DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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National Institutes of Health
National Institute of Allergy
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Bethesda, MD 20892

March 31, 2006

Edward Hammond, Director
The Sunshine Project
PO Box 41987
Austin TX 78704

Re: FOI Case No. 32402

Dear Mr. Hammond:

This is a final response to your March 14, 2006, Freedom of Information Act (FOIA) request addressed to Lee Thompson at our Rocky Mountain Laboratory, Division of Intramural Research, National Institute of Allergy and Infectious Diseases. Your request was forwarded to our office for review and direct response. You requested copies of all meetings of the Rocky Mountain Laboratories Institutional Biosafety Committee since May 1, 2003.

We queried our Rocky Mountain Laboratory and located 18 pages responsive to your request. Enclosed are copies of the minutes from RML IBC meetings dated May 18, 2004 (2 pages); October 27, 2004 (2 pages); February 3, 2005 (2 pages); May 3, 2005 (3 pages); August 17, 2005 (2 pages); November 15, 2005 (7 pages).

With respect to your request that we answer a specific question about the Rocky Mountain Laboratories IBC, please understand that the FOIA is mechanism for the public to obtain identifiable government records. The FOIA does not require us to answer questions, nor is it a means to seek answers to questions. Your question of whether the Rocky Mountain Laboratories IBC has/has not implemented written policies for the identification, review and oversight of research involving any of the seven categories of experiments of concern identified by the National Academies of Science in its report *Biotechnology Research in an Age of Terrorism* (the "Fink Committee" report) cannot be addressed by this office.

Provisions of the FOIA and Department of Health and Human Services FOIA Regulations allow us to recover part of the cost of responding to your request. Because the cost is below the $25 minimum, there is no charge for the enclosed materials.

Sincerely,

Susan H. Boyle

Susan H. Boyle
Freedom of Information Coordinator (Acting)
National Institute of Allergy and Infectious Diseases

Enclosures: 18 pages

Minutes: RML Biosafety Committee Meeting
May 18, 2004
3:00 pm, Bldg 9 conference room

Committee members present
Dr. Patti Rosa, Chair
Dr. Nancy Hoe, Biosafety Officer
Dr. Ted Hackstadt, Select Agent Responsible Official
Dr. Frank Gherardini
Dr. Don Lodmell
Dr. Don Gardner
Greg Raymond
Debbie Crane
Alida Merritt, Community Representative
Paul Carlson, ex officio member, Safety Officer, RML
Dr. George Risi, ex officio member, Infectious Disease Consultant, RML
Also present
Ken Pekoc
Robin Ireland
Dr. Olivia Steele-Mortimer

Committee members absent
Dr. Marshall Bloom, ex officio member, Associate Director, RML
Pat Stewart, ex officio member, AFMS Chief, RML
Dr. Alan Applebury, retired veterinarian, Community Representative
Dr. Teresa Borino, physician, Community Representative
Dr. Mike Parnell, RML veterinarian

Old Business

1. Minutes of the February 24th meeting were read by Patti Rosa, corrected and approved.
2. Clarification was added to the proposed RML Biosafety Committee Guidelines regarding forms on which Chair and Biosafety Officer had authority to sign, as requested by Pat Stewart.
3. The proposed incident investigation form was revised in response to discussion at the February 2004 meeting, such that that it now serves as a post-exposure checklist rather than a report form. Consistent with this function, signatures are not required.
4. Letter regarding students working in laboratories was sent out May 3, 2004 to all P.I's. Documentation of laboratory-specific training, as found in the students' orientation handbook, must be signed by both student and supervisor, and a copy provided to Paul Carlson.
5. Dr. Bloom sent a letter April 17, 2004 in response to an inquiry from Mr. Edward Hammond of the Sunshine Project, assuring him that RML is registered to handle select agents.

New Business

1. Subsequent to the February 2004 meeting, RML scientist Kathy Wehrly resigned due to her pending retirement and Greg Raymond was appointed in her place. Community Representative Susan Brown also resigned and Alan Applebury, D.V.M. was appointed to fill her position.
2. Patti reminded the committee that she had received and forwarded an email from Alan Shipp of NIH on March 5, 2004 regarding a new biosecurity initiative to address "dual use research", which is defined as legitimate life sciences research that nonetheless has the potential to be misused in ways that could threaten public health or national security. A National Science Advisory Board is being established to advise all Federal departments or agencies that conduct research that could fall into this category. Guidelines will be established that address the role of IBCs in the review and approval process for "dual use research". The point of the email was to notify IBCs of this new biosecurity initiative, and to clarify that in the meantime the role and responsibilities of the IBC has not changed.
3. Biosafety Officer report
    a. Nancy Hoe reviewed routine registration documents that did not present any special concerns and which had been approved since the February 2004 meeting. These included minor updates to existing Registration of Recombinant DNA Experiment documents from investigators Chesebro, Otto, and Lodmell, and new documents from Bloom and Caldwell. New or revised documents for Registration of Materials (potentially) Infectious for Humans were approved for investigators DeLeo, Schwan and Bloom. Dr. Otto received permission for a summer student to work with *Staphylococcus epidermidis*. A new request for Registration of Recombinant DNA Experiments was received from Dr. Sumby, reviewed by the committee via e-mail and approved.
    b. An SOP for TSE experiments in the animal BL3 facility in Bldg 25 was received from Dr. Rick Race and Greg Raymond and electronically circulated to the committee for review. Comments were conveyed to Greg Raymond and most were minor. Mike Parnell, facility veterinarian, had more extensive comments and Greg was working with him on suggested revisions to the SOP.
    c. Don Gardner was asked to describe his findings regarding recommendations for processing histopathology specimens resulting from TSE experiments conducted at the BL3 level. He reported that whenever possible, dedicated equipment located in a BL3 lab should be utilized. The committee concurred with this opinion and will support a request to purchase dedicated equipment for this purpose. An addendum to the BL3 TSE SOP describing the processing of histopathology specimens is needed.
    d. Nancy handed out additional requests for Registration of Recombinant DNA Experiments from investigators Hinnebusch, Rosa and Schwan. Committee members will review these and submit comments or suggested revisions to Dr. Hoe.

e. Nancy reported on a recent biocontainment conference she attended to obtain training and information pertinent to her position as Biosafety Officer.

4. Ted Hackstadt reported that he had received Dept. of Justice ID numbers from the CDC for people who they have been trying to get registered to work with select agents. This was necessary before FBI FD-961 forms can be processed for background checks. Additional forms will still need to be submitted to comply with DHHS requirements.
5. A report was filed with the IBSC regarding a laboratory incident involving a needle puncture and possible exposure to the relapsing fever spirochete *Borrelia hermsii*. The circumstances and events preceding the accident were carefully reviewed by the individual involved and their supervisor, and an improper procedure was identified (recapping a used needle) that will not be repeated. The accident was immediately reported by the supervisor to Patti Rosa and emails sent to Paul Carlson and Dr. George Risi after attempts to contact them by phone were unsuccessful. Because the likelihood of exposure to infectious organisms was considered low, antibiotics were not initiated. However, the individual was instructed to have a blood sample drawn immediately and another taken in four weeks to assess seroconversion to *B. hermsii*. This happened approximately 2 months prior and the individual remains well. In addition to the incident report filed with the Biosafety Chair, documentation of the accident was submitted to Paul Carlson on forms that he provided.
6. A potential lab-acquired Salmonella infection was reviewed. The individual involved and their supervisor were invited to this portion of the meeting. Tests to compare the patient's isolate and the laboratory strain with which they worked are underway at the State Health Department in Helena and results were not available at this time. No accident or potential exposure in the laboratory was identified. The supervisor has arranged for a desk for the individual outside of the laboratory to reduce the risk of inadvertent exposure to infectious agents. The committee concurred that this would be a good practice to implement throughout RML. Currently, a number of technicians and students do not have desks outside the laboratory in which they work. Concern was expressed that the patient's right to confidentiality was not respected fully by people at RML who had been informed of this possible lab-acquired infection. Concern was also expressed that the publicity and attention surrounding this possible lab-acquired infection would deter other laboratory workers from reporting potential exposures or lab-acquired illnesses.
7. Miscellaneous – future IBSC meetings will be scheduled earlier in the afternoon to avoid running past 4:30 pm.

RML Institutional Biosafety Committee Meeting
October 27, 2004
2 p.m. – 3:45 p.m.

Attendees:

Pat Stewart, Paul Carlson, Nancy Hoe, Don Gardner, Don Lodmell, George Risi, Marshall Bloom, Mike Parnell, Frank Gherardini, Patti Rosa, Debbie Crane, Greg Raymond, Ted Hackstad, Alida Merritt, Teresa Borino.

Guests: Lee Thompson, LaDea Petersen, Ken Pekoc.

Absent:

Alan Applebury

Old Business:

1. Minutes from the May 18, 2004, meeting were read verbatim and approved without change.

The committee decided, however, that rather than reading minutes verbatim at each meeting, the chair would continue to distribute draft minutes prior to meetings, but only suggested changes to draft minutes would be discussed at the start of the next meeting, prior to final approval.

2. Sunshine Project Request: Patti Rosa mentioned a June 2004 letter received from Edward Hammond of the Sunshine Project. He is seeking additional committee minutes through February 2004 and does not believe he must use the Freedom of Information Act (FOIA) process. The letter was forwarded to FOIA officials at NIH. At this time, all requested documents have been received by Mr Hammond through the FOIA process.

Marshall noted that minutes of NIH and RML Biosafety Committee are identifiable as Federal documents and thus are subject to FOIA regulations. In this instance, the NIH regulations supersede the Recombinant DNA guidelines.

3. Committee members summarized the employee **Salmonella exposure** from last spring. Tests at the State lab were unable to distinguish between the patient's strain and that which was worked on at RML. RML notified the public about this episode and a presentation to the RML CLG was made.

Issues subsequent to the exposure:

- HIPAA provisions, patient confidentiality and workers' compensation filing.
- Paul Carlson has reminded employees about patient privacy.
- The committee will request a final report from the principal investigator whose lab experienced the Salmonella exposure.

New Business:

1. Associate Director Report:

A. Marshall discussed the **settlement agreement** reached in the lawsuit involving the Integrated Research Facility. One term of that agreement directly affects the committee.

Settlement Item 16: *NIH agrees that it will invite the following persons to act as members of the RML Institutional Biosafety Committee (IBC): (1) one person who will represent all three plaintiffs; (2) a local health officer; and (3) a local health board member. NIH agrees to inform the IBC of BSL4 and any weaponized pathogens prior to bringing them to RML.*

Marshall said he had sent letters to these parties and is awaiting responses.

B. It was clarified that if an IBC member is unable to attend a meeting, there is no provision for alternate representatives.

Marshall clarified two points for Patti; settlement item 18 is different from the Sunshine Project request and is a previous FOB FOIA request; the RML health officer referred to in items 12 and 13 is BSO Nancy Hoe at this time.

C. Marshall introduced **Lee Thompson**, director of biocontainment and biosafety at the University of Texas Medical Branch in Galveston. Lee is a consultant to RML on the IRF project. He has been involved in the design of the past five BSL-4 labs built. He is developing the IRF safety manual, emergency response plan and BSL-4 safety plan. He will incorporate into his work the exposure guidelines that Dr. Risi has developed.

2. Safety Officer Report:

A. Paul Carlson discussed laboratory workers wearing **lab coats and gloves** while in RML corridors; he sent a reminder in January 2004 about this being potentially inappropriate, but is still receiving complaints. The only time it is appropriate to wear coats or gloves in common public areas is when carrying hazardous material to protect the sample or person carrying it.

Paul said that even if the coats / gloves have not been in an area exposed to lab work, wearing them in common public areas carries the impression that they may contain something infectious.

The committee discussed ways to make sure employees are aware of this protocol and follow it, including working through PIs and WIP sessions.

B. Paul discussed **four minor injuries** since the last committee meeting:

- 6-15-04 employee needle stick involving a synthetic peptide. Happened after injecting a mouse and while attempting to replace the mouse in cage. Stick to the left hand 1-inch below the left index finger. No time loss, no medical attention.
- 6-29-04 employee washing a pair of scissors received a small cut on the left thumb. No time loss, no medical attention.
- 7-23-04 employee received a cut on the right index finger after opening a glass ampule containing BSA. There was a piece of jagged glass on the ampule. No time loss, no medical attention.
- 9-13-04 while inoculating a mouse with streptococcus, using the left hand, a second mouse attempted to climb up the employee's sleeve. While maneuvering, the employee stuck the needle in the middle finger of the left hand. No time loss, but medical attention sought for antibiotics. Dr. Risi consulted. No illness.

C. Paul is preparing for his **annual safety training** and asked for input to improve or refocus the information.

3. Biosafety Officer Report:

Nancy distributed and discussed her report.

In addition:

- The committee discussed whether some items listed under 1(b), "Registration of Materials (Potentially) Infectious for Humans," belonged on the list, in particular work of Kim Hasenkrug and Rick Race. Some group members indicated that this work was not infectious to humans. However, this is the title of the form on which such work is required to be registered.

- In section 3a., the group discussed optional vaccinations for RML employees who work with Q fever and tularemia. Bob Heinzen asked the committee to consider whether proactive vaccination would be possible. Bob and Nancy Hoe conferred with various NIH officials, staff at USAMRIID and Dr. Risi. They have determined that a feasible approach is to see if optional vaccines can be offered locally via Dr. Risi. If it is deemed feasible, about 20 people would be offered the optional vaccine. Nancy is corresponding with Dr. Ernie Takafuji of NIAID in this regard.

- In section 3b, it was determined that the updated BMBL handbook is far from complete so there still should be time to provide input. Committee members are concerned, though, that they won't be provided an opportunity to comment. Pat Stewart offered to discuss this with Dr. Tom Kindt to try and arrange a review method.

4. Incidental Items from Committee:

Don Gardner described a concern expressed by a stockroom employee about receiving packages that contain infectious material. This was precipitated by a recent shipment that involved a select agent (Burkholderia) that was properly shipped to RML from out-of-state, but was transported from Missoula to Hamilton by a private courier. The package was shipped to Missoula by Federal Express and then transferred to the courier as part of a standing arrangement by RML for FedEx packages that require prompt delivery.

A second component of this topic involves concern among RML stockroom personnel over their lack of awareness that a select agent was expected at RML. Select agents require specific handling upon arrival and staff was not aware / prepared.

Committee members agreed that these are issues relevant to the committee and identified them as such:

- Concern over procedure
- Concern over courier

Nancy and Ted said that they will meet to make the necessary protocol changes to assure that select agent shipments are only transported by authorized carriers and that advance notification is given to stockroom staff who receive packages.

Patti said she would talk with shipping staff to thank them for bringing this to the committee's attention and to let them know that their concerns are valid and would be addressed.

RML Institutional Biosafety Committee Meeting
February 3, 2005
2 p.m. – 3:15 p.m.

Attendees:

Patti Rosa, Chair	Alan Applebury	Marshall Bloom	Teresa Borino
Harlan Caldwell	Paul Carlson	Greg Chilcott	Debbie Crane
Richard Eggleston	Don Gardner	Frank Gherardini	Alexandra Gorman
Ted Hackstadt	Nancy Hoe	Don Lodmell	Alida Merritt
Mike Parnell	Greg Raymond	George Risi	Pat Stewart

Guests: Sue Priola, Ken Pekoc, Virginia Tobiason

Absent:

Bruce Chesebro, Suzanne Krall, Tom Schwan, Randy Williamson

Minutes:

1. **Meeting minutes from 10/27/04 meeting.**

   Discussion: Safety Officer Report re: wearing gloves/lab coats in hallways to transport hazardous materials. Don L. questioned need for coats/gloves since all hazardous materials should be transported in secondary containers. Committee discussed feasibility of secondary containment for all items transported in light of the physical arrangement of most labs (adjoining rooms or rooms across the hall from each other). Consensus was that coats/gloves are still needed in some instances and that information regarding safe transport of hazardous material is currently conveyed to employees during yearly safety training.

   Action: Paul will remind employees of proper procedures for the safe intra-building transport of hazardous materials at annual safety training.

Old Business:

1. **New committee members**: Patti Rosa welcomed the new community members on the committee: Richard Eggleston, the Ravalli County Health Officer, Alexandra Gorman, a representative for the Coalition for a Safe Lab/Friends of the Bitterroot/Women's Voices for the Earth, and Greg Chilcott, a member of the Ravalli County Health Board. Introductions of all in attendance were then made around the room.
2. **Final report-Salmonella exposure**: The final report was distributed to the committee. Discussion followed about what is public and private information. The decision was reached that the report should not leave the room since it contains personal information.

Action: Report was handed back.

New Business:

1. **Recent studies on inactivation of "prion" agents**: Sue Priola gave a presentation summarizing the findings of a study demonstrating the inactivation of prion agents using incinerator conditions like those in use at RML (Ref: Brown P., Rau E.H., Lemieux P., Johnson B.K., Bacote A.E., and Gajdusek D.C. 2004. Infectivity studies of both ash and air emissions from simulated incineration of scrapie-contaminated tissues. Environ Sci Technol 38: 6155-60). Alexandra asked if the RML incinerator temperatures had changed as she remembers different chamber temperatures than what Sue was stating. Sue clarified the RML incinerator burning characteristics and reiterated that they are sufficient to inactivate prion agents. George asked how many infectious particles were in a prion-infected monkey carcass. Sue replied that that is not easy to determine, but she would estimate it to be 10 to 1000 times lower than that in an infected hamster.

BSO Report- Dr. Nancy Hoe

1. Nancy distributed and discussed her report (attached).
2. **Update on request for information regarding Q fever vaccination**: Nancy reported that Dr. Ernie Takafuji, Assistant Director for Biodefense Research at NIAID, informed her that NIAID has granted approval for vaccinations through the USAMRIID Special Immunizations Program (SIP). This approval means that NIAID will pay for an employee's participation in the SIP up front, although procedures to implement the program are still being worked out. Nancy will continue to correspond with Dr. Takafuji regarding this matter.
3. **Updated pathogen registration and recombinant DNA forms**: Forms have been updated in Word format to streamline electronic distribution and the annual review process. Pathogen registration forms for all labs have been transferred to the new format and e-mailed to PIs for updating.
4. **Draft of revised building 25 (BSL-3) SOP**: The SOP has been updated to include procedures for the new proximity access cards, and receiving/shipping of Select Agents. Copies of the SOP were distributed to the committee and comments requested.

OHSM Report – Paul Carlson

1. **Update to training/certification for shipping dangerous goods**: Paul distributed and discussed a handout outlining the changes, effective January 1st, to the 2005 IATA (International Air Transport Association) dangerous goods shipping regulations. Employee training on the updated regulations can be obtained by watching a CD or through lectures given by Paul. Alexandra asked why certain regulations were being relaxed. Paul replied that IATA guidelines are the most stringent and the changes bring

them more into line with DOT regulations. Nancy clarified that the changes do not mean the regulations are more relaxed, just more practical and streamlined.

2. **Safety Manual**: Paul said the manual is being prepared in electronic format. Patti asked if it is distinct from the current RML Emergency Response Manual flip chart that is a handy reference for emergencies. Paul clarified that the Emergency Response Manual is a separate document from the Safety Manual.

Associate Director Report – Dr. Marshall Bloom

1. Marshall distributed new IBC rosters (attached).
2. **Update on lawsuit settlement agreement**: Marshall discussed progress toward meeting several terms of the lawsuit settlement.
    a. RML has appointed 3 new community members to the IBC (see Old Minutes Section in this document, Item 1).
    b. Plans for an isolation room at RML have been approved as part of the plans for the new Integrated Research Facility (IRF). The isolation unit will consist of an anteroom, patient/treatment room, and bathroom with shower. The room will be under negative pressure and air will be HEPA-filtered.
    c. Requirements for the isolation room at the Regional Referral Hospital (RRH) in Missoula are being written into a Request for Proposals (RFP) for RRH candidates. The room would be similar to the one planned for RML, but would be larger (up to 4 patients). Patti asked why the RRH would be located in Missoula. Marshall indicated that an electronic medical record system was needed, and Alida stated that Marcus Daly Hospital does not have a system for electronic medical records. Marshall added that the infrastructure of Marcus Daly was not sufficient for the treatment of BSL-4-level exposures.
    d. RML has an MOU in place with an Emergency Medical Service (EMS) service.
    e. RML provided detailed information on HEPA filters to the plaintiff's attorney.
    f. RML provided the assessment of the Back-Flow Preventer to the plaintiff's attorney.
    g. RML is developing Emergency Response and Exposure Management Plans for the IRF.
3. **IBC Charter**: A draft copy of a charter for the RML Biosafety Committee was distributed to the committee for comments (attached). The charter is based on NIH policy requirements for the NIH Biosafety Committee. As part of the charter, Marshall also introduced the idea of a project application form to be used by the committee to approve work with hazardous biological agents. There was much discussion about the purpose and use of this form, with the main questions being if the form was appropriate for BSL-2 level projects, and if it might be redundant given the forms already in use. It was decided to delay further discussion until the form is more complete.
4. **Biocontainment Exposure Assessment Team (BEAT)**: Marshall discussed the establishment of an RML BEAT, and explained that it is part of the Exposure Management Plans being developed for the IRF that include management guidelines and procedures for responding to laboratory exposures. Marshall clarified for Patti that Plan procedures include notification of the IBC.

Other Business:

1. Alexandra expressed that she was please to be part of the IBC, and said she was looking forward to working with RML on biosafety matters.
2. Patti explained to new committee members how committee business is conducted between formal meetings.

RML Institutional Biosafety Committee Meeting
May 3, 2005
2 p.m. – 3:40 p.m.

Attendees:

Patti Rosa, Chair	Alan Applebury	Marshall Bloom	Paul Carlson
Debbie Crane	Frank Gherardini	Alexandra Gorman	Nancy Hoe
Don Lodmell	George Risi	Pat Stewart	

Guests: Ken Pekoc

Absent:

Teresa Borino, Harlan Caldwell, Bruce Chesebro, Greg Chilcott, Richard Eggleston, Don Gardner, Ted Hackstadt, Suzanne Krall, Alida Merritt, Mike Parnell, Greg Raymond, Tom Schwan, Randy Williamson

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Minutes:

1. **Meeting minutes from 2/3/05 meeting.**

   Discussion: Patti pointed out that the date in the Minutes section should be corrected to read "10/27/04".

   Action: Minutes approved with this minor correction.

Old Business:

1. **Coxiella incident**: Nancy distributed her final report to the committee and provided a verbal summary of the incident, including the RML response, an update on the condition of the employee involved, and measures taken to prevent such incidents in the future. In summary, the Q fever spill was contained in a piece of equipment in the laboratory suite in the BSL-3 facility, proper clean-up, decontamination, and notification procedures were followed, and there was no evidence of actual exposure or infection.

   Frank commented that his lab uses newer versions of the type of Beckman centrifuge rotor and bottles that were involved in the spill. These utilize a double O-ring and improved cap design. Frank also stated that his lab disposes of this type of centrifuge bottle on a regular basis, depending on wear. He will provide Nancy with the bottle ordering information for her to pass on to Dr. Heinzen, the PI in whose lab the incident occurred. Debbie expressed concerns with the old designs and noted that she had also had problems with leakage from the old bottles at an earlier date.

In response to a question from Alan, Nancy described the procedures followed for decontamination of the BSL-3 lab suite with formaldehyde gas.

Alexandra suggested notifying Beckman or the CDC of the problems/concerns with the rotors/bottles. Debbie stated that she had spoken with Beckman and they are aware of the hazard since they did modify the designs.

Alan asked if an individual could have Q fever without a rise in antibody titer. George explained that most cases of Q fever are asymptomatic and so a rise in antibody titer is the only way to confirm an infection.

Don L. said that a follow-up press release should be issued in which it states that the incident resulted in no exposure or infection. Marshall replied that a statement sent to the Community Liaison Group the Monday after the incident (2/14) included such wording.

Frank suggested that the centrifuge bottles and rotor involved in the incident should be removed from the BSL-3 suite. Nancy will speak to Dr. Heinzen about this.

2. **Review reporting and press release policy**: Patti stated that following the Q fever spill there was concern among several of the scientific staff that the resultant publicity was detrimental to subsequent reporting of such incidents by RML staff. She felt that the committee should discuss the general issue of how to balance the need to keep the public informed with maintaining employee confidentiality, and that it would be beneficial to get input on this matter from the community members of the committee. She thought a committee consensus opinion on the matter could be conveyed to those making reporting decisions for subsequent incidents. Patti explained the order and substance of the Q fever press releases issued including Marshall's response to inquiries from Kirsten Lang of the Coalition for a Safe Lab. She then read an email sent to her from Dr. Heinzen in which he stated that excessive disclosure and publicity of such incidents would discourage personnel from reporting incidents, unnecessarily alarm the public, and be disruptive to the lab involved. He also stated that there was no confidentiality and that it was his feeling that unless the incident posed a public health risk, the current reporting requirements (notifying Dr. Eggleston and the IBC) were sufficient.

   Pat S. explained that her role in the general notification process is to notify Dr. Kindt, who then notifies Dr. Fauci. They and the NIH Office of Communications advise her as to what actions to take including whether to issue a press release.

   Marshall stated that employee confidentiality was not compromised during the management and reporting of the Q fever spill. He said he is discussing notification issues with Dr. Risi, Dr. Eggleston, and Dr. Wilson (Director of Safety for NIH) and that in the future, reporting decisions will probably be made on a case-by-case basis. It was a general consensus of the committee that reporting decisions should be decided based on the details of the particular incident (e.g. whether it involved an illness or just an exposure, virulence of the organism,

etc.). Alexandra commented that it is good to have a press release instead of just hearing rumors, and that she appreciated the timeliness of the press release in the Q fever incident.

Other committee comments:

- press releases help build positive public trust
- it is better to report the name of the pathogen, otherwise the public may become unduly alarmed
- RML employees should be apprised of any press release policy
- timing of the release of any press statement is critical

3. **Review BU/tularemia incident**: Patti provided an overview of Boston University's handling of 3 cases of tularemia. She pointed out that BU's subsequent problems with the public and media were due to BU's failure to recognize and report the tularemia cases in a timely manner. George and Marshall clarified that BU did report once they identified the illnesses as being tularemia. Nancy followed this by reading the statement contained in RML BSL-3 standard operating procedures describing the RML policy for reporting illness in lab workers. A discussion followed on the importance of monitoring lab workers and reporting illnesses in a timely manner. Patti commented that the PI sets the example. Debbie praised Dr. Caldwell's approach of insisting that when employees seek medical treatment they inform the treating physician that they work with infectious agents (Chlamydia). Frank commented that communication was key to preventing illness in shared lab spaces. Alexandra commented on a West Nile Virus lab exposure she had researched as an example of a lab employee working with West Nile who was exposed to the virus and became sick but was in denial that he was ill from the virus.

4. **RML IBC charter**: The charter was distributed at the last committee meeting. Marshall commented that it was in the final form but minor changes could still be incorporated.

   Alex requested that the section describing the duties of the committee be modified to contain the specific wording found in the NIH guidelines section IV-B-2-b-1 describing the functions of an IBC. She also requested clarification from the committee about whether they could raise the biosafety level for a specific experiment or organism. She cited a case in Wisconsin in which she thought a researcher had previously worked with influenza under BSL-4 conditions but the IBC at their new job in Wisconsin allowed them to work with it under BSL-3 conditions. Patti stated that IBCs cannot lower biosafety levels for certain agents or experiments from what is described in the NIH guidelines. Marshall clarified that influenza strains are BSL-2 agents but that the CDC is drafting recommendations that will raise pandemic strains to BSL-3. He also commented that initially categorizing SARS as a BSL-4 agent would have severely slowed progress on its identification and characterization.

   Alexandra suggested having a comment box for the IBC in which employees could offer anonymous suggestions, observations of safety problems, etc. The rest of the committee concurred that such a box was not needed, as they had seen no evidence that RML employees were shy in sharing their concerns with the appropriate safety staff.

   Action: Nancy will modify charter and distribute electronically.

New Business:

BSO/Responsible Official Report- Dr. Nancy Hoe

1. Nancy distributed and discussed her report (attached). In discussing Select Agent issues, she confirmed that 2 employees in Receiving had received clearance to handle packages containing Select Agents. Frank commented that NIAID had contracted with BEI Resources to supply NIAID researchers with bacterial strains including Select Agents, but their inventory of available strains was very limited at this time.
2. **Update on request for information regarding Q fever vaccination**: Nancy reported that Dr. Ernie Takafuji, Assistant Director for Biodefense Research at NIAID, informed her that NIAID has granted approval for vaccinations through the USAMRIID Special Immunizations Program (SIP). In addition to offering vaccines to all intramural staff, NIAID will also offer this program to all extramural research grantees and public health personnel. They are considering the establishment of either regional vaccine centers (such as the CDC in Ft. Collins) or traveling vaccine teams. However, Ernie estimates the program will not be implemented until FY07. He recommends making arrangements directly with USAMRIID for any individuals requesting enrollment in the SIP now. Nancy will contact the PIs at RML who expressed interest in the SIP to find out how they want to proceed, and will continue to correspond with Dr. Takafuji regarding this matter.

OHSM Report – Paul Carlson

1. **Campus-wide safety training:** refresher safety training for all RML employees has been completed. Paul mentioned that the RML intranet site containing safety policies and procedures will be up and running in the near future.
2. **Summer students arriving**: new student safety training will occur every other week during the first part of the summer, with individual training occurring as late arrivals are hired on.
3. **Emergency response drills scheduled**: evacuation drills will occur in June, followed by lock-down drills. The drills will also encompass Select Agent emergency response and security plans. Paul commented that he will face some communication challenges in the quad. Frank suggested alarms with different sounds or using the phone system. Paul said he is still working out the details.
4. **Starting annual safety inspections**: Paul and Nancy will perform annual safety inspections starting soon. These are in addition to the periodic inspections throughout the year.

Other Business:

1. **Criteria for working in the BSL-3**: Patti explained that there had been some questions recently regarding the employment status and degree requirements for working in the BSL-3. She stated that she and Nancy had agreed that the individual needed to be an adult, adequately trained, and be associated with NIH through a formal appointment mechanism. The committee concurred with this opinion.
2. **Review of material between meetings**: In response to a request from Patti, the committee decided that ex-officio members did not need to receive electronic protocols for review between meetings.

Around the Room:

1. Patti noted that Don L. would be retiring soon, and thanked him for his service as a member of the committee. Don confirmed that he is retiring in September and reminded the committee they would need to appoint a new member from LPVD.
2. Debbie asked if Nancy was planning to provide BSL-3 training to staff. Nancy replied that she hopes to set this up in the near future. Marshall added that RML is setting up a mock lab that can be used for BSL-3 and BSL-4 training.
3. Alexandra asked about the status of the report on the Salmonella exposure, and whether she could have a copy. Marshall replied that as a member of the committee she could see a non-redacted copy. Patti asked if a redacted copy, omitting the name of the employee, was sufficient. Alexandra replied that it was. Patti will give Nancy a copy of the redacted report to distribute to the committee with the minutes.
4. Ken Pekoc pointed out that people are still talking about the BU incident, and thought this demonstrated the need to report laboratory incidents to the press in a timely manner. He suggested that those involved with management of such incidents at RML could add handling press releases to their "mental list" of response procedures.

Meeting adjourned.

RML Institutional Bio-Safety Committee Minutes

File Until: / /

Meeting date: 11-15-05
Meeting Time: 2:00 p.m. – 3:50 pm
RML Seminar Room A

Members:

	P	A		P	A		P	A
Dr. Patti Rosa, Chair	☒	☐	Debbie Crane	☒	☐	Don Lodmell	☐	☒
Alan Applebury	☒	☐	Richard Eggleston	☐	☒	Alida Merritt	☒	☐
Marshall Bloom	☒	☐	Don Gardner	☒	☐	Mike Parnell	☐	☒
Teresa Borino	☒	☐	Frank Gherardini	☒	☐	Greg Raymond	☒	☐
Harlan Caldwell	☐	☒	Alexandra Gorman	☒	☐	George Risi	☒	☐
Paul Carlson	☒	☐	Ted Hackstadt	☒	☐	Tom Schwan	☐	☒
Bruce Chesebro	☐	☒	Nancy Hoe	☒	☐	Pat Stewart	☒	☐
Greg Chilcott	☒	☐	Suzanne Krall	☐	☒	Randy Williamson	☐	☒

(P=present; A=absent)
Additional Attendees: Sue Priola, Ken Pekoc, Barri Twardoski

Minutes: Meeting minutes from 8-17-05 meeting

approved ☒ **not-approved** ☐

Patti R. – one minor correction, Patti did not mention the BEAT during the last meeting

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Old Business: *Summarized discussion not resolved at last meeting*

Item 1:	**Laboratory waste management** ■ Paul Carlson discussed the RML waste management plan describing improvements in RML recycling program and the separation of waste material.

Item 2	Noted – Don Lodmell has retired and his name will be removed from attendance roster. Marshall discussed the rotation of committee members. He explained to community members that they did not have to rotate off the committee and were welcome to stay on. Marshall stated that he would meet with the Lab Chiefs to discuss and finalize committee chairs and members. Marshall thanked Patti Rosa for chairing the bio-safety committee and thanked the community members for their support. Paul introduced Barri Twardoski, an Environmental Engineer who will be responsible for environmental compliance at RML. Nancy thanked the community members for their support

New Business: *Summarized discussion of new items the committee addresses*

BSO Report – Dr. Nancy Hoe

Report	**Best Recomb DNA** Nancy discussed Sonya Best's recombinant DNA application for growing Langat/Dengue-4 chimeric virus in Vero cells. Virus will be handled in BSL-2 lab in a Biosafety Cabinet. **Action**: Committee approved application **Gherardini: *Burkholderia cepacia, B. cenocepacia*** Nancy discussed the need for requiring a Pathogen Registration form for B. cepacia, which Frank works with in his lab. She described a concern brought forward by an RML contractor. The contractor's son has Cystic Fibrosis (CF), a condition for which B. cepacia infections can be fatal, and the person was concerned about the risk or carrying the bacteria back home to their child. Nancy and the contractor consulted with Dr. John LiPuma, a leading researcher and expert on CF and B. cepacia infections, and Dr. George Risi, who determined that the risk to the employee and their child was very low. They agreed on a conservative approach to mitigate the very low risk to the contractor of exposure to B. cepacia that includes limiting the contractor's access to the area where B. cepacia work is conducted and having the contractor shower out before leaving the campus for the day. Patti inquired as to where B. cepacia is found. Frank responded that B. cepacia is found in the environment such as in the soil and in onions. Nancy reported that most CF patients have a strain of B. cepacia that is not normally found in the soil and described reservoirs in hospitals and a recent case where it was found in non-alcohol based mouthwash. George responded that it is found in water and basically everywhere.

	Ted inquired if it has been found in Montana and George confirmed that it has been found in Montana. Frank added that 70% of the cepacia infections in CF patients are secondary infections. Frank's research is aimed at trying to figure out why cepacia may be so prevalent. George added that sputum of CF patients is more supportive to cepacia than normal healthy individuals. Teresa inquired if showering out is necessary. The contractor responded that they are taking excessive measures to protect their child. Greg Raymond inquired as to how long the pathogen survives on clothing. George answered that, based on a study performed by Dr. LiPuma, it survives for approximately 20 minutes on clothing.
Report	**Biosafety Training Performed** Nancy briefly covered some of the new employees safety orientation that has occurred since last meeting.
Report	**Safety Audits and Inspections** Nancy read the IRF settlement agreement requirement that safety audits and inspections be provided regularly to the local health officer or designee. To ensure compliance with this requirement, she will include a heading for this subject in her regular BSO report.

Report	**Accidental transfer of R. rickettsii to University of CA, Berkeley** Nancy handed out and read her report covering this incident dated November 9, 2005 (see attached). She also handed out an SOP dated October 4, 2005 titled "Recovery of archived *Rickettsia spp.* Seed Stocks. The incident occurred when samples of *Rickettsia parkeri* sent to UCB were later identified as *R. rickettsia*. Because the CDC categorizes *R. rickettsii*, but not *R. parkeri*, as a Select Agent, RML needed to comply with the CDC reporting requirements for the transfer of such agents. There was no evidence of actual exposure or infection, and there was no risk to public health or safety as a result of the incident. Patti mentioned her concerns that the issue was not brought forth to the IBC earlier. Marshall and Nancy apologized for not bringing it forward sooner as noted in the November 9, 2005 incident report. Marshall requested one typo correction on page 2. Nancy corrected typo. Marshall discussed the naming of the pathogen with Ted. Alan inquired into how infectious R. rickettsia is. Ted responded by describing the hazards associated with generating aerosols. Alan asked where this pathogen is from. Marshall responded that it was isolated in 1976 and addressed the challenges with growing this pathogen. Ted/Patti discussed the type of strains, using gene sequencing to make an identification, and issues/challenges with isolating virulent vs. non-virulent strains of rickettsii. Alexandra asked if there were tracking mechanisms in place to track the *R. rickettsii* strains sent from RML between 1976 and 2004. Ted stated that strains from RML have been sent around the world. Marshal discussed the meticulous records that are kept related to pathogens and the possibility that there may have been improper labeling in 1976. Marshall stated that if it had been labeled correctly it would have been handled as a select agent. George inquired as to how items are tracked. Nancy described IATA shipping guidelines. Patti suggested that shipping records be kept longer than one year and discussed the option of having certified stock. Marshall explained how PCR testing is used to distinguish virulent and attenuated strains of tularemia.

	Patti suggested that the receiving party verify that the pathogen ordered is actually the pathogen received citing the Boston incident with tularemia. Frank stated that when he receives request for strains he refers the requestor to the BEI stock collection. He also mentioned that if a mutant was requested he would describe to the requestor how to develop the mutant. Alexandra inquired as to how pathogens are received. Frank confirmed that when they receive a pathogen they complete PCR to confirm pathogen identity prior to commencing work. Patti stated that shipments have been received incorrectly and that there is a need to test the pathogen when received. Marshall stated that testing is difficult for all pathogens and that there may be a chance that two different pathogens may be sent as one sample. Marshall further discussed the sequencing that occurs in his lab. Nancy suggested that additional wording was need in the SOPs relative to testing. The committee agreed that she should include language in the BSL-3 SOP to address this. Greg R. inquired as to the committee roles. What does the committee need to provide input on? Patti would like to have a better process in place to report to the IBC. Marshall again referred to last paragraph in the incident report. Patti stated that she was fine with testing BSL-2 agents to verify that they are not BSL-3 agents. **Action**: Committee approved SOP dated October 4, 2005 titled "Recovery of archived *Rickettsia spp*. Seed stocks.

Other issues	**Liquid Nitrogen handling in BSL-3 TSE lab** Nancy handed out protocol written by Greg Raymond for review. Greg discussed the need for mammalian cells to be stored in liquid nitrogen. Stated that the ultra lows are only good at preserving mammalian cells for about 1 year and disussed their need to preserve cells longer than this. Greg described his protocol and cross contamination issues. Marshall inquired as to why not keep the dewars in the common freezer room instead of the lab. Committee discussed the concern of a greater risk of transferring the pathogen to the freezer room. Patti asked Marshall how they store their material and Marshall replied in an ultra low. Marshall discussed issues of vials shattering as they are removed from liquid nitrogen storage. Greg discussed their methods for removing the vials from the liquid nitrogen and stated that they utilize plastic vials instead of glass vials. Ted inquired about the "clean zone" in this lab. Greg explained that it was located next the anteroom and was marked with tape. **Action**: committee approved procedure.
Other issues	**Update on Q fever vaccine** Nancy described background and stated that she was working with Carol Hudgeons (NIH) to give vaccine to 24 people at RML.

Other issues	**Overview of ABSA meeting** Nancy attended ABSA annual meeting (Vancouver) with approximately 600 other attendees in October. Stated that ABSA has approximately 1500 members. Nancy gave a brief overview of the conference.

Associate Director Report	**RML Master Plan (Marshall)** The IRF is 60% completed. is 1 year from completion, and within budget. A BSL-4 mock training lab in is being developed in building 5 and will provide additional abilities to try out products while wearing a BSL-4 suit and 3 pairs of gloves. The BSL-4 training suits are on order. The pandemic influenza presentation to the Hamilton City Council is tonight (11/15) with Charmell Owens and Ron Nichols. The DVD that was recorded during RML's presentation on influenza is available from Marshall. Marshall mentioned the 20 year campus "Master Plan" and that an EIS (land use plan) was being developed. Marshall stated that quartely updates would be provided by Ron Wilson with a Notice of Intent during the 1st year with 18 months to final EIS. This would put a ceiling on number of employees at campus. Marshall also discussed the tabletop exercise involving external emergency response officials. (crane toppling into bldg. 25) Pat Stewart mentioned that tabletop exercises would continue and become more complex each time.

Miscellaneous items	**2005 annual report to OBA** This report is due in November. Patti discussed the need to report participant's roles. She also read a list of IBC training opportunities for committee members. She was not sure who would finance attendance if someone wanted to go. **Recombinant DNA applications** Patti inquired as to when recombinant DNA registration forms were needed. She specifically inquired as to whether, if she had an approved application describing experiments to reintroduce DNA from the same species back into itself (to inactivate a gene or complement a mutation), was a separate application needed before initiating experiments in which DNA from another species is introduced. Ted responded stating that recombinant DNA registration was clear but that the committee would review them case-by-case defining exemptions if pertinent. Patti inquired if a general proposal describing the general objectives, vectors and DNA was enough for these separate experiments or if a

	proposal needed to be submitted for each experiment. The consensus of the committee was that a separate, general proposal describing the objectives of the experiments, the vectors, and foreign DNA to be introduced was sufficient. **Action**: committee decided that separate recombinant DNA registration forms must be submitted to the IBC and approved before initiating experiments in which DNA from another species is introduced into an organism.

Miscellaneous items	**Around the room** Alexandra requested that the IBC be informed of all situations such as the Rickettsia incident.

Next Meeting: *To be determined.*

- Date: ____/____/_2006__
- Place: Bld. 1 conference room
- Time: 2:00 PM

National Institutes of Health
National Institute of Allergy and Infectious Diseases
Rocky Mountain Laboratories
Office of the Associate Director

DATE: November 9, 2005

FROM: Nancy Hoe, RML Biosafety Officer, RML Select Agent Responsible Official

SUBJECT: Accidental transfer of *Rickettsia rickettsii* to the University of CA, Berkeley

TO: RML Institutional Biosafety Committee,
NIH Division of Occupational Health and Safety

Incident description and response: In October and November of 2004, thirty-one vials of a purified organism labeled *Rickettsia parkeri* were sent from RML to the University of California, Berkeley (UCB). *R. parkeri* rarely causes human disease (1 case documented in Paddock, *et al.*, Clin Infect Dis. 2004 38(6):805-11), but it is closely related to *Rickettsia rickettsii*, the etiologic agent of Rocky Mountain Spotted Fever (RMSF). During the course of recent studies at UCB to molecularly characterize the organism, the sequence of a gene of interest revealed greatest similarity to the equivalent gene of *R. rickettsii*. On September 8th, 2005, the RML Principal Investigator who shipped the samples learned of this finding from the investigator at UCB, and on September 9th, 2005, the RML PI provided initial notification of this finding to the Director of the NIAID Division of Intramural Research, the Director of Safety at NIH, the Chief of the Laboratory of Intracellular Pathogens, the Associate Director of RML, and myself, as the RML Select Agent Responsible Official. Because the CDC categorizes *R. rickettsii*, but not *R. parkeri*, as a Select Agent, this finding needed to be confirmed, as RML would then need to comply with the CDC reporting requirements for the transfer of such agents. Subsequent sequence analysis by RML of one of the few known genes of *R. parkeri* confirmed the identity of the shipped organism as *R. rickettsii*. On September 20th, 2005, this information was disseminated to the Director of the NIAID

Division of Intramural Research, the Director of Safety at NIH, the Chief of the Laboratory of Intracellular Pathogens, the Associate Director of RML, myself, as the RML Select Agent Responsible Official, and the Business and Program Manager for RML. The next day, since I was out of the country on programmatic travel, the RML Alternate Responsible Official sent a letter to the CDC Select Agent program describing the incident. On September 27th, a follow-up letter was sent to Dr. Lori Bane, a Compliance Officer for the program.

In accordance with NIH policy and the terms of the lawsuit settlement between NIH and The Friends of the Bitterroot, Women's Voices for the Earth, and Coalition for a Safe Lab, the Associate Director for RML reported the incident to the Ravalli County public health officer on Wednesday, September 21st, 2005. The RML Infectious Disease Advisor and the county public health nursing department were also informed on the same day. None of the individuals contacted felt that the issuance of a press release or public notification was warranted.

Nevertheless, a draft press release describing the incident was considered, with the following being contacted: the Chief of Staff, Office of the Director, NIH, the Office of General Counsel, NIH, the Director of Safety at NIH, the acting Director of the Office of Communications, NIAID, the acting Associate Director for Management and Operations, NIAID, the Director and Deputy Directors of the NIAID Division of Intramural Research, the Chief of the Laboratory of Intracellular Pathogens, the RML Principal Investigator who shipped the samples, the Associate Director of RML, the Business and Program Manager for RML, and the RML Public Affairs Officer. It was decided not to issue a press release.

There had been no evidence of symptoms or illness consistent with rickettsial infection in anyone involved at RML or UCB. The researcher who received the samples at UCB confirmed with RML that all samples of the organism shipped to UCB had been accounted for and destroyed and only nucleic acid retained for further identification purposes. The UCB safety staff was also informed of the incident.

Serum samples were collected on September 26th from the Principal Investigator and the

employee that prepared the organism for shipment to UCB. These samples and previously archived samples were sent to the Montana State Public Health Laboratory on October 6th to test for the presence of antibodies to RMSF.

The bacterial samples prepared at RML were handled in a BSL-2 laboratory, but using BSL-3 precautions (i.e. access to the lab is restricted, disposable lab coat and gloves are worn, all manipulations are done in a Biosafety Cabinet). The 31 vials were packaged and shipped in accordance with International Air Transport Association regulations for Infectious Substances. BSL-2 precautions were used at UCB upon receipt of the organism until their disposal.

Strain information: All strains of rickettsia identified as *R. rickettsii* are stored and handled in accordance with strict procedures mandated by the CDC and RML. All rickettsial stocks at RML, regardless of biosafety level and select agent status are, and have been, kept in locked -80° freezers in a secured room under video surveillance in the BSL-3 laboratories.

The misidentified specimen shipped to UCB can be traced to a 30 yr old vial in the RML culture collection supposedly containing a type strain of *R. parkeri*. This strain was passaged twice in 1991 and re-frozen until broken out and expanded in 2004. The 1976 seed stock is depleted but the two seed stocks from 1991 and one from 2004 are available.

Follow up: A letter from Dr. Charles Brokopp, Director of the Select Agent Program was received October 5th, thanking RML for promptly reporting the incident and stating that no further action would be taken.

At no time after the incident has any employee at RML or UCB exhibited any signs or symptoms of RMSF. Reports from the State Lab were sent to me from the RML Infectious Disease Advisor on October 14th. All serum samples tested were negative for antibodies to RMSF.

Experiments are underway to determine where the mislabeling/contamination may have occurred, however, there are no remaining ampoules from 1976 and samples from the 1991 expansion and plaque cloning have not yet successfully PCR-amplified a DNA product for sequence analysis. The failure of the PCR is likely due to the overwhelming presence of host cell DNA in the stocks. *R. rickettsii* was present in the lab in 1991 thus it is possible that contamination occurred at that time. The 2004 manipulations are not considered a source of the contamination since *R. rickettsii* was not being worked with at the time. I will provide updates if any new information arises regarding this matter.

Corrective actions: RML has an extensive archived collection of rickettsial strains that have been the type strains used around the world. Many of these were initially isolated at RML. It should be noted that rickettsiae are bacterial obligate intracellular parasites and are difficult to propagate even under the best of conditions. There are no known phenotypes and few genetic markers to identify strains conclusively. This is particularly true for those species that have little to no association with human disease, such as *R. parkeri.*

To reduce the chance of an incident of this type happening again, we are immediately implementing a policy that no rickettsial isolates will be transferred from the RML until plaque-purified (to address the possibility of co-infections) and the identities confirmed by genetic techniques or other accepted procedures. These procedures will be documented in the Standard Operating Procedures of the laboratory, and all archived specimens will remain in place and sealed until the SOP is approved. The fragility of the rickettsia and the fact that many are frozen in sealed glass ampoules precludes immediate testing of all stored samples, as all archival strains must be propagated and partially purified before confirmation of identity. All rickettsial strains to be recovered from archival specimens will be handled under BSL-3 conditions until their identity is confirmed.

While officials at NIH, NIAID, RML, and Ravalli County were notified of the incident, the Chairperson of the RML Institutional Biosafety Committee was not informed at the time, or included in any of the subsequent discussions. This was an oversight made by the Associate Director of RML and myself. No active or conscious decision was made to

exclude the Chairperson or the IBC from any discussions. To reduce the possibility of this oversight occurring in the future, I will ensure that the Chairperson is informed of any biosafety incidents that I report to or discuss with the Associate Director of RML.

In conclusion, there was no evidence of actual exposure or infection, and there was no risk to public health or safety as a result of this incident.

Respectfully submitted,

Nancy Hoe

Nancy P. Hoe, Ph.D.
Biosafety Officer
RML Select Agent Responsible Official
Rocky Mountain Laboratories

Title: **Recovery of archived *Rickettsia spp.* seed stocks.**
SOP #: **BL3-100-13**
Date: **October 4, 2005**
Purpose: To provide guidance for safe handling and containment of historical *Rickettsia spp.* stocks from the RML culture collection.

13.0 Recovery of archived *Rickettsia spp.* seed stocks

13.1 The Rocky Mountain Laboratories has an extensive archived collection of rickettsial strains that have been the type strains used around the world.

The CDC/NIH manual *Biosafety in Microbiological and Biomedical Laboratories, 4th ed.* (Rickettsial Agents, section VII-E, pg. 149.), lists certain rickettsial agents causing human disease and specific practices and procedures that require BSL-3 containment. Work with certain species not associated with human disease can be conducted under lower containment conditions.

13.2 Most of the archived rickettsial strain collection at RML consists of non-clonal isolates potentially containing unknown rickettsiae, possibly with pathogenic potential. Therefore, to minimize the potential for accidental exposure or release, **all strains being recovered from the culture collection will be handled under BSL-3 level conditions until the organisms are plaque-cloned and a definitive identification is made.**

13.3 No specimens will be removed from BSL-3 containment or transferred to other institutions until plaque-cloned and identities confirmed by DNA sequencing of selected genes.

13.4 Strains not consistent with their expected identities will be destroyed by autoclaving all specimens from that seed stock.

13.5 If any archived material is discovered to be a Select Agent (*R. rickettsii* or *R. prowazekii*), the RML Responsible Official will be notified immediately.

RML Institutional Biosafety Committee Meeting
August 17, 2005
2:05 p.m. - 3:20 p.m.

Attendees:

Patti Rosa, Chair	Marshall Bloom	Paul Carlson	Debbie Crane
Richard Eggleston	Don Gardner	Frank Gherardini	Alexandra Gorman
Ted Hackstadt	Nancy Hoe	Alida Merritt	Mike Parnell
Greg Raymond	George Risi		

Absent:
Alan Applebury, Teresa Borino, Harlan Caldwell, Bruce Chesebro, Greg Chilcott, Suzanne Krall, Don Lodmell, Tom Schwan, Pat Stewart, Randy Williamson

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Minutes:

1. **Meeting minutes from 5/3/05 meeting.**

   Discussion: No discussion

   Action: Minutes approved.

Old Business:

1. **RML IBC Charter –Revised draft.** Mike pointed out that a statement in the charter describing committee approval of applications to use hazardous biological agents conflicted with actual procedures. The charter states, "Approval by other RML committees, e.g., RML Institutional Animal Care and Use, Radiation Safety, and Safety Committees, must be obtained when relevant prior to final authorization." Mike stated that the ACUC needs approval from the other committees before it will approve an animal protocol. Committee agreed final wording should omit "...prior to final authorization." Greg R. asked if another statement of IBC duties, "Receives, reviews and approves standard applications for the use of hazardous biological agents (BSL-2 or above)..." should be changed to "BSL-3 or above". Patti noted that "standard applications" was relevant for BSL-2 projects. The committee agreed the original wording should stand.

   Action: Charter is approved with minor modification.

2. **New IBC Members**: Patti asked Marshall about Don Lodmell's replacement on the committee since Don is retiring. Marshall will discuss this at the next Lab Chief's meeting. Marshall also notified the committee that Lee Thompson, a biosafety, biocontainment, and

biosecurity consultant for RML will be added as a committee member. Marshall will send Lee's CV to Patti to forward to Bethesda.

New Business:

BSO/Responsible Official Report- Dr. Nancy Hoe

1. Nancy distributed and discussed her report (attached). Sonja Best needs to complete recombinant DNA paper work. Nancy will follow up with Sonja.
2. **Update on request for information regarding Q fever vaccination**: Nancy will meet with Dr. Ernie Takafuji, Assistant Director for Biodefense Research at NIAID, the week of August 22nd to discuss how to move forward with a plan to get RML employees vaccinated for Q fever. Bob Heinzen is requesting vaccinations for lab staff and animal caretakers and estimates the cost of sending them to USAMRIID at $200K, excluding travel. Nancy stated she has heard that some researchers at Montana State University went to Australia to receive the vaccine. Ted asked if Nancy could inquire about the legal aspects of this.
3. **Building 25 Maintenance Standard Operating Procedures (SOPs)**: Nancy reported that SOPs for the isolation of individual suites in building 25 prior to decontamination have been developed and implemented. She presented slides showing the location of the SOP book in the interstitial space in building 25, Kevin Mora (the IRF Facility Manager) providing training to maintenance staff, the labeling of valves and duct work, and the demarcation of lab suites in the interstitial space.
4. **International High Containment Biosafety Workshop:** Nancy reported on her attendance at the workshop at the Canadian Science Centre for Human and Animal Health in Winnipeg, Canada. She showed slides highlighting the different areas covered during the workshop: certification of biosafety cabinets, integrity testing of BSL-4 suits, daily checks for the BSL-4 laboratory (chemical shower tanks, breathing air), effluent treatments systems and mock spill clean-up, HEPA filter decontamination and certification, room pressure decay tests, and validation of vaporized hydrogen peroxide decontamination.

OHSM Report – Paul Carlson

1. **NIAID annual safety inspections completed**: Paul reported that 89 labs were inspected and that safety in the labs continues to improve. The most common corrective actions involved labeling of secondary containers and labeling freezers with biohazard signs.
2. **Third-quarter biosafety cabinet (BSC), chemical fume hood, and downdraft table certifications**: Paul reported these were occurring the week of August 15th (this week). Alex asked if any of the BSC filters needed to be changed. Paul said that some were replaced. Frank asked if Paul had ever seen a filter rupture and Paul said no. George asked if there were more than one manufacturer for HEPA filters. Paul said no. Mike replied that there are only a few and that usually equipment manufacturers make them

using proprietary licenses so they can only be bought from the specific equipment manufacturer.

3. **Emergency Response Drills**: These were conducted in June. The drills went well with all occupants evacuating occupied buildings in under 4 minutes. The next drills are scheduled for mid to late October 2005. Paul stated that Lock-Down drills would probably take place next year.

Other Business:

1. **IRF tour feedback**: Marshall reported the most common response was "When will there be another tour?" He stated that a good time would be in another year. He noted that construction is slated for completion by 11/06 and the building is to be turned over to RML on 2/07. He explained that there is a commissioning and inspection process prior to turn over, and then there is a 30-day period for verification and testing by NIH.

Around the Room:

1. Alida reported on the training hosted by Marcus Daly on the Hospital Emergency Incident Command System (HEICS). This training was made possible by a grant from the Homeland Security Department and included OSHA HAZMAT operations and Decon training, and a Decon exercise. She reported that Marcus Daly purchased 5 powered air-purifying respirators (PAPRs).
2. Ted asked if the committee had reached a consensus on issuing press releases in response to potential employee exposures. Patti replied that the decisions would be made on a case-by-case basis, as it is difficult to establish specific rules since each situation is different. The Biological Exposure Assessment Team would discuss the issue and make recommendations. Marshall explained the Incident Notification System (INS) being developed by RML. Alida discussed occurrence reporting procedures at Marcus Daly. She noted there has been a reluctance to report by some employees due to perceptions about the formal reporting process but that she feels this is decreasing over time. Alex said she appreciated how fast the Q fever incident was reported. She thought it had a good effect and was reassuring to the public. Mike commented that this issue highlighted the advantages and disadvantages of living in a small community.
3. Patti inquired about proper glove disposal in the laboratory, specifically if all gloves needed to be disposed of in the biohazard (orange) bags even if they had not been used for infectious work. Nancy and Paul explained that they were requiring that all gloves be put in the orange bags because the janitorial staff cannot distinguish between what is contaminated and what isn't. Mike agreed and stated that this requirement is more important now since general refuse is being disposed of off-site. Marshall explained to the committee the new waste handling procedures being implemented at RML to divide waste streams into biohazard waste, lab waste, and general refuse. There was much discussion by the committee about what constituted biohazard or lab waste and questions

were raised about general disposal practices in the lab. The committee finally agreed to ask Paul to ask the Safety Committee to make the final policy regarding the matter.

4. Patti inquired about BSL-4 training. Nancy replied that RML would have a Biocontainment Specialist who would provide the training. Marshall added that a lab in building 5 is being set up as a mock BSL-4 lab for training and trying out new equipment in a non-hazardous environment. Ted asked if there would be a training room in the IRF. Mike said there will be breathing air drops in the animal holding rooms so they could be utilized for training.

Meeting adjourned at 3:19 pm.