorganisms or recombinant DNA below BSL 2 level of concern will be reviewed by both the Chairperson, and the Biosafety Officer. All projects requiring microorganisms or recombinant DNA work at or above BSL2 will require full review and approval by the IBC, 3) the expansion of IBC membership, 4) elimination of regularly scheduled meetings, instead, the IBC will meet within 2 weeks of receipt of any completed and signed full application, 5) a new definition of quorum requiring one of the chairs, the BSO or the BSO alternate, and 3 members with no conflict of interest concerning the applications under review, and 6) a developing database to record Registrations and Full Approvals, and to automate maintenance activities such as renewals.

Kathleen Noonan commented on why the IBC should review matters that are already covered by the IRB process. Her concern was focused on the inclusion in our new form of a section on human and animal tissues, fluids and cultures. Al agreed that there is overlap, but argued that for all 3, but particularly for cultures, the safety evaluation

should be done by the BSO. Whether this is the best way to ensure this needs further discussion involving the other safety teams.

Karolyn Burkhart-Schultz was concerned that the new 2-level process was yet another layer of administration and was perhaps unfair to the investigators. Mort and Al tried to reassure her that the new forms go a long way toward making it easier for the scientist, and that with everyone's help we would continue to clarify and simplify wherever possible.

Al Jin assured the committee members that a summary of all the intervening registration and renewal actions will be discussed at each meeting and will be incorporated in the minutes of each meeting.

Mort announced that the IBC has three new members since our last meeting. The names of the new members are Joanne Horn (Energy and Environment Directorate), Exemption 6 , and Michael Ascher (BBRP, BioDefense Division). At Patsy's suggestion, there was a round of introductions of everyone present. Mort asked for more recommendations for committee members, emphasizing the need for diversity and increased numbers.

Al Jin has decided to get more involved with national security issues at NAI and is being replaced by Glenn Funk as the Institutional Biosafety Officer (BSO)). Al will continue on the Committee as the BSO alternate. Glenn taught the HS3040 Class on Biosurety at LLNL and was the BSO for UCSF for many years. Glenn unfortunately could not be here today.

Proposal to Amend Chain/Smith/McCready Project:
"Virus Genomics: Toward better signature development and understanding of phylogeny" to
Chain/Smith/McCready/Messenger Project: "Virus Genomics: Toward better signature development and understanding of phylogeny & Tailored Assays for the Detection of Agroterrorism Agents"

Sharon Messenger was on travel and the project-overview was presented by Kimothy Smith. The main thrust of the application is to amend the current application to add Messenger and her work on agriculturally oriented potential terrorism agents. The amendment includes:

- Adding Sharon Messenger as the PI on the Project
- Listing additional personnel to handle the additional work,
- Removing the requirement that Kimothy Smith is the sole person capable of fragmenting intact RG3 and RG4 viral nucleic acids.

In the process, all the procedures have been updated and clarified to the point where any one of the qualified staff is able to carry out the work. Thus many of the prior concerns about the safety of manipulating and sequencing the genomes of dangerous viruses have been greatly alleviated. The project continues at biosafety level 2.

The residual problems with the application are minor, mostly administrative and listed as follows:

- The Health & Safety Manual, Chapter 30 reference has now been changed to Document 13.1 or the ES&H Manual. The changes should be reflected twice on page 7 of the application.
- The word "household" should be added whenever bleach is referenced. The change should be reflected on page 8 of the application. Peter Agron questioned about the special practices listed on Page 8, using bleach or a disinfectant. Al Jin asked to leave this generic (ie, as is) because it is basically a Safety Team issue.
- The diagram describing the viral taxonomy tree on page 15 should be amended to include viruses from the Togavirdae, and Picornaviridae families which were not included in the original application.
- Peter Agron said the procedures all looked fine but there was an error on page 13, host vector systems: ColE1 is a self-transmissible plasmid, thus the application should read: "non-transmissible ColEl derivatives" and not "ColE1 or derivatives".
- Joanne Horn commented on page 3 that the date of USDA certification should be 11-11-03 and not 5-2-02.
- Karolyn Burkhart-Schultz commented on page 14, the second sentence under Security Considerations is incorrect. The word "not" was deleted and should read, "Personnel not already approved to work in this room will "NOT" be allowed to work without proper supervision by approved personnel.
- Karolyn Burkhart-Schultz continued to say that on page 16 Foreign Animal Diseases (FAD), using nucleic acids are not actual organisms.
- Karolyn Burkhart-Schultz also stated that a memo regarding the room addition, Exemption 2 is needed since it is not on the application.

The USDA approval for this work is presently limited to Exemption 2, however the plan is for most of the work to be done Exemption 2. Thus the project needs an interim approval Exemption 2 while the USDA extension to Exemption 2 being expedited. An onsite inspection is needed but should not be a problem since Glenn Funk is already involved in the details of this amendment.

Al Jin wondered whether all the PI's listed on the first page should be co-signers on the signature page of the application. Kathleen Noonan disagreed. It is LLNL policy for the Responsible Individual to have signature authority. She feels that only the Responsible Individual should sign. In this case, that would be Paula McCready. Another alternative was to break the application into four parts so that each PI could sign for his or her section. These policy and procedures issues were then tabled for later discussion, with the understanding that the McCready signature would be sufficient for now.

Patsy Gilbert moved to approve this application with the recommended changes and Kathleen Noonan seconded. All were in favor, with the abstention of Kimothy Smith and Kris Montgomery.

New Proposal
Kimothy Smith: Title "Detection of microorganisms from various media"

Wendy Wilson presented this project. It is a new protocol, not an amendment as checked on the form. It is related to an existing application #2003-05, Paula McCready: Validation of DNA Signatures- Virus Work.

The project explores the possible effect of the medium from which samples are taken on the efficiency of detection by current DNA-oriented methods using two organisms: spores of the Ames strain of Bacillus anthracis, and the LVS strain of Francisella tularensis. Approximately 100 ul of each agent will be inoculated on various media including paper, plastic, metal, wood and liquids. After incubating the impregnated media under a variety of conditions, the samples will be tested for viability using colony formation and for presence, using quantitative PCR.

Discussion Points Include:

- Peter Agron asked why they are using a virulent strain of F. tularensis. The response was that they have chosen the least virulent strain, LVS, used for producing vaccine. It is orders of magnitude less infectious then the fully virulent strains. Also, the F. tularensis will be handled through an offsite IWS to do the work in Richmond. We are not asking for approval to work with it onsite.

- Al Jin states that Francisella tularensis LVS is still a risk group 3 by definition. As a result, the classification of this organism on page 2, under risk group 2 should be changed to risk group 3. In the next column insert Biosafety level 2 as the required level of containment. On page 7, the word, "nucleic acids" in Exemption 2 should be deleted. When they are ready to use this material they can write a memo for the file.

Exemption 6 asked if they knew of an affective dose. The response was again that it was orders of magnitude below the other F. tularensis strains, and that it must be low since the vaccine was developed for military personnel.

- Patsy Gilbert thought that maybe this should be broken down into two applications, instead of one. The committee members did not feel it was necessary split the application. Patsy also wanted to know why Wendy Wilson was listed on the application but not working on the project and the answer was because Wendy is working in the same room.

- Sharon Messenger and Kimothy Smith are not listed on the approval for Ex 2 Ex 2 If they are working with Select Agents then the permit needs to be amended (permit under the name Pamala Coker). The only agents being stored in Ex 2 Ex 2 are the ones belonging to Pamala Coker (see page 3). The committee members felt that the column in the IBC form labeled as "Name of RI" should be eliminated for clarity.

- Do not list nucleic acid on this application, write 'DNA of the following organisms.'

- Patsy needed clarification as to why Sharon Messenger was listed as the Responsible Individual for Ex 2 – Kathleen Noonan feels she should be listed on page 5 under responsibility. Wendy Wilson is not on this project but is the Responsible Individual. Kris Montgomery's name should be listed as the alternate. The committee members felt that the column labeled as "Name of RI" should be eliminated for clarity.

- Karolyn Burkhart-Schultz wanted to know what is the Ames strain? Kimothy Smith stated it's a generic demo originally from a ranch in Texas. Karolyn also wants this described in the protocol.

- Karolyn Burkhart-Schultz wanted to know under "special practices: Lab directed access restricted". Should be PI (or RI) not Lab Director.

- Karolyn Burkhart-Schultz wanted the building and the room listed because of Select Agents storing issues and because they are working with DNA.

Kris Montgomery needs an IBC number so she can put it on her IWS form. Mort told her she would get a number once the IBC office receives a clean, final, signed copy of the application.

Patsy motioned to approve with the recommended changes, and Kathleen Noonan 2nds. Approved. Kimothy Smith and Kris Montgomery abstained because of conflict of interest (they work on this project).

Garrett Keating: Amendment – Titled: "Aerosol Test Facility"

Garrett wanted to expand his current aerosol chamber to a room-sized chamber completely enclosed by HEPA filters. The room will have to be sealed at the floor level. The current expected use is for calibrating and comparing HEPA sampling systems. He also stated that others at LLNL might want to use this chamber in the future.

This application is sensitive and was already visited by public affairs. It is currently only a risk group 1, biosafety level 2 project.

Glenn Funk looked at the room and didn't see any problems.

- Kris Montgomery wants to know the risk group and the biosafety level because of the aerosolizing. Alan Casamajor says it is risk group 1 because the organism is risk group 1. Al Jin agrees that the risk group is one for all the currently planned organisms. While the biosafety level is 2 because of the aerosolization.

- Kathleen Noonan would like more clarification on the ventilation systems and how the building should be designed. She also wants to know what experiments are being done – Vern Bergman answered that they will test planar and other airflows, as well as the size and types of HEPA filters. Current filters are rated at 0.03% efficiency.

- Al Jin wants further definition on the yeasts being used. Some yeast are risk group 2 agents. The information should be incorporated on page 3.

- Al Jin wants it noted that the testing equipment and materials that leave the room need to be decontaminated, and the equipment must be properly labeled as "contaminated". A disclaimer statement should be added in the application.

- On page 5, Gloria Murphy's training needs to be listed and her education (MS in Microbiology). See Kris Montgomery's application for an example of how to word this.

Patsy Gilbert motions to approve this amendment pending the corrections discussed, and Kathleen Noonan seconds. All were in favor with no abstentions.

LLNL *Institutional Biosafety Committe*

Institutional Biosafety Committee
Biology and Biotechnology Research Program
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IBC Office Administrator, Nancy Wrigley
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October 1, 2004

IBC Meeting Minutes
August 31, 2004
1:30-2:30
B361, Room 1155 McClintok Room

Attendees:
IBC Members: Rod Balhorn (Co-Chair), [illegible], Alan Casamajor, Glenn Funk (BSO), [illegible] Patsy Gilbert (Co-Chair), Joanne Horn, Mort Mendelsohn, Kris Montgomery, Kimothy Smith.
Observers: Al Jin, Mary Gross
Guests: Marco Plomb (Presenter)
IBC Office: Nancy Wrigley (Administrator)

Welcome and Introductions:
Patsy welcomed the committee members and gave background information about her now that she is the new Co-Chair of the IBC.

Review minutes from the June 1, 2004 Meeting:
The minutes from the June 1, 2004 meeting were distributed. Comments and/or corrections should be directed to the IBC Office.

Presentation:
Robert Maxwell IBC#2004-034 (Marco Plomb presented)
Title: AFM analysis of bacterial spores, cells

Scope of Work:
Biological risk group 1 agents (bacterial spores and vegetative cells, and proteins) will be analyzed with AFM (Atomic Force Microscopy). AFM will be used as a forensic tool to probe the structure of a variety of Bacillus spores, and, during germination experiments, vegetative cells.

Description:
AFM Bacterial Spore and Vegetative Cell Analysis Risk group 1 bacterial spores and vegetative cells will be studied with the AFM equipment. Spore preparations from cultures will be made by the group of prof. [illegible] at the Children's Hospital of Oakland Research Institute (CHORI). For AFM analysis, spores will be deposited on sample disks in [illegible] from small (< 10 microliter) droplets of spore suspensions. Spores on the disk will be studied using AFM in [illegible] During germination experiments, spores will develop into vegetative cells.

Discussions:

- This application went through the LBOC on July 8, 2004.
- Considered to be a RG1.
- The BSO originally felt this project was a RG2 because of the Bacillus Cereus, which is non-evasive in food.
- The project is a BSL2 but being approved at a BSL1 level project because the samples will not be grown onsite.
- The ATCC lists as a BSL1.
- IWS lists as RG2, and all IH's have been told to flag all IWS's with this organism.
- [illegible] not clear on this project but recommends the IBC be in compliance with the NIH guidelines and lists this project as a RG2.
- Accept application with changes (below).

Actions:

- Everyone working in Lab must frequently wash their hands and before leaving the room, including technicians that may enter the room to repair equipment.
- Clean area with 10% bleach solution and soak.
- Change application, Question 1, to Yes and complete the last section of the application.

Motion to accept the application by Glenn Funk, and Kris Montgomery concurs.

New Business:

Laurie Gordon had an issue with the USDA wanting her to sign a transportation permit. She felt very uncomfortable about it and had Glenn work the issue with the USDA. Since we do not regulate fragments for transporting or holding these fragments the issue went away. Dr. Robert Flanders will send us a letter of explanation.

We currently have a weekly meeting with the IBC Administrator, the Co-Chairs and the BSO to review applications (registrations and delegated reviews). Also, as IWS's are updated we review the IBC that coincides with that IWS.

Exemption 6 Participating Guest status needs to be renewed and Nancy is processing the paperwork so they can pick up their new badges before our next meeting.

Nancy reported that LLNL will now be paying our outside members (Participating Guests) $50 per meeting. An expense report will be submitted by Nancy and a check distributed to all outside members in December of each year.

Patsy Gilbert and Glenn Funk explained the Registration and Delegated Review process vs. a Full Committee review. Even though the committee was told of these new procedures at the last meeting, Patsy wanted to update the committee to be sure everyone approved of this new process.

The Co-Chairs and BSO meet weekly and decide on the applications that have been submitted as being just a registration, a delegated review, or needs Full Committee review.

Registrations are those that are considered a BSL1 with little or no risk (not biologically hazardous but using as a catalog for LLNL). No inspection is done by the BSO, but the Hazards Team does a review of the lab(s) the work is being done in.

Delegated Reviews are applications that could potentially be a BSL2 project but downgrade to a BSL1 because of the low-risk factor. The BSO reviews the facility and completes an inspection report. Also, DOE is invited to the meetings when we have applications needing a Delegated Review.

Full Committee reviews are for those applications that are clearly RG2 or 3 and BSL2 (soon BSL3 work will need Full Committee review once the BSL3 lab is completed). When an application is submitted that clearly needs IBC review we will try to have a meeting scheduled within 2 weeks of receiving the application. We will ask five members that have the certain area of expertise for their availability first. Once we decide on a date and time we will invite the entire committee. We no longer will have a meeting bi-monthly on the last Wednesday of the month like we have been doing for years (Quarterly meetings will be scheduled though even if we have no applications to discuss).

Patsy told the committee that today's presentation was a good example of a delegated review. Future applications like this one presented today will not need Full Committee, but because Glenn was unsure of the Bacillus Cereus he felt it should go to Full Committee for review.

Patsy discussed how the LBOC (Laboratory Biosafety Operations Committee) operates. All LBOC applications are now being submitted on the IBC application form. No IBC application is approved until the LBOC reviews the project. The LBOC consists of various people around the Lab (RO, IBC Co-Chairs, Health Services, Subject Matter Experts, BSO, ES&H Teams, IH's). The IRB Administrator attends as an invited guest.

LBOC does a general review of the project and the various members give input and suggestions to help the project work safely. Because this committee reviews projects Lab-wide, the IBC gets much more cooperation from the RI's.

The IWS process is also part of the IBC process. No IWS is approved unless the IBC application has been reviewed and approved, and the RI has an actual IBC Approval Memo and Application Number.

Correspondence with the Sunshine Group and the TriValley Cares Group has been continuing. TriValley Cares would like to be able to attend our IBC meetings. We need to discuss this at a future Quarterly Meeting.

NIH would like the IBC to meet at least annually. Glenn thought this would be a good idea and said we are in a growth time and we need to formalize more the IBC for LLNL. Attendance to these meetings should be mandatory.

By looking at the rosters we do not have regular attendance from some members. We need to ask these members if they still want to be on the IBC because we are going to start to have regular quarterly meetings. Members were asked to provide Nancy with their best available day(s) and time(s).

An agenda at the first Quarterly meeting will be something like this:

- Policies and Procedures: Discuss and develop policies (review website and policies and procedures the Co-Chairs, BSO and the IBC Administrator have been establishing this past year).
- Discuss any problems with certain applications that have come up within the quarter.
- BSO report, from Glenn and he will have a list of IBC approvals and their levels of approval. (R, DR and FC). Nancy will run a report of all applications received and their status.
- There will be time to discuss any particular project that the Co-Chairs and BSO have approved in the quarter.
- Permits and Licenses will be discussed.
- Discuss any other type of report the committee would like Nancy to run.
- Permits and Licensing: USDA and Export Licenses (see below).
- Accidents and Incidents/Lessons Learned: report (if any for the quarter).
- BSO and Co-Chairs will share information from conferences they have attended.

The IBC applications, minutes and agenda are all OUO (Official Use Only) documents. If you do not secure them in a location when you leave the meeting, please leave all documents in the conference room so that they can be shredded.

Permits and Licensing: Much discussion on this subject. Kimothy had a request from the Canadian Department of Commerce to approve as an outside reviewer.

Vaccinia –There are no controls to prevent them from moving/exporting offsite unless it is a Select Agent (SA). What assurance could the IBC provide him? There is no control mechanism in place. Shipping has no requirements when shipping infectious items. Should we follow the DOT regulations in the approval package? We need to have some administrative controls for things being shipped offsite.
At UCSF Glenn Funk reported that all permit controls went through his office. This is something the Committee needs to address and decide upon (maybe at the next Quarterly meeting).
LLNL's shipping department should be calling Patsy, Rod, or Glenn for approvals before shipping infectious items.
Each RI should be applying for their own permits and review the applications with Glenn, who will include this information in his BSO report for the Quarterly IBC meetings.

Accidents and Incidents: There was a recent incident where a PI found something in his refrigerator/freezer that he was not familiar with. He asked someone if it was stored properly because it had no identification on the package. The problem arose because LLNL was not permitted to have this particular item onsite, or so that was what the PI thought. After some further review it was decided that the package was nonhazardous and the LLNL was not in violation of any kind.
LLNL then had a 'stand down' and all work was stopped until every lab, storage area and freezer were inspected. This took a week and a half to accomplish. LLNL brought in outside BSO's to do the inspecting. LLNL now has a complete overview of what we are working with, and also gave senior management a better idea of just how we all take safety and our positions seriously. A Lessons Learned will come out soon and we will share it with the IBC. There will be some follow up meetings to all this and we may just change the title of the Accidents and Incidents report to Lessons Learned. We know for sure that there will be a database to track all agents onsite, but we are waiting for the outside BSO inspection report before implementing any new procedures and policies.

LLNL *Institutional Biosafety Committe*

Institutional Biosafety Committee
Biology and Biotechnology Research Program
Patsy Gilbert, Rod Balhorn Co-chairs
IBC Office Administrator, Nancy Wrigley
Lawrence Livermore National Laboratory
P.O. Box 808. L-448
Livermore, CA 94551-9900
Telephone: (925) 423-6287

January 12, 2005

IBC Meeting Minutes
November 12, 2004
3:00-4:30pm
B361, Room 1155 McClintok Room

Attendees:
IBC Members: Mike Ascher, Rod Balhorn (Co-Chair) EX 6 Karolyn Burkhart-Schultz, Alan Casamajor, Glenn Funk (BSO), EX 6 , Patsy Gilbert (Co-Chair), Joanne Horn, Manny Lateiner, Mort Mendelsohn, Kris Montgomery, Kimothy Smith.
Observers: Al Jin, Brent Ricks, Trish Barbosa, Brynte Johnson and Bruce McDowell
Guests: Pejman Naraghi-arani (Presenter)
IBC Office: Nancy Wrigley (Administrator)

Welcome and Introductions:
The meeting came to order at 3:05pm. Patsy welcomed the committee members and asked for everyone to introduce themselves because we had new members and/or members that did not know everyone.

Review minutes from August 31, 2004 Meeting:
The minutes from the August meeting were distributed. Comments and/or corrections should be directed to the IBC Office.

Presentation:
Kimothy Smith presented IBC# 2004-017. Kimothy is the RI, and Brent Ricks will be the alternate contact. Title of project: "Preparation of organism stocks for a BSL3 Laboratory".

DISCUSSIONS:

- DNA prep cultivation to make stalk cultures and freeze samples.
- Organism level discrete. But will be complete for the final proposal.
- Joanne Horn wanted to know how the filters were going to be treated. How will they get the bugs out? By testing the system?
- A leak from the filter is possible. Plan on testing the filter. The filter will be disposed and treated like biohazardous waste.
- Small centrifuges will be inside biosafety cabinets.
- Following standard Ops procedures and safety plan.
- Lab to be inspected periodically. This is mentioned in the IWS as well.
- There will be a meeting in January to view the BSL3 building and the SOP will be viewed at that time as well.
- Personnel all vaccinated?
- Visitors entering the BSL3 must be escorted.
- CDC approved.
- Discussion about the start dates. Cannot put on application until they know when the building will be complete and operational.
- Room numbers were verified. Room 101 is an equipment locker. There are two labs and one animal lab.
- Gilda has taken the training and the CDC, for working, has cleared her with select agents.
- Amendments will be made periodically as things change. If there are major amendments another IBC full committee review might be necessary. This particular project will be approved just for the archiving. Another application will need to be submitted for any new research.
- Cell culture activity to come later on in the project, will amend application then.

Actions:

- Biosafety level organisms need to be more accurately stated on the list (BSL3).
- Instead of heat soaked in the description put in parenthesis the word 'boiled'.
- Facility terminology, refer to the SOP. Reference BMBL and the work smart standards.
- Need clarification on the personnel being vaccinated.
- Contact Bill Periera in Health Services and make him aware of this project.
- Make a statement about visitors being escorted into the facility.
- Need to add in the description about how the disinfecting will be done (0.5% bleach).
- The IBC application for this project will remain pending until all the training has been completed and the labs have been inspected, and all personnel is on medical surveillance.

- To reduce writing out, refer to the Work Smart Standards in the project description.

Motion to approve subject to revisions, Alan Casamajor. Karolyn Burkhart-Schultz seconds. All in favor.

Pejman Naraghi-Arani presented IBC# 2004-048. Pejman is the RI, and Kris Montgomery will be the alternate contact. Title of project: "Human and Agricultural assays nucleic acid pipeline".

DISCUSSION:

- Tissue culture in Ex 2 Work with viruses in Exemption 2
- No virus will leave Ex 2 alive.
- Agricultural viruses most likely coming from UC Davis.
- Nominal infectious to humans.
- USDA permit already on these viruses. Not on Select Agent list.
- Cleaning containers: Spray down. Bleach renders viruses – very effective. A primary precaution then will be to put in bags and autoclave. Concentrations proposed are in small amounts. Will spray cell culture flasks. Disinfectant: 1-10 diluted bleach. All dry material, and flasks are sprayed with bleach only. Once the flask is used, bacteria contaminated, bleach, and see color change. Use granule chlorine to cut down waste (not allowed here according to Patsy Gilbert).
- Everyone has been vaccinated.
- Doors are TESA locked and only vaccinated people can enter the room/lab.

ACTION ITEMS:

- RI to supply the IBC Office with a copy of the USDA permit when submitting the signed application.
- If RI decides to work with cowpox an amendment must be submitted and approval must be given before bringing onsite.
- Include name of vector (PCR 2.1).
- Add sentence about bleach treatment (discussed in LBOC as well). Spray down containers with bleach.
- BMBL reference and Work Smart Standards.
- Reference LLNL safety, safety equipment and primary barriers.
- Check on medical waste permit to be sure bleach is on there and is listed as a cleaning procedure.
- Make reference that everyone working on the project will be under medical surveillance and be vaccinated (discuss with Dr. Bill Periera in Health Services). The IWS will be very specific as to what vaccines will be used/needed.

- Attach a copy of the USDA permit when submitting final signed version of the IBC application.

Motion to approve pending updating and review from Dr. Bill Periera, Alan Casamajor. Mike Ascher seconds. All in favor.

New Business:

Bruce McDowell, BSL3 facility update:
Working on finishing the building and the autoclave is being installed. Once everything installed we will be sure it us all functional, then they will declare readiness. An independent team, NNSA,(to review the readiness that will authorize the facility) will review the building. Building to be ready the end of December. Possibly operational by Mid-February '05.

Notice of an appeal: Briefs have been filed – could take years.
A question was asked about using the BSL3 lab to do BSL2 work. No restrictions but the building still needs approval from NNSA.
Unless a review panel issues an injunction we are okay to move forward.

BSO Report:
Glenn Funk handed out a report about the IBC applications that have been approved either by Registration, Delegated Review, or Full Committee Review. He will report to the IBC quarterly whether we have applications to review or not. The report listed all the IBC's submitted from January 2004 to present. In the future the committee will see only the most recent quarter. We will also provide a list of all BSL3 approvals.
Glenn also will report quarterly on permits, incidents and accidents if any, and other possible LBOC/IBC issues.

Glenn also commented on training for the IBC members, and outside members. He will try and have something for our first quarterly meeting next year in 2005.

Al Jin asked if the minutes should be OUO. Manny Lateiner responded. Manny said he would ask Dave Brown. Manny didn't think they had to be marked because there is public attendance on the committee and they are not cleared. Maybe put on the top of the page 'Limited Distribution'. NIH guidelines say that we are to make the minutes available to the public unless the project is a classified project.

Patsy reported that Marilee Kelly wants to know how we pick our outside members. Patsy referred her to Jennifer Szutu in Lab Legal Services.

At one of our quarterly meetings in 2005 we will be able to tour the BSL3 building. We will notify everyone ahead of time.

Meeting was adjourned at 4:35pm.

Date: Thu, 16 Mar 2006 13:09:29 -0800
To: "Nancy E. Wrigley" <wrigley2@llnl.gov>
From: Marina Chiarappa-Zucca <chiarappazucca1@llnl.gov>
Subject: IBC# 2004-011
Cc: "Christine A. Little" <little10@llnl.gov>,
"Frank M. Bailey Jr." <bailey4@llnl.gov>,
"Joanne M. Horn" <horn3@llnl.gov>, Dave Camp <camp2@llnl.gov>

Nancy,
We are moving Joanne Horn's biological material to next week (3/21).
Interim storage for her material will be in a Exemption 2
. I was told to contact you so that you could make a note on her IBC.
Joanne is currently updating her IBC for work that will be conducted in
Exemption 2

Thanks,
Marina
--
Marina Chiarappa-Zucca
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LLNL *Institutional Biosafety Committe*

Institutional Biosafety Committee
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March 22, 2005

IBC Meeting Minutes
March 4, 2005
10:30-Noon
B361, Room 1155 McClintok Room

Attendees:
IBC Members: Exemption 6 Ann-Marie Dake, Alan Casamajor, Glenn Funk (BSO), Patsy Gilbert (Co-Chair), Mort Mendelsohn
Observers: Brynte Johnson
Guests: Sandra McCutchen-Maloney (Presenter)
IBC Office: Nancy Wrigley (Administrator)

Welcome and Introductions:
The meeting came to order at 10:35. Patsy welcomed the committee.

Review minutes from November 12, 2004 Meeting:
The minutes from the November meeting were distributed. Alan Casamajor motioned to approve, and Glenn Funk second, all in favor.

Presentation:
Sandra McCutcheon-Maloney IBC#2002-003. Titled "Methods to study the mechanisms of virulence".

This project is being presented to the IBC to review major amendments to Sandra's project

Sandra explained to the committee that pathogens would be used in two areas of the research. 1) host (cells/cerum) responses to bacterial exposures. 2) bacterial virulence mechanisms study.

In the host response studies, 2-DE and mass spectrometry will be used to profile, identify, and characterize host proteins that exhibit differential expression patterns after bacterial exposures. Rodents, cells and blood will be exposed to bacteria. After exposures, cells, plasma and tissue will be harvested, and proteins will be extracted. Protein samples will be sterilized by filtering. Sterilized proteins will be further tested for viability.

In bacterial virulence studies, we are studying real-time expression of virulence factors, proteomic content of diverse strains and phenotypic/metabolomics of Ex 2 Ex 2 DNA will be used to amplify specific regulatory promoter elements of genes of interests by PCR. These promoter sequences will be cloned into a commercially available reporter GFP plasmid and transformed into Y. pestis or B. anthracis respectively.

Both Ex 2 can cause serious or lethal human diseases, although some strains used are attenuated strains or nonvirulent strains. All the work described will be performed strictly following Standard Operating Practices Ex 2 Ex 2

Sandra has both IRB and IACUC approvals for this work.

Another part of this project will be working with the University of Texas A. M. This will be a collaborative effort working with bovine. Sandra wanted to know if she would need to amend this application or would she have to submit a totally brand new IBC application. The committee told her she could amend this as needed.

Regarding the work done in Texas and then sent to LLNL. Kris Montgomery will receive it in Ex 2 and verify that it is all certified killed. Kris will run and culture the material before it leaves Ex 2

Some monkey and swine models will be coming from Walter Reed (this will be another amendment). Sandra wants to collect blood and tissue samples to follow the host responses using francisellas, but this is BSL3 work so she will wait until B368 is open.

Patsy told Sandra that they are still discussing how the BSL3 lab will operate and how the research will be run and processed. Of course research will need to be scheduled with the B368 Manager, and a core group will perform work in B368. This is still in the discussion phase.

Since it took the CDC six months to approve the BSL3 lab, Alan Casamajor suggested to Sandra to apply for her approvals now. She was going to see if she could just work under Kimothy Smith's.

Emilio Garcia felt that Sandra should spell out rather than use acronyms for the different strains.

Actions:

- Add to application a paragraph on receiving certified swine samples from Walter Reid and Texas A & M.
- Specify the strains more.
- Test for sterility periodically. Write this procedure in application.
- Have Glenn and Brynte do a Risk Assessment on the lab(s) where this work will be done.
- On page 6, 2nd paragraph reads 'stains' should be strains.

2004 Status Report (handout)
There have been no incidences since our last IBC meeting, November, 2004. The status report handed out is for the last quarter of 2004, (September – December), and the first quarter of 2005 (January 1, 2005 to present). We already have in 2005 ten new applications

Alan Casamajor commented that Paula Imbro and Kimothy Smith do not have a USDA permit in order to do their work Ex 2 LBOC/IBC has not been notified of any of this either.

The Select Agent workers are being trained on Select Agent Human Reliability Program (SAHRP).

New Business

Patsy invited our community members to come out and tour the Biosciences facilities and the BSL-3 lab sometime before the BSL3 is open for business (August/September 2005).

Continue further discussions on Sandra McCutchen-Maloney's application on Monday or Tuesday. Nancy Wrigley arranged the meeting and invited Kimothy Smith to attend as a valuable source on a similar project.

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March 25, 2005

IBC Meeting Minutes
March 22, 2005
11:00-1:00
B361, Room 1155 McClintok Room

Attendees:
IBC Members: Rod Balhorn (Co-Chair), Ex 6 Karolyn Burkhart-Schultz, Alan Casamajor, Glenn Funk (BSO), Patsy Gilbert (Co-Chair), Joanne Horn, Manny Lateiner, Ron Lehman, Mort Mendelsohn, Kris Montgomery, Bill Pereira,
Observers: Trish Barbosa, Ann-Marie Dake, Brynte Johnson (Alternate BSO)
Guests: Mary Gross, Sue Martin, Cheryl Strout
IBC Office: Nancy Wrigley (Administrator)

Welcome and Introductions:

The meeting came to order at 11:06 am. Patsy welcomed the committee.

Minutes from the March 10, 2005 IBC meeting is still being worked on. Nancy will distribute to all members by the end of the week.

Presentation by Sue Martin IBC#2003-007. Titled "Real-time Bio-aerosol detection". Relevant IWS#(s) 11835 and 11839.

This project is being presented to the IBC to review a major amendment. Maurice Pitesky presented the original project in June 2003. Sue Martin is the RI replacing Maurice, Maurice left LLNL.

Description of the Project:

Sue Martin works in the Bio-Aerosol Mass Spectrometry Group.

Discussion and Questions:

Sue had a viewgraph presentation titled "Signature development and identification of aerosolized RG1 surrogates using mass spectrometry".

Suggested Action Items:

1. Change the terminology in your project description regarding a virulent.
2. Add medical surveillance to the application.
3. Also add safety classes that will be required for anyone working on the project and note that everyone currently on the project has already been trained.
4. Arrange a time that Glenn and/or Brynte can meet with the employees to go over the immuno-compromised issue.
5. Add a paragraph about how the system will be cleaned and swabbed.

*Note that this project was originally presented by Maurice Pitesky at the June 1, 2003 IBC meeting, not November 2003 as Sue Martin had stated.

Alan Casamajor motioned to approve this application once the complete narrative is transferred onto the final application, and Karolyn Burkhart-Schultz's second. All in favor.

Presentation by Cheryl Strout and Lyle Probst IBC#2005-011. Titled "BioNet mobile laboratory". Relevant IWS#12412.

Description of the Project:

This mobile laboratory will be used to process and analyze both extraordinary questioned environmental samples and previously characterized environmental samples for the detection of DNA/RNA based pathogens. The number of organism in samples received into the mobile laboratory are typically low and the assay used to identify the organism is a multi-loci genome identification assay. This facility is a high-throughput, semi-automated, deployable sample-processing laboratory for bio-agents using technologies designed for the Advanced Bio Sampling and Assay Technologies project, ABSAT. The ABSAT system was developed for use in the detection of DNA/RNA based pathogens in environmental samples. Samples matrices such as, but not limited to, air, soil, water, swabs and swipes are processed and analyzed for DNA/RNA from these environmental samples and detection is performed on the Luminex 1000 platform. Once results are analyzed all product and consumables are autoclaved. This mobile laboratory is designed to be used for BSL-2 work. No aerosolization or growth of organism will take place in this facility. Other work to be performed in the mobile lab will consist of using environmental samples, previously shown to be negative by Bio Watch or by ABSAT, that are spiked with risk group 1 organisms or DNA isolated from risk group 2-3 human non-viral pathogens certified as non-infectious. Additional safety features include glove

boxes to house the robotic equipment and for sample processing, a pass through autoclave, a vaporous hydrogen peroxide (VHP) system and negative pressure.

Discussion and Questions:

This project was initially awarded a contract to build two of these vans but only one is being built at this time. Once this one becomes functional a request to build another one will be submitted.

This application is regarding an actual van that is still being built. Approval of this application will not be completely done until the van has had a BSO inspection.

This project is similar to the BioWatch project only the work is being done in a mobile van. Currently this project is funded only as a demo van. There currently is no funding to work in this lab on or off site. Lyle would like to be able to give a demonstration of how the process will work once the van is onsite.

The van is being built to be similar to Kris Montgomery's lab. Exemption 2

Manny Lateiner, who is a legal council rep for the committee asked Patsy to contact Kathryn Rauhut, who is a subject matter expert on this type of project. She should be the one to review this application.

Patsy spoke with the people in NEPA and they have agreed not to approve the Cx until IBC has approved this project, and until the van is built and inspected there will be no approval.

Exemption 2 Exemption 2

[redacted] The RI is working with local authorities regarding a security plan.

It will have a BSL2 layout enhanced as a safety precaution, and could stand up to a BSL3 if needed.

The unit will not be bringing back anything with them. Everything will be done and destroyed offsite.

No FSPs, or SOPs have been written yet for this project.

Exemption 2

It has a VHP system to go into the B368, BSL3 building. They can decontaminate through the VHP system in approximately two hours.

If they do get a 'hit' they will have a portion of the original sample contained in another location (wrapped and in a freezer).

The people listed on the application are not necessarily the ones that will be going out on deployment in the van.

Suggested Action Items:

1. Section 5 in the table regarding Biomaterial. (Target genomic markers.) Change the application and take out the BSL levels. Don't use RG or BSL less than 100 base pairs. Small genome fragments not the organism.

2. List where 'it' comes from in the narrative not in the table.

3. The list of personnel should only be the people working on this project. If there is a deployment and others are deployed we can add them as an amendment to the application.

4. Change the IWS . No medical surveillance at this time but if they get a 'hit' they may add it later.

5. Since this application is written only as a demo and will not be approved for anything else but, add the words "Demo only".

6. Do not put deployment list of people in this application, only the people working on the demo.

7. Need to write FSP's and SOPs for this project.

8. Work with Patsy regarding the training of personnel for this project.

Motion to approve only for preparations and demo portion of this project, Glenn Funk. Second with conditions, Kris Montgomery. All in favor.

New Business

Patsy discussed with the committee the outcome of Sandy McCutchen-Maloney's IBC. Sandy had given us incorrect information at the meeting on how she handles samples. After an extended meeting with a limited number of IBC members everything was resolved and her amendment was approved.

Glenn had nothing to report since he had just given his BSO report at our last IBC meeting March 4, 2005.

B368 will be operational sometime in September. Patsy would like to take the LBOC members on a tour of the building at our next meeting, May 18, 2005. Hardhats and safety glasses may be required. Those of you with hats and glasses, please remember to bring them.

Also at our next IBC meeting we will discuss redefining the delegated review process.

Exemption 6 If anyone has any suggestions on some other members, please let Patsy and/or Nancy know. We will try and arrange interviews between now and our next IBC meeting.\

Adjourn 12:25 pm

LLNL *Institutional Biosafety Committe*

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June 8, 2005

IBC Meeting Minutes
May 18, 2005
1:45-3:00
B361, Room 1155 McClintok Room

Attendees:
IBC Members: Rod Balhorn (Co-Chair), Ex 6 Glenn Funk (BSO), Patsy Gilbert (Co-Chair), Joanne Horn, Brynte Johnson, Kris Montgomery, Bill Pereira
Observers: Trish Barbosa, Al Jin
Guests: Sharon Messenger and Paul Jackson
IBC Office: Nancy Wrigley (Administrator)

Welcome and Introductions:
The meeting came to order at 1:55. Patsy welcomed the committee.

Review minutes from March 22, 2005:
The minutes from the March meeting were distributed. Patsy asked that anyone with comments, send them to Nancy in the IBC Office

BSO Report – given by Brynte Johnson

Not many things have happened this past quarter. Kimothy Smith is no longer at LLNL and his projects have been transferred to Mary McBride, pending an inspection in B368 (BSL3 not opened yet).

No incidences this year until May 17, 2005. There was a small fire in B368 (minor fire) on the southeast corner. It was put out within a half hour. A flash from a welder while he was grounding cables caused it. This will not effect internal operations of the building and repairs will be done next week.

The condition of the HEPA filters will be checked for smoke damage as well as inside the building and mechanical room.

There was an emergency drill involving the fire department and professional services (ES&H team, all the hazard techs, etc.) in B368. It lasted about one hour. The fire department, one fire captain, and three paramedics responded. The scenario was that a person had fallen (Brent Ricks played the victim). Kris Montgomery was the innocent bystander. She was sure to decontaminate the victim before he was carried out, and as various people left the building they had to be sprayed with bleach before leaving. The patient was even taken over to Health Services and they continued the drill there. The drill went very well and the fire department now has a better understanding of the facility and how to respond in an emergency if they need to.

Tour of B368, BSL3 Laboratory

Patsy took the committee out to building 368 to show everyone what will soon be LLNL's first BSL3 laboratory.

Presentation:

Paul Jackson IBC#2005-015. Titled "The impact of different bacteriophasge on *B. anthracis* and *Y. pestis*".

Summary:

We are funded to study the impact of different bacteriophage on *B. anthracis* and *Y. pestis*. The Lawrence Livermore Bacillus bacteriophage studies will be carried out using *B. anthracis* Sterne and Delta Ames strains and several other non-virulent *B. cereus* and *B. thuringiensis* strains as hosts for the different Bacillus bacteriophage. Our *B. anthracis* Sterne isolate has been shown to be devoid of pX02 by PCR using a battery of PCR primers that amplify a battery of genes located on pX02. Our Delta Ames isolate has been shown to be devoid of pX01 by PCR using a battery of PCR primers that amplify the toxin genes on pX01. The *Y. pestis* bacteriophage studies will use non-virulent attenuated *Y. pestis* strains [strains that are Pgm- due to a deletion of a 102-kb region of the chromosome termed the *pgm* locus (Examples are *Y. pestis* strain E.V. or various sub-strains such as EV 76) or *Y. pestis* strains devoid of the 75 kb low-calcium response (Lcr) virulence plasmid (e.g., Tjiwidej S and CDC A1122)]. These can be handled at BSL-1 or 2 and are not considered select agents. These *Y. pestis* strains have been shown to be missing their respective regions by PCR using primers that amplify portions of the missing sequences. We will also plate phage on different *Y. enterocolitica* and *Y. pseudotuberculosis* isolates to determine the host range for the different phage. The use of these hosts is required to complete the work because the bacteriophage of interest must be shown to grow on *B. anthracis* and *Y. pestis* isolates to be of use to the sponsor.

Discussion and Action Items:

Paul told the committee that some of the details of this project are classified and he would not be able to discuss.

Because B368 is not ready yet, Paul will work in Los Alamos until the building becomes available.

A question was brought up about having a permit for collecting the soil samples. It was decided that a permit was not needed in the United States. There are a few states that California will not allow soil to be brought in from, but Paul won't be going to those states.

- Work with Team 3 on the safety issues.
- Page 8, Risk Assessment. B anthracis host avirulent, change 'host' to strain to keep consistent with the rest of the narrative. Do the same on page 4, in parenthesis change to bacteria host cells.
- Be sure to put the soil sample collecting, and the transportation information into the IWS.

Kris Montgomery motioned to approve pending an updated application, IWS and lab inspection. [illegible] second, and all in favor.

2004 Status Report (handout)

Distributed the status report for all the applications the IBC Office has received this Quarter. There were 10 applications reviewed, one needing full committee review, which we reviewed today.

New Business

During Paul's presentation is was brought to the committee's attention that on Page 6 of the application, Number 7, the question is formulated strangely. The question needs to be rewritten (regarding IRB and IACUC). This will be discussed at our next management team meeting (usually meet weekly on Tuesdays).

We are currently updating our IBC website and it should be complete by our next Quarterly meeting in September (September 7, 2005 at 1:30).

The Management Team will no longer be having delegated reviews for applications. We will either have a registration or a full committee review. Since we do review all the applications at our weekly meetings and the applications get a thorough review at the LBOC meeting it doesn't make sense to call it a Delegated Review.

Distributed the status report of activity from the past quarter. We received 10 applications this quarter. One needing review by the full IBC, which we reviewed today.

Discussion about retiring applications, or closing files. When the RI notifies the IBC office that his project is ending either for funding reasons, or it just was completed. The IBC office notifies the BSO, the Program Safety Officer, the ES&H Team Leader and the Team Industrial Hygienist to be sure that no more work will be done and the IWS will need to be revised or closed.

Ex 6 had some concerns about verifying avirulent strains even though we require documentation. How do you avoid human error? Kris Montgomery tests everything that comes to LLNL. Brynte Johnson said this was an area he should probably be looking into and has said he would take the project on. He said the BSO's need to set a policy on this and will have the IBC review it once it is written. Maybe incorporate it into the application.

Meeting adjourned at 3:05pm

Lawrence Livermore National Laboratory
Institutional Biosafety Committee

IBC Meeting Minutes
September 19. 2005
10:30-12:30
B361, Room 1155 McClintock Room

Attendees:
IBC Members: Ex 6 Karolyn Burkhart-Schultz, Alan Casamajor, Glenn Funk (BSO), Patsy Gilbert (Co-Chair), Joanne Horn, Brynte Johnson, Mort Mendelsohn, Kris Montgomery, Bill Pereira
Observers: Monica Borucki, Christine Little
Guests: Lynn Suer
IBC Office: Nancy Wrigley (Administrator)

Welcome and Introductions:
The meeting came to order at 10:35 am and Patsy welcomed the committee.

Emilio Garcia was originally going to present, but has decided to close the project. The work will be done elsewhere and not by any LLNL personnel. If that decision changes, he will reopen and present his project to the IBC.

Patsy announced that any applications that come through the IBC office for B368 would only be sent electronically to those that have Entrust. Anyone not on the Entrust system needs to have it put on your computers. Community members will receive all applications through Federal Express as usual. Once the applications have been reviewed they need to be shredded or kept in a locked drawer in your office.

Review minutes from May 18, 2005: The minutes from the May meeting were distributed. Patsy asked that anyone with comments, send them to Nancy in the IBC Office (wrigley2@llnl.gov).

PRESENTATIONS:

Joanne Horn, IBC#2004-011. Titled "Microbial forensics".

Summary:
Two major activities are associated with this work, which may be separate or inter-related, depending on need. The first is the growth of a Bacillus thuringiensis strain

israelensis (ATCC 35646) and Bacillus anthracis strain Sterne (non-virulent) in volumes of up to 10 L. to facilitate dispersal of homogeneous spore samples to various institutions for follow-on studies to detect forensic physio-chemical signatures. Alternatively, we would generate spores on solidified media in large plastic Petri dishes; we have already carried this out for B. thuringiensis. After sporulation, cultures are harvested by centrifugation (6 L centrifuge capacity) in the case broth-grown cultures or scraping spores off of agar when grown in Petri dishes, then spores are either washed with water or detergents, and dried by either lyophilization in closed containers or acetone dried in close containers. After weighing and aliquoting, dried samples are irradiated (in the past we have used the 60Co source), and sent out to collaborating laboratories through the Shipping Dept. at LLNL in accordance with DOT/CDC/NIH regulations, along with a certification of death (example attached). Live samples are dispersed to other research groups at LLNL using secondary containment to transport samples across the LLNL site.

All the experiments described above entail culturing in closed vessels, escape of organisms into the surrounding environment is prevented by vessel closures and (in the cases of 10 L cultures) filters (0.2μm) on the reactor exhaust/condenser. Large volume reactors are autoclaved in situ, and this process can be checked by occasional testing using bacillus spore preparations intended for this purpose.

Discussion:

Joanne presented this last year, but because some of the project has changed, she was told to present again and explain what this all entailed. She had a viewgraph presentation, one titled "Growth and sporulation of B. thuringenesis and B. anthracis stern in batch volumes of up to 10 liters". She would like to have 15 liters but the IBC would not approve that larger of volume. If she would like to use a larger volume she will need to come back to the IBC for approval.

Joanne showed a picture of the fermenter and explained that it has a cleaning mechanism already built into the machine so it basically autoclaves it self. It is rinsed out with soap and water and drains out the bottom through many ports. There's an electric steam unit built right in to the fermenter. Once cleaned samples are taken to be sure nothing got contaminated.

Samples were to come from an outside vendor but currently only will use samples in house. If we decide to get samples from an outside collaborator, the RI will need to amend this application and possibly present again to the IBC.

There was a discussion of taking soil samples from around the building and testing them to see if there is any contamination already in the ground. This way no one can accuse the project of contamination if it was there before this experiment happened. Patsy decided to let the BSO's make the call.

The BSL3 is not needed to perform this work. It can be done at a BSL2 level.

Karolyn Burkhart-Schultz motioned to approve this application with the changes noted below and also an inspection is done on the Lab and the Biosafety Cabinet. Alan Casamajor seconds the motion. All in favor, none opposed.

Action:

- The title needs to be more specific that "Microbial forensics".

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- The mention of BBRP needs to be changed to Biosciences (the form has been updated online to reflect this change, July 2005). Joanne used the form that was online at the time in 2004.
- Page 1, the first question needs to be answered Yes and the remainder of the application needs to be completed.
- Biosafety cabinet on order. Once installed have room inspected and be sure to test the exhaust fans as well. The exhaust fans work extremely well to the point some could be disconnected.
- Add David Camp to the application on Page 8, B1. He is the Group Leader for the RI and is also knowledgeable about this project.
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Lynn Suer, IBC#2005-029. Titled "West Nile virus growth and mouse studies in at BSL3".

Summary:

The goal of our experiments is to provide proof of concept, using a West Nile virus vaccine, for the efficacy, safety, efficiency and rapidity of synthetic vaccine production in comparison with current methods of vaccine production.
In the first experiment, West Nile virus (WNV) NY99 (wild or virulent strain) will be grown in cell culture, titered by plaquing, stored frozen, thawed and diluted to determine the LD50 in mice. About 30 mice will be injected IP with small amounts of virus and observed for two weeks. The injected dose will be titered again in cells to confirm the dosage. In the second experiment, WNV ETH76b (a mouse-attenuated strain) will be grown in cell culture, titered by plaquing, stored frozen, thawed and diluted to determine immunogenicity in mice. About 56 mice will be injected IP with small amounts of virus. After 3 weeks, the mice will be bled from the saphenous vein and the spleens will be removed from some mice. The mice will be challenged IP with varying amounts of WNV NY99 and observed for two weeks to determine protection levels. Both virus dosages will be confirmed in cells. In the third experiment, about 100 mice will be divided into 10 groups. The various groups will be injected with commercial WNV vaccines, the natural virus, and high and low doses of synthesized WNV DNA, with and without an adjuvant. The synthesized WNV DNA adsorbed on gold microbeads will be administered in the right and left legs of the mice with a Gene Gun. After 3 weeks, the mice will be bled saphenously, spleens will be removed from some mice, and the remainder will be challenged with a pre-determined number of LD50 of WNV NY99. The mice will be observed for two weeks to determine protection. The pooled sera and spleen cells from all the groups will be tested for antibody and cytokine levels, and the results compared for all groups of mice. Antibody titer will be determined by plaque reduction neutralization assay, and cytokine production by ELISA or Luminex assay.
All procedures involving live virus will be contained in a BSC in a BSL-3 lab. All safety procedures for the BSL-3 lab will be carefully followed, including the use of PPE. The production of aerosols will be minimized insofar as is possible by special techniques such as avoiding the "blow-out" mode with pipettors and pipets when virus is pipetted. Microtiter plates will be transported in biosafety containers (secondary containment) between incubator and BSC. Lidded metal pans lined with a biohazard bag will be used

for waste disposal so there will be no possibility of puncture of sealed bags by pipets or pipettor tips. Autoclaving of waste will be done promptly, on the same day, if possible. Any spills will be immediately contained and disinfected with 10% bleach. Release of materials to the environment is extremely unlikely. All viruses we request will be shipped to Kris Montgomery according to LLNL policy. The hazard level is low; in clinical laboratories, this virus may be handled at the BSL-2 level with the permission of the laboratory director.

Discussion:

Lynn had some view graphs to show during her presentation. She also explained that this project is the second phase of a project that she started earlier this year.
Because of safety concerns there are strict BSL3 containment procedures that need to be followed.
Lynn gave statistics regarding the West Nile Virus (WNV) infection and disease. She said most people are diagnosed at a normal clinical exam. Some people get flu-like symptoms. One in 150 people injected with the virus get encephalitis. People can get WNV either by transfusion, a puncture wound, a transplant or a mosquito bite. There have been two reports of WNV from someone working with a blue jay that had necropsy.
Sandy McCutchen-Maloney, a Biosciences PI, wants to use some of the specimens/spleen cells from mice that Lynn will have from the second phase of this project.
The mice will be injected with a Gene Gun that is from BioRad. The gene gun will be used to make injections into the legs of each mouse to get their virus cells.
Infected tissue will need to be disinfected in the BSL3 before taking to Ex 2 4
certificate of killed data will be required.
Motion to approve this application pending completion of all corrections was made by Glenn Funk, and Mort Mendelsohn second. All in favor. None opposed.

Action:

- Add the people that are authorized for B368 to the list of personnel on page 7. Be sure to include Monica Borucki (The PPOC for B368).
- Page 2, Question 5, List Risk Group under viruses.
- Section 6 (scope of work). Second page, 4 sentences from the bottom. Add 10% household bleach.
- Page 7, B2. Check Shared Room. List room numbers.
- Page 6, A2, check yes, and answer the question.
- Page 7. Equipment. List the Biosafety cabinet information (Christine Little can help you locate the information).
- Page 7, B2 Add mice as biological materials.
- Page 4, Question 7. Need IACUC information.
- Page 1; list room number(s).
- Need to write an SOP (Standard Operating Procedures) for the use of the Gene Gun.
- Attach documentation on the anti viral, a review article defining how it works would be good. (Glenn Funk requested this)

- Only state the B368 work in this application. All other non-BSL3 work needs to be on a separate IBC.
- See Health Services, Dr. Bill Pereira for medical surveillance for all personnel.
- Add a statement in the scope of work regarding the artificially synthesized WNV genome will be utilized in this work.

Kris Montgomery presented two applications for Sharon Messenger/Monica Borucki. IBC#2005-034. Titled "Extraction of nucleic acids from bacteria and viruses in the BSL3 laboratory".

Summary:

It is our intent to extract nucleic acids from the organisms listed above. We will be interacting collaboratively with several outside institutions to acquire the organisms. The nucleic acids will be used to screen signatures using Taqman real-time detection methodology and the PCR luminex methodology.
The arboviruses (arthropod-borne viruses) are a heterogeneous group of more than 500 that share common modes of vector-borne transmission. All of the viruses listed above are arboviruses. Most arboviruses are transmitted between specific arthropod vectors and vertebrate hosts. Approximately 150 cause illness in humans. The majority of arboviral infections result in simple febrile illnesses that cannot be distinguished from other common viral infections. Lymphadenopathy may be prominent in West Nile fever.

Discussion:

This project is all simple Risk Group 2 work. Just to familiarize everyone to the new facility in a BSL3 laboratory. Will be receiving RG2 organisms from other collaborators. Will extract the nucleic acid and do PCR on them. Grow up on plates and freeze at 80°C . Everything will be done in a biosafety cabinet.
The only changes from when Kimothy presented this is the biosafety levels of certain viruses and bacteria are now RG3.
Monica Borucki will be the Responsible Individual on all the projects in B368. Kris Montgomery will be doing most of the work in the lab(s), but everyone will have specific tasks.
Everyone working in B368 will need to be on the Medical Surveillance list.
Motion to approve pending inspection and corrections listed below (Action Items), by Karolyn Burkhart-Schultz. Joanne Horn seconds. All in favor. None opposed.

Action:

- Page 8, B2 under Shared Room, answer should be Yes.
- Page 9, B3, Biosafety cabinet information missing. Need ID number.
- Change all the BSL2s listed on page 3 to BSL3s, and all the Risk Groups to RG3s.
- Work with Brynte Johnson on the list of cell lines that will be used.
- Page 4, fifth paragraph, fifth sentence needs rewording (autoclaved on the liquid cycle . . . .).

- Page 9, change first sentence to read "All personnel are enrolled in **Biohazardous** medical surveillance.
- Page 1, change RI to Monica Borucki and add her contact information.

The second IBC Application Kris Montgomery presented was IBC# 2004-017. Originally submitted by Kimothy Smith. He terminated LLNL earlier this year. The title is "Preparations of organism stocks in the BSL3 laboratory".

Summary:

Organisms will be obtained from various collaborators, such as CDC, USAMRIID, Brigham Young University, and UC Davis. Upon receipt, the organism will be grown on a blood agar plate or appropriate agar. After incubation and good colony growth, about five colonies, will be picked and grown in two to three milliliters of appropriate media. Once a good turbidity is reached, the liquid culture will then be supplemented with 15% glycerol. One-milliliter aliquots will be stored in two-milliliter cryo tubes and stored at -80°C. The purpose of this is to create a viable stock of organisms, which can be grown at later dates as is necessitated by research demands. All organism stocks will be documented in the electronic inventory.

Discussion:

Kris presented both of these applications at the same time. The discussions listed above are similar for this project as well.
Monica Borucki will be the Responsible Individual on all the projects in B368. Kris Montgomery will be doing most of the work in the lab(s), but everyone will have specific tasks.
Everyone working in B368 will need to be on the Medical Surveillance list.
Motion to approve pending inspection and corrections listed below (Action Items) by Alan Casamajor, and EX 6 seconds. All in favor. None opposed.

Action:

- Change all the BSL2s listed on page 3 to BSL3s, and all the Risk Groups to RG3s.
- Page 7, remove Mary McBride as the RI and add Monica Borucki.
- Work with Christine Little on finding the ID numbers for the biosafety cabinets.
- Page 8, change first sentence to read "All personnel are enrolled in **Biohazardous** medical surveillance.
- Page 7, put Yes under Shared Room.

New Business:

Reviewed minutes from the last IBC meeting we had in May 2005. Comments and/or corrections need to be sent to Nancy Wrigley at wrigley2@llnl.gov.

There was no time for the BSO's to give their quarterly report or do the training of the committee members. May try to have the training at the November meeting.

Next meeting is scheduled for November 16, 2005. Nancy will be sending out an email notice and an agenda.

Adjourned at 12:10pm

Lawrence Livermore National Laboratory
Institutional Biosafety Committee

IBC Meeting Minutes
November 16, 2005
3:00-4:30
T3703, R1006

Attendees:
IBC Members: Mike Ascher, Ex 6 Karolyn Burkhart-Schultz, Patsy Gilbert (Co-Chair), Joanne Horn, Brynte Johnson (BSO), Mort Mendelsohn, Kris Montgomery, Bill Pereira
Observers: Trish Barbosa, Leslie Hofherr (Alt BSO), and Christine Little
Guests: David Counts, Roy Kamimura, Yong Kim, and Dan Knight
IBC Office: Nancy Wrigley (Administrator)

Welcome and Introductions:

The meeting came to order at 3:02pm and Patsy welcomed the committee.

Review minutes from September 19, 2005. Mort Mendelsohn motioned to accept the minutes, and Brynte Johnson seconds. All approve. Any further comments can be sent to the IBC Office, Nancy Wrigley (wrigley2@llnl.gov).

Patsy asked the members if they knew of anyone interested in being part of this committee. We have lost a few members recently and need to have some new people. Dave Counts was invited to this meeting to get an idea of what this committee does. Dave works in NAI as their Assurance Manager. Ex 6 a new community member was introduced. He works at Livermore High School as the Bioscience Teacher. Leslie Hofherr was introduced as the Alternate BSO working with Brynte Johnson. Leslie comes from UCSF and UCLA where she worked with their IBC's.

Since we are reviewing applications that contain sensitive information, Patsy would like all LLNL employees that are on this committee to be sure their computers are Entrusted. We will be sending minutes and applications through email but they will all be Entrusted. Mike Ascher, representing Biosciences, has a different computer system and is trying to find a way he can be Entrusted as well. The IBC Office will hand deliver everything to him, and our Community Members will receive packages through an overnight courier.

PRESENTATIONS:

Joanne Horn, IBC#2005-047.

Summary:

Exemption 2

Exemption 2

Exemption 2

Action:

- Once this gets approved Patsy should contact the Public Affairs Department so they are prepared to answer any inquiries should there be any.
- Add Paul Jackson to this application, and his training and experience.
- Validate inefficiency of the deactivation process and prove it works.
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Exemption 2

- Need to find a glove box that can fit inside the fume hood. Leslie says there are glove boxes that have a ventilation system all in one unit. She will look into this and get back to Joanne.
- Everyone working on this project will need medical surveillance. Contact Dr. Bill Pereira at Health Services. Arrange for him to talk to everyone on the project and make them aware of the risks.
- Need to include the Fire Department and Emergency Response people onsite when any training is done for clean-up and decontamination processes are being taught.
- Need to discuss this project more with Michelle Dahlstrom, Biosciences Security Representative. Discuss TESA locks for the lab doors and other controls needed for this project.
- Page 4, change 100 grams to 100 milligrams.
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Exemption 2

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- Develop a database or some form of record keeping for your inventory of the beans and the mash. Send an example to the IBC office along with an updated application with these changes added.
- Third full paragraph on page 4, talking about sending inactive preparations to other DOE Laboratories needs to be reworded, unless you can verify they are indeed inactive.
- Send Patsy a copy of the SOP for her to review.

New Business:

- Short discussion on the Delegated Review process and the Institutional Biosafety Committee Management Team (IBCM) and how the process has evolved over the past two years. Explained mainly to the new members and guests.

- B368 progress: Still fixing some mechanical devices and CDC still is not done with their investigation and review with Bob Hull. Once the CDC is satisfied with their investigation, and the VHP has been validated (and everyone is trained). There are some ventilation problems and there's some issues with the quality of the equipment that is in the building. The equipment is still under warranty (August 2005-August 2006). Once all these issues are taken care of we can open the building to users.

- BSO Report: All Select Agent work has been suspended. Request from both CDC and the LSO asking LLNL to validate the current procedures that are in place for Select Agent work. The CDC sent LLNL a report with 29 points we need to address. We have 30 days to respond because Brynte is the Responsible Official (RO) he will be working these issues and will report back to the committee hopefully at our next meeting (March 2006).

Mort Mendelsohn motioned to adjourn the meeting at 4:45pm, and Kris Montgomery seconds. All in favor.