

Safety Review Committee

December 17, 2004

10:00 AM – 12:00 PM

Minutes

Members Present

Joel Ager, Michael Banda, John Bercovitz, Dennis Collins, Sharon Doyle, Ben Feinberg, Peter Lichty, Don Lucas, Karen Ramorino, Linfeng Rao, Pat Thomas (for Peter Seidl), Scott Taylor, Weyland Wong, Hisao Yokota

Members Absent

Ken Fletcher, Richard Kadel, Mack Kennedy, Augusto Macchiavelli, Linda Smith

Others Present

Eleanor Blakely, Paul Blodgett, Bruce King, Tamas Torok

Minutes of November Meeting

The minutes of the November meeting were approved.

Comments from the Chair

Committee Membership

Paul Blodgett will be replacing Peter Lichty as the EH&S Division representative. Peter is rotating off due to a scheduling conflict.

Electrical Safety

- Dennis Collins and Ben Feinberg are collecting comments on possible revisions to the electrical safety policy for contractors.
- The accident investigation report for the arc blast accident at SLAC has been released. A copy of the executive summary was distributed to the Committee. Dennis Collins, Tom Caronna, Dennis Nielsen, and Kevin Trigales assisted SLAC in evaluating their electrical safety and rigging safety programs.

2004 Highlights

Our annual meeting with the Lab Director is scheduled on January 21. An annual report is being prepared. A draft copy of the 2004 Highlights was distributed for comments. More information is needed on Legacy Waste issues, particularly at Calvin and Donner. Carbon 14 in Calvin has been cleaned up to allow free access to accessible areas. Chris Donahue has additional information. It was also suggested that information be added about the improvement in accident rates. Last year, we were in last place among the Office of Science laboratories. This year, we are number 2 in TRC and number 1 in DART. Any additional information to be included in the highlights should be sent to Pat Thomas.

Ben Feinberg noted that the EH&S database improvement funding supported by the SRC has been approved.

Institutional Biosafety Committee

Tamas Torok, chairman of the LBNL Institutional Biosafety Committee, described the history of the committee and current issues affecting biosafety reviews at Berkeley Lab. The committee operates under the general principles that research must be safe, ethical, and meaningful, and that research shall not be limited or interrupted. Physical safety and security measures are designed to protect healthy people and the environment. The population is changing, and there are more people are living with health impairments and they must be protected. Scientists should shape the requirements and govern themselves, because they are most knowledgeable about the safety issues of their work. Biosafety cannot be achieved without outreach and education within the Lab and beyond.

Cloning experiments in the early 1970's raised public concerns about safety and resulted in a moratorium on this type of work. The February 1975 Asilomar conference led to development of the National Institute of Health (NIH) "Guidelines for Research Involving Recombinant DNA Molecules". These guidelines required institutions receiving NIH funding to establish Institutional Biosafety Committees (IBCs) as peer group review forums. The guidelines are being updated.

There are 7 Divisions at LBNL doing bioresearch. There are more non-biologists working with biomaterials in recent years. LBNL is held responsible for work conducted at or sponsored by LBNL. The NIH is a major funding source. DOE requires safety and security oversight for all bioresearch that includes potential etiological agents. We expect changes in the DOE requirements. There are also federal regulations requiring control of the possession, use, or transfer of "select agents" that could be used for terrorism. UC has a "select agent reliability program" that does not include LBNL. There is one laboratory at LBNL that is certified by the Center for Disease Control. The Joint Genome Institute is not required to be certified at this time because there are no living organisms being studied.

Jim Bartholomew and Jack Bartley were involved in setting up a biosafety committee in the 1980's. By 1996, the current IBC structure was established and a Biosafety Manual was developed, and in 1997, the Berkeley Lab Policy on Pathogens was issued. A website has been established, and there are classroom and web-based training courses available. The IBC reports to the Lab Director. The goal is to balance Principal Investigator and institutional/contractor responsibilities.

The review process required PIs to submit forms describing proposed projects that involve biological agents. For Risk Group 1 agents (not associated with disease in healthy humans) or NIH-exempt recombinant DNA, the Chair of the IBC reviews and signs the forms, and notifies the IBC. Higher risk projects require full review and approval by the IBC. The IBC review process includes information gathering, cross-checking the risk group and suggested containment levels, and reviewing the goals, protocols, facilities, equipment, and training records.

There are 15 IBC members. Twelve members represent LBNL divisions or user facilities, and 3 represent the community. Two of the community members are biologists from the Berkeley area, and the other is the LLNL biosafety officer. The Human Subject committee and Animal Welfare Committee are also represented. The IBC meets four times a year, and the meetings are open to the public. IBC members volunteer their time. The number of applications is increasing. Most applications do not require full review, or are completed electronically between meetings.

The IBC recommends changes to PUB-3000. Changes to the IBC charter have been proposed to the Lab Director. The review forms are being simplified. It is anticipated that there will be three levels of review: notification, registration, and authorization. They would like to have web-based forms.

The "Sunshine Report" was an independent study of IBCs at various institutions. LBNL did well and was rated in the top 7%. Our IBC has also been asked to help LANL and USDA improve their IBCs.

There are several new developments that will present challenges to the IBC. The California stem cell research initiative will provide funding and increase the number of proposed projects. Physical security is an increasing concern for agents with dual use capability. New CDC and NIH guidelines are expected in 2005. The National Academy of Sciences' Fisk Report on bioterrorism described 7 activities of concern.

There is some controversy over what role, if any, the IBC should play in determining qualifications of researchers. Traditionally, this has been a Division/Department responsibility, and the researchers would like it to remain that way. It is difficult to determine the competence of users from other institutions.

There is also some disagreement over the scope of projects requiring review. Practices differ between institutions. Most UC campuses require reviews for Risk Group 2 and above, and recombinant DNA. About 1/3 of the campuses look at all biosafety work to screen for the risk group. At LANL, human and primate work is reviewed as Risk Group 2. Sometimes the risk group is unclear in the initial proposal, and the IBC can advise the researchers on steps that can be taken to limit risk. The researchers would like the IBC to set clear guidelines that can be enforced by Divisions/Departments. Line Management signatures are required on work at Risk Group 2 or above. Prion research is new and reviews are not required by regulations, but this could change. For bloodborne pathogens, a research protocol and training may be sufficient. Some bacteria have moved from Risk Group 1 to 2 because of experience with infections. The review criteria need to be kept up to date.

Some researchers are unhappy about the complexity of reviews and the time it takes to get a project approved. They sometimes have to respond to multiple requests for additional information. There can be duplicate or overlapping requests for information from different IBC members, or from the Human Use or Animal Welfare committees. Reviews should be coordinated so that all the relevant questions are asked at one time and recorded. The researchers want the PIs to be held responsible for assessing risk in accordance with a risk assessment criteria and protocol. It is hard to find all the biosafety requirements in PUB-3000. The IBC and Divisions need to ensure everyone knows that all recombinant DNA work proposals are required to go through the IBC.

The IBC is concerned about the consequences if some biosafety work is not properly reviewed. The NIH may do site visits, cut grant funding, or require direct NIH approval for work. The Lab Director must sign an annual certificate of compliance and submit it to DOE. There is also a report that goes to the Army. LANL had a bioresearch shut-down, and it could happen here if someone is out of compliance.

The Lab Director will determine the scope of IBC responsibilities in committee charter. The IBC has submitted a draft to the Lab Director. The affected Division Directors have not seen the draft charter.

LBNL Safety Shutdown/Start-up Contingency Planning

SLAC and LANL have experienced shut-downs after major safety incidents that have had significant adverse impacts to research. SLAC has lost several months of research time on the B-Factory, which might prevent several professors from achieving tenure. At LANL, life sciences researchers lost cultures because they were not allowed access to labs to refill liquid nitrogen dewars. LBNL needs to have a plan in place to minimize damage and ensure safe restart if we have a similar event. We need to be able to answer three questions: What facilities/programs should be shut down? What activities should be done during the shutdown? What actions need to be completed before restart? We want to be able to respond to emergencies strongly and locally. Phyllis Pei is working on a plan for LBNL.

Farewell Comments

Robin Wendt will be retiring from LBNL at the beginning of the winter break. Robin thanked the committee for their support. Institutional committees such as the SRC strengthen LBNL's safety program. LBNL's line management ownership of safety was noted by the ISM Review Board.

The meeting was adjourned at 12:00 noon.

Respectfully submitted,

Patricia M. Thomas, SRC Secretary