



MCV Campus

V i r g i n i a C o m m o n w e a l t h U n i v e r s i t y

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April 27, 2006

Edward H. Hammond
Director
The Sunshine Project
P.O. Box 41987
Austin, TX 78704-0545

RE: Your request dated 15 March 2006

Dear Mr. Hammond:

Pursuant to your request to Mr. David Jones of the Virginia Commonwealth University Office of Environmental Health and Safety dated 15 March 2006, I am enclosing copies of the minutes of the University's Institutional Biosafety Committee for the period since 1 May 2003. Items of a proprietary, personal, or security nature not related to rDNA have been redacted as allowed by the NIH FAQ document (May 14, 04).

Should you have questions, please do not hesitate to contact me or Mr. Jones. Also, if you want or need these documents in electronic format, please let me know.

Thank you for your interest in Virginia Commonwealth University.

Sincerely,

A handwritten signature in blue ink, appearing to read "David L. Ross".

David L. Ross
General Counsel

Enclosures

Institutional Biosafety Committee**Minutes***March 19, 2003*

Name	Department	Jun 02	Sep 02	Dec 02	Mar 03 XX
Dr. Dean Broga	Director, OEHS	x	Exc		
Ms. Kuei Lan Chuang	IRB, VP for Research	x	Exc		
Dr. William Eggleston	Assoc. Professor Biology	x			
Mr. Michael Elliott	Chemical/Biological Safety	x	x		
Dr. William Henry	Director, Animal Resources		Exc		
Mr. David Lohr		n/a	Exc		
Mr. Larry Mendoza	Biosafety Officer	x	Exc		
Ms. C. L. Jones	Animal Resources	x			
Mr. David Jones	Chemical/Biological Safety	x	x		
Dr. Dennis Ohman	Chair, Micro/Immunology	x	x		
Dr. Harvey Schenkein	Asst. Dean for Research Dentistry/Research	x	x		
Dr. Robert Stroube	VA Dept. of Health				
Dr. Frank Tortorella	Director of Employee Health	x	x		
Dr. Kristoffer Valerie	Professor Radiation Oncology	x	x		
Dr. Ed Wong	Infectious Diseases McGuire VA Medical Ctr				
Guests					

I. The meeting was called to order at 10:05 a.m. There were no guests or substitutes.

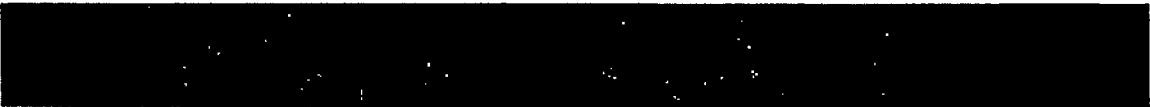
II. The minutes were accepted as written.

III. Ongoing Program Updates

A. Protocol Review - There were 6 MEAs. [REDACTED]

B. Laboratory Inspection Program - There have been three inspections under the new program. There has been a new inspection program instituted in Chemical Safety using PDAs. This information is upload to a database that will allow queries of information, thus being better oversight of the laboratories.

- C. Autoclave QA Program - Inspections will be performed monthly.
- D. Dangerous Good Training Program - On March 5, there were 26 attendees at the training. The program has been modified to accommodate the new regulations. The on-line program has a new 2003 edition. To date 4 individuals have used the on-line training since last quarter. On May 2, Chemical Safety will send Larry Mendoza and Michael Elliott to the Safety Pac "Train the Trainer" presentation on Dangerous good at the Raddison Hotel.
- E. Biological Safety Cabinet Program - Dr. Smoke is working on getting a group rate for the Life Sciences division. The question was asked what would be required to get a group rate for the entire university on the cabinet certifications.


- 
- F. Laboratory Training Program - An on-line training program has been developed with 5 different modules. There is a test at the end of the training that is be graded by the supervisor. Small training sessions are also offered. This training will be added to the IACUC's lab training list.

IV. Old Business

- A. IRB - IBC Protocol Review Collaboration - The Chemical Safety Office is currently working with the Office of Compliance to collaborate review of protocols by both offices.



IV. New Business

- A. UNC IBC Survey - Dave Jones will email the slide presentation to all committee members.
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Institutional Biosafety Committee

Minutes


June 18, 2003

- I. Meeting was called to order at 10 a.m.
- II. The minutes were approved with the following corrections:

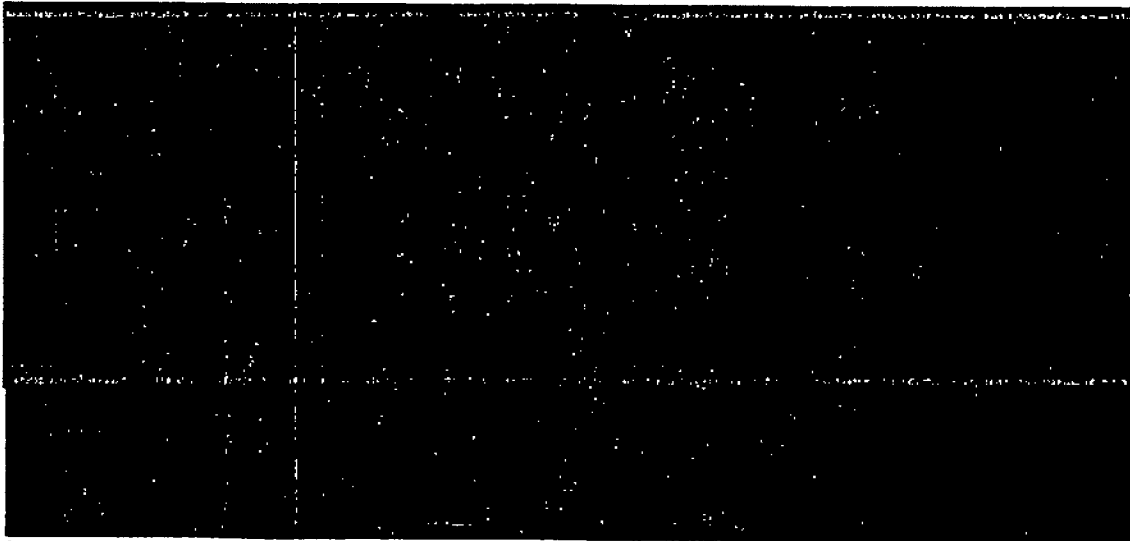
A. Date Change



III. On-going Program Updates

- A. Protocol Review - There were 5 MUAs,  reviewed.

- B. Laboratory Inspection Program - Biosafety Lab inspection numbers since March 19 are: 61 laboratory spaces inspected, 20 PIs and 0 animal rooms.



- D. Autoclave QA Program - This was a good quarter. There are now monthly inspections being performed. Two autoclaves have been added to the QA Program, one in School of Engineering and one in Sanger Hall.
- E. Dangerous Goods Training Program - There 18 attendees at the last platform presentation and 3 persons trained on-line. There will be a session held on the west campus on September 4.

- F. Biological Safety Cabinet Program - Seventy-four cabinets were identified to the Biosafety Officer by researchers interested in reducing certification cost. Mr. Jones indicated that the Biosafety Office will explore cost reduction options.



- H. Laboratory Training Program - The laboratory safety modules on the CBSS website received over 1000 hits since inception. This illustrates the distance learning concept for laboratory safety is reasonably well accepted within the research community.

IV. Old Business



- B. Office of Compliance/IRB Interaction - The effort to get OEHS/CBSS web link on the Office of Compliance web site has been accomplished. This issue is closed.

IV. New Business

- A. Facility Safety Plan - The facility safety plan renewal is due this quarter.

Dr. Harvey Schoenkein, Chair

Date

Institutional Biosafety Committee**Minutes***September 17, 2003*

Name	Department	Sep 02	Dec 02	Mar 03	June 03	Sep 03
Dr. Dean Broga	Director, OHS	Exc	x	Exc	x	x
Ms. Kuei Lan Chuang	IRB, VP for Research	Exc	x	x	x	x
Dr. William Eggleston	Assoc. Professor Biology		x	x	x	
Mr. Michael Ellison	Chemical/Biology Safety	x	x	x	x	x
Dr. William Henry	Director, Animal Resources	Exc	Exc	x	x	
Mr. David R. Lohr		Exc	x	x	x	
Mr. Larry Mendoza	Chemical/Biological Safety	Exc	x	x	x	x
Ms. C. L. Jones	Animal Resources		x	x	x	x
Mr. David Jones	Chemical/Biological Safety	x	x	x	x	Exc
Dr. Dennis Ohman	Chair, Micro/Immunology	x	x	x	x	
Dr. Harvey Schenkein	Asst. Dean for Research Dentistry/Research	x	x	x	x	x
Dr. Robert Stroube	VA Department of Health					
Dr. Frank Tortorella	Director of Employee Health	x	x	Exc	x	Exc
Dr. Kristoffer Valarie	Professor, Radiation Oncology	x	x	x		x
Dr. Ed Wong	Infectious Disease McGuire VA Medical Ctr.					
Guests						

The meeting was called to order by the chair, Dr. Harvey Schenkein.

There were no new members or guests. Dr. Broga suggested that Dr. Ed Wong be removed from the committee since he has not attended any meetings.



Old Business

Protocol Review - There were 10 MUAs. [REDACTED]

Laboratory Inspections - Laboratory inspections involved 33 PIs in 65 Laboratories and 7 animal rooms. There were no major deficiencies reported. [REDACTED]

Autoclave QA Program - There were no issues to report.

Dangerous Good Training - Four individuals attended the last training session on the medical campus. There was a class held on the Academic Campus that was requested by specific investigators and there was no one in attendance.

Biological Safety Cabinets - There are no new issues to report.

[REDACTED]

Laboratory Training Program - There were over 1000 hits on the on-line training program on the OEHS web page. An email will be sent to all laboratories outlining the important issues that must be addressed with all laboratory workers including power outages and that all employees must have fire extinguisher training within the last twelve months. Dr. Broga suggested that a power outage module be added to the on-line training.

The Chemical/Biological Safety section (CBSS) has set up its Pendragon program to be used with its laboratory inspection program. This program allows the CBSS staff to use hand held devices to conduct and record laboratory inspections and download the information to its on-line data base. The department is also in the process of hiring a full time industrial hygienist to work in the health system.

New Business

AALAC Inspections - The inspection is expected to take place on November 24-25, 2003. OEHS is working with Department of Animal Resources to resolve any possible issues.

The next meeting will be held on December 17, 2003, at 10 a.m. in room 4-037 of Sanger Hall.



Dr. Harvey Schenkein, Chair

Institutional Biosafety Committee
Minutes
 December 17, 2003

Name	Department	Dec 02	Mar 03	June 03	Sep 03	Dec 03
Dr. Dean Broga	Director, OEHHS	x	Exc	x	x	x
Ms. Kuei Lan Chuang	IRB, VP for Research	x	x	x	x	
Dr. William Eggleston	Assoc. Professor Biology	x	x	x		
Mr. Michael Elliott	Chemical/Biology Safety	x	x	x	x	exc
Dr. William Henry	Director, Animal Resources	Exc	x	x		exc
Mr. David R. Lohr		x	x	x		x
Mr. Larry Mendoza	Chemical/Biological Safety	x	x	x	x	x
Ms. C. L. Jones	Animal Resources	x	x	x	x	x
Mr. David Jones	Chemical/Biological Safety	x	x	x	Exc	exc
Dr. Dennis Ohman	Chair, Micro/Immunology	x	x	x		
Dr. Harvey Schenkein	Asst. Dean for Research Dentistry/Research	x	x	x	x	x
Dr. Robert Stroube	VA Department of Health					x
Dr. Frank Tortorella	Director of Employee Health	x	Exc	x	Exc	x
Dr. Kristoffer Valarie	Professor, Radiation Oncology	x	x		x	x
Guests						
Ervin Bass, DVM	Animal Resources					

The meeting was called to order by the chair, Dr. Harvey Schenkein at 10:07 a.m.

Dr. Ervin Bass of Animal Resources was sitting in for Dr. William Henry.

The minutes were reviewed and accepted as written.

On-going Program Updates

Protocol Review - There were 6 MUAs, [REDACTED]
[REDACTED]

Laboratory Inspection Program - Laboratory inspections involved 56 spaces, 13 Pls, and 13 animal rooms (all AAALAC related).

Autoclave QA Program - There were no notable events this quarter.

Dangerous Goods Training - There were 67 individuals trained on the medical campus at the December 3, 2003 training. There were 3 individuals who choose to use the computer training workstation in OEHS.

Biological Safety Cabinet Program - There were no notable events this quarter.

[REDACTED]

Laboratory Training Program - OEHS is currently showing 410 labs hits in our web-based laboratory training modules program.

Old Business

AAALAC Inspections - David Jones and Larry Mendoza participated in the pre-official AAALAC inspections.

New Business

[REDACTED]

Biosafety Manual Revision - The manual has been updated and will be uploaded to the OEHS web site.

BrDu Webpage - This has been completed and uploaded.

Job Hazard Analysis - This was sent out in October 2003. IACUC is requesting that all IACUC governed Pls complete and return the form before AAALAC arrives.

The next meeting is scheduled for March 17, 2004 in room 1-006 of Sanger Hall.



Dr. Harvey Schenkein, Chair

Institutional Biosafety Committee
Minutes
March 17, 2004

Name	Department	Mar 03	June 03	Sep 03	Dec 03	Mar 04
Dr. Dean Broga	Director, OEHS	Exc	x	x	x	x
Ms. Kuei Lan Chuang	IRB, VP for Research	x	x	x		
Dr. William Eggleston	Assoc. Professor Biology	x	x			
Mr. Michael Elliott	Chemical/Biology Safety	x	x	x	exc	x
Dr. William Henry	Director, Animal Resources	x	x		exc	
Mr. David R. Lohr		x	x		x	x
Mr. Larry Mendoza	Chemical/Biological Safety	x	x	x	x	
Ms. C. L. Jones	Animal Resources	x	x	x	x	x
Mr. David Jones	Chemical/Biological Safety	x	x	Exc	exc	x
Dr. Dennis Ohman	Chair, Micro/Immunology	x	x			
Dr. Harvey Schenkein	Asst. Dean for Research Dentistry/Research	x	x	x	x	Exc
Dr. Robert Stroube	VA Department of Health				x	x
Dr. Frank Torterella	Director of Employee Health	Exc	x	Exc	x	x
Dr. Kristoffer Valarie	Professor, Radiation Oncology	x		x	x	
Guests						

The meeting was called to order by the David Jones, Asst. Director OEHS/CBSS.

There were no visitors or guests.

The minutes were reviewed and accepted as written.

On-going Program Updates

Protocol Review - There were 4 MUAs, [REDACTED]

Laboratory Inspection Program - Laboratory inspections involved 65 spaces, 20 PIs, and 40 animal rooms.

Autoclave QA Program - This was a good quarter for the program and there was general compliance in all areas.

Dangerous Goods Training - There were 31 individuals trained on the medical campus at the March 3, 2004 training. There were 3 individuals who choose to use the computer training workstation in OEHS.

Biological Safety Cabinet Program - There were no notable events this quarter.

[REDACTED]

[REDACTED]

Laboratory Training Program - David Jones reported that the online training module has been highly used and will be looked at for enhancements. CBSS has performed several small training sessions in Blood Borne Pathogens and Dangerous Goods. Larry Mendoza of the CBSS staff is currently involved in teaching BIO 300, a course in biosafety techniques in the Trani Building on the academic campus.

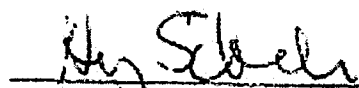
Old Business

[REDACTED]

New Business

CBSS Program Info Sheet - CBSS has developed a new form which outlines all the various programs associated with them that will be given to all new PIs to the university. A staff member from CBSS will go out and meet with the new PI, give them the information, explain the program and try to answer any questions they may have. The Biosafety Officer will send the informational sheet to the IBC committee members.

Annual Report - The IBC annual report was provided to NIH for the preceding year.



Dr. Harvey Schenkein, Chair

INSTITUTIONAL BIOSAFETY COMMITTEE AGENDA

June 16, 2004

I. Introduction of Members and Guests

II. Review of minutes from March 17, 2004, Meeting.

III. Ongoing Program Updates


A. Protocol Review: 50

B. Laboratory Inspection Program: 107

Note on Laboratory Inspection Program: OEHS has been directed to complete all laboratory inspections during the balance of the year. The effect of this directive is to defer consideration and implementation of any new initiatives we might have wished to pursue. During this period, we will continue to satisfy regulatory, legal, and best management practices within the biosafety program at VCU.

C. Regulated Medical Waste Management Program: Autoclave program was conducted in each of the three preceding months. Great progress has been made in working with laboratory personnel to the point of substantial compliance from month to month. During the past month, there was one autoclave QC program which required significant intervention, the balance (eleven autoclaves) were compliant with the QC program.

D. Dangerous Goods Training Program: Eleven participants in classroom instruction, no training activities through the interactive CD. Prior to each iteration of platform training, OEHS makes broad distribution of training dates both within the university and the health system. OEHS has ordered an updated version of the training CD to keep interactive training materials current.



F. Laboratory Training Program: Laboratory inspectors are examining laboratory training module documentation and recommending to PIs personnel not training should participate in the web-based training modules.

IV. Old Business:

None

V. New Business:

None



Dr. Harvey Schenkein, Chair

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

September 15, 2004

I. Introduction of Members and Guests

II. Review of minutes from March 17, 2004, meeting and the activity update which was circulated to committee membership via email in lieu of the June 15, 2004 meeting. The June meeting was not held because of a dearth of considerations which required full committee consideration.

III. Ongoing Program Updates

A. Protocol Review: 63 protocols were reviewed since 3/17/04 (20 MUAs. [REDACTED])

B. Laboratory Inspection Program: 218 laboratories were inspected since 3/17/04. OEHS has completed inspections within all university laboratories, with the exception of 10 spaces. It is likely that some of the 10 outstanding spaces are not functional research facilities. OEHS will confirm status and complete necessary inspections by the end of next week (9/24/04).

C. Regulated Medical Waste Management Program: Compliance with VDEQ regulations is generally being maintained at each university autoclave location. OEHS conducted a major cleanout of biohazardous materials and expired chemicals within the Sanger Hall 6th floor walk-in refrigerator. A second major clean-out action has been scheduled to occur within the Sanger Hall 12th floor walk-in refrigerator within the next two weeks.

D. Dangerous Goods Training Program: 10 staff members were certified during 6/02/04 platform training event. The 9/01/04 platform training event was postponed due to effects of tropical storm Gaston. OEHS is currently attempting to reschedule the platform event. Staff in dire need of certification will be provided with special training sessions - two such events are scheduled for 9/20/04 (to be provided to Pathology and Psychiatry Depts). OEHS held dangerous goods training sessions for Pharm/Cox and Pharmacology - 30 staff members and students were certified during these events. OEHS also continues to offer training via Sanger B2 computer station, only 2 staff members completed certification through computer station during the last quarter.

[REDACTED]

[REDACTED]

F. Laboratory Training Program: The OEHS e traffic counter indicated that approximately 900 people have visited the interactive laboratory safety training website since the beginning of the year. OEHS is currently reviewing the existing training modules to determine needed updates/improvements. Revision of the training modules should be completed during the next quarter (by 12/15/04). OEHS offered special biosafety training sessions to staff and students of the Pharm/Tox, Life Sciences, Microbiology, and Medicinal Chemistry departments. OEHS also continues to assist with the presentation of Biology 300 (Biotechniques) and Microbiology 512 (Laboratory Safety).



IV. Old Business: None

V. New Business:

A. Chemical Fume Hoods: The Chemical/Biological Safety Office has been tasked with identifying substandard hoods and providing work orders to Customer Services for necessary repairs. This new commitment will necessitate the dedication of significant amount of OEHS staff hours.



[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. OEHS has developed a flyer that highlights all chemical/biological safety-related programs and notifies PIs of basic university requirements. The flyer is being provided to all new PIs during new faculty orientation. OEHS staff have also begun the practice of meeting one-on-one with new PIs (when we receive notification of their arrival) in an effort to familiarize them with university requirements and to assist them in setting up safe work places from day one.

3. Dr. Tortorella informed the committee that DAR will be sponsoring a comprehensive orientation program on 9/27-28/04 for all new PIs who will be conducting research involving animals. This will provide another opportunity to get our message out to new researchers.

D. Issues Involving Students/Visitors/Volunteers in Research Laboratories: There was an extended conversation regarding PI requirements prior to allowing student, visitors (including visiting researchers), and volunteers into their laboratories. Allowing such persons into the lab without conducting right-to-know training and disclosure could make the PI liable should personal injury occur. Where students and visitors are concerned, OEHS maintains a full right-to-know and disclosure policy on its website. Procedures to be followed with volunteers, however, need to be further clarified. The committee will research volunteer orientation requirements and discuss further at the next meeting (12/15/04).



Dr. Harvey Schenkein, Chair

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

December 15, 2004

I. Introduction of Members and Guests

II. Review of minutes from September 15, 2004. Minutes accepted with one minor change in verbiage.

III. Ongoing Program Updates

A. Protocol Review: 21 protocols were reviewed since 09/15/04 (11 MUAs, [REDACTED]).

B. Laboratory Inspection Program: Cycle completed, next inspection cycle to begin 01/01/05.

C. Regulated Medical Waste Management Program: Compliance with VDEQ regulations is generally being maintained at each university autoclave location. [REDACTED]

D. Dangerous Goods Training Program: 40 staff members were certified during two platform training events. 30 additional staff members were certified in three special training sessions. The software for the computer training station has been updated. [REDACTED]

F. Laboratory Training Program: Software glitch which prevented access to training modules for some of the campus community has been corrected. Requirement for participation of all university laboratory personnel will be enforced during next laboratory inspection cycle. Training deficiencies will be noted in the laboratory inspection report sent to PIs/laboratory supervisors following their annual inspection. In addition to the computer modules OEHS provided personal/hands-on training sessions to several departments including Microbiology, Pathology, PharmTox, and Cardiology. OEHS provided support (lecturing, laboratory

presentation) on two graduate courses (Micro 512, Pharmacy 612) and one undergraduate course (Biology 300).

IV. Old Business

A. OEHS attended Atlantic Coast OEHS Conference during quarter -- discussion with sister OEHSs indicated generally similar handling of Sunshine Project questionnaire.

C. No new comments were made in relation to orientation/training policies for students, visitors, and volunteers.

V. New Business

A. Laboratory Safety Training Modules have been revised and software glitches have been corrected.

B. CFA Information Page: OEHS is currently constructing to clear up frequent confusion and health and safety issues associated with use of CFA in research protocols.

C. IBC Web Site: The VCU Research Office home page currently does not provide information about the IBC. OEHS will construct an IBC website and work with the Research Office webmaster to have page posted.

D. New IACUC Biohazard Forms: IACUC is replacing its old protocol review forms with new forms that were developed with assistance from the IBC. The new forms are much more coherent (clearly breaks hazards out into three classes: biological, chemical, radiation) and will prompt the PI. Use of the forms will also facilitate the use of a new "toxic material guide" which OEHS plans to develop during 2005 to aid PIs during protocol planning.

E. Duval St. Demolition: Event scheduled for 07/05, new storage location for chemical waste will need to be found/developed. The [REDACTED] is one of the possible locations currently under consideration.


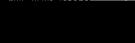

Dr. Harvey Schenkein, Chair

**INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
March 16, 2005**

I. Introduction of Members and Guests

II. Review of minutes from December 15, 2004. There were no corrections and the minutes from the December 15, 2004 meeting were accepted without change.

III. Ongoing Program Updates


A. Protocol Review: 23 protocols were reviewed since 12/16/04 14 MUAs. 


B. Laboratory Inspection Program: As of 03/16/05 yearly inspections completed included 64 (laboratories with biological concerns) and 18 associated principal investigators.

C. Regulated Medical Waste Management Program:

(1) Compliance with VDEQ regulations is generally being maintained at each university autoclave location. Biosafety Office continued bimonthly inspection of MCVH RMW staging areas, slow progress, still many issues to be resolved.

(2) OEHS transferred Ophthalmology Department mixed waste (20 boxes of mixed regulated medical waste and preservative containing picric acid) to Duval Building. Waste to be transferred off site for disposal by Onyx Inc.


D. Dangerous Goods Training Program: 22 staff members were certified via platform training event and computer station.





F. Laboratory Training Program:

(1) Lab safety inspections thus far are indicating increasing participation in the OEHS web-based training modules. Laboratory inspectors will continue checking compliance with training requirements throughout the 2005 inspection cycle.

(2) The software problem which prevented access to training modules for some of the campus community last year has been corrected. In addition to the computer modules, the Biosafety Office provided biosafety and chemical safety training to 60 VCU/health system PIs and laboratory supervisors during three "Safety for Supervisors" sessions. Cam Jones asked if it was possible for notification of upcoming Safety for Supervisors events to be posted on university schedule - Dr. Broga agreed to query Amy Henderson (event coordinator) as to feasibility.



IV. Old Business:

A. CFA information page has been completed and posted to OEHS website.

B. IBC home page has been completed and posted to OEHS website. Biosafety Office is currently working with Research Office to have IBC home page posted to "Resources for Researchers" section of Research Office home page. Committee members were encouraged to visit the preliminary IBC home page and provide comments to Biosafety Office within the next several days so that committee recommendations can be evaluated and incorporated prior to formal posting on Research Office home page.

C. IACUC protocols involving hazardous chemicals guide for PIs is under construction. The new guide will aid PIs in completing the new hazard assessment sheets which the IACUC will be instituting later this year. The new sheets will separate biohazards, rDNA, hazardous chemicals, and radioisotopes which will improve IBC tracking and oversight. Dr. Collins voiced concerns regarding flaws in the current review process in that DAR is typically not provided

biohazard assessment pages prior to protocol review/approval by the IACUC. The Biosafety Office agreed to directly e-mail reviews to DAR for all IACUC protocols requiring IBC involvement/comment prior to submission to IACUC. Dr. Broga, Dr Collins, and other committee members voiced concerns regarding submission (and resubmission for 3 year renewal) of protocols which are deficient in defining all potential hazards. The Biosafety Officer added that current OEHS efforts at working more closely with PIs, particularly new PIs should help to improve the quality of protocol submissions and foster an atmosphere of improved cooperation. Improved interfacing with DAR on protocol reviews should also go a long way toward improving situation.

V. New Business:

B. Laboratory Signage: Dr. Collins questioned the committee regarding availability and responsibility for posting of hazard signs on laboratory entrances. The Biosafety Officer informed the committee that the Biosafety Office had created hazard sign templates (MS Word fill-in documents) which are available at the OEHS website. The signs offer the full range of hazard classes, PPE requirements, and other pertinent information. PIs can access OEHS sign resources and construct hazard signs which meet their specific needs. Dr. Collins asked the committee who at the university is responsible for posting of hazard signs whereupon the committee indicated that posting is the responsibility of the PI. Cam Jones requested that OEHS be responsible for making determination of what signage is appropriate. The Biosafety Office indicated that OEHS will assist PIs as required; however, the primary responsibility for signage rests with the PI. Additionally, the Biosafety Office will continue to review signage as part of the annual laboratory safety inspection. Cam Jones also pointed out that hazard signage should be removed or appropriately modified when hazards are not in use with affected spaces.




Dr. Harvey Schenkein, Chair

**INSTITUTIONAL BIOSAFETY COMMITTEE
MINUTES
June 15, 2005**

I. Introduction of Members and Guests

II. Review of minutes from March 16, 2005. There were no corrections and the minutes from the March 16, 2005 meeting were accepted without change.

III. Ongoing Program Updates

A. Protocol Review: During the preceding quarter, the Biosafety Office [REDACTED] 14 MUAs, [REDACTED] The committee was briefed regarding key details (PI, chemical/biohazardous agents, rDNA concerns, [REDACTED] comments) of each protocol. The committee discussed the expanded review of research protocols and the following determinations/clarifications were made:

1. Henceforth, the Biosafety Office will provide quarterly protocol details to members via electronic mail at least one week prior to IBC meeting dates. This will allow members more time and opportunity to review protocols and prepare comments for the meeting. Members may also request additional protocol information from the Biosafety Office if they wish to clarify items/conduct a more in depth review.

2. Review of protocols involving significant chemical, biological, and/or rDNA concerns will involve entire Biosafety Office (Biosafety Officer, Sr. Safety Engineer, and Biosafety Inspector) whenever possible.

3. If the Biosafety Office encounters protocols during the quarter involving procedures or agents for which it lacks familiarity/expertise, selected members or the full committee may be called upon to assist with review.

B. Laboratory Inspection Program: During the quarter the biosafety inspector conducted laboratory inspection in 130 laboratories (with biosafety concerns) under 21 PIs. The total number of biosafety laboratory inspections for the year as of 06/15/05 was 194 spaces under 39 PIs.

C. Regulated Medical Waste Management Program:

(1) Compliance with VDEQ regulations is generally being maintained at each university autoclave location.

(2) The Biosafety Office continues bimonthly inspection of MCVH regulated medical waste (RMW) staging areas, progress continues, assistance from the Epidemiology Dept (Janis

Ober) appears to be having positive results. Improvement of hospital RMW segregation and packaging practices will continue to be focal point.

[REDACTED]

(4) OEHS is in the process of moving the chemical waste storage/handling facility to the former location [REDACTED]. The Duval Shops Building is scheduled to be demolished by the end of August 2005. A new hazardous waste facility will be incorporated into the parking deck to be constructed on the site of the former Shops Building. Completion date of new chemical waste facility is estimated to be July of 2006.

D. Dangerous Goods Training Program: Quarterly platform training/certification event set for June 2, 2005 was cancelled due to extensive changes in the shipping regulations and the necessity for the new requirements to be included in the training materials. Two OEHS staff members attended/completed certification in comprehensive dangerous goods training program including all hazard classifications. Platform training for shipping of infectious materials, diagnostic specimens, and dry ice is set to resume on September 7, 2005. In addition to the routine infectious/diagnostic training session, OEHS is considering adding a second dangerous goods certification course which will concentrate on shipping of hazardous chemicals (to be instituted during 2006). The plan would be to conduct one training session in January to gauge interest. If there is sufficient interest in these shipping classifications, the chemical and biological shipping presentation would be alternated throughout the year.

[REDACTED]

F. Laboratory Training Program:


(1) Staff participation in laboratory safety training is being tracked through annual lab safety inspections. Laboratory inspectors will continue checking compliance with training requirements throughout the 2005 inspection cycle.

(2) The Biosafety Officer has received feedback from a limited number of PIs.

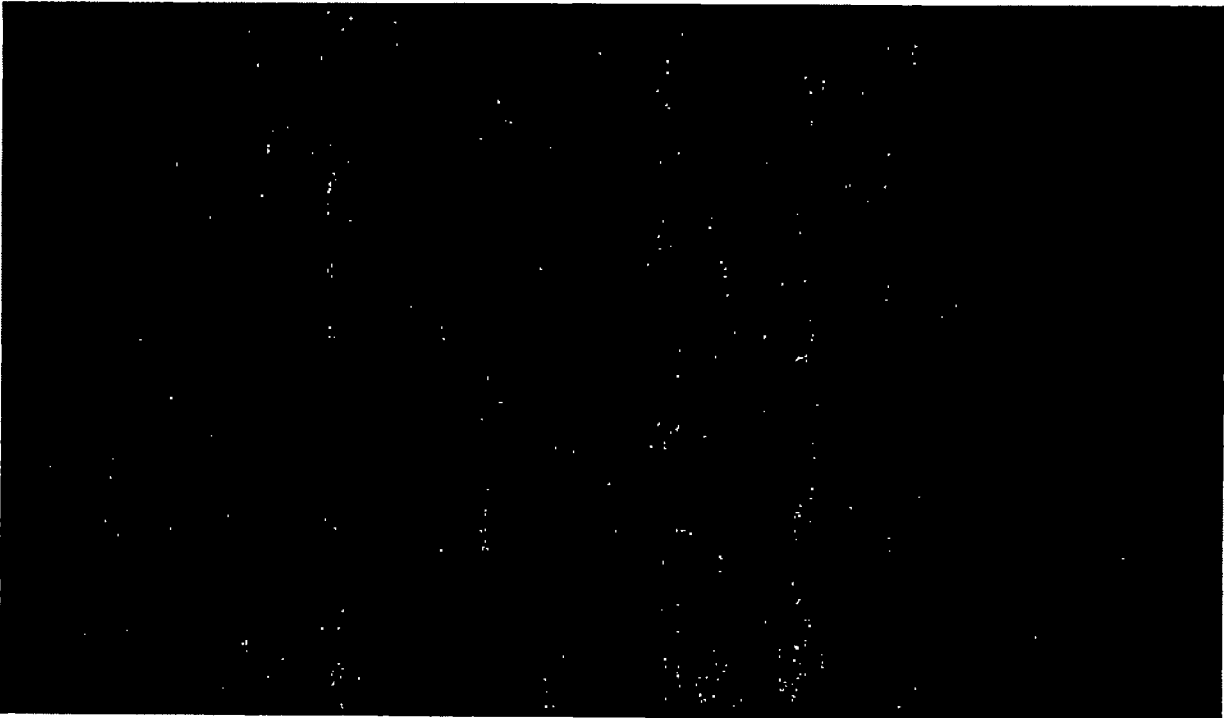
a. Some PIs have commented that the level of training is far below the expertise of their laboratory staffs. The Biosafety Officer has advised PIs that they may make individual determinations as to which training modules are prudent for each of their employees.

b. Other PIs questioned whether PIs were required to complete training modules. The Biosafety Officer clarified that PIs are welcome to, but not required to, complete training modules. Through grading tests of their employees, PIs are involved in the process to a great extent regardless of whether they complete modules on their own.

(3) Personalized Training Sessions: The Biosafety Office provided biosafety and rDNA safety training through several sessions presented to individual laboratories during the quarter.



IV. Old Business:



B. Guide for Developing Protocols involving Hazardous Chemicals. The guide has been completed and posted on the OEHHS website. The Biosafety Office will request that the IACUC Coordinator add direct link to the guide on IACUC protocol sheets. IACUC is in the process of changing to revised protocol hazardous material review forms which were developed by the Biosafety Office.



V. New Business:





C. Human Cell Lines. The Biosafety Officer reported that new CDC interpretations (BMBL 4th Edition) and policies established by several peer universities call for handling all human, primate, other mammalian, and untested cell lines under BSL-2. The policy changes are also related to disclaimers issued by ATCC and other cell line providers which advise handling several cell line products as if they were HIV contaminated. Dr. Valerie and other committee members voiced concerns that instituting a policy requiring all mammalian cell lines to be managed at BSL-2 would be quite disruptive and could present a difficult task to laboratories lacking suitable engineering controls. The chairman requested that the cell line policy be tabled till next quarterly meeting and tasked the Biosafety Office with preparing a report which justifies the action and provides workable solutions for allowing research to continue in laboratories currently lacking suitable engineering controls. The Biosafety Office will develop recommendations to be presented at the next quarterly meeting..




Dr. Harvey Schenkein, Chair

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

September 21, 2005

I. Introduction of Members and Guests

II. Review of minutes from June 15, 2005. The committee had not received the June 15 minutes. The June 15 minutes were sent immediately after the meeting by Dr. Broga.

III. Ongoing Program Updates

Protocol Review -

[REDACTED] The committee was handed synopses of protocols regarding key details (PI, chemical/biohazardous agents, rDNA concerns, Biosafety Office [REDACTED] and comments) of each protocol.

Laboratory Inspection Program - Annual cycle complete: 323 "red" labs inspected. David Jones participated in the semiannual IACUC animal room inspections sweep.

Regulated Medical Waste Management Program (RMW)

(1) Compliance with VDEQ regulations is generally being maintained at each university autoclave location.

(2) The Biosafety Office continues bimonthly inspection of MCVH regulated medical waste (RMW) staging areas and progress continues [REDACTED]

[REDACTED] Improvement of hospital RMW segregation and packaging practices will continue to be focal point. Copies of the RMW reports are sent to MCVH Epidemiology, Director of Logistics, and the housekeeping supervisor.

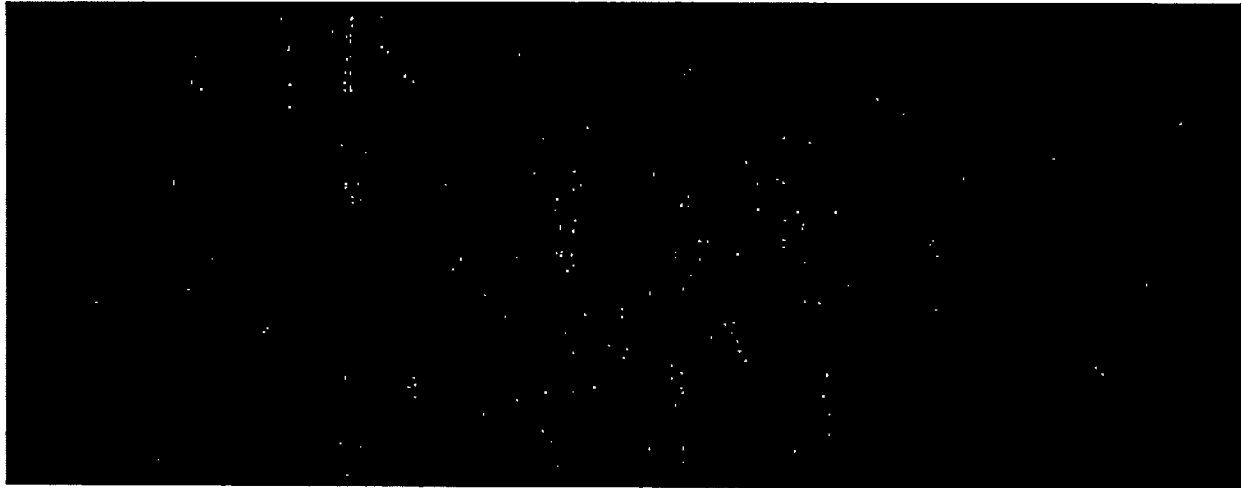
[REDACTED]

(4) Duval demolition is complete. Sanger hall loading dock cage is the staging area for hazardous waste until the new facility in the [REDACTED] building underneath the visitors deck can be renovated (renovation work will begin within a month). Interim hazardous waste disposal costs average \$1000-1500 per week for waste pick up from Sanger Hall.

(5) The Army Corps of Engineers, Norfolk District, and Region 3, United States EPA conducted a site visit to ascertain the status of two hazardous waste treatment, storage, and disposal (TSD) facilities which have been on record since 1991. The purpose of the visit was to determine if

these facilities could be closed and removed from the USEPA listing of TSD facilities. The existence of these two facilities (Sanger hazardous waste cage and Oliver Hall hazardous waste storage room) are administrative artifacts from the early 1990's when the USEPA converted all hazardous waste storage sites to interim TSD status for administrative reasons. These sites were never removed from the TSD list and are still officially carried as TSD facilities. OEHS is actively working with the Norfolk District and the USEPA to have these facilities removed from the TSD roster.

Dangerous Goods Training Program - 20 people attended the quarterly platform training/certification event conducted September 7, 2005 and no special sessions were given. One computer session was completed this quarter.



Laboratory Training Program

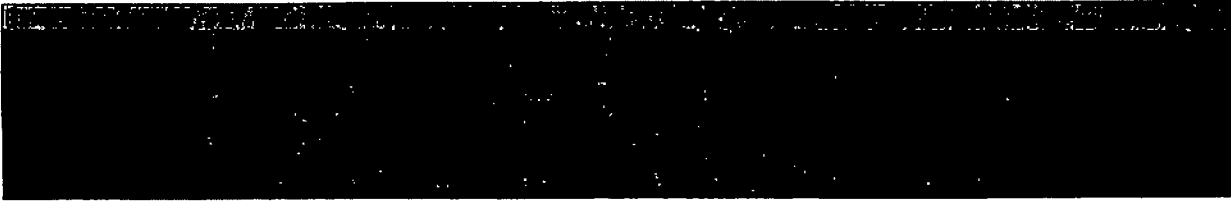
(1) Staff participation in laboratory safety training is being tracked through annual laboratory safety inspections. Out of 323 biosafety laboratories, 232 participated in the program.

(2) Personalized Training Sessions: The Biosafety Office conducted comprehensive biosafety training session for Dr. Grant and his staff (approximately 20 participants).



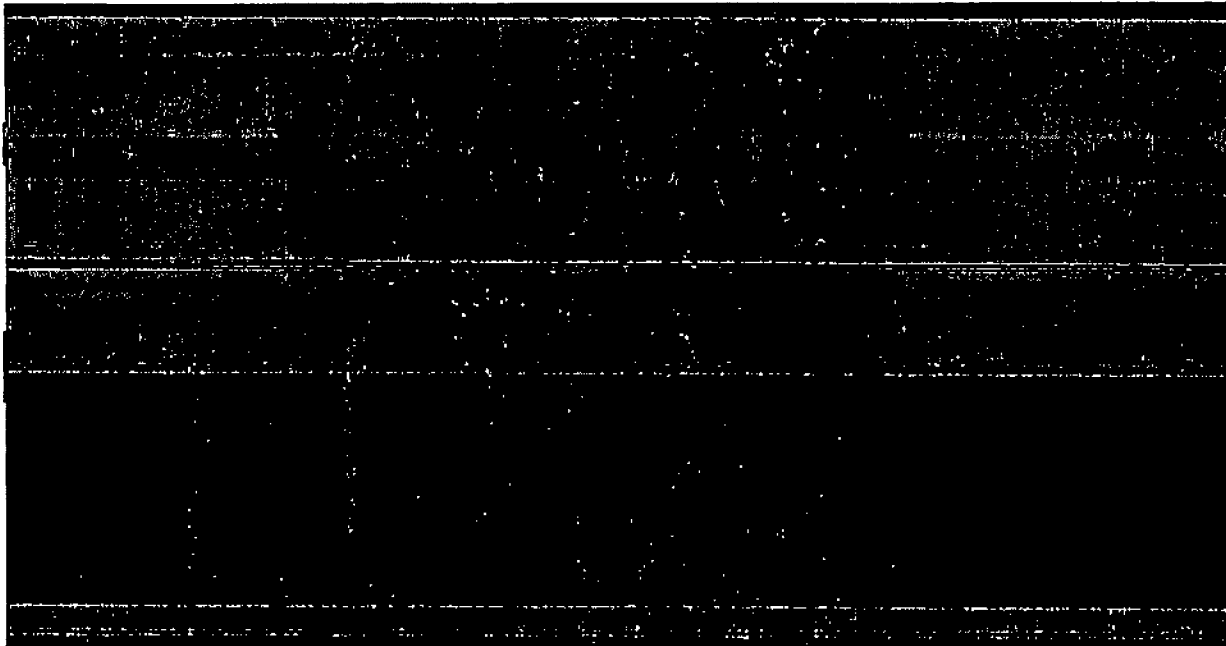
IV. Old Business





New Business

Medical Science Building (MSB)



Human Cell Lines - The Biosafety Officer reported that new CDC interpretations (BMBL 4th Edition) and policies established by several peer universities call for handling all human, primate, other mammalian, and untested cell lines under BSL-2 precautions. The policy changes are also related to disclaimers issued by ATCC and other cell line providers which advise handling several cell line products as if they were HIV contaminated. There was no dissention among committee members after reviewing appropriate supporting documentation.



The next meeting will be held on **December 7, 2005 at 10 a.m. in room 1-006 of Sanger Hall.**

The tentative meeting dates for 2006 are:

March 15, 2006

June 21, 2006

September 20, 2006

December 13, 2006

All meetings will be held from 10 to 11:30 a.m. The room assignment will be announced once we have received the confirmations.



Dr. Harvey Schenkein, Chair

INSTITUTIONAL BIOSAFETY COMMITTEE MINUTES

December 7, 2005

I. Introduction of Members and Guests

II. Review of minutes from September 21, 2005. There were no corrections and the minutes were accepted without change.

III. Ongoing Program Updates

A. Protocol Review: During the preceding quarter, the Biosafety Office reviewed [REDACTED]

[REDACTED] 5 MUAs. [REDACTED] The committee was provided with key details of the Biosafety Office review (PI, chemical/biohazardous agents, rDNA concerns, [REDACTED] and comments) via attachment protocol review meeting minutes.

B. Laboratory Inspection Program: The annual inspection cycle has been completed. CBSS is currently preparing to initiate 2006 inspection cycle.

C. Regulated Medical Waste Management Program:

(1) Compliance with VDEQ regulations is generally being maintained at each university autoclave location. The Biochemistry Department activated a new orange bag autoclave facility during the quarter. The Biosafety is currently working with the Biochemistry Departmental contact to bring the unit into compliance with VDEQ regulations and university policy.

(2) The Biosafety Office continues bimonthly inspection of MCVH regulated medical waste (RMW) staging areas; problems continue with RMW segregation and packaging practices.

[REDACTED]

(4) Joint Commission on Accreditation of Health Care Organizations (JCAHO) inspection is expected to take place within MCVH in January of 2006. CBSS is currently working closely with the hospital to ensure that MSDSs and other documentation are in order.

D. Dangerous Goods Training Program: Quarterly platform training/certification event was conducted on November 30, 2005. Nineteen university and hospital employees attended the event.

[REDACTED]



F. Laboratory Training Program: Revision of the training modules is currently in progress.

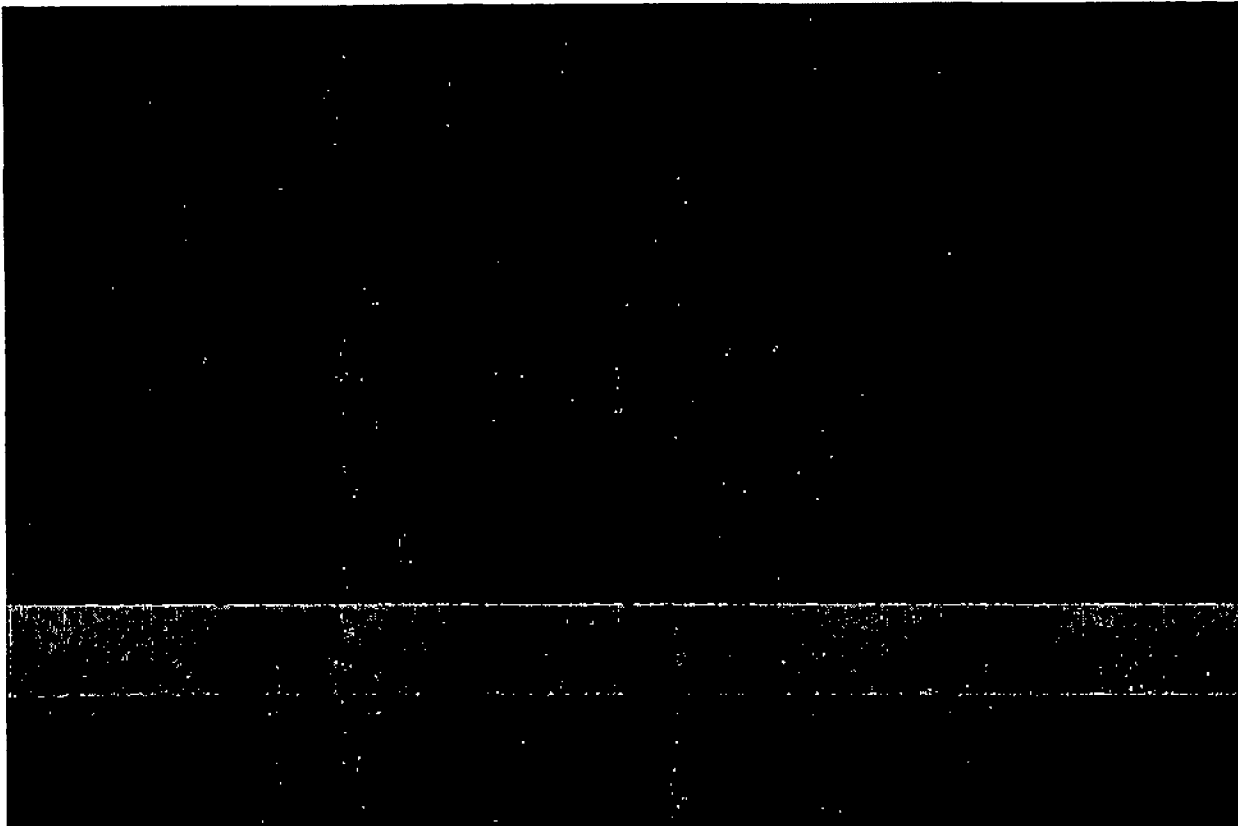


IV. Old Business:

A. EPA site inspection: CBSS received an initial draft of the findings of inspections conducted at both university chemical waste staging areas from the Army Corps of Engineers on September 1, 2005. While the initial report was encouraging, the Corps of Engineers indicated that the final decision on removal of the Sanger and Oliver sites from the EPA TSD list rests with EPA Region III.


V. New Business

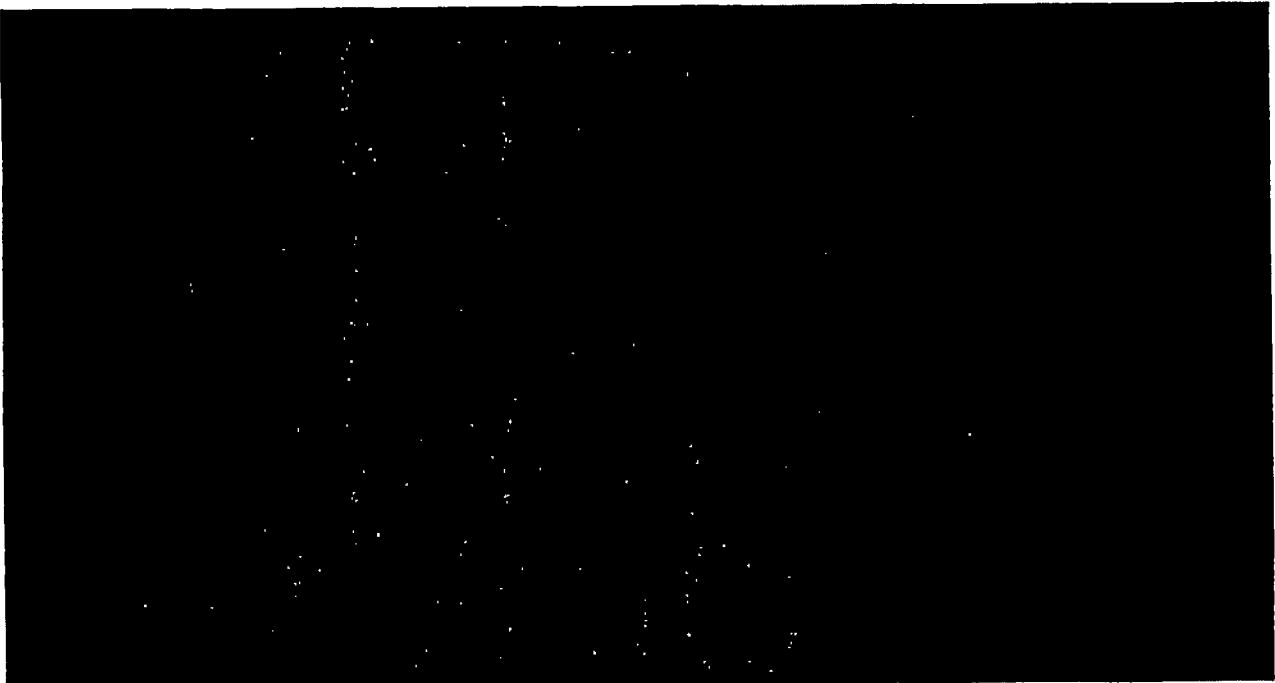
A. Office of Research Representative: Amy Chaung was officially welcomed as a new member of the IBC; she will serve as representative for the Office of Research.



G. Dr. Buck: New protocol involving *Cryptosporidium parvum*. The Biosafety Office and Dr. Collins worked with Dr. Buck to develop SOPs and health and safety measures for upcoming vaccine research involving mice and *C. parvum* infection. Dr. Buck will incorporate these precautions into the MUA/IACUC protocols.

H. A new "Urethane Information Page" has been posted on the CBSS website. Urethane has been categorized as a known mutagen and a suspected human carcinogen. In light of a number of recent protocol submissions involving the administration of urethane as a surgical anesthetic, the Biosafety Office opted to create an information page to aid researchers in developing protocols with complete health and safety information. The Urethane Information Page has been posted on the CBSS website (<http://www.rcu.edu/cehs/chemical/biosafe/urethane.pdf>).


Dr. Harvey Scheikein, Chair



D. Hu Lab: *In vivo* research involving lentivirus. The Biosafety Office and Dr. Collins worked with Dr. Hu to develop SOPs/health and safety measures for upcoming project involving administration of lentivirus to rabbits. Dr. Hu will incorporate these precautions into the MUA/IACUC protocols.



F. Dr. Chalfant. New protocol approved at BSL-2+. The Biosafety Office recently approved an MUA submitted by Dr. Chalfant involving research utilizing "PAN specific" retroviruses. The MUA was initially submitted at BSL-3, an inspection of the proposed research location (Sanger Hall 2nd floor virus room) revealed that BSL-2+ was the highest obtainable biosafety level. A review of the BMBL revealed that BSL-2+ conditions were suitable for the manipulations listed on the MUA. The PI resubmitted the MUA at BSL-2+ and the protocol was approved by the Biosafety Office. The Biosafety Office has informed Dr. Chalfant that a thorough laboratory safety inspection will be required prior to actual research involving the pan-specific retrovirus.