North Carolina State University is a land-grant university and a constituent institution of The University of North Carolina

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NC STATE UNIVERSITY

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May 3, 2006

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

Dear Mr. Hammond:

In response to your letter dated March 15, 2006 requesting copies of our Institutional Biosafety Committee minutes, I have enclosed the requested minutes. Please note that upon advice of our institutional legal counsel, which is based on security concerns, the names of all individuals referred to with the IBC minutes have been blacked-out.

In response to the question posed in your information request letter as to whether 'the North Carolina State University IBC has or 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),' the NCSU IBC **has** implemented appropriate written policies in compliance with NIH oversight procedures.

Sincerely,

Amy M. Grunden, PhD
North Carolina State University
Associate Professor, Department of Microbiology
Institutional Biosafety Committee Chair

the sunshine project

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15 March 2006

[redacted]
North Carolina State University
Box 7622
Raleigh NC 27695-7622

NCSU EHS
919 513 2690

By fax:

Dear [redacted]

Pursuant to the National Institutes of Health Guidelines on Research Involving Recombinant DNA Molecules (NIH Guidelines), Section IV-B-2-a-(7),[85] the Sunshine Project hereby requests the Minutes of all meetings of the North Carolina State University Institutional Biosafety Committee (IBC) since 1 May 2003.

Please send the minutes to the address above. The NIH Guidelines require that minutes be made available "upon request". I request that you send your reply by Friday, 28 April 2006.

This letter is sent to you because IBC registration records of the National Institutes of Health Office of Biotechnology Activities indicate that you are responsible for the North Carolina State University IBC.

This letter is sent to you as part of a national survey of compliance with the NIH Guidelines.

When you respond, I would appreciate your answer to the following question (please circle one):

> The North Carolina State University 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).

Please feel free to attach any additional explanatory materials that you feel are appropriate. Thank you very much for your attention to this request.

Sincerely,

[redacted]

[redacted]
Director

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[85] *Section IV-B-2-a-(7). Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes...*

Biosafety Committee Meeting Minutes

Place: CVM A-231
Date: 2/13/06
Time: 10:00 AM
Adjourned: 11:15 AM

Attendance:

[redacted]

Topics Discussed:

1. Review of the access request forms for the CVM-NCSU BSL3 Biocontainment facilities

2. Update on the university biohazard waste disposal procedures

3. Review of current BUA and rDNA forms to address whether any changes are required to improve their utility

    1. Prior to the IBC meeting, [redacted] had provided the IBC chair with the BSL3 Biocontainment Facility Project Request Form and the accompanying memorandum that describes the specific requirements that must be met by the investigator seeking access to the BSL3 Biocontainment Facility. The chair distributed copies of the request form and memorandum at the beginning of the meeting [redacted] gave

an overview of the development of the BSL3 lab space access forms and spoke about the time-line for granting access to investigators wanting to use the BSL3 laboratory space. The project request form and memorandum are included as an addendum to the minutes.

2. [redacted] briefed the committee on problems with the current procedures used by the university for disposal of biohazard waste into the [redacted] landfill. Currently, the county waste transfer stations are refusing to accept "red-bag" (inactivated biohazard waste) from the university, and as a result inactivated biohazard waste must be separated from the other university waste-stream and transported directly to the [redacted] landfill. There is growing concern from university EHS officials that the [redacted] landfill may also refuse to accept inactivated biohazard waste from the university in the near future, in which case a contract biohazard waste company would have to be used to dispose of the inactivated biohazard waste generated by the university. The use of a contract biohazard waste company would incur considerable expense that would be passed along to individual departments and Principal Investigators on campus. To avoid this possibility, [redacted] Macdonald has proposed to develop a series of biohazard waste disposal procedures that will be adopted campus-wide which would insure that all biohazard waste generated at the university is verifiably inactivated. As part of this plan, [redacted] proposed requiring the use of a chemical-based autoclave test pack each time biohazard waste is autoclaved on campus and that a log be maintained to record proper autoclave inactivation of each biohazard waste bag. [redacted] recommended the use of the 3M Comply™ Sterigage™ Steam Chemical Integrator Test Pack since it is considered to be a Class 5 test as is the biological spore test. [redacted] will keep the IBC updated as the plans for the university biohazard waste disposal program are formalized.

3. For over a year, the whole IBC has been reviewing the BUAs and RDNA registration forms submitted by campus researchers. Based on this experience, the committee chair solicited feedback from the committee on whether there was a perceived need to modify or clarify any portion of the registration forms. The committee agreed to provide feedback on any suggested form changes to the chair via email. It was noted that a modification requiring the insertion of language describing verification of biohazard waste be included in the BUA and rDNA forms as part of the university-wide compliance with the proposed university biohazard waste disposal program being developed (see topic 2).

MEMORANDUM
ACCESS TO CVM-NCSU BSL3 BIOCONTAINMENT LABORATORIES

TO: All potential users of the CVM-NCSU Biocontainment Facility

FROM: [redacted] DVM
Director, CVM-NCSU BSL3 Biocontainment Facility

[redacted]
Facility Manager, CVM-NCSU BSL3 Biocontainment Facility

RE: Procedural mechanisms to gain access to containment facility.

DATE: Feb, 2006

STAGE I
To be addressed before a request for space in the CVM-NCSU BSL3 Biocontainment Facility will be considered. There are additional requirements that must be met before space can be assigned (Stage II).

1. All prospective investigators shall contact the Facility Director or Manager in order to inform them of the intended research project and projected timeline. The information will be provided on the attached **form** which constitutes the Request For Space. **Electronic copy of form available from** [redacted]

2. All prospective investigators must have completed a Biological Use Authorization (**BUA**) for biological agents and recombinant DNA through the NCSU Institutional Biosafety Committee. (BUA form is available on NCSU website under EH&S.)

3. The PI will specify whether the proposed work is to involve select agents. If select agents are proposed, PI must contact EH&S. Research involving agents that are on the CDC/NIAID Category A, B, and C lists must be approved by the Institutional Biosafety Committee (~30 days) with subsequent approval and registration with Federal Institutions, CDC or USDA, as appropriate (~120 days +/-).

STAGE II

1. For all projects, Standard Operating Protocol(s) and agent identification information (characteristics of infectious agent and primary laboratory hazards of working with the agent) must be provided in writing to the Facility Manager by PI.
2. Training for all users includes:
    - Documentation and verification of proficiency in basic laboratory procedures. Please submit copy of CV +/or resume indicating work experience.
    - Training in BSL3 procedures by BSL3 Manager (read CDC's BMBL and CVM's BSL3 SOP).
    - 2 weeks supervised access to BSL3 lab (signed Provisional Access Request form). Upon satisfactory completion of supervised period, trainer may approve new user for independent access to BSL3 Facility.
    - Completed Training Checklist and Certificate of Training to be attached to SOPs pertinent to PI's project and kept on file in BSL3 Facility.
3. Request for immunizations as deemed appropriate by Student Health Services for agents involved in individual projects and other agents in use in BSL3 Facility. (See NCSU medical surveillance program website for request forms: <<www.ncsu.edu/ehs/www99/right/handsMan/worker/med.html#access>>.) When complete, bring copy of immunization form signed by Student Health Services, or comparable verification from other institutions, to BSL3 Director or Manager. Exposure potentials are subject to change due to introduction of new research projects/agents to the facility.
4. Signed Affidavit of Eligibility under USA Patriot Act of 2001, if select agents are involved, to be kept on file in BSL3 Facility.

Final approval and authority for assignment of space resides strictly with the director of the laboratory facility. In the event that space is denied, investigators may request a review of the decision by [redacted] Activation of card access will not be made until all approvals have been obtained.

CVM BSL3 Biocontainment Facility will be operated on a cost recovery basis. Usage rates as assessed by the NCSU Office of Contracts and Grants will be charged on a daily basis ($70.82) with a minimum commitment of 3 months to gain access to the facility. A 2 week shutdown for repairs and certification will be scheduled annually.

Project Request Form for Biocontainment Facility

		Agents (s)
Biological Agent	Bacteria	_____
	Fungal	_____
	Virus	_____
Select Agent	Yes	
	No	
		Funding Source
Project type	Pilot study	_____
	Contract	_____
	Grant	_____

Proposed start date _____

Proposed duration of project _____ Weeks
_____ Months
_____ Years (resubmission of BUA necessary every 3 years or with change in protocol or personnel)

Frequency of lab use
Daily
Weekly
Monthly

Estimated # of users _____

Intended use of radioisotopes Yes _____approved protocol number
No

Equipment provided for use in the BSL3 Biocontainment Facility includes:
NuAire Biosafety Cabinets type II A2 or B2 with automatic pipettor.
4C Refrigerator
Labline -20CFreezer
Revco brand -80C freezers (Space to be assigned by manager *Racks, if desired, supplied by PI. Select agents must be stored in locking racks. There will be a $20/month fee assessed for storage of agents beyond the duration of projects.)
Isotemp water jacketed CO_2 incubators
AccuSpin 3R centrifuge with speed range 300 rpm (19 X G)-13,000rpm (16,000 X G) and an assortment of aerosol containing buckets
Eppendorf Microcentrifuges with aerosol containment
Mixers/rotators
Inverted microscope with 4, 10, and 25X objectives
Standard laboratory microscope with 4, 10, 40, and 100X objectives
Ohaus balance with draft shield
Ultrasonic bath
Waterbath
Eppendorf pipettor sets of 10, 100, 1000ul

*If additional equipment is needed for project, care should be given to choice of equipment brought into the lab. All equipment brought into the lab can not be removed from facility due to biosafety issues, unless thoroughly decontaminated which can be deleterious to some equipment. Method of cleaning and sterilization for equipment brought in by any staff member must be ascertained by PI.

_____
_____
_____
_____

Disposables provided: PPE (one gown per week provided), gloves, goggles, simple surgical masks, shoe covers, autoclave bags, and disinfectants.
*Respirators required by EH&S, to be provided by PI.

_____

* Items not provided by BSL3 Facility that are the responsibility of PI.

Questions or comments _____
_____
_____
_____
_____
_____

Biosafety/IBC Committee Minutes
February 2, 2005 2:00 P.M.
CVM B-222

Attendance: [redacted]

Agenda

Discussion of oversight of the new BSL 3 labs coming on line at the CVM new research facility

1. A SOP for the BSL3 labs was submitted by [redacted] to the committee for review. The SOP was the starting point toward understanding how the BSL 3 labs would function.
2. Training for all personnel using the BSL 3 lab is imperative. The question arose who would do the training.
3. Who is accountable for overseeing the labs was a question posed to [redacted] At this time no decision had been made. The committee suggested that a Faculty member rather than a staff person be in charge. Staff personnel would have no authority over Faculty and thereby undermine any control measures implemented.
4. The labs will have multiply users. Some of these users would be from outside NC State system. For example, [redacted] researchers. How much turnover would occur won't be determined until the labs are up and running.
5. The question arose about the use of select agents and authorization of personnel in the area of the select agent. CDC has stated as long as the select agent is in a secure location, access available to users only and a written procedure for use of the agent is developed, all personnel in the lab do not need to go through the authorization process.
6. The committee suggested that reference to serum banking in the SOP be deleted. A previous discussion with HR in the last committee meeting, HR suggested not using WHO guidelines for physicals and serum banking. A suggestion was made that a medical questionnaire similar to the one used for animal handlers be used as an assessment tool. The medical surveillance physician can make a decision based on the questionnaire whether testing is needed for the employee.
7. The committee approved of the SOP submitted with the corrections suggested.
8. The committee also encourages the CVM administration to quickly make a decision on picking a director to oversee the BSL 3 labs.
9. Members of the IBC were invited to tour the newly constructed NC State System BSL3 Laboratory by the [redacted] in order to observe the state system's BSL3 protocols and certification process.

Meeting adjourned at 3:30 P.M.

NCSU CVM
BSL3

STANDARD OPERATING PROTOCOL
Jan. 5, 2005

I. LABORATORY ACCESS

A. GENERAL

The proposed BLS3 will be a restricted access facility. Biohazards, Radiation hazards and Chemical hazards are assumed in all the BSL2 and BSL3 laboratory areas within the building. Therefore, strict adherence to any and all Standard Operating Procedures, Guidelines and Recommendations is required.

1. All visitors must sign the guest register in the reception area before proceeding to the laboratory areas.

2. Children under 18 years of age are not to be admitted inside the facility.

3. Visiting scientists must be cleared by principal investigator and laboratory supervisor before working in any CVM BSL3 laboratory. If a visitor (scientist or vendor) needs to perform work in the BSL3 containment facility, a liability waiver must be signed. Visitors are the responsibility of the principal investigator and should be informed of all safety and technical restrictions applicable to them during their stay.

4. Maintenance Support Staff

<u>NCSU CVM personnel.</u> It will be the responsibility of the individual departments and Principal Investigators to develop and maintain surveillance programs for their employees providing services within the CVM BSL3 facility.

<u>Non-NCSU personnel.</u> It will be the responsibility of the CVM staff to advise Non-NCSU CVM personnel of the hazards and safety issues applicable to them while working in the facility. Personnel who will be working in the BSL3 containment area must sign a liability waiver prior to entry. Optimally, service personnel should be accompanied while working in the BSL3 laboratory and a "decontaminated" area provided for their instruments. When possible, tools should be wiped down with 70% EtOH/1% Triton X-100 before removal from the area.

B. NCSU CVM STAFF

1. Access to CVM BSL3 laboratory will be restricted to approved personnel. A current listing of approved personnel will be kept posted on the laboratory door.

2. New personnel will not be permitted to perform work in the BSL3 laboratory until they have completed a safety orientation session with the BSL3 supervisor. This session includes orientation and review of general safely practices, as well as the proper handling of biohazards and radioactive materials. The orientation should be completed within the first week of employment, and completion will be documented by an affidavit signed by the employee and the orientation instructor.
3. In addition to the safety orientation, new personnel will familiarize themselves with the procedures specific for their particular biohazardous agents, as well as chemical and radioactive reagents to be used. Individuals will also document attendance at radiation safety training (if required). New personnel will also familiarize themselves with the CVM Standard Operating Procedures (SOP) associated with waste disposal (including biohazardous materials, radiochemicals, organic solvents), handling sharps and broken glass, and emergency procedures associated with chemical and radiochemical and biohazardous spills.

4. Individuals who are pregnant or at an increased risk for acquiring infection should consult their immediate supervisor before working in the BSL3 Laboratory. Individuals at risk would include those who are immunosuppressed or undergoing immunosuppressive therapy, and individuals having recent surgical procedures or injuries in which the integrity of the skin has been significantly altered or compromised.

   By their own choosing or at the request of their immediate supervisor, individuals may contact EOHS for medical consultations. Requests should be made through the director (?).

I. BSL3 LABORTORY PROCEDURES

1. Only approved personnel will be allowed entry to the BSL3 containment facility. Prior to entry, individuals must complete the general safety orientation session describe above, demonstrate proficiency in the handling of biohazards and radioactive materials to their immediate supervisor.

2. Personal items should be stored in cabinets and drawers in the antechamber (if available in new building).

3. Eating and drinking is strictly forbidden in laboratory areas. If radioisotopes are used in the laboratory, the work area must be identified by taping around the area with radioactive tape. If individuals have questions specifically regarding radiation safety issues, see the Radiation Safety Office.

4. All reagents should be labeled according to the Hazardous Material Identification Guide (HMIG) and Material Safety Data Sheets (MSDS) available for each. All employees are to be informed of the location of the MSDS and instructed on how to utilize this information, and the HMIB rating system.

5. Appropriate clothing must be worn when performing work using radioisotopes and/or hazardous chemicals. Clothing will be considered "appropriate" only if it covers areas of the skin that are likely to be contacted by splashes and spills. Disposable Tyvek gowns should be worn to cover street clothes and should be closed in the front. Personnel must provide adequate personal clothing when planning to perform these procedures. Don gown and gloves in the outer room adjacent to the materials rack prior to entering the main laboratory. Discard all wrapping materials in the trash receptacles provided.

6. All employees should know the proper procedure for handling chemical, biohazard and radioactive spills. In the event of a spill, contact the laboratory supervisor and/or Principal Investigator in charge for assistance.

7. All freezers, refrigerators and other storage areas containing biohazards, radiochemicals and/or chemical hazards will be appropriately identified with labels. All personnel accessing these freezers, refrigerators or other storage areas for **ANY PURPOSE** will use protective gloves. In addition, individuals accessing any samples from a Liquid Nitrogen storage area containing hazardous materials must wear protective full-face shields and disposal barrier gowns.

8. To ensure the safety of others and minimize errors, work areas should be decontaminated and left in an orderly fashion at the close of the work session. For radiation areas, this includes monitoring for possible contamination and documenting results.

9. Laboratory personnel are to receive instruction on the proper use and care of an instrument prior to using equipment belonging to another laboratory or a piece of

common equipment.

10. Each user is responsible for maintaining common areas. All equipment, plastics, reagents and trash should be removed at the close of the work session.

11. **General Safety Considerations**

•A. Eating, drinking, or smoking is NOT permitted in the BSL3 laboratory.

•B. Mouth pipetting is NOT permitted.

•C. Gowns and gloves MUST be worn at all times in BSL3 areas.

•D. All work with potentially infectious materials that pose a threat of exposure by splashes or aerosols must be performed in approved physical containment devices (i.e. biological safety cabinets (BSC) or centrifuge designed for aerosol containment). Some notable exceptions are cell counting with hemocytometers and microscopic examination of experiments. When handling hemocytometers, personnel will be extremely cautious due to the potential sharps hazard of working with glass cover slips and slides in the BSL3 laboratory.

•E. All containers used for storage, transport or shipping of potentially infectious materials must be labeled with the biohazard symbol.

•F. Vacuum outlets are present in the BSL3 laboratories but their use is strongly discouraged. If employed, a disinfectant trap consisting of 10% Clorox followed by an in-line HEPA filter must be included.

•G. Glassware, glass pipettes (Pasteur or serologic) and needles are **not** permitted in BSL3 laboratory.

•H. While working in BSL3 laboratory, personnel should wear **two** layers of gloves. A gloved hand removed from a biological safety cabinet (BSC) is considered contaminated and the outer glove should be removed and replaced immediately.

•I. Wash hands before exiting lab to prevent contamination of doors, doorknobs, and fixtures.

•J. For any spills, which occur outside of the biological safety cabinet, please refer to the procedure contained in Appendix A of this document. Each laboratory is responsible for maintaining an appropriate Biohazard Spill Kit as specified in Appendix A.

•K. For your own safety and the safety of other individuals, all BSC must

be maintained in a clean and orderly manner. Individuals using Biological Safety Cabinets should be instructed on the design and proper use of the BSC. The inside surfaces (including the back panel) must be free of any splashed/spilled media, blood, etc. Upon completion of work session, the individual using the hood is responsible for cleaning it. This is most effectively done by wiping the surfaces with 70% EtOH/1% Triton X-100.

•L. All counter surfaces must be cleaned upon the completion of each working session.

•M. All centrifugations must be performed with cups or buckets designed specifically for containment purposes.

12. **Handling of Biohazard Waste**

All infectious materials must be placed inside biohazard bags placed within autoclavable pans located in the BSC. All pans and waste bins are lined with two biohazard bags and are located within the Biological Safety Cabinets. Biohazard bags are **NOT filled above the top of the side panel of the bin**. This practice minimizes the potential for spillage during transport from the BSC to the autoclave and the potential for spillage during the sterilization cycle. If a waste bin cannot be removed from the BSC without disengaging the window panel, it is too full and the waste needs to be redistributed to a second waste bin. Biohazard bags must remain permeable to steam so that the interior of each bag will be effectively decontaminated. Prior to removing a filled waste bin from the BSC, the inner bag should be left unclosed and the outer bag should be closed with rubber bands provided for this purpose. When closing the outer bag, individuals should NOT twist the outer bag closed prior to applying the rubber band closure. The exterior bag is labeled with the certification sticker and autoclave tape prior to loading the waste bin into the autoclave.

A. **LIQUID WASTE**

Liquid waste generated in BSL3 laboratory will be divided into two categories: A) **NONINFECTIOUS** and B) **INFECTIOUS**. Small volumes of liquid, i.e. less than 20 ml (with either designation) may be discarded directly into the waste bins if they are contained within a closed vessel. **However, caps MUST be loosened slightly** to allow steam penetration, otherwise decontamination cannot be insured.

B. **NONINFECTIOUS LIQUID WASTE**

Noninfectious waste will be defined as liquids associated with whole blood from normal human or animal donors, liquids from uninfected tissue culture

lines, or liquids from uninfected primary cell cultures. Liquids from infected cell lines **are NOT included** in this category. If in doubt about the designation of Liquid waste, treat as Infectious liquid waste as described below.

Noninfectious waste should be handled as follows:

Waste is collected into designated bottles and stored until the bottle is no more than 90% full. When the noninfectious waste bottle is sufficiently full, Clorox is added to a final concentration of 10% (v/v). The Clorox/waste solution is allowed to sit for 24 hours and then discarded down the sink, rinsing with large volumes of water. It is important to rinse with large volumes of water to prevent residual Clorox from attacking/eating through the metal sinks.

C. INECTIOUS LIQUID WASTE

Infectious waste will be defined as liquids associated with (i.e. contacting) infected cells or cell cultures. These include any cultures infected with HIV-1, HIV-2, SIV, EBV, CMV, Vaccinia, HVS or any other agent, which would be considered a human pathogen or potential human pathogen. Infectious waste also includes any human or animal blood, serum or plasma, which is not known to be free of any human pathogens or potential pathogens.

Infectious liquid waste is handled as follows:

Waste should be collected into designated autoclavable bottles. 100 ml of 10% Triton X100 will be added to bottles designated for Infectious Liquid waste prior to filling with infectious materials. Bottles containing Infectious Liquid waste will not be filled beyond 80% of its capacity (i.e. no more than 800 ml in a 1 L container). This is to insure that the liquid material does not boil over in the autoclave, presenting a burn and exposure hazard. Bottles containing infectious liquid waste will remain in the Biological Safety Cabinet (BSC) until full at which time the caps are closed and the bottles are placed in a waste bin containing biohazard autoclave bags/liners. Note, these bags **do NOT** get closed (as opposed to Solid Waste Procedures), but merely serve as liners for the waste bins. No more than 5 bottles of infectious liquid waste are place into each waste bin. Once a week, the waste bins containing infectious liquid waste are place on a cart next to the autoclave so that they may be sterilized on Friday morning after the bottle caps have been loosened to permit steam penetration.

D. SOLID WASTE

Solid Waste is classified as either infectious solid waste or noninfectious solid waste. Infectious Solid waste will include all plasticware (i.e. pipettes, flasks, tubes, tips, etc.) or other solid material (i.e. paper towel, gauze, pads, etc.) that has contacted any infected culture material, fluids, or the interior surface of the

BSC. Solid waste is discarded into waste bins located in the BSC. The waste bins are treated as described above. Briefly, waste bins in the hoods should be double bagged and should not be filled above the side panels. If the bin cannot be removed from the hood without disengaging the window panel, it is too full, and the waste needs to be redistributed to a second bin. The interior bag is to be left open, and the exterior bag closed with rubber bands, labeled with certification sticker and autoclave tape prior to loading into the autoclave.

I.) Noninfectious solid waste includes paper towels, pipette sleeves or tips, which have not contacted contaminated materials or surfaces. These materials should be placed into trash receptacles that are located outside the BSC and lined with a biohazard bag. Dry waste from the trash receptacles should not contain any liquids or items (such as pipettes) that have the potential to puncture the bag and cause injury to personnel handling them. When Trash receptacle is full, the biohazard bag should be closed using the rubber band closure provided. The bag should NOT be twisted closed, thus insuring that an opening for steam penetration is provided.

II.) Cardboard boxes, shipping containers, etc. should be broken down and placed into biohazard bags which should be closed with the rubber band closure provided. Do not load any cardboard into the autoclave if it is not in a bag as the paper clogs the drain inside the autoclave.

III.) Cardboard containers from supplies taken into the BSL3 area can be removed from the laboratory area without autoclaving provided that: a) the container is immediately placed on a clean surface (i.e. placed in a non-contaminated area and b) the container does not contact any contaminated surfaces), and c) that the container is unpacked and handled in a clean manner (i.e. handled with clean gloves).

IV.) Recyle water bottles and tip boxes regularly. These are heavy use items and may be kept in the laboratories for extended amounts of time.

V.) Loading the Autoclave: It is the responsibility of each lab to load their own waste. Personnel are encouraged to extend courtesy to neighboring labs by assisting with pick-up if they are not available during the loading times. In order to keep up with the increasing amount of waste, it is important that runs be full but not packed.

1. Remember to Load bag on the **BOTTOM** shelf. Per AMSCO recommendations, do not puncture bags and **DO NOT PACK THEM TIGHTLY.**

2. Load bins on the **TOP** shelf.

3. Check trash receptacles in de-gowning area and empty if full. When

full, discarded gowns, masks, shoe covers and gloves should be removed from the trash receptacles in the degowning area and placed into the autoclave during one of the available loading times.

The autoclave will be available for loading periodically throughout the day. Individuals are responsible for loading their own trash during these times. Bags and bins are not to be stacked at any time, as incomplete decontamination may occur. Bins should always be given priority over bagged trash when loading into the autoclave. When full, the autoclave should be closed and a run started. Individuals initiating a sterilization cycle must log the run on the clipboard next to the autoclave.

VI.) Handling of Radioactive Waste

A. Radioisotopes use in the BSL3 laboratory are hazardous from both a radioactive and biohazard standpoint and should be handled accordingly. When feasible, samples to be removed from the BSL3 area for further testing in BSL2 laboratories should be treated with detergent to inactivate virus and vessel surfaces should be decontaminated with 70% EtOH or 10% Clorox prior to removal. Samples should be handled with added caution and all materials autoclaved after use.
B. Radioactive materials that will be autoclaved **MUST** be clearly labeled with radioactive tape and the name of the user. Once autoclaved, it will be the responsibility of the user to dispose of the waste in the appropriate waste disposal barrel(s).

VII.) To exit the BSL3 area, remove and discard gown, mask and gloves in clean zone near door using the trash receptacles provided. Wash hands thoroughly. Before exiting through antechamber.

VIII.) All equipment to be removed from the BSL3 laboratory for servicing must be decontaminated or prepared for decontamination prior to removal. If possible, items should be steam or gas sterilized to ensure internal decontamination. Equipment that is to be serviced in house should be decontaminated with 70% EtOH/1% Triton X100 and service representative apprised of any potential hazards that may exist as a result of incomplete cleaning.

II. MEDICAL SURVEILLANCE

NCSU Occupational Health Service (EOHS) will perform medical surveillance on all personnel.

A. VACCINATIONS

1. Due to the hazards of handling infectious blood products, all personnel are strongly advised to obtain vaccination against Hepatitis B. This vaccine is administered at no charge by EOHS.

B. FIRST-AID AND ACCIDENT REPORTING

1. All BSL2 and 3 laboratories should be equipped with first-aid kits and personnel apprised of its location.

2. All laboratories are equipped with an emergency eyewash station (located by sinks) and should be used in the event of splashes to the eyes.

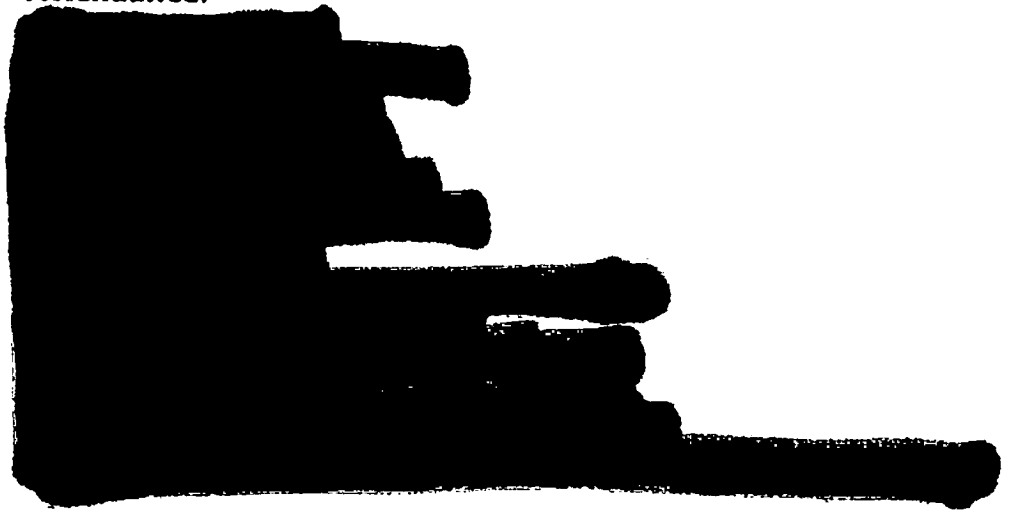
3. Emergency showers are located in the corridor of both BSL2 and BSL3 laboratories.

4. **ALL** accidents, especially those involving percutaneous exposure to infectious materials MUST immediately be reported to the laboratory supervisor, and to the appropriate Principal Investigator(s). Accidents involving possible exposure to human pathogens (HIV, Hepatitis) 2/1/05should also be reported to EOHS and at their discretion; individuals may be entered into an "exposure surveillance protocol."

Biosafety Committee Meeting

Place: CVM A-231
Date: 10/6/04
Time: 2:00 P.M.
Adjourned: 3:30 P.M.

Attendance:



Topics

1. Sunshine Project
2. BSL 3 Labs – Medical Surveillance
3. Disposal of Biohazard Bags in Regular Trash
4. Report of R-DNA, BUA new registrations and renewal

1. [redacted] gave an overview of the Sunshine Project purview. The Project got its list of names from NIH. The purpose of the Project was to see if institutions were keeping minutes of their IBC meetings.
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2. BSL 3 Labs and Medical Surveillance

   Copies of the WHO guidelines were passed out to members.

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The objectives of health and medical surveillance programs for basic laboratories – Biosafety Levels 1
and 2 also apply to containment laboratories – Biosafety Level 3, except where modified as follows.
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examination.
2. A baseline serum sample should be obtained and stored for future reference.
3. Individuals who are immunocompromised should not be employed in facilities with Biosafety Level 3
containment laboratories.
4. Special consideration should be given to the employment of pregnant women (see section on Guidelines for the surveillance of laboratory workers handling microorganisms in Risk Group 2 in Chapter 3).
5. After a satisfactory clinical assessment, the examinee should be provided with a medical contact card
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and should always be carried by the holder.
Note. The name(s) of the contact persons to be entered will need to be agreed locally but might include the laboratory director, medical adviser and/or biosafety officer.

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Facilities Operations and EHS are working on a solution. No indication has been given when [redacted] will put their plan into affect.

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(Fax)	919.515.6307

March 31, 2004

Biosafety/IBC Committee Minutes
March 29,2004 3 P.M
CVM A-231

Attendance [redacted]

Guests – [redacted]

1. Sunshine Project – University notified to submit IBC minutes and Select Agent information. NIH states that IBC minutes are public and needs to be sent when requested. Minutes were sent to the group. Select agents are not subject to public request and therefore no information on select agents was submitted to this group.
2. Nat'l Advisory Board – see attachment Effects dual use research. Could affect publications and what can be released. There may be more impact on publications than on research. The committee has not selected members and further definition of what the committee will focus on will be determined.
3. [redacted] – Cow Pox research – Each have similar issues although they will be using different agents. Tim at times will use Barbara's lab.
    a. First significant work at NC State using cow pox
    b. Pox viruses are BSL2 organisms
    c. Vaccinia/cow pox will be used. Cow pox can infect humans and is mildly pathogenic. Risk varies with the individual based on immuno status
    d. Can be transmitted via aerosol route
    e. Vaccination does offer protection
    f. There are no Federal or State regulation governing the use of cow pox within the state.
    g. Small rodents are the natural reservoir for the virus. Cow pox is not a major threat to animals
    h. Tim will use a modified strain (MVA). r-DNA to make specific genes to put into the virus. Hybrid virus to be made and all will be done in cell culture.
    i. [redacted] will use mice for her research. MVA, DryVac and Cow pox will be the three sources used.
    j. [redacted] is looking for adverse cardiac effects. Will use 7 mouse strains to see cardiac damage. Mice will be in biocontainment in the LAR. All excrement will be treated as biohazard material
    k. Both PI's have or will be vaccinated at [redacted] since they have an affiliation and are collaborating with a [redacted] researcher.
    l. Efforts are being made to find someone to vaccinate NC State staff who will be working with the virus. So far, Student Health is the most likely.

The committee approved the experiments and the level of protection to be taken.

National Science Advisory Board for Biosecurity

The NSABB has been established to provide advice to federal departments and agencies on ways to minimize the possibility that knowledge and technologies emanating from vitally important biological research will be misused to threaten public health or national security. The NSABB is a critical component of a set of federal initiatives to promote biosecurity in life science research.

The NSABB is charged specifically with guiding the development of:

- A system of institutional and federal research review that allows for fulfillment of important research objectives while addressing national security concerns;
- Guidelines for the identification and conduct of research that may require special attention and security surveillance;
- Professional codes of conduct for scientists and laboratory workers that can be adopted by professional organizations and institutions engaged in life science research; and
- Materials and resources to educate the research community about effective biosecurity.

The NSABB is chartered to have up to 25 voting members with a broad range of expertise in molecular biology, microbiology, infectious diseases, biosafety, public health, veterinary medicine, plant health, national security, biodefense, law enforcement, scientific publishing, and related field. The NSABB also includes nonvoting ex officio members from 15 federal agencies and departments. NSABB members are presently being appointed.

Please visit this site frequently for updates on the NSABB and its activities.

Last updated 3/4/2004

Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892-7985

Email: oba@od.nih.gov
Phone: 301-496-9838
Fax: 301-496-9839

Biosafety Committee Meeting

Place: CVM A-231
Date: 10/6/04
Time: 2:00 P.M.
Adjourned: 3:30 P.M.

Attendance:

[redacted]

Topics

1. Sunshine Project
2. BSL 3 Labs – Medical Surveillance
3. Disposal of Biohazard Bags in Regular Trash
4. Report of R-DNA, BUA new registrations and renewal

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[redacted]

Services	Currently Provided	Plan to Provide	Percent Complete	Relative Priority	Program Develop Time	Program Admin Time	Campus Implementation	Quality
Biosafety/ Agent Registration								
Biosafety Forms/ Protocol Review								
Biosafety Level Specifications								
Biosecurity Plan								
Bloodborne Pathogen Exposure Control Plan								
Emergency Procedures in Biohazard Laboratories								
Foot & Mouth Disease NCSU								
Interface with IACUC								
Laboratory Registration and Select Agent Tracking								
Mail Handling Procedure								
Medical Waste Disposal / Biowaste/Autoclaves/Sharps.								
NC Biological Agents Registry Rules Penalties								
Norovirus								
Norovirus Update								
Questions Cocerning Select Agents								
Recombinant DNA								
Restricted Animal Pathogens								
Risk Assessment of Biological Hazards								
SARS								
Select Agent Listing								
Sterilization and Disinfection								
US Patriot Act								
Vacuum Tube Blood Collection Systems								
Vertebrate Animal Biosafety								
Biological Safety Cabinets								
Safety Plan Program								

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Office of Legal Affairs
Box 7008
Raleigh, NC 27695-7008

NC STATE UNIVERSITY

919.515.3071 Phone
919.515.3060 Fax

February 5, 2007

Mr. Edward Hammond
The Sunshine Project
1920 Stuart Street
Berkeley, CA 94703

Re: IBC Records Request

Dear Mr. Hammond:

This is in response to your e-mail inquiry dated January 25, 2007 to Dr. Amy Grunden. Dr. Grunden no longer serves as the Chair of the North Carolina State (NC State) Institutional Biosafety Committee (IBC). Your e-mail note requested that NC State provide (1) policies adopted to respond to the Fink Report; (2) IBC meeting minutes previously provided to you, without redactions; and (3) minutes of all IBC meetings that have occurred since February 13, 2006.

With respect to your first request, NC State has not adopted policies specifically in response to the Fink Report. NC State **has** adopted policies that implement NIH's Guidelines on Research Involving rDNA Molecules, the USA Patriot Act, and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. You can view NC State's policies on biosafety at http://www.ncsu.edu/ehs.

With regard to items (2) and (3) above, enclosed are copies of the minutes of the NC State IBC dated 10/23/06; 2/13/06; 2/2/2005; 10/6/04 and 3/31/04. Consistent with NIH Guidelines on Research Involving rDNA Molecules, specifically Section IV-B-2-a-(6)(7), the names of individual investigators have been redacted to protect the privacy and security of those individuals and the security of any covered biologicals.

Should you have any questions concerning this response, please contact me at (919) 515-2696.

Sincerely,

Judith Curry
Associate General Counsel

Cc: David Rainer, Associate Vice Chancellor
Bruce MacDonald, Safety Programs and Biosafety Manager

NC State University Biosafety Committee Meeting Minutes

Place: CVM A-231
Date: 10/23/06
Time: 3:00
Adjourned: 4:30

Members Present

Jonathan Olson –Chair. Microbiology
Stephen Dempsey – College of Veterinary Medicine
Rebecca Weingarten - Microbiology
Michael Levy College of Veterinary Medicine
Greg Upchurch - Plant Pathology
Jim Ligon – Community Contact
Sam Jones - College of Veterinary Medicine
Frank Scholle – Microbiology
Ed Breischwerdt - College of Veterinary Medicine
David Rainer – Environmental Health and Safety
Amy Grunden - Microbiology
Royden Saah - Community Contact
Bruce Macdonald – Biosafety Specialist

Members Absent

None

Others Attending:

[redacted]

Plans Reviewed and Approved:
2006-06-283, 2006-07-284R, 2006-07-285; 2006-07-286; 2006-08-287; 2006-09-288; 2006-10-289R; 2006-10-290R; 2006-10-291R; 2006-10-292

Agenda:

1. Discussion of new requirements for BUA and rDNA approval
2. Discussion of individual BUA form
3. Recommendation for monitoring Autoclave performance
4. Other Business
5. Tour of the new CVM facility (if time allows)

The meeting began at 3:00

Agenda item 1. New procedures were adopted for BUA and rDNA approval

David Rainer introduced a motion to make it required that BUA and rDNA forms be approved in writing by a quorum of the IBC members. In the past, only negative votes from members were collected, and non-responses were considered to be approvals.

Discussion was then held on what constitutes a quorum, and it was decided to that for the IBC a quorum would consist of one half of the members + 1. It was also discussed that any member of the committee should still have veto power over any application, meaning that all the concerns of each member would need to be addressed before approval.

The motion was seconded by Ed Breischwerdt and unanimously approved by the full committee.

It was also discussed that the minutes of the IBC meeting would then reflect the approval of BUA and rDNA forms that had been handled since the previous meeting.

Agenda item # 2. Discussion of individual BUA form

[redacted] was then asked to address the committee concerning his biological use application. 3 questions were raised:

1. Training of personnel involved in HIV handling
2. Standard operating procedures (especially centrifugation of live virus and inactivation)
3. Screening cell lines for pathogens.

[redacted] specifically addressed all three questions to the committee. [redacted] was then invited to leave the meeting and after a brief discussion Ed Breischwerdt called for approval of the [redacted] BUA. Bruce MacDonald 2nd the motion, and the motion was approved unanimously by the full committee

Agenda item # 3. Recommendation for monitoring Autoclave performance

Several committee members wanted to reach a consensus as to what level of monitoring should be required to verify inactivation via autoclave (this specifically relates to question 8 of biological use application). It was brought up that some investigators were answering only "autoclave" or "autoclave tape" for this question, neither of which verify successful inactivation of biologicals and were being rejected.

It was discussed that the BUA should conform to the university policy as stated in the memorandum dated September 28, 2006 (see attached). It was decided that only protocols that conformed to this standard (i.e. a positive result from SteriGage test pack) would be approved.

Agenda item # 4. Other Business

It was brought up that several of the application forms had been filled out by hand and legibility was a problem. It was decided that forms would be made available to investigators in word format to facilitate the typing of forms for those who did not have the software to use the currently available PDF format, and that in the future only typed applications would be submitted

The committee also discussed a request from Paul Nelson to have input on the design of the green houses to be built at the Dole facility in Kannapolis. It was decided that without knowing what organisms would be housed in the facility the IBC could not recommend a bio safety level.

4:30 Formal Meeting adjourned.

Interested parties (4 committee members) were then led by [redacted] on a tour of the new CVM laboratories.

Attachment: University memorandum of September 28, 2006 "Generators of Sharps an Biomedical wastes"

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Radiation Safety	919.515.2894
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September 28, 2006

MEMORANDUM

TO: Generators of Sharps and Biomedical Waste

FROM: David Rainer, Associate Vice Chancellor for Environmental Safety and Public Safety
Jack Colby, Assistant Vice Chancellor for Facilities Operations

RE: Management of Autoclaved Waste, Sharps and Animal Carcasses

Wake County Solid Waste Services exercising its authority to refuse certain types of solid waste will not accept the University's autoclaved waste at the South Wake Transfer Station. As a result of this exclusion, the following changes are being implemented to comply with County solid waste program requirements:

1. A red waste container marked, "Autoclave Waste Only" is positioned next to the brown municipal waste dumpster in each location where autoclaved waste is produced. All autoclaved waste must be placed in the red waste container. The red waste container may NOT be used for municipal solid waste.

2. All autoclave bags must be clear bags with the biohazard symbol. These will replace the orange/red bags previously used.

3. Each autoclave load must be tested for inactivation. Each researcher autoclaving waste is responsible for their specific loads and documentation. The procedure for testing is attached to this notice.

4. All sharps containers will be picked up by Environmental Health and Safety using the current hazardous waste pickup procedure. Simply declare your containerized sharps on the Environmental Health and Safety hazardous waste system. Sharps may not be placed either in the municipal waste dumpster or in the red autoclave dumpster.

5. Environmental Health and Safety will pick up dead animals or animal parts that need disposal. Do not throw animals or animal parts into the trash. To arrange for pickup declare this type of waste on the Environmental Health and Safety hazardous waste system. http://www.ncsu.edu/ehs/waste/wasteform.htm

Centennial Biomedical Campus:
Current handling practices of regulated biomedical waste at CBC will still apply. Autoclave waste from CBC will need to be handled according to the above regulations.

To comply with county rules, NC State will implement these controls immediately. Please provide comments to Nessa Stone at nessa_stone@ncsu.edu about accessibility of the waste container located closest to you. Although containers were placed based on availability of space, if practicable and based on suggestions, containers will be relocated to enhance convenience.

Attachments

cc: Select Department Heads
Biosafety Committee
CALS Safety Committee

Autoclave Testing Program

Performance Verification

Each load of biohazardous waste processed in an autoclave must meet the operating conditions and be tested.

Autoclaves Testing

a. The operator will incorporate with each load a Chemical Integrator Test Pack (CITP), evaluate the performance of the autoclave based on color changed of the CITP; and document the results in a User Log. All bags autoclaved with a failed CITP will be autoclaved again. 3M SteriGage Test Packs #41360 is currently the system accepted for this test.
b. Users should make sure that the autoclave is working properly before re-autoclaving. If the autoclave needs repair a tag "Out of Service" must be placed on the autoclave.
c. Monthly, a biological challenge will be performed with a standard load. The biological challenge needs to be incubated for 48 hours. Test results will be documented – date tested, initial of person doing test; test results.

The ABC's of Autoclaving

Wear Personal Protective Equipment
Eye and Face Protection, gloves, lab coat

A. Packaging and Loading

a. Use approved autoclave bags- clear bags with biohazard symbol
b. Prepare and load material to ensure steam penetration
c. Ensure all containers including bags are vented
d. Do not overfill containers
e. Ensure sufficient water in load to allow steam penetration or add 250 ml. Water to bags containing solids
f. Use secondary containers
g. Do not mix clean and contaminated material in the same load
h. Do not allow bags to touch sides of autoclave
i. Put in a SteriGage test pack in with each load (in between two bags)

B. Operating an Autoclave

a. Make sure the autoclave is operating properly before starting
b. Determine the appropriate exposure time for the load.
c. Do a monthly biological test challenge with a representative load

C. Unloading the Autoclave

a. Wait until the chamber pressure gauge reads zero before opening
b. Open slightly to allow steam to escape
c. Wait 10 minutes for the contents for the autoclave to cool
d. Remove the waste
e. Read and log the test results of the SteriGage test pack.
f. Incubate the biological test challenge and record results in 24-48 hrs. after incubation

Biosafety Committee Meeting Minutes

Place: CVM A-231
Date: 2/13/06
Time: 10:00 AM
Adjourned: 11:15 AM

Attendance:
Stephen Dempsey- Interim Asst. Vice Chancellor and University Attending Veterinarian
Jonanthan Olson – Microbiology
Craig Altier – PHP
Ed Breitschwerdt – DOCS
Sam Jones – Clinical Sciences
Greg Upchurch – Plant Pathology
Amy Grunden – Biosafety Committee Chair – Microbiology
Royden Saah – NC Public Health
Bruce Macdonald – Biosafety Specialist – EHS
Alice Lee – Student representative, Microbiology
Barbara Hegarty – CVM-NCSU BSL3 Biocontainment Facility Manager
Duane Knudson – EHS, Environmental Affairs Manager

Topics Discussed:

1. Review of the access request forms for the CVM-NCSU BSL3 Biocontainment facilities

2. Update on the university biohazard waste disposal procedures

3. Review of current BUA and rDNA forms to address whether any changes are required to improve their utility

    1. Prior to the IBC meeting, Barbara Hegarty had provided the IBC chair with the BSL3 Biocontainment Facility Project Request Form and the accompanying memorandum that describes the specific requirements that must be met by the investigator seeking access to the BSL3 Biocontainment Facility. The chair distributed copies of the request form and memorandum at the beginning of the meeting. Barbara Hegarty gave

an overview of the development of the BSL3 lab space access forms and spoke about the time-line for granting access to investigators wanting to use the BSL3 laboratory space. The project request form and memorandum are included as an addendum to the minutes.

2. Duane Knudson briefed the committee on problems with the current procedures used by the university for disposal of biohazard waste into the Wake County landfill. Currently, the county waste transfer stations are refusing to accept "red-bag" (inactivated biohazard waste) from the university, and as a result inactivated biohazard waste must be separated from the other university waste-stream and transported directly to the North Wake County landfill. There is growing concern from university EHS officials that the North Wake County landfill may also refuse to accept inactivated biohazard waste from the university in the near future, in which case a contract biohazard waste company would have to be used to dispose of the inactivated biohazard waste generated by the university. The use of a contract biohazard waste company would incur considerable expense that would be passed along to individual departments and Principal Investigators on campus. To avoid this possibility, Bruce Macdonald has proposed to develop a series of biohazard waste disposal procedures that will be adopted campus-wide which would insure that all biohazard waste generated at the university is verifiably inactivated. As part of this plan, Bruce proposed requiring the use of a chemical-based autoclave test pack each time biohazard waste is autoclaved on campus and that a log be maintained to record proper autoclave inactivation of each biohazard waste bag. Bruce recommended the use of the 3M Comply™ Sterigage™ Steam Chemical Integrator Test Pack since it is considered to be a Class 5 test as is the biological spore test. Bruce will keep the IBC updated as the plans for the university biohazard waste disposal program are formalized.

3. For over a year, the whole IBC has been reviewing the BUAs and RDNA registration forms submitted by campus researchers. Based on this experience, the committee chair solicited feedback from the committee on whether there was a perceived need to modify or clarify any portion of the registration forms. The committee agreed to provide feedback on any suggested form changes to the chair via email. It was noted that a modification requiring the insertion of language describing verification of biohazard waste be included in the BUA and rDNA forms as part of the university-wide compliance with the proposed university biohazard waste disposal program being developed (see topic 2).

MEMORANDUM
ACCESS TO CVM-NCSU BSL3 BIOCONTAINMENT LABORATORIES

TO: All potential users of the CVM-NCSU Biocontainment Facility

FROM: Edward B. Breitschwerdt, DVM
Director, CVM-NCSU BSL3 Biocontainment Facility

Barbara Hegarty
Facility Manager, CVM-NCSU BSL3 Biocontainment Facility

RE: Procedural mechanisms to gain access to containment facility.

DATE: Feb, 2006

STAGE I
To be addressed before a request for space in the CVM-NCSU BSL3 Biocontainment Facility will be considered. There are additional requirements that must be met before space can be assigned (Stage II).

1. All prospective investigators shall contact the Facility Director or Manager in order to inform them of the intended research project and projected timeline. The information will be provided on the attached **form** which constitutes the Request For Space. **Electronic copy of form available from <Barbara_Hegarty@ncsu.edu>.**

2. All prospective investigators must have completed a Biological Use Authorization (**BUA**) for biological agents and recombinant DNA through the NCSU Institutional Biosafety Committee. (BUA form is available on NCSU website under EH&S.)

3. The PI will specify whether the proposed work is to involve select agents. If select agents are proposed, PI must contact EH&S. Research involving agents that are on the CDC/NIAID Category A, B, and C lists must be approved by the Institutional Biosafety Committee (~30 days) with subsequent approval and registration with Federal Institutions, CDC or USDA, as appropriate (~120 days +/-).

STAGE II

1. For all projects, Standard Operating Protocol(s) and agent identification information (characteristics of infectious agent and primary laboratory hazards of working with the agent) must be provided in writing to the Facility Manager by PI.
2. Training for all users includes:
    - Documentation and verification of proficiency in basic laboratory procedures. Please submit copy of CV +/or resume indicating work experience.
    - Training in BSL3 procedures by BSL3 Manager (read CDC's BMBL and CVM's BSL3 SOP).
    - 2 weeks supervised access to BSL3 lab (signed Provisional Access Request form). Upon satisfactory completion of supervised period, trainer may approve new user for independent access to BSL3 Facility.
    - Completed Training Checklist and Certificate of Training to be attached to SOPs pertinent to PI's project and kept on file in BSL3 Facility.
3. Request for immunizations as deemed appropriate by Student Health Services for agents involved in individual projects and other agents in use in BSL3 Facility. (See NCSU medical surveillance program website for request forms: <<www.ncsu.edu/ehs/www99/right/handsMan/worker/med.html#access>>.) When complete, bring copy of immunization form signed by Student Health Services, or comparable verification from other institutions, to BSL3 Director or Manager. Exposure potentials are subject to change due to introduction of new research projects/agents to the facility.
4. Signed Affidavit of Eligibility under USA Patriot Act of 2001, if select agents are involved, to be kept on file in BSL3 Facility.

Final approval and authority for assignment of space resides strictly with the director of the laboratory facility. In the event that space is denied, investigators may request a review of the decision by the Associate Director of Research, Dr. Neil Olson. Activation of card access will not be made until all approvals have been obtained.

CVM BSL3 Biocontainment Facility will be operated on a cost recovery basis. Usage rates as assessed by the NCSU Office of Contracts and Grants will be charged on a daily basis ($70.82) with a minimum commitment of 3 months to gain access to the facility. A 2 week shutdown for repairs and certification will be scheduled annually.

Project Request Form for Biocontainment Facility

		Agents (s)
Biological Agent	Bacteria	_____
	Fungal	_____
	Virus	_____

Select Agent	Yes
	No

		Funding Source
Project type	Pilot study	_____
	Contract	_____
	Grant	_____

Proposed start date _____

Proposed duration of project _____ Weeks
_____ Months
_____ Years (resubmission of BUA necessary every 3 years or with change in protocol or personnel)

Frequency of lab use
Daily
Weekly
Monthly

Estimated # of users _____

Intended use of radioisotopes Yes _____approved protocol number
No

Equipment provided for use in the BSL3 Biocontainment Facility includes:
NuAire Biosafety Cabinets type II A2 or B2 with automatic pipettor.
4C Refrigerator
Labline -20CFreezer
Revco brand -80C freezers (Space to be assigned by manager *Racks, if desired, supplied by PI. Select agents must be stored in locking racks. There will be a $20/month fee assessed for storage of agents beyond the duration of projects.)
Isotemp water jacketed CO_2 incubators
AccuSpin 3R centrifuge with speed range 300 rpm (19 X G)-13,000rpm (16,000 X G) and an assortment of aerosol containing buckets
Eppendorf Microcentrifuges with aerosol containment
Mixers/rotators
Inverted microscope with 4, 10, and 25X objectives
Standard laboratory microscope with 4, 10, 40, and 100X objectives
Ohaus balance with draft shield
Ultrasonic bath
Waterbath
Eppendorf pipettor sets of 10, 100, 1000ul

*If additional equipment is needed for project, care should be given to choice of equipment brought into the lab. All equipment brought into the lab can not be removed from facility due to biosafety issues, unless thoroughly decontaminated which can be deleterious to some equipment. Method of cleaning and sterilization for equipment brought in by any staff member must be ascertained by PI.

Disposables provided: PPE (one gown per week provided), gloves, goggles, simple surgical masks, shoe covers, autoclave bags, and disinfectants.
*Respirators required by EH&S, to be provided by PI.

* Items not provided by BSL3 Facility that are the responsibility of PI.

Questions or comments

Biosafety/IBC Committee Minutes
February 2, 2005 2:00 P.M.
CVM B-222

Attendance: Greg Upchurch – Plant Pathology; Amy Grunden – Chair – Microbiology; Jonathan Olson – Microbiology; Mike Levy – CVM; Alice Lee - Mircorbiology; Stephen Harvey – CALS-BRF; Bruce Macdonald – Biosafety Specialist – EHS; David Rainer – EHS; Ed Breitschwerdt – CVM; Neil Olson – CVM; Craig Altier – CVM; Royden Saah – NC State Lab – Public Health Dept, Chris Goforty – NC State Lab – Public Health Dept.; Barbara Hegarty - CVM

Agenda

Discussion of oversight of the new BSL 3 labs coming on line at the CVM new research facility

1. A SOP for the BSL3 labs was submitted by Barbara Hegarty to the committee for review. The SOP was the starting point toward understanding how the BSL 3 labs would function.
2. Training for all personnel using the BSL 3 lab is imperative. The question arose who would do the training.
3. Who is accountable for overseeing the labs was a question posed to Neil Olson. At this time no decision had been made. The committee suggested that a Faculty member rather than a staff person be in charge. Staff personnel would have no authority over Faculty and thereby undermine any control measures implemented.
4. The labs will have multiply users. Some of these users would be from outside NC State system. For example, UNC or Duke researchers. How much turnover would occur won't be determined until the labs are up and running.
5. The question arose about the use of select agents and authorization of personnel in the area of the select agent. CDC has stated as long as the select agent is in a secure location, access available to users only and a written procedure for use of the agent is developed, all personnel in the lab do not need to go through the authorization process.
6. The committee suggested that reference to serum banking in the SOP be deleted. A previous discussion with HR in the last committee meeting, HR suggested not using WHO guidelines for physicals and serum banking. A suggestion was made that a medical questionnaire similar to the one used for animal handlers be used as an assessment tool. The medical surveillance physician can make a decision based on the questionnaire whether testing is needed for the employee.
7. The committee approved of the SOP submitted with the corrections suggested.
8. The committee also encourages the CVM administration to quickly make a decision on picking a director to oversee the BSL 3 labs.
9. **Members of the IBC were invited to tour the newly constructed NC State System BSL3 Laboratory by the Director, Royden Saah in order to observe the state system's BSL3 protocols and certification process.**

Meeting adjourned at 3:30 P.M.

NCSU CVM
BSL3

STANDARD OPERATING PROTOCOL
Jan. 5, 2005

I. LABORATORY ACCESS

A. GENERAL

The proposed BLS3 will be a restricted access facility. Biohazards, Radiation hazards and Chemical hazards are assumed in all the BSL2 and BSL3 laboratory areas within the building. Therefore, strict adherence to any and all Standard Operating Procedures, Guidelines and Recommendations is required.

1. All visitors must sign the guest register in the reception area before proceeding to the laboratory areas.

2. Children under 18 years of age are not to be admitted inside the facility.

3. Visiting scientists must be cleared by principal investigator and laboratory supervisor before working in any CVM BSL3 laboratory. If a visitor (scientist or vendor) needs to perform work in the BSL3 containment facility, a liability waiver must be signed. Visitors are the responsibility of the principal investigator and should be informed of all safety and technical restrictions applicable to them during their stay.

4. Maintenance Support Staff

NCSU CVM personnel. It will be the responsibility of the individual departments and Principal Investigators to develop and maintain surveillance programs for their employees providing services within the CVM BSL3 facility.

Non-NCSU personnel. It will be the responsibility of the CVM staff to advise Non-NCSU CVM personnel of the hazards and safety issues applicable to them while working in the facility. Personnel who will be working in the BSL3 containment area must sign a liability waiver prior to entry. Optimally, service personnel should be accompanied while working in the BSL3 laboratory and a "decontaminated" area provided for their instruments. When possible, tools should be wiped down with 70% EtOH/1% Triton X-100 before removal from the area.

B. NCSU CVM STAFF

1. Access to CVM BSL3 laboratory will be restricted to approved personnel. A current listing of approved personnel will be kept posted on the laboratory door.

2. New personnel will not be permitted to perform work in the BSL3 laboratory until they have completed a safety orientation session with the BSL3 supervisor. This session includes orientation and review of general safely practices, as well as the proper handling of biohazards and radioactive materials. The orientation should be completed within the first week of employment, and completion will be documented by an affidavit signed by the employee and the orientation instructor.
3. In addition to the safety orientation, new personnel will familiarize themselves with the procedures specific for their particular biohazardous agents, as well as chemical and radioactive reagents to be used. Individuals will also document attendance at radiation safety training (if required). New personnel will also familiarize themselves with the CVM Standard Operating Procedures (SOP) associated with waste disposal (including biohazardous materials, radiochemicals, organic solvents), handling sharps and broken glass, and emergency procedures associated with chemical and radiochemical and biohazardous spills.

4. Individuals who are pregnant or at an increased risk for acquiring infection should consult their immediate supervisor before working in the BSL3 Laboratory. Individuals at risk would include those who are immunosuppressed or undergoing immunosuppressive therapy, and individuals having recent surgical procedures or injuries in which the integrity of the skin has been significantly altered or compromised.

   By their own choosing or at the request of their immediate supervisor, individuals may contact EOHS for medical consultations. Requests should be made through the director (?).

I. BSL3 LABORTORY PROCEDURES

1. Only approved personnel will be allowed entry to the BSL3 containment facility. Prior to entry, individuals must complete the general safety orientation session describe above, demonstrate proficiency in the handling of biohazards and radioactive materials to their immediate supervisor.

2. Personal items should be stored in cabinets and drawers in the antechamber (if available in new building).

3. Eating and drinking is strictly forbidden in laboratory areas. If radioisotopes are used in the laboratory, the work area must be identified by taping around the area with radioactive tape. If individuals have questions specifically regarding radiation safety issues, see the Radiation Safety Office.

4. All reagents should be labeled according to the Hazardous Material Identification Guide (HMIG) and Material Safety Data Sheets (MSDS) available for each. All employees are to be informed of the location of the MSDS and instructed on how to utilize this information, and the HMIB rating system.

5. Appropriate clothing must be worn when performing work using radioisotopes and/or hazardous chemicals. Clothing will be considered "appropriate" only if it covers areas of the skin that are likely to be contacted by splashes and spills. Disposable Tyvek gowns should be worn to cover street clothes and should be closed in the front. Personnel must provide adequate personal clothing when planning to perform these procedures. Don gown and gloves in the outer room adjacent to the materials rack prior to entering the main laboratory. Discard all wrapping materials in the trash receptacles provided.

6. All employees should know the proper procedure for handling chemical, biohazard and radioactive spills. In the event of a spill, contact the laboratory supervisor and/or Principal Investigator in charge for assistance.

7. All freezers, refrigerators and other storage areas containing biohazards, radiochemicals and/or chemical hazards will be appropriately identified with labels. All personnel accessing these freezers, refrigerators or other storage areas for **ANY PURPOSE** will use protective gloves. In addition, individuals accessing any samples from a Liquid Nitrogen storage area containing hazardous materials must wear protective full-face shields and disposal barrier gowns.

8. To ensure the safety of others and minimize errors, work areas should be decontaminated and left in an orderly fashion at the close of the work session. For radiation areas, this includes monitoring for possible contamination and documenting results.

9. Laboratory personnel are to receive instruction on the proper use and care of an instrument prior to using equipment belonging to another laboratory or a piece of

common equipment.

10. Each user is responsible for maintaining common areas. All equipment, plastics, reagents and trash should be removed at the close of the work session.

11. **General Safety Considerations**

•A. Eating, drinking, or smoking is NOT permitted in the BSL3 laboratory.

•B. Mouth pipetting is NOT permitted.

•C. Gowns and gloves MUST be worn at all times in BSL3 areas.

•D. All work with potentially infectious materials that pose a threat of exposure by splashes or aerosols must be performed in approved physical containment devices (i.e. biological safety cabinets (BSC) or centrifuge designed for aerosol containment). Some notable exceptions are cell counting with hemocytometers and microscopic examination of experiments. When handling hemocytometers, personnel will be extremely cautious due to the potential sharps hazard of working with glass cover slips and slides in the BSL3 laboratory.

•E. All containers used for storage, transport or shipping of potentially infectious materials must be labeled with the biohazard symbol.

•F. Vacuum outlets are present in the BSL3 laboratories but their use is strongly discouraged. If employed, a disinfectant trap consisting of 10% Clorox followed by an in-line HEPA filter must be included.

•G. Glassware, glass pipettes (Pasteur or serologic) and needles are **not** permitted in BSL3 laboratory.

•H. While working in BSL3 laboratory, personnel should wear **two** layers of gloves. A gloved hand removed from a biological safety cabinet (BSC) is considered contaminated and the outer glove should be removed and replaced immediately.

•I. Wash hands before exiting lab to prevent contamination of doors, doorknobs, and fixtures.

•J. For any spills, which occur outside of the biological safety cabinet, please refer to the procedure contained in Appendix A of this document. Each laboratory is responsible for maintaining an appropriate Biohazard Spill Kit as specified in Appendix A.

•K. For your own safety and the safety of other individuals, all BSC must

be maintained in a clean and orderly manner. Individuals using Biological Safety Cabinets should be instructed on the design and proper use of the BSC. The inside surfaces (including the back panel) must be free of any splashed/spilled media, blood, etc. Upon completion of work session, the individual using the hood is responsible for cleaning it. This is most effectively done by wiping the surfaces with 70% EtOH/1% Triton X-100.

•L. All counter surfaces must be cleaned upon the completion of each working session.

•M. All centrifugations must be performed with cups or buckets designed specifically for containment purposes.

12. **Handling of Biohazard Waste**

All infectious materials must be placed inside biohazard bags placed within autoclavable pans located in the BSC. All pans and waste bins are lined with two biohazard bags and are located within the Biological Safety Cabinets. Biohazard bags are **NOT filled above the top of the side panel of the bin**. This practice minimizes the potential for spillage during transport from the BSC to the autoclave and the potential for spillage during the sterilization cycle. If a waste bin cannot be removed from the BSC without disengaging the window panel, it is too full and the waste needs to be redistributed to a second waste bin. Biohazard bags must remain permeable to steam so that the interior of each bag will be effectively decontaminated. Prior to removing a filled waste bin from the BSC, the inner bag should be left unclosed and the outer bag should be closed with rubber bands provided for this purpose. When closing the outer bag, individuals should NOT twist the outer bag closed prior to applying the rubber band closure. The exterior bag is labeled with the certification sticker and autoclave tape prior to loading the waste bin into the autoclave.

A. **LIQUID WASTE**

Liquid waste generated in BSL3 laboratory will be divided into two categories: A) **NONINFECTIOUS** and B) **INFECTIOUS**. Small volumes of liquid, i.e. less than 20 ml (with either designation) may be discarded directly into the waste bins if they are contained within a closed vessel. **However, caps MUST be loosened slightly** to allow steam penetration, otherwise decontamination cannot be insured.

B. **NONINFECTIOUS LIQUID WASTE**

Noninfectious waste will be defined as liquids associated with whole blood from normal human or animal donors, liquids from uninfected tissue culture

lines, or liquids from uninfected primary cell cultures. Liquids from infected cell lines **are NOT included** in this category. If in doubt about the designation of Liquid waste, treat as Infectious liquid waste as described below.

Noninfectious waste should be handled as follows:

Waste is collected into designated bottles and stored until the bottle is no more than 90% full. When the noninfectious waste bottle is sufficiently full, Clorox is added to a final concentration of 10% (v/v). The Clorox/waste solution is allowed to sit for 24 hours and then discarded down the sink, rinsing with large volumes of water. It is important to rinse with large volumes of water to prevent residual Clorox from attacking/eating through the metal sinks.

C. INECTIOUS LIQUID WASTE

Infectious waste will be defined as liquids associated with (i.e. contacting) infected cells or cell cultures. These include any cultures infected with HIV-1, HIV-2, SIV, EBV, CMV, Vaccinia, HVS or any other agent, which would be considered a human pathogen or potential human pathogen. Infectious waste also includes any human or animal blood, serum or plasma, which is not known to be free of any human pathogens or potential pathogens.

Infectious liquid waste is handled as follows:

Waste should be collected into designated autoclavable bottles. 100 ml of 10% Triton X100 will be added to bottles designated for Infectious Liquid waste prior to filling with infectious materials. Bottles containing Infectious Liquid waste will not be filled beyond 80% of its capacity (i.e. no more than 800 ml in a 1 L container). This is to insure that the liquid material does not boil over in the autoclave, presenting a burn and exposure hazard. Bottles containing infectious liquid waste will remain in the Biological Safety Cabinet (BSC) until full at which time the caps are closed and the bottles are placed in a waste bin containing biohazard autoclave bags/liners. Note, these bags **do NOT** get closed (as opposed to Solid Waste Procedures), but merely serve as liners for the waste bins. No more than 5 bottles of infectious liquid waste are place into each waste bin. Once a week, the waste bins containing infectious liquid waste are place on a cart next to the autoclave so that they may be sterilized on Friday morning after the bottle caps have been loosened to permit steam penetration.

D. SOLID WASTE

Solid Waste is classified as either infectious solid waste or noninfectious solid waste. Infectious Solid waste will include all plasticware (i.e. pipettes, flasks, tubes, tips, etc.) or other solid material (i.e. paper towel, gauze, pads, etc.) that has contacted any infected culture material, fluids, or the interior surface of the

BSC. Solid waste is discarded into waste bins located in the BSC. The waste bins are treated as described above. Briefly, waste bins in the hoods should be double bagged and should not be filled above the side panels. If the bin cannot be removed from the hood without disengaging the window panel, it is too full, and the waste needs to be redistributed to a second bin. The interior bag is to be left open, and the exterior bag closed with rubber bands, labeled with certification sticker and autoclave tape prior to loading into the autoclave.

I.) Noninfectious solid waste includes paper towels, pipette sleeves or tips, which have not contacted contaminated materials or surfaces. These materials should be placed into trash receptacles that are located outside the BSC and lined with a biohazard bag. Dry waste from the trash receptacles should not contain any liquids or items (such as pipettes) that have the potential to puncture the bag and cause injury to personnel handling them. When Trash receptacle is full, the biohazard bag should be closed using the rubber band closure provided. The bag should NOT be twisted closed, thus insuring that an opening for steam penetration is provided.

II.) Cardboard boxes, shipping containers, etc. should be broken down and placed into biohazard bags which should be closed with the rubber band closure provided. Do not load any cardboard into the autoclave if it is not in a bag as the paper clogs the drain inside the autoclave.

III.) Cardboard containers from supplies taken into the BSL3 area can be removed from the laboratory area without autoclaving provided that: a) the container is immediately placed on a clean surface (i.e. placed in a non-contaminated area and b) the container does not contact any contaminated surfaces), and c) that the container is unpacked and handled in a clean manner (i.e. handled with clean gloves).

IV.) Recyle water bottles and tip boxes regularly. These are heavy use items and may be kept in the laboratories for extended amounts of time.

V.) Loading the Autoclave: It is the responsibility of each lab to load their own waste. Personnel are encouraged to extend courtesy to neighboring labs by assisting with pick-up if they are not available during the loading times. In order to keep up with the increasing amount of waste, it is important that runs be full but not packed.

1. Remember to Load bag on the **BOTTOM** shelf. Per AMSCO recommendations, do not puncture bags and **DO NOT PACK THEM TIGHTLY.**

2. Load bins on the **TOP** shelf.

3. Check trash receptacles in de-gowning area and empty if full. When

full, discarded gowns, masks, shoe covers and gloves should be removed from the trash receptacles in the degowning area and placed into the autoclave during one of the available loading times.

The autoclave will be available for loading periodically throughout the day. Individuals are responsible for loading their own trash during these times. Bags and bins are not to be stacked at any time, as incomplete decontamination may occur. Bins should always be given priority over bagged trash when loading into the autoclave. When full, the autoclave should be closed and a run started. Individuals initiating a sterilization cycle must log the run on the clipboard next to the autoclave.

VI.) Handling of Radioactive Waste

A. Radioisotopes use in the BSL3 laboratory are hazardous from both a radioactive and biohazard standpoint and should be handled accordingly. When feasible, samples to be removed from the BSL3 area for further testing in BSL2 laboratories should be treated with detergent to inactivate virus and vessel surfaces should be decontaminated with 70% EtOH or 10% Clorox prior to removal. Samples should be handled with added caution and all materials autoclaved after use.
B. Radioactive materials that will be autoclaved **MUST** be clearly labeled with radioactive tape and the name of the user. Once autoclaved, it will be the responsibility of the user to dispose of the waste in the appropriate waste disposal barrel(s).

VII.) To exit the BSL3 area, remove and discard gown, mask and gloves in clean zone near door using the trash receptacles provided. Wash hands thoroughly. Before exiting through antechamber.

VIII.) All equipment to be removed from the BSL3 laboratory for servicing must be decontaminated or prepared for decontamination prior to removal. If possible, items should be steam or gas sterilized to ensure internal decontamination. Equipment that is to be serviced in house should be decontaminated with 70% EtOH/1% Triton X100 and service representative apprised of any potential hazards that may exist as a result of incomplete cleaning.

II. MEDICAL SURVEILLANCE

NCSU Occupational Health Service (EOHS) will perform medical surveillance on all personnel.

A. VACCINATIONS

1. Due to the hazards of handling infectious blood products, all personnel are strongly advised to obtain vaccination against Hepatitis B. This vaccine is administered at no charge by EOHS.

B. FIRST-AID AND ACCIDENT REPORTING

1. All BSL2 and 3 laboratories should be equipped with first-aid kits and personnel apprised of its location.

2. All laboratories are equipped with an emergency eyewash station (located by sinks) and should be used in the event of splashes to the eyes.

3. Emergency showers are located in the corridor of both BSL2 and BSL3 laboratories.

4. **ALL** accidents, especially those involving percutaneous exposure to infectious materials MUST immediately be reported to the laboratory supervisor, and to the appropriate Principal Investigator(s). Accidents involving possible exposure to human pathogens (HIV, Hepatitis) 2/1/05should also be reported to EOHS and at their discretion; individuals may be entered into an "exposure surveillance protocol."

Biosafety Committee Meeting

Place: CVM A-231
Date: 10/6/04
Time: 2:00 P.M.
Adjourned: 3:30 P.M.

Attendance:
Stephen Harvey – BRF
Jonanthan Olson – Microbiology
Craig Altier – PHP
Ed Breitschwerdt – DOCS
Jim Ligon – Syngenta Biotech
Greg Upchurch – Plant Pathology
David Rainer – EHS
Amy Grunden – Biosafety Chair – Microbiology
Roydan Saah – NC Public Health
Bruce Macdonald – Biosafety Specialist – EHS
Mike Levy
Alice Lee – Student representative, Microbiology
Kathy Lambert - Assistant Director for Employment and Compensation

Topics

1. Sunshine Project
2. BSL 3 Labs – Medical Surveillance
3. Disposal of Biohazard Bags in Regular Trash
4. Report of R-DNA, BUA new registrations and renewal

1. Dave gave an overview of the Sunshine Project purview. The Project got its list of names from NIH. The purpose of the Project was to see if institutions were keeping minutes of their IBC meetings.
   The Project published a list of their findings rating the locations based on eh quality of the minutes submitted to them.
   The committee talked about the level of detail that needed to go into the minutes. NIH does not prescribe the level of detail that must be captured in the minutes.
   The guidance given is that the minutes should offer sufficient detail to serve as a record of major points of discussion.
   To this end, the committee felt that no names of the researchers for projects reviewed would be kept in the minutes.

To facilitate review of all new registrations, an electronic submittal of protocols will be developed. The submittal process will mimic the IACUC procedure for review. Protocols received by the Biosafety Specialist will be sent to the Biosafety chair who will then distribute it to the committee members.

2. BSL 3 Labs and Medical Surveillance

   Copies of the WHO guidelines were passed out to members.

Health and medical surveillance

The objectives of health and medical surveillance programs for basic laboratories – Biosafety Levels 1
and 2 also apply to containment laboratories – Biosafety Level 3, except where modified as follows.

1. Medical examination of all laboratory personnel who work in Biosafety Level 3 containment laboratories is mandatory. This should include recording of a detailed medical history and a physical
examination.
2. A baseline serum sample should be obtained and stored for future reference.
3. Individuals who are immunocompromised should not be employed in facilities with Biosafety Level 3
containment laboratories.
4. Special consideration should be given to the employment of pregnant women (see section on Guidelines for the surveillance of laboratory workers handling microorganisms in Risk Group 2 in Chapter 3).
5. After a satisfactory clinical assessment, the examinee should be provided with a medical contact card
(Fig. 2) stating that he or she is employed in a facility with a containment laboratory – Biosafety Level 3. It is suggested that this card should include a picture of the card holder, should be walletsized
and should always be carried by the holder.

Note. The name(s) of the contact persons to be entered will need to be agreed locally but might include the laboratory director, medical adviser and/or biosafety officer.

Bruce Macdonald raised the question whether WHO's medical surveillance component for BSL3 labs should be adopted by NC State University.

After discussion the committee felt there were too many issue with the WHO one being employment discrimination. The committee opted not to adopt WHO's medical surveillance for BSL3 labs.

Since the BSL3 labs will be multi-user the committee felt a director needs to be appointed to oversee these labs. The committee recommended a memo be sent to Neil Olson to find out how he plans to apply the BMBL guides by CDC/NIH to the BSL3 labs and who will be the director.

3. Bruce Macdonald mentioned that biohazard bags will not be accepted in the regular trash dumpster. Wake Co. is currently prohibiting these bags from being disposed in the transfer station that NC State uses for its trash.

There is indication that Wake Co. will prohibit disposal of these bags in all its landfills. This will present a challenge to the University since there is a large quantity generated by researchers.

Facilities Operations and EHS are working on a solution. No indication has been given when Wake Co. will put their plan into affect.

4. The committee unanimously voted to have Dave Rainer converted from a voting member to a non-voting member. Dave is currently the VC of Facilities. Since the committee advises the VC of Facilities Dave's voting status would appear as a conflict of interest and need to be resolved.

5. In 2004 there have been 19 new r-DNA registrations; 10 new BUA registrations; 4 r-DNA renewals; 12 BUA renewals.

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Radiation Protection	919.515.2894
(Fax)	919.515.6307

March 31, 2004

Biosafety/IBC Committee Minutes
March 29,2004 3 P.M
CVM A-231

Attendance: Greg Upchurch – Plant Pathology; Amy Grunden – Chair – Microbiology; Jonathan Olson – Microbiology; Mike Levy – CVM; Sam Jones – DOCS; Stephen Harvey – CALS-BRF; Bruce Macdonald – Biosafety Specialist – EHS

Guests – [redacted]

1. Sunshine Project – University notified to submit IBC minutes and Select Agent information. NIH states that IBC minutes are public and needs to be sent when requested. Minutes were sent to the group. Select agents are not subject to public request and therefore no information on select agents was submitted to this group.
2. Nat'l Advisory Board – see attachment Effects dual use research. Could affect publications and what can be released. There may be more impact on publications than on research. The committee has not selected members and further definition of what the committee will focus on will be determined.
3. [redacted] – Cow Pox research – Each have similar issues although they will be using different agents. Tim at times will use [redacted] lab.
    a. First significant work at NC State using cow pox
    b. Pox viruses are BSL2 organisms
    c. Vaccinia/cow pox will be used. Cow pox can infect humans and is mildly pathogenic. Risk varies with the individual based on immuno status
    d. Can be transmitted via aerosol route
    e. Vaccination does offer protection
    f. There are no Federal or State regulation governing the use of cow pox within the state.
    g. Small rodents are the natural reservoir for the virus. Cow pox is not a major threat to animals
    h. [redacted] will use a modified strain (MVA). r-DNA to make specific genes to put into the virus. Hybrid virus to be made and all will be done in cell culture.
    i. [redacted] will use mice for her research. MVA, DryVac and Cow pox will be the three sources used.
    j. [redacted] looking for adverse cardiac effects. Will use 7 mouse strains to see cardiac damage. Mice will be in biocontainment in the LAR. All excrement will be treated as biohazard material
    k. Both PI's have or will be vaccinated at Duke since they have an affiliation and are collaborating with a Duke researcher.
    l. Efforts are being made to find someone to vaccinate NC State staff who will be working with the virus. So far, Student Health is the most likely.

The committee approved the experiments and the level of protection to be taken.

National Science Advisory Board for Biosecurity

The NSABB has been established to provide advice to federal departments and agencies on ways to minimize the possibility that knowledge and technologies emanating from vitally important biological research will be misused to threaten public health or national security. The NSABB is a critical component of a set of federal initiatives to promote biosecurity in life science research.

The NSABB is charged specifically with guiding the development of:

- A system of institutional and federal research review that allows for fulfillment of important research objectives while addressing national security concerns;
- Guidelines for the identification and conduct of research that may require special attention and security surveillance;
- Professional codes of conduct for scientists and laboratory workers that can be adopted by professional organizations and institutions engaged in life science research; and
- Materials and resources to educate the research community about effective biosecurity.

The NSABB is chartered to have up to 25 voting members with a broad range of expertise in molecular biology, microbiology, infectious diseases, biosafety, public health, veterinary medicine, plant health, national security, biodefense, law enforcement, scientific publishing, and related field. The NSABB also includes nonvoting ex officio members from 15 federal agencies and departments. NSABB members are presently being appointed.

Please visit this site frequently for updates on the NSABB and its activities.

Last updated 3/4/2004

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