

State of the Environment

2004-05 Annual Report

Prepared for theAssociate Vice President for Campus Services

Presented by the
Environmental Health & Safety Division
and
Committee on Safety and Environmental Health

September 2005



State of the Environment University of Kentucky

68 80

2004-05 Annual Report

Jointly submitted by the Environmental Health & Safety Division and the

Committee on Safety and Environmental Health

to

Ken Clevidence Associate Vice President for Campus Services

on the 28th day of September 2005 by

David Hibbard, Director Environmental Health & Safety Division Herb Strobel, Chair Committee on Safety and Environmental Health

Contents

Report of the Environmental Health & Safety Division	
Major Accomplishments	2
Significant Projects	4
Regulatory Activities	6
Key Indicators for EH&S	
Hazardous Waste Cost Trend Report	10
Hazardous Waste Quantity Trend Report	11
Radioactive Waste Cost Trend Report	12
Injury and Illness Trend Report	13
Environmental Remediation Cost History	14
EH&S Training Efforts	15
Cost of Enforcement Actions Since 1990	16
Departmental Reports	
Biological Safety	17
Environmental Management	27
Occupational Health and Safety	37
Radiation Safety	46
University Fire Marshal	63
Report of the Committee on Safety and Environmental Health	
Certificates of Appreciation	74
Minutes of the Committee on Environmental Health and Safety	76
Minutes of the Subcommittees	
Chemical Safety Committee	83
Institutional Biosafety Committee	88
Radiation Safety Committee	123

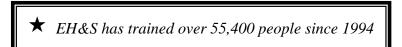
Report of the Environmental Health and Safety Division



Environmental Health & Safety Main Office

Major Accomplishments

1. Continued to expand web-based delivery of safety training. EH&S added Emergency Eyewash/Shower Operation and Fire Extinguisher courses to the web and modified existing online programs for hazardous waste and bloodborne pathogens. Response to EH&S' online course offerings continues to be excellent, and overall EH&S trained nearly 9% more people in 2004-05 than the previous year.



2. **Improved handling of biohazardous waste.** EH&S negotiated an agreement between UK, LFUCG's Division of Solid Waste, the Kentucky Division of Waste Management, and M&M Sanitation for autoclaved waste to be hauled to a landfill as part of the general waste stream rather than under special handling and disposal conditions. The new agreement will save the University Hospital at least \$45,000 annually.



Clinical Waste Packed for Disposal

3. **Enhanced fire safety**. Reviewed, revised, and/or approved evacuation plans for numerous classroom, research, and residential buildings. In many cases, fire drills were conducted to evaluate the evacuation plans, including one drill that involved students moving through a smoke-filled corridor.



Evacuation Training

4. **Evaluated fume hood safety.** All chemical fume hoods in the College of Engineering were tested in accordance with ASHRAE standards. Tracer gas testing was performed to evaluate the hoods' effectiveness and the results were compiled and communicated to the end users.



Fume Hood Testing

5. **Improved waste minimization**. The pressurized cylinder recycling program was expanded to include aerosol cans, and new equipment was purchased to allow bulk handling of the cans' contents at a reduced cost. In addition, the storage capacity for flammable liquids at the Environmental Quality Management Center was increased, allowing a lower unit rate for disposal of flammable liquids to be negotiated.



Significant Projects

1. Animal Care and Use. Guidance for selection of personal protective equipment was provided to employees who wash and transport primate cages in order to reduce potential exposure to the Herpes B virus. In addition, EHS worked with IACUC to conduct occupational health and safety inspections in areas used by animal care workers. EHS also worked with IACUC to correct safety deficiencies identified in research protocols involving the use of animals.

★ 264 Animal Care and Use Protocols Reviewed

2. Radiation Equipment Removal. A teletherapy unit formerly used in the Radiation Medicine Department was removed and shipped to another licensee for reuse. A GammaCell irradiator unit formerly used in Radiation Medicine was returned to the original vendor for disposal.



GammaCell Unit

3. Environmental Remediation. Closure was received from the Kentucky Division of Waste Management on a 10-year project to investigate and clean up four former chemical disposal sites on the North Farms. In addition, a major cleanup/demolition project was completed at the former LR Cooke Chevrolet property in downtown Lexington. The project included asbestos abatement, removal of an underground storage tank, removal of hydraulic lift systems, cleanup of various petroleum products, building demolition, and site restoration.



Excavation of Underground Storage Tank

4. **Biological Safety Training**. A new training module on the principles of biological safety cabinets and their safe use was developed. Proper use of biological safety cabinets not only protects the person working with biological materials but also protects the materials themselves from contaminants in the room.



Biological Safety Cabinet

5. **Fire safety**. Conducted campus life safety and pre-attack tours of University buildings with the Lexington-Fayette Urban County Government's Division of Fire. The purpose of the tours was to familiarize fire department personnel with University buildings, particularly high-hazard areas, and to improve fire response time.

Regulatory Activities

1. A comprehensive application to renew the University's hazardous waste treatment, storage and disposal permit was prepared and submitted to the Kentucky Division of Waste Management in June 2005. The new permit is expected to be issued by October 2005.



Environmental Quality Management Center

2. UK responded to the final report issued by the Inspector General's Office of the U.S. Department of Health and Human Services covering a 2004 inspection of UK's Select Agent program. UK's response detailed changes and corrections made in response to recommendations made after the inspection.



3. On May 25 and 26, 2005, personnel from the Kentucky Division of Waste Management and the U.S. Environmental Protection Agency conducted a hazardous waste compliance inspection. The University's hazardous waste facility and related waste handling documents were reviewed, and the inspectors toured labs in the Agricultural Science Center North, Barnhart Agricultural Engineering Building, Plant Science Building, and Chemistry-Physics Building. Labeling and container violations were noted in twenty-one labs during the inspection but were corrected immediately or within one day. The formal inspection report had not been received at the end of the fiscal year.

★ 80 labs were inspected

- 4. A Notice of Violation was received from the Kentucky Division for Air Quality during an asbestos abatement project at the Western Kentucky Agriculture Substation in Princeton. The violations were primarily associated with contractor actions and were corrected in a timely manner. No enforcement action or penalties were assessed.
- 5. The University's broad medical and teletherapy/gamma knife radioactive materials licenses were inspected in May 2004. No noncompliance findings were noted.

Key Indicators for EH&S

The numbers and costs below are provided to give an indication of the level of activity within EH&S units when conducting their day to day business.

Biosafety Office

Research protocols approved/registered	93
Approved research protocols in database	436
Training class attendees	718
Laboratory audits	93
Biosafety investigations	2
Contact hours (total):	2,483
IBC Registrations	549
Biosafety	1,216
Training and presentations	718

Environmental Management

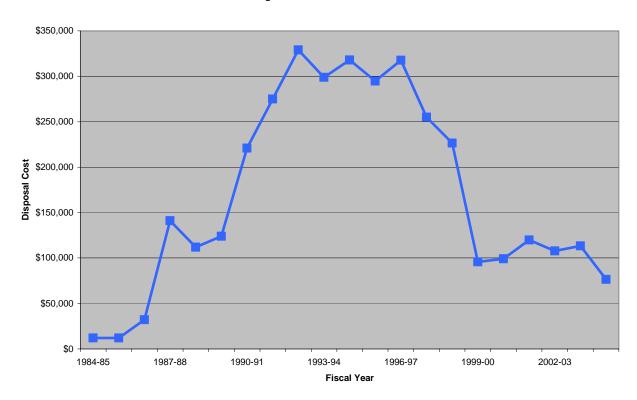
mientai wanagement	
Asbestos and lead samples analyzed (cost)	640 (\$15,332)
Asbestos abatement projects	128
Asbestos abatement costs	\$349,776
SPCC Plan training attendees	21
Other environmental sampling (air, water, soil, etc.)	863
Groundwater Protection Plan inspections	19
Environmental remediation costs	\$115,321
Hazardous waste generators	403
Pounds of regulated waste shipped	151,367
Waste disposal cost (total UK)	\$76,574
Waste minimization cost savings	\$14,640
Waste containers picked up	9,004
Fluorescent bulbs recycled	7,750
Batteries recycled	1,117
Hazardous waste/IATA class attendees	984
Incidents/releases responded to	38
Glass bottles/good chemicals recycled	1,777
Mercury thermometers exchanged	34

Occupational Health and Safety	
Research laboratories in the Chemical Hygiene databa	se 1,491
Laboratories inspected	1,109
Fume hoods tested	1,250
Indoor air quality investigations	65
Industrial hygiene samples	87
Ergonomic assessments	91
Training class attendance (total):	2,658
Chemical Hygiene Plan/Laboratory Safety	312
Hazard Communication	205
PPE Hazard Assessment	1
Back Safety	35
Construction Safety	6
Respiratory Protection	153
Bloodborne Pathogens	277
Ergonomics	13
15 Passenger Van Driver Safety Awareness	48
New Employee Orientation (EH&S Section)	1,396
SuperVISION (EHS Section)	170
Straight Truck & Van Safe Driving	39
Emergency Eyewash and Shower	3
Radiation Safety	212 (205)
Authorized users (laboratories)	213 (295)
Radionuclide purchases, cost (millicuries)	\$878,142 (109,385)
Radionuclide orders received	1,304
Radiation source inspections/surveys	1,653
Sealed source leak tests	260
Radiation instruments calibrated	193
Patient therapies (Brachytherapy)	1
Patient therapies (Thyroid)	98
Radiation safety class participants	1,475
Personnel monitoring – film badges, etc.	8,944
Level I ALARA reports	74
Level II ALARA reports	24
Waste disposal cost	\$100,171
Dry solid, long-lived, radioactive (cu. ft. shippe	
Dry solid, short-lived, decayed (cu. ft. disposed	*
Liquid (cu. ft. shipped)	87
University Fire Marshal	
Fire extinguishers inspected	6,686
Fire extinguisher/fire prevention training attendees	3,290
Fire alarms	478
Actual fires	38
Plan reviews of new construction/renovation projects	110

Hazardous Waste Cost Trend Report

Total UK Regulated Waste Disposal

Regulated Waste Costs



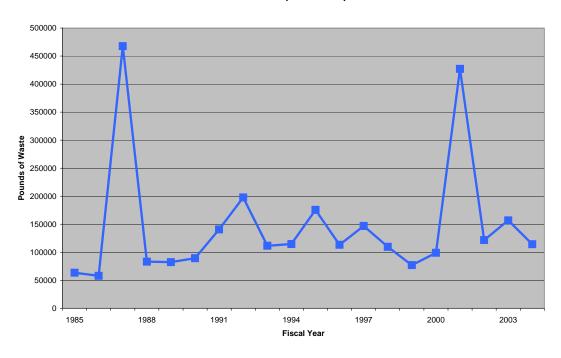
Note: Figure for 2001-02 includes \$15,392 for disposal of contaminated soil from Barker Hall.

Source: Year-ending FRS Account Statement for Environmental Management and Disposal of Wastes

Hazardous Waste Quantity Trend Report

Hazardous Waste Disposal per Calendar Year (in Pounds)

Hazardous Waste Disposal - Campus



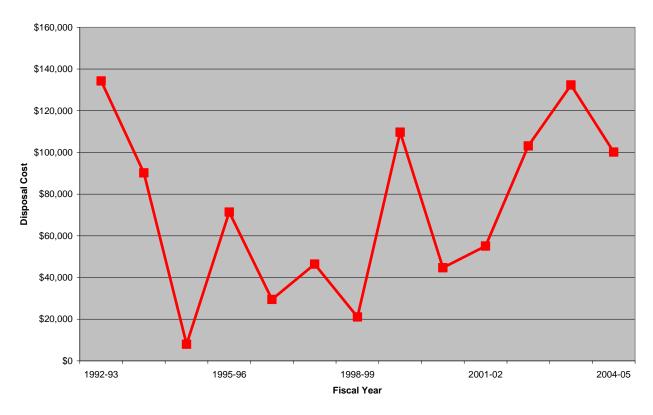
Notes

- 1. Figure for 1987 includes 365,576 pounds of waste from the South Farm cleanup project
- 2. Figure for 1998 includes 16,847 pounds of waste from the South Farm cleanup project
- 3. Figure for 2001 includes 345,800 pounds of waste from the Barker Hall cleanup project

Source: Hazardous Waste Annual Reports filed with the Kentucky Natural Resources and Environmental Protection Cabinet

Radioactive Waste Cost Trend Report*

Radioactive Waste Costs

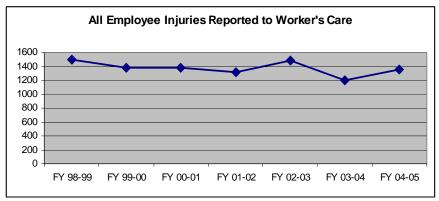


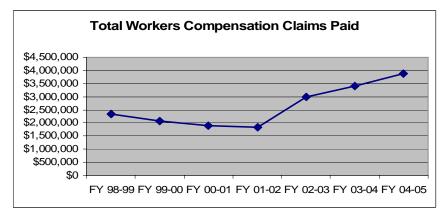
* Excluding mixed radioactive-hazardous waste

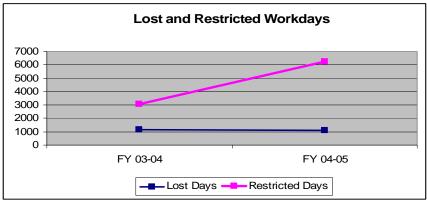
Source: Year-ending FRS Account Statement for Radiation Safety Waste Disposal

Injury and Illness Trend Report

OHS tracks the occurrence of workplace-related injuries and illnesses at UK. Between FY 98-99 and FY 02-03, the data show that reported injuries had minimal variance. Reported injuries increased by 11 percent from the previous Fiscal Year. Total Workers Compensation (WC) claims paid had minimal variance between FY 98-99 and FY 01-02. Since then, claim costs have been increasing. The majority of injuries continue to be classified as cut/puncture/laceration and sprain/strain. Major causes of injuries continue to be attributed to needle sticks, slips/trips/falls, and lifting. Further analysis of the WC claim data has determined that musculoskeletal injuries/illnesses, e.g., strains, sprains, have consistently accounted for more than half of the total WC claims paid each year. In comparison to last Fiscal Year, there was minimal variance to the number of lost workdays. Restricted workdays increased by approximately 50 percent.







Environmental Remediation Cost History

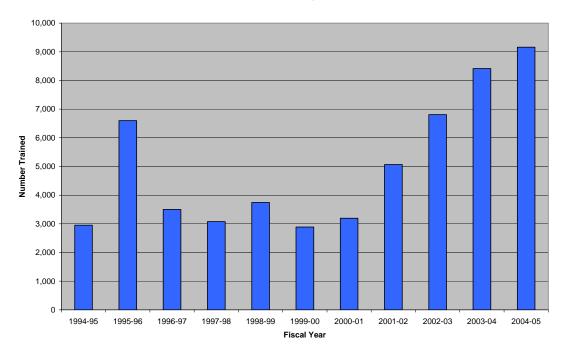
Pristine, OH Superfund Settlement (1990)	\$236,609
Administration Building Lead Cleanup (1990)	\$29,660
Jet Fuel Release (1990 – 1994)	\$63,500
Agriculture Motor Pool UST Cleanup (1990 – 1997)	\$22,866
UST-related Remediation Projects (1990 – 2000)	\$155,474
Seymour, IN Superfund Settlement (1991)	\$4,917
Robinson Forest Cleanup (1994 – 1995)	\$829,981
Maxey Flats, KY Superfund Settlement (1995)	\$124,320
Barker Hall Firing Range Lead Cleanup (1995)	\$15,590
South Farm Tract A Soil Excavation (1996)	\$37,152
North Farm Chemical Disposal Sites Remediation (1996 – 2004)	\$316,416
Carnahan House USTs Cleanup (1996 – 1997)	\$50,973
Reynolds #2 PCB Spill (1997)	\$68,500
PPD Pole Yard PCB Spill (1997)	\$14,662
Closure of Hazardous Waste Storage Facilities (1998)	\$55,205
Central Heating Plant USTs Cleanup (1998 – 2000)	\$28,993
Haggin Hall PCB Spill (1999)	\$5,900
Chemistry-Physics Mercury Remediation (1999 – Present)	\$269,420
Closure of College of Ag USTs (2000)	\$84,297
Barker Hall Firing Range Soil Removal (2000 – 2001)	\$104,330
Arboretum Hydraulic Oil Spill (2001)	\$2,500
Student Center PCB Spill (2001)	\$1,200
Reynolds #1 Oil Spill (2001)	\$375
CAER Diesel Spill (2001)	\$1,600
Maine Chance Farm Diesel Spill (2002)	\$4,100
Nutter Fieldhouse Oil Dumping (2002)	\$1,835
Main Building Mercury Release (2003)	\$13,193
Manhole E-408/University Hospital Cleanout (2003)	\$9,810
Lead Dust Cleanups (2004 – Present)	\$23,775
Former LR Cooke Chevrolet (2004 – Present)	\$90,977

Total \$2,668,130

EH&S Training Efforts

<u>Fiscal Year</u>	# Trained
1994-95	2,950
1995-96	6,600
1996-97	3,500
1997-98	3,076
1998-99	3,742
1999-00	2,888
2000-01	3,193
2001-02	5,066
2002-03	6,810
2003-04	8,416
2004-05	9,162
Total	55,403

EH&S Training



Cost of Enforcement Actions Since 1990

The figures below include penalties imposed on the University as part of state and federal enforcement actions. They do not include the costs of corrective actions or environmental remediation.

		Total	\$192,552
KY Div. of Waste Mgmt.	1999 UST violations, Med Center		\$1,500
KY Labor Cabinet (KOSH)	1998 Asbestos violation, Taylor Ed Building		\$5,625
KY Div. of Waste Mgmt.	1997 Hazardous waste violations		\$25,000
US EPA	PCB violations, Lex Campus		\$22,597*
KY Div. for Air Quality KY Labor Cabinet (KOSH)	1996 Asbestos violation, Central Htg Plant OSHA violations, Central Htg Plant		\$12,500 \$18,000
KY Labor Cabinet (KOSH) KY Div. for Air Quality	1995 Asbestos violation, Admin Building Incinerator violation, Med Center		\$500 \$5,000
KY Div. of Waste Mgmt.	1993 Hazardous waste violations		\$5,000
KY Div. of Waste Mgmt.	1992 Hazardous waste violations		\$20,000
KY Div. of Water	1991 Jet fuel release		\$1,330
US EPA US EPA	1990 PCB violations, Lex Campus PCB violations, Med Center		\$27,250 \$48,250

^{*} Includes a penalty payment of \$3,600 and a Supplemental Environmental Project of \$18,997 (for removal of a PCB transformer at Gillis Building).

Report of the Biological Safety Department

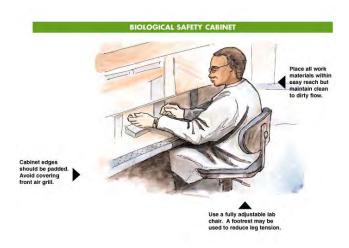
Biological Safety Annual Report Fiscal Year 2004 - 2005

Major Accomplishments

Brokered agreement between UK, Lexington Fayette County Urban Government (Solid Waste Program), State of Kentucky (Division of Waste Management), and M&M Sanitation (contractor for LFCUG) for autoclaved waste from the UK Hospital to be hauled to and disposed of in the LFCUG owned landfill. Developed a Quality Assurance program in compliance with Federal EPA standards for the separation of medically regulated waste (hauled for incineration by an outside contractor, Stericycle) from waste which is autoclaved on site and hauled to the landfill by M&M Sanitation. This program includes documentation of routine testing to ensure proper autoclave conditions are meet for decontamination of potentially biohazardous waste. This eliminates the special waste stream the hospital was going to have to implement and the renovation of the dumpster site behind the hospital. Being able to put the autoclaved waste into the general hospital waste stream after it is compacted will save the hospital at least \$45,000/year. If the city and state had persisted in refusing autoclaved waste this status, they could have imposed the implementation of a separate waste stream in each building housing research laboratories, at a potential cost of probably \$100,000/year for the entire campus.

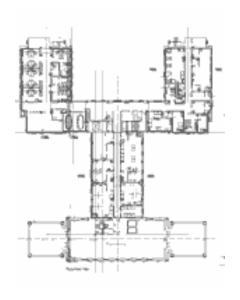


Adapted training module on the principles of biological safety cabinets (BSC) and safe work procedures for BSCs. Successful completion of the test sends a certificate to the trainee and enters their information into the EH&S training database. BSCs are used in research laboratories working with infectious agents, recombinant DNA, or tissue/cell culture. They are primary containment equipment for protecting the worker from the material in the cabinet and for protecting the material being manipulated in the cabinet from contaminants in the room through the use of HEPA filters. Inappropriate procedures can endanger the worker and the experiment.



Member of the NIH grant application team from Provost and Executive Vice President for Research offices. Grant was for new research facilities to serve the investigators engaged in infectious disease research.

Developed specifications for the renovation of laboratory facilities in Dorothy E. Combs Cancer Research Building to create a "clean room" appropriate for the preparation of immunotherapeutics for a FDA approved, industry sponsored clinical trial. Collaborated with the Provost's office to monitor and expedite the renovations.



Consulted with researchers and vendor to design custom built containment equipment and facilities for the injection of recombinant viral vectors into research animals in the research animal facility in BBSRB. This equipment is now housed in a dedicated procedure room in the animal facility and has been tested and certified.



Assumed responsibilities of the Responsible Official for the federal Select Agent program on the UK campus.

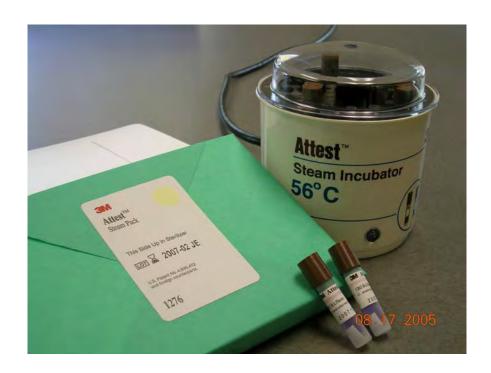
Significant Projects

Enhanced and expanded the campus-wide Autoclave Performance Verification Program. Implementation of this program allows the University of Kentucky to ensure and document that all autoclaved infectious/biohazardous materials are rendered noninfectious by the autoclaving process. Results of the monthly performance tests, all maintenance and repairs, and training of personnel operating the autoclaves are documented.

Training was developed and performed for all persons responsible for autoclave facilities decontaminating biohazardous waste from research laboratories. 60 persons attended

Signs were designed for the assigned autoclaves processing biohazardous or recombinant DNA waste and were distributed to appropriate facilities. .

Supplies and equipment for the monthly spore testing were purchased by Research and distributed by Biological Safety staff to each autoclave facility and responsible person (designated by the department owning the autoclaves).



Expanded information available on-line at the biosafety webpage

- "Fact Sheets" on adenoviral and lentiviral work practices and TAT-Fusion Protein Use
- Autoclave Verification Program
- Biosafety audit checklist
- Ultraviolet lights in the laboratory



Developed procedures and physician's guidelines for wildlife biology students who might be potentially exposed to hantavirus while conducting census studies of small mammals as part of field research (in collaboration with UK mammalian expert, UK Employee and Occupational Health, and Centers for Disease Control). This was prompted by the death from hantavirus infection last summer of a graduate student in West Virginia who was conducting similar research.



Additional Accomplishments and Events

Expanded staff with addition of second Biological Safety Specialist, March 21, 2005

Conducted 93 laboratory biosafety audits.

Reduced processing time for IBC full review protocols and registrations by approximately 30 percent.

Collaborated with Provost's Office and Research to identify and tag all large autoclaves and all biological safety cabinets in research facilities for the campus wide inventory system. This will facilitate monitoring of the autoclave verification program and the implementation of the EH&S coordinated annual certifications of biological safety cabinets in research laboratories.

Developed agreement with Central Kentucky Blood Center for the release of human blood and blood products to UK researchers. Information is shared between the UK Biosafety

Department and CKBC so that researchers without IBC registration will not receive human blood from CKBC. This was prompted by the use of human blood in a research project in the College of Engineering without IBC registration, and no knowledge by the researchers of the OSHA Blood Borne Pathogen regulations.

Developed and administered the following training sessions:

- Orientation and safety training for researchers and their staff members moving into BBSRB: what to do before the move, how to update compliance documents, safety issues in the open lab. 136 attended in 5 sessions
- IRB staff training on IBC Issues in Human Gene Transfer Trials. 25 attended
- Training in the autoclave verification program. 60 attended
- "Biological Safety for Graduate Students" presented at orientation or seminars to College of Agriculture, 150 attended Center for Nutritional Studies, 30 attended College of Pharmacy, 20
- Lecture in Pharmacy PHR 764
- Bloodborne pathogen training for researchers in Sanders Brown Center for Aging to address the issues of prion contaminated human tissue in research and autopsies: 44 attended
- Training on Select Agents for Medical Center Physical Plant Department: 40 attended 3 sessions
- Individual training and consultations as requested by investigators:

Biochemistry Departmental meeting Pharmacology Departmental meeting 25 individual consultations

Regulatory Events

Responded to the final written report from the security audit of the Select Agent program performed by the Office of the Inspector General in the Department of Health and Human Services. Provided documentation of changes made in response to the preliminary recommendations made immediately after the audit in 2004.



Professional Development Activities

Marcia Finucane, MS, Biological Safety Officer

Attended the following courses:

- Plant Biosafety (American Biological Safety Association): 4 hours
- Animal Biosafety Level 3 Containment Facilities Design to Operations (American Biological Safety Association): 4 hours
- Design and Construction of BSL3 Facilities (Eagleson Institute): 16 hours
- Safe BSL3 Work Procedures and Practices (Eagleson Institute): 16 hours
- Human Subject Protection Conference, UK Office of Research Integrity: 6 hours

Participated in UK DOT/IATA shipping class

American Society for Microbiology, Member

American Biological Safety Association, Member

Maintained registration as a medical technologist (MT) with the American Society for Clinical Pathology (ASCP)

Maintained registration as Certified Biological Safety Professional by the American Biological Safety Association

Maintained Specialist Microbiology (SM) by National Registry for Microbiologists/American Society for Microbiology (ASM)

Katherine Sandford, MSPH, Biological Safety Specialist

Completed workshops on "Basic Virology & Virus Based Gene Vectors" (8 hours), Select Agent Regulations (8 hours) (American Biological Safety Association)
Participated in UK DOT/IATA shipping class

American Biological Safety Association, Member

Kentucky Public Health Association, Member

Derek Adams, BS, Biological Safety Specialist

Attended Bioethics lecture, UK Medical Center Participated in UK DOT/IATA shipping class

Attended as observer to <u>National Science Advisory Board for Biosecurity</u> conference (National Institute of Health):

Community Outreach

Participated as judge in Fayette county schools science fair as a representative from UK part of the UK Partnership in Education initiative.

Participated in Lexington Fayette County Urban Government emergency planning drill (Strategic National Stockpile Emergency Preparedness Exercise) as representative from UK Biological Safety.

INSTITUTIONAL BIOSAFETY COMMITTEE (IBC) SUMMARY OF ACTIONS FOR FY 2004-2005

Full committee review and approval of 65 protocols including two Human Gene Transfer protocols.

The BSO reviewed and registered 22 protocols and 6 modifications.

Completed annual training on NIH regulations and IBC approval process as mandated by the NIH and presented by the BSO.

Reduced backlog of researchers needing Institutional Biosafety Committee renewals by 78% (from 97 to 21 protocols). Determined which were inactive due to change in research or severance with UK, which still needed to renew. Notices sent out quarterly.

Key Indicators for Biological Safety: 2004-2005

I.	Institutional Biosafety Committee		Total
	IBC Protocols approved/registered:New or renewalModificationRegistration only		93 65 6 22
	·		
	Approved Protocols in Database		436
II.	Biosafety		
	Laboratory audits completed		93
	People trained by Biological Safety		718
	New training modules		1
	Programs expanded - Autoclave Verificat	ion	1
III.	Investigations		
	Serious research irregularities investigated Serious laboratory incidents investigated	1	1 1
IV.	Contact hours		
	With investigators or IBC Registration Re	eview	
	New protocol review/approvalBasic Registration review	7 hours/each 4 hours/each	455 hours 94 hours
	On biosafety		
	Laboratory auditsModification per protocolFacility consultations	2 hours/each 1 hours/each	186 hours 30 hours 1000 hours
	Training Opportunities Presented • About IBC		45 hours
	 Biosafety topics 		619 hours
	 Select Agent Professional Development 		54 hours
	Training/Workshops/Courses Attended		66 hours

Report of the Environmental Management Department

ENVIRONMENTAL MANAGEMENT

Annual Report

FY 04-05



Environmental Quality Management Center

Accomplishments and Major Events

- 1. The contingency plan for the Environmental Quality Management Center (EQMC) was revised in August 2004 to reflect current operating conditions and spill response procedures. The revised plan was distributed to the Kentucky Division of Waste Management and applicable emergency response agencies.
- 2. A comprehensive application to renew the University's hazardous waste treatment, storage, and disposal permit was prepared and submitted to the Kentucky Division of Waste Management's Hazardous Waste Branch in June 2005. The new permit is expected to be issued by October 2005.
- 3. On May 25 and 26, 2005, personnel from the Kentucky Division of Waste Management and the United States Environmental Protection Agency conducted a hazardous waste compliance inspection. The University's hazardous waste facility and related waste handling documents were reviewed, and the inspectors toured a total of eighty labs in Agricultural Science Center North, Barnhart Agricultural Engineering Building, Plant Science Building, and the Chemistry-Physics Building. Labeling and container violations were noted in twenty-one labs during the inspection but were corrected immediately or within one day. The formal inspection reports had not been received by the end of FY 04-05.
- 4. A Notice of Violation was received from the Kentucky Division for Air Quality during an asbestos abatement project at the Western Kentucky Agriculture Substation in Princeton. The violations were primarily associated with contractor actions and were corrected in a timely manner. No enforcement action or penalties were assessed.
- 5. In the third phase of a multi-year project, lead-based paint risk assessments were completed at Maine Chance Farm, Spindletop Farm, the Woodford County Animal Research Center, and Eden Shale Farm. Cleanup was performed to remove lead dust and/or paint chips following identification of lead hazards. Clearance testing conducted following completion of the projects demonstrated that the hazards had been abated. Work is continuing in College of Agriculture housing.

- 6. Standard operating procedures were developed for waste treatment procedures not specifically defined in the University's hazardous waste permit. Specifically, SOPs were developed for treatment of oxidizers and neutralization of acids and bases.
- 7. Waste minimization was improved by expanding the pressurized cylinder recycling program to include aerosol cans. New equipment was purchased to allow the cans' contents to be recovered and disposed of in bulk at a significantly reduced cost.
- 8. The flammable liquid storage room at the EQMC was reconfigured to increase its storage capacity. As a result of the increased capacity, a new unit cost for disposal of bulk flammable liquids was negotiated with the University's waste contractor.
- 9. An emergency asbestos abatement project was completed at Boyd Hall in October 2004 following failure of asbestos-containing ceiling plaster. The affected area was isolated and a certified asbestos abatement contractor was retained to clean up the fallen plaster and repair the damaged areas.
- 10. A major cleanup/demolition project was completed at the former LR Cooke Chevrolet property in downtown Lexington. The project included asbestos abatement, removal of an underground storage tank, removal of underground hydraulic lift systems, cleanup of motor oil, hydraulic oil, and other petroleum products, demolition of the building, and restoration of the site.
- 11. Monitoring conducted by the LFUCG's Division of Sanitary Sewers indicated that mercury and lead concentrations in the wastewater discharge from the Medical Center were above acceptable limits. Wastewater monitoring was conducted to determine the source(s) of the lead and mercury, and sink and fume hood traps were screened in the Sanders-Brown Center on Aging. Work is expected to continue in 2005-06.
- 12. In accordance with new Department of Transportation regulations, a hazardous materials transportation security plan was developed to cover shipping activities at the EQMC. Additional information was developed for distribution to on-campus shippers of dangerous goods.
- 13. Environmental Management personnel responded to spills or releases of chemicals and other substances 38 times during Fiscal Year 2004-05. Spills occurred in laboratories, clinical settings, parking areas, dumpsters, roadways, dumpsters, storm sewers and storage areas. In most cases, spilled materials were treated with neutralizing agents or absorbents and then cleaned up for proper disposal.
- 14. Improper disturbance and/or removal of known or presumed asbestos-containing materials took place at several locations (listed below). Both contractor and UK personnel were involved. Although the circumstances vary, in each case an investigation was performed and remedial measures including, but not limited to, cleanup, additional education, and awareness, were provided.
 - Kentucky Clinic (disturbance of floor tile and mastic)
 - Boyd Hall (disturbance of plaster)
 - Research #3 (disturbance of fume hood and countertops)
- 15. Closure was received from the Kentucky Division of Waste Management in October 2004 on a ten-year project to investigate and clean up four former chemical disposal sites on the North Farms.

Other Activities

- 1. Assisted the Hospital's clinical laboratories during an FAA inspection and by delivering suspected select agents to the state laboratory in Frankfort.
- 2. Reviewed environmental assessment reports and conducted a site visit to the former Vogt Machinery property in Louisville in support of the College of Design.
- 3. Performed site visits to abandoned mine lease property in Robinson Forest to assess potential environmental impact and to proposed leased property in downtown Lexington.
- 4. Revised the University's hazardous waste manual and associated online training class curriculum and exam.
- 5. Made presentation on DOT/IATA requirements at the Clinical Lab Manager's Association meeting.
- 6. Established a new contract for NVLAP-accredited asbestos laboratory services.
- 7. Conducted semiannual wastewater compliance monitoring in accordance with requirements of the University's wastewater discharge permit.
- 8. Performed perchlorate salt testing in fume hood exhaust ducts at Agricultural Science Center North and the T.P. Cooper Building.
- 9. Participated in a Hospital/ER chemical decontamination drill and later removed potentially-contaminated water from the ER decontamination unit.
- 10. Facilitated tours of the EQMC by Lexington Fire Department personnel and UK College of Public Health students.
- 11. Monitored compliance of underground storage tank leak detection methods.
- 12. Posted asbestos warning signs in fraternities and sororities.
- 13. Supported research in the College of Pharmacy by conducting analysis on a developmental scintillation cocktail.
- 14. Prepared and submitted hazardous waste annual reports, tax assessments, and facility registrations.
- 15. Renewed the University's asbestos abatement certification.
- 16. Coordinated payment of underground storage tank registration fees.
- 17. Revised and updated the University's Groundwater Protection Plan and conducted required annual inspections.
- 18. Completed and submitted SARA Title III Tier II and Tab Q-7 forms.
- 19. Supported the College of Agriculture on a potential PCB spill at the Western Kentucky 4-H camp.
- 20. Assisted with cleanout of acid dilution pits at KTDRC and the Dental Wing.

Key Indicators and Routine Functions

1. Hazardous Waste

- Hazardous waste generators **403** locations
- Waste shipments **151,367** pounds of regulated waste
- Waste disposal costs \$76,574
- Waste pickups **9,004** containers

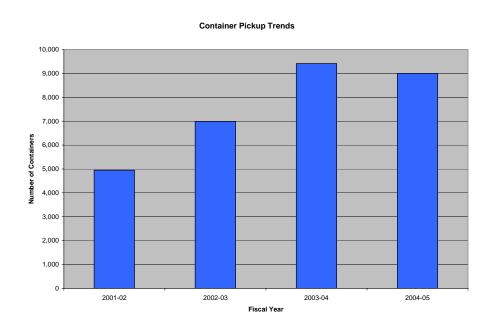


Table 1

Total UK Regulated Waste Disposal

Fiscal Year	Disposal Cost (\$)
1996-97	317,591
1997-98	254,932
1998-99	226,506
1999-00	95,668
2000-01	99,226
2001-02	119,938
2002-03	107,809
2003-04	113,444
2004-05	76,574

Note: Figure for 2001-02 includes \$15,392 for disposal of contaminated soil from Barker Hall.

Table 2
Hazardous Waste Disposal per Calendar Year (in Pounds)

Calendar Year	Campus	CAER	North Farms	Animal Diagnostics
1996	113,222	1,476		2,701
1997	146,812	25,650	6,646	4,374
1998	109,558	2,085	7,776	5,084
1999	76,875	4,949	500	4,400
2000	98,926	3,434	1,900	4,401
2001	427,162 ¹	3,407		4,551
2002	121,531	2,926	800	3,200
2003	156,795	1,301		3,461
2004	114,171	3,161	3,400	3,185

¹Includes 345,800 pounds of waste from the Barker Hall cleanup project

2. Asbestos/Lead

- Asbestos abatement 128 projects totaling approximately \$349,776
- Sampling for asbestos & lead-based paint 640 samples (\$15,332 survey/testing cost)
- Lead-based paint risk assessments **11** locations

3. Environmental Protection

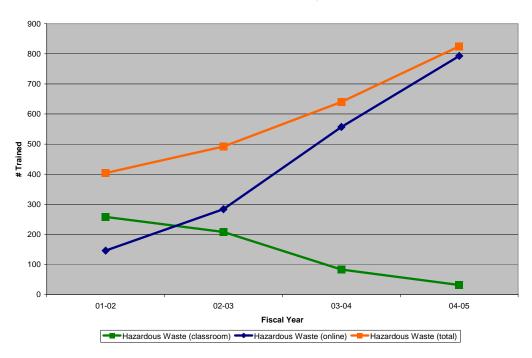
- Environmental sampling (air, radon, water, soil, waste, etc.) **863** samples
- Groundwater Protection Plan inspections **19** locations
- Environmental remediation costs \$115,321

4. Training

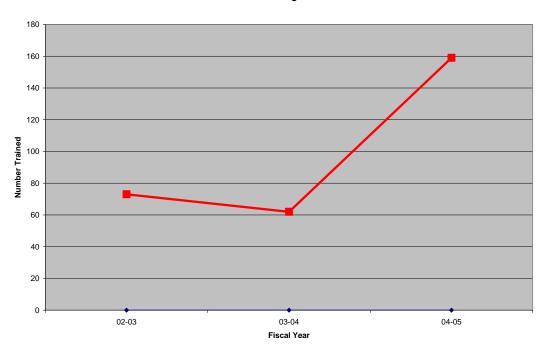
- Hazardous waste training **825** attendees (up 29% from last year)
- DOT/IATA training **159** attendees (up 156% from last year)
- Asbestos awareness training **10** attendees
- SPCC training 21 attendees
- 15-passenger van training **6** attendees

Environmental Management Training Trends

Hazardous Waste Training Trends



DOT/IATA Training Trends



Waste Minimization

• Waste Treatment

Acids / bases neutralized 5,029 pounds

Oxidizers reduced 18.5 pounds

Gas cylinders treated 52 cylinders

Aerosol cans recycled 175 cans

Total Savings \$14,640

• Recycling

Fluorescent bulbs 7,750 bulbs

Batteries 1,670 pounds

Batteries – to off-site vendors 1,117

Glass bottles 1,771

Good chemicals 6

Thermometer exchanges 34

Laboratory Moves

<u>Date</u>	Location / PI	Quantity
2/4/05	Chen	27 boxes
2/25/05	Geddes	8 boxes
3/15/05	Voss	24 boxes
6/2/05	Sullivan	7 boxes
6/3/05	MS-268	17 boxes
6/28/05	Hersh	20 boxes
6/30/05	MS-668	9 boxes

Laboratory Cleanouts

<u>Date</u>	<u>Location / PI</u>	Number of Containers
8/2/04	218 KTDRC	50
8/4/04	Garrigus Building Storeroom	99
8/5/04	220 Cooper	100
8/6/04	S-222 Ag Science North	239
8/26/04	Medical Center MS-636	45
9/1/04	211 Research #3	75
10/12/04	220 Cooper Building	287
10/18/04	Medical Center MN-248	177
10/19/04	323 Combs Building	300
10/22/04	S-222 Ag Science North	210
11/23/04	117 Funkhouser Building	535
2/17/05	B008 T.H. Morgan Building	93
3/9/05	323 Combs Building	55
3/23/05	105 Research #3	33
3/25/05	049 Roach Building	41
6/23/05	Medical Center MN-326A	233

University Service and Professional Development

Mike Blackard

- Staff Senate Precinct 19 representative
- Maintained Commercial Drivers License with Hazardous Materials endorsement
- Maintained accreditation as a Senior Level Certified Hazardous Materials Manager
- Received accreditation as an Asbestos Inspector
- Attended training course on DOT/IATA regulations
- Completed course on National Incident Management System
- Academy of Certified Hazardous Materials Managers Member

Brian Butler

- Attended Practical Compliance with EPA Regulations course
- Completed course on National Incident Management System
- Attended course on DOT/IATA regulations

Attended College/University Hazardous Waste Conference

Lee Faulkner

- Maintained accreditation as a Senior Level Certified Hazardous Materials Manager
- Completed course on National Incident Management System
- Attended College/University Hazardous Waste Conference
- Academy of Certified Hazardous Materials Managers Member

Tommy Taylor

- Maintained accreditation as an Asbestos Inspector / Management Planner
- Maintained accreditation as a Lead-based Paint Inspector / Risk Assessor
- Completed the final installment of the College Business Management Institute
- Attended course on excavation, trenching, and soil mechanics

Woody Bottom

- Maintained registration as a Professional Geologist authorized to practice in the Commonwealth of Kentucky
- Completed course on National Incident Management System
- Completed course on WMD Incident Management / Unified Command
- Maintained accreditation as an Asbestos Inspector / Management Planner
- Maintained accreditation as a Lead-based Paint Inspector / Risk Assessor
- Served on Chemical Safety, Environmental Health & Safety, & Hospital Environment of Care Committees
- Represented the University at meetings of the Royal Spring Water Supply Protection Committee
- Attended 3rd Annual Kentucky Environmental Conference
- Attended KENA/APCO/KEMA Emergency Services Conference
- American Society of Testing and Materials Member
- American Society of Safety Engineers Member
- Environmental Information Association Member

Report of the Occupational Health and Safety Department

Occupational Health & Safety Team Accomplishments/Events

01.JUL04 - 30.JUN05

- 1. Developed an information seminar for occupants moving into the new BBSRB facility. Conducted 6 orientation sessions and training 182 new occupants. This facilitated incident-free moves of the departments of Biochemistry and Physiology as well other individual labs.
- 2. Developed an eyewash/shower testing procedure to be used along with the new eyewash/shower online training module.
- 3. Evaluated and provided guidance for selection of personal protective equipment for DLAR employees that wash and transport primate animal cages. These changes reduced the probability of potentially fatal exposures to Herpes B virus.
- 4. Provided Hazard Communication for the College of Dentistry as part of the continued training effort. Over 72 employees were trained in 2 sessions.
- 5. Developed Construction Safety training course and presented it to project managers in CPMD. This program instructs UK employees of the proper procedures and safety precautions to take while on construction sites.
- 6. Collaborated with UK Hospital to modify OHS's Bloodborne Pathogens online training course. The new course more efficiently and effectively allows for Hospital employees to meet their training needs and comply with regulatory requirements.
- 7. Performed exposure monitoring in Biology dissection laboratory. Identified overexposures to formaldehyde and made recommendations for abating the hazard.
- 8. Collaborated with Biological Safety to test the HSRB BSL-2 containment. OHS used smoke and tracer gas to identify leaks and worked with PPD to ensure those areas were sealed.
- 9. Continued eyewash shower project in Anderson Tower. Replaced handled that were not compliant with code and added several showers to needed areas.
- 10. Submitted annual Facility Safety Plan Status Report for the U. S. Army Medical Research Material Command (USAMRMC). Updating this report sustains UK as an eligible institution to receive Department of Defense grants.
- 11. Collaborated with the Lexington Fire Department by assisting them on four external incidents. This collaboration has allowed for quicker, better and safer responses to incidents on campus.

- 12. Continued to issue electronic laboratory inspection reports to individual faculty and staff. Refined data entry and review process to increase accuracy of data.
- 13. Sustained an Eastern Kentucky University, College of Health Sciences undergraduate internship position within the department to provide for an additional resource for existing OHS Team projects and enhancement of OHS services provided to customers.
- 14. Performed noise dosimetry of PPD Grounds Workers. Evaluated 24 workers over a three week period. Ten workers were identified as having noise exposure in excess of the OSHA action level of 85 decibels. Evaluation is ongoing with recommendations pending completion of the project.
- 15. Performed exposure monitoring for newly installed sterilizer that utilizes ethylene oxide. Measured employee exposure while operating sterilizer. No overexposures were identified.
- 16. Conducted safety audits in conjunction with laboratory inspections in CRMS and several College of Engineering spaces. This team approach to inspections allowed for more specific and detailed inspections relating to regulatory compliance. It also allowed departmental contact and escorts to more efficient use of their time.
- 17. Continually provided guidance and OHS design oversight for all new construction/renovation projects involving the following areas: Wethington, Plant Sciences, Slone, BBSRB and BBSRB 4th floor fit-up, Chemistry/Physics, CPST, Ag. Regulatory Services, Medical Science Building, MDR#3, and LDDC.
- 18. Coordinated effort on providing EHS booth display at UK New Faculty Orientation in improving employee EHS awareness.
- 19. In support of the university's research function, OHS conducted 38 comprehensive laboratory inspections and EHS program reviews associated with DOD Grant Proposals.
- 20. OHS continued to serve as the EH&S trainer for the EH&S orientation of all new employees and supervisors.
- 21. Conducted a total of 65 Indoor Air Quality Investigations in response to employee solicitations. These investigations involved 28 different buildings.
- 22. Continued to investigate significant incidents involving employee/student injury, fire, and/or chemical releases including the HCl release in Chemistry/Physics and shock to contract employee in Singletary Center.
- 23. Assisted Dr. Yanelli's lab by identifying contaminant pathways for vaccine production. This was done by performing bioaerosol monitoring which identified particular mold species. OHS also provided guidance in renovation of space to eliminate mold production and dispersion.
- 24. Conducted exposure monitoring for xylene and formaldehyde in Oral Pathology Lab in College of Dentistry. Two lab workers were overexposed to formaldehyde.

Major Accomplishments

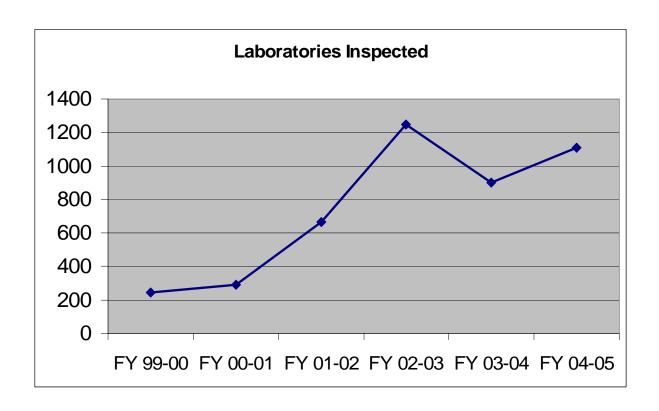
1. All chemical hoods in the College of Engineering were ASHRAE 110 tested. OHS identified need, coordinated effort and compiles results. All hoods passed the tracer gas studies.

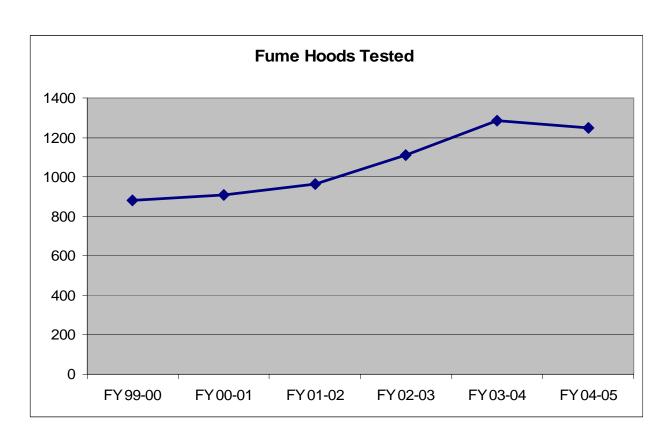


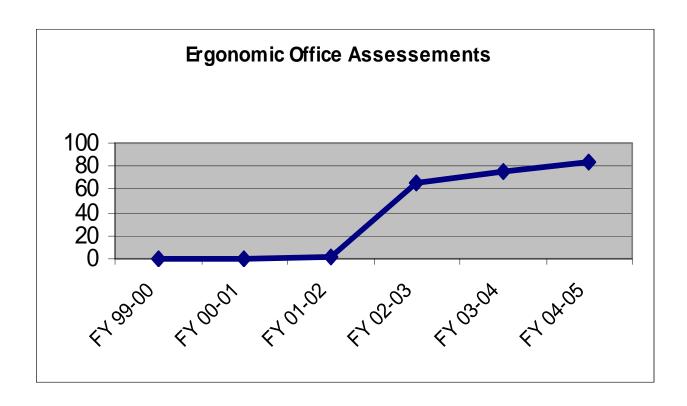
Key Indicators for Occupational Health and Safety

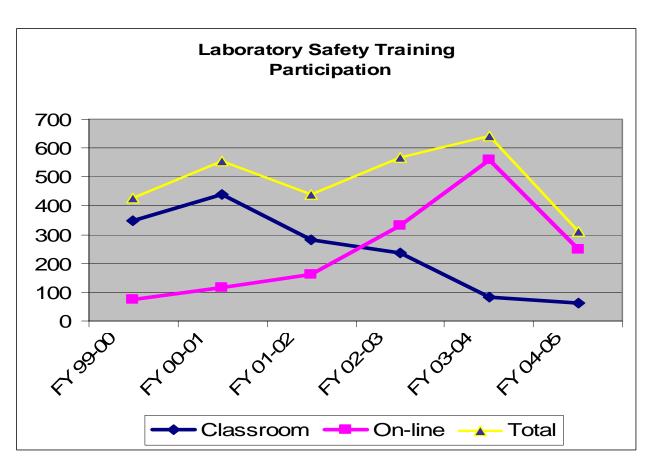
Laboratories in the Chemical Hygiene database	1,491
Laboratories inspected	1109
Fume hoods tested	1250
IACUC Protocol Reviews	264
New Applications	(172)
Major Modifications	(92)
USAMRMC Grant Proposal Reviews	38
Indoor Air Quality investigations	65
Respirator Fit-tests	134
Industrial Hygiene samples	87
Ergonomic Office Assessments	83
Ergonomic Assessments (non-office)	8
Training Class Attendance	
Chemical Hygiene Plan/Laboratory Safety	312
Classroom Training	(64)
On-line Training	(248)
Laboratory Safety (specialized)	
Hazard Communication	205
Classroom Training	(76)
On-line Training	(129)
Hazard Assessment for the Use of Personal Protective Equipment	1
Hot Work Permitting	0
Lockout/Tagout - Control of Hazardous Energy	0
Respiratory Protection	153
Bloodborne Pathogens (on-line)	277
Ergonomics	13
15-Passenger Van Driver Safety Awareness	48
Straight Truck & Van Safe Driving Strategies	39
New Employee Orientation (EH&S Section)	1396
SuperVISION (EH&S Section)	170
Back Safety	35
Construction Safety	6
Emergency Evewash and Shower	3

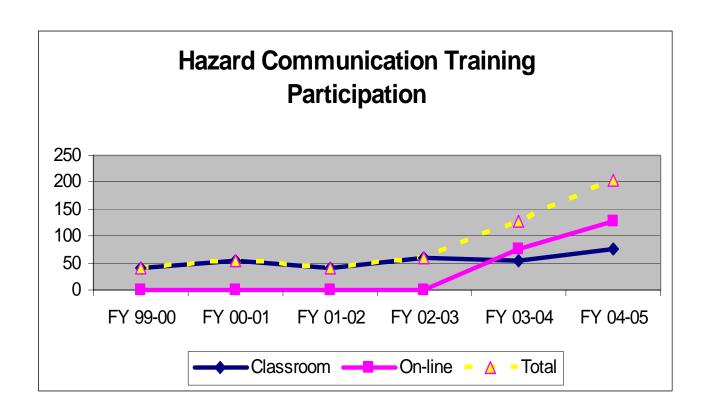
Trends for Select Key Indicators

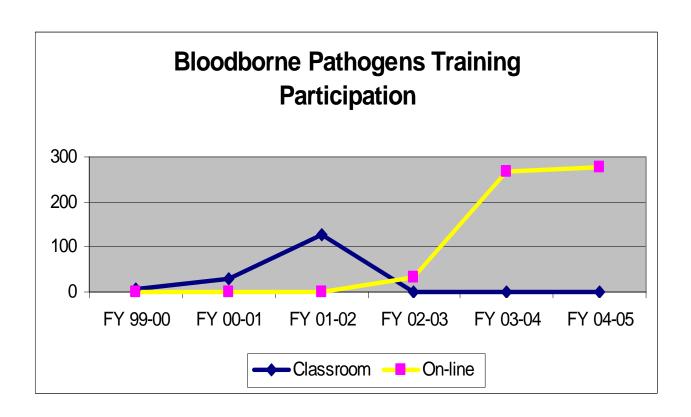












Professional Development and Outreach Activities Occupational Health and Safety

Lee Poore

- Attended American Industrial Hygiene Conference and Exposition (AIHCE) and received training on the National Incident Management System (NIMS)
- Maintained certification as a Certified Industrial Hygienist as recognized by the American Board of Industrial Hygiene
- Maintained certification as a Certified Chemical Hygiene Officer as recognized by the National Registry of Certified Chemists
- Attended College Business Managers Institute and graduated from the three year program
- American Chemical Society Member

Bob Cadle (retired February 2005)

• Served as Secretary of the American Society of Safety Engineers – Bluegrass Chapter

David Acker

- Assisted Lexington Fire Department's Special Operations/Hazardous Materials Unit on 4 incidents
- American Conference of Governmental Industrial Hygienists Full Member.

Angie Renick

- Attended Eastern Ergonomics Conference and Exposition
- Completed first year of College Business Managers Institute

Academic Participation for 2003-2004 School Year

Provided lectures, seminars, etc. in UK courses (contact hours)

Lee Poore

Chemistry: Seminar in Chemistry - Chemical Safety, CHE-772 (5 hours)

David Acker

Preventive Medicine and Environmental Health: <u>Respiratory Protection, PM-601</u> (3.0

hours)

Report of the Radiation Safety Department

Introduction

The Radiation Safety Officer is required to submit an annual report regarding the state of radiation safety to the University of Kentucky Radiation Safety Committee. The Report for Fiscal Year (FY) 2004-05 is provided herein.

Significant Occurrences

This is a summary report on major incidents, agency actions, and other regulatory activity involving UK this fiscal year.

Regulatory Inspections

The broad medical and teletherapy / gamma knife licenses were both inspected in May 2004. No compliance findings were noted.

Radiological Incidents

August 18, 2004 - The waste alarm sounded, and the person dumped the waste in the compactor because they didn't speak English. Radiation Safety Staff responded and the dispatcher in Station 3 repeated that story that a worker didn't know the procedure, and ignored Veronica Edmunds when she tried to get him to stop. The cart was surveyed and no levels above background were detected. Radiation Safety Staff then went outside and surveyed the dumpster with the GM meter. A level of 0.12 millirem per hour was detected 2/3 back and 5 feet high on the dumpster. Subsequent survey with a Na-I detector read 200 dpm above background. Analysis with the MCI indicated Tc-99m spectrum. The dumpster remained sequestered and guarded by security staff until it was decayed.

October 22, 2004 - Irradiator Incident: Radiation Safety Staff were preparing to give an Irradiator Radiation Safety Course to a new technician at 2 PM. They checked the interlock on the machine and the source rod lifted with the machine in the Off position indicating a malfunction of the safety interlock. Radiation Safety Staff then turned on the power to the irradiator and opened the door and lifted the source into the exposed position while the door was open, also indicating a malfunction of the safety interlock. Radiation Safety Staff placed the probe of the Geiger counter in the compartment of the machine while the door was open and lifted the source rod, and the needle went offscale. Radiation Safety Staff labeled the irradiator 'Do Not Use', and put a lockout device on the power cord of the irradiator. The irradiator was repaired and put back into service.

Misadministrations

There were no patient misadministrations in FY 04-05.

Accomplishments and Major Events

- **1.** A new Radiation Safety Officer was hired and started on January 3, 2005. All licenses were amended to reflect the change in personnel.
- 2. The teletherapy unit formerly used in the Radiation Medicine department was removed and shipped to another licensee for reuse.
- **3.** The GammaCell 200 irradiator formerly used in the Radiation Medicine department was returned to the original vendor for disposal.
- **4.** Radiation Safety Office staff members became members of the regional Bluegrass Emergency Response Team (BERT) and active in its Equipment Committee. Consultation was provided on the selection and use of radiation monitoring equipment.
- **5.** The annual National Emission Standards for Hazardous Air Pollutants (NESHAP) report on radioactivity releases was completed. UK passed the standard for released radioactivity.
- **6.** The irradiator license was amended to reflect additional commitments based on the October 2004 incident. Three authorized users now control access to the unit. All users have been trained on the new requirements. A fixed radiation detector was also installed in the area.

Academic Participation by Radiation Safety Office Staff 2004-05 Academic Year

1. Gave lectures, seminars, etc. in UK courses

Fred Rawlings

Radiation Medicine: Radiation Protection,

RM/BIO 740 Mammalian Radiation Biology(1 hour) 12/09/04

Andy Miller

Radiation Science class lecture on Regulatory Issues

2. Taught undergraduate and graduate students as part of EH&S safety courses.

Fred Rawlings

Basic and Initial Radiation Safety courses.

Staff technical in-service training classes.

Ancillary and Police staff in-service safety classes.

Irradiator Training.

Occupational Health and Safety: Occupational and Environmental Health

PM 601 Radiation Dose Risk (1 hour)

Industrial Uses of Radiation (1 hour)

Gerald Schlenker

Laser Radiation Safety courses (standby for Basic, Initial and other training).

Initial and Refresher Radiation Safety classes for nursing staff.

Medical School Ph.D candidate Radiation Safety Orientation class.

Staff technical in-service training classes.

Ancillary and Security staff in-service safety classes.

Bob Wilson

Initial Radiation Safety classes.

Irradiator safety classes.

Hospital / Medical Center safety classes.

Andy Miller

Irradiator safety classes

3. Participation in Outside Activities

Gerry Schlenker and Bill Garner continue to plat an active role in the Bluegrass Emergency Response Team.

Andy Miller continues to serve on the Part II panel of examiners for the American Board of Health Physics.

Key Indicators for Radiation Safety

The numbers and costs below are provided to give an indication of the level of activity within EH&S units when conducting their day-to-day business.

Authorized users		213
Authorized laboratories		295
Radionuclide purchases, cost		\$878,142
Radionuclide purchases, millicuries		109,385
Radionuclide orders received		1304
Laboratory inspections/surveys		1653
Laboratories	1430	
X-ray machines	158	
Lasers	65	
Sealed source leak tests		260
Patient therapies:		
Brachytherapy		1
Thyroid		98
Radiation safety class participants		1475
Personnel Monitoring		
Film badges, etc. used 8,944		
ALARA reports, Level I		74
Level II		24
Radioactive waste disposal		

Dry solid, long-lived (cu. ft. shipped)	193.5
Dry solid, short-lived, decayed (cu. ft. disposed)	90.0
Liquid (cu. ft. shipped)	87.35
Waste disposal cost	\$100,171
Radiation instruments calibrated	193

Surveys

Radiation Safety Office personnel periodically (at least quarterly) inspect the laboratories and facilities of Authorized Users to monitor the lab's radiation safety program. Radiation exposure rates and removable contamination levels are measured and record keeping systems reviewed during the surveys. The frequency of surveys is determined by the type of source, quantity of radioactive materials used, results of previous surveys, and general compliance with State regulations and University policies.

During FY 04-05 the Radiation Safety Office conducted one thousand three hundred and seventy (1,370) AU facility surveys, in about three hundred and twenty (320) AU facilities. Ninety-two percent (92.08%) of the AUs were found to be in compliance.

The most frequently observed non-compliance item was lack of survey records (5.60%). Such records are required to show that the Authorized User is controlling contamination and radiation exposure in his/her laboratory. The frequency depends on the amount of material used, but area surveys are typically conducted each month.

The second most common item of non-compliance is evidence of eating or drinking in the lab (1.78%). The third item is appropriate survey meter not used or unavailable (1.64%). The fourth item is radioactive materials not properly secured (1.23%). These items are also identified for priority compliance action.

No contamination was found in laboratories by the Radiation Safety Office during this Fiscal Year. This citation has been below 1 percent of the labs for some time.

The most serious issue observed continues to be a lack of performance or documentation of area surveys. Compliance follow-up action continues to bring about significant improvements.

The revised survey form put into use three years ago continues to be useful for tracking trends on noncompliance issues for specific laboratories and for the overall situation.

Table 1

Non-Compliance Issues Observed During FY 04-05

Item #	Occurrence	Percent	Violation
01	1	0.014	UK Notice to Employees not posted
02	3	0.41	Radioactive Materials sign not posted
07	1	0.14	Emergency procedures not posted
14	1	0.14	Emergency #s on lab entrance not posted
22	41	5.60	Contamination Survey results not available
23	12	1.64	Appropriate survey meter not used or unavailable
26	13	1.78	Evidence of personnel eating and/or drinking in area designated for Radioactive use
35	9	1.23	Radionuclides not secured against unauthorized access or removal
48	674	92.08	No items on noncompliance

Authorizations

To obtain authorization to procure and use radioactive material, a prospective Authorized User must complete an "Application for Authorization to Possess and Use Radioactive Material". The Radiation Safety Officer reviews the application, evaluating the facilities available, the training and experience of the applicant and staff for the proposed use, and the details of the work to be performed. After the review, including any necessary modifications, the application will be forwarded to the appropriate Radiation Safety Subcommittee (medical or campus) with a recommendation for approval or disapproval. The application must be approved by a two-thirds majority vote.

There were 213 Authorized Users with approximately 295 laboratories in FY 04-05. Table 2 provides locations for the most common AU facilities.

Table 2

Authorized Users (AU) and Radioactive Material Laboratories*

Location	Number of AUs	Number of Labs
Animal Pathology	1	1
ASCN	6	10
ASTeCC	2	3
CAER	1	2
Chem-Physics	6	12
College of Health Science Bldg	18	29
Combs	12	23
Funkhouser	1	1

Garrigus		4	6
Gill Hear	Gill Heart		3
Gluck		5	7
HSRB		15	30
KY Tobacco Re	search	6	6
Markey Cancer	Center	2	2
MRI		1	1
Pharmacy	Pharmacy		31
Plant Scien	Plant Science		20
Research #	Research #3		3
Sanders Bro	Sanders Brown		10
Sloan	Sloan		1
T.H. Morg	T.H. Morgan		6
UKMC	UKMC		87
Wenner Gr	en	1	1
	Total	169	295

^{*}This table does not include AU authorized for sealed sources.

During FY 04-05, twelve (12) new AUs and ten (10) authorization amendments were approved. Thirteen (13) authorizations were terminated (by choice, leaving, etc.). Table 3 provides the number of new users, terminated authorizations, amendments and total users for the campus and Medical Center.

Authorized Users are required to submit 5-year renewal of their authorization upon request by the Radiation Safety Office. Ten (10) AUs received their 5-year authorization renewal. The five-year renewal program is up-to-date and on schedule.

Table 3

Total and Changes in the Number of Authorizations for FY 04-05

	Medical Center	Campus
Total Users	145	74
New Users	13	6
Terminated	4	8
Amendments	3	2
5 Yr Renewals	21	15

52

Radiation Safety Training

The Radiation Safety Office provides radiation safety training for all registered radiation workers and principal investigators new to UK. This is done primarily through two regularly scheduled courses. Annual training is also done for ancillary staff, UK police, MC security, Markey nursing staff and others as needed.

The Basic Radiation Safety course is for radiation workers new to UK and especially for those with no previous radiation safety training or experience. This course is given monthly and lasts three (3) hours. Topics include rules and regulations, radiation safety at U.K., fundamentals of radiation safety, laboratory practices, waste management and emergency procedures. A short test is given at each session, with a passing grade of 60 percent. New radiation workers can be approved to start work promptly by taking the On-Site and Initial Training orientation provided on demand by the AU and the Radiation Safety Office. The Basic Course is, however, still required. Upon satisfactory completion, a certificate is awarded. The Basic Course must be completed within 4 month of beginning work.

The Advanced Radiation Safety Course is for faculty and staff new to UK but with previous training and experience. This course is available on line through the Environmental Health & Safety website. Topics cover lab or facility radiation safety management at UK. Quizzes are given, and certificates of completion awarded.

Table 4

Radiation Safety Training Attendance

Title	Number offered	Number of attendees
Basic Radiation Safety	12	134
Advanced Radiation Safety	On-Line	74
UK Police	4	21
Ancillary Staff	4	253
Initial Training (prereq. For Basic)	117	117
Nurses	7	108
Laser	On-Line	10
Analytical X-Ray	On-Line	3
Irradiator Training	20	54
Medical Center class participants		701
	Total	1475

Dosimetry

Dosimetry (film badges, TLD, pocket dosimeters, Luxel, etc.) for individual who may be exposed to ionizing radiation is provided by the Radiation Safety Office. Any individual potentially exposed to gamma, beta x-rays, or neutrons and could receive an annual dose in

excess of 10 percent of the limit must wear dosimetry. The standard monitoring device is a clipon radiation body or ring badge bearing the individual assignee's name, date of the monitoring period and a unique identification number. The individual may be issued monthly or quarterly badges depending on the potential for exposure. Typically, individuals working in research operations use quarterly badges. Individuals working in Nuclear Medicine, Radiation Medicine, and Radiology typically use monthly badges.

The Radiation Safety Office issued 6751 monthly radiation badges and 859 quarterly badges during FY 04-05. In addition, the Office issued 765 ring badges, 47 neutron badges, and 232 double badges. Two hundred and thirty-two (232) selected EDE calculations per year were performed. The total cost for film badges for FY 04-05 was \$15076.50.

Table 5 **Dosimetry Issued in F.Y. 04-05**

Quarterly Badges

Type of dosimetry	Total Issued	Aver. per shipment
Whole Body	859	214
Rings	162	41
Neutron	47	12
Area Monitor	36	9

Monthly Badges

Type of dosimetry	Total Issued	Aver. per shipment
Whole Body	6751	563
Rings	603	50
Double Badges	232	19
EDE Calculations	232	19
New Badges	254	21

The maximum dose for an individual during a particular month can be found in Table 6 for each of the organs monitored, deep, lens of the eye, skin and extremities.

Table 6

Maximum Observed Monthly Radiation Exposures

Organ	Dose (mrem)	Department	Date
Deep	3512	Diagnostic Radiology	03/05
Lens of the Eye	1034	Cath Lab	03/05
Skin (Shallow)	3512	Diagnostic Radiology	03/05
Extremity	25610	Environmental Health &	10/04
		Safety	

Table 7 **Annual Whole Body Exposure for Selected Departments**

Department	# Badged Personnel	Total Exposure (mrem)	Average Exposure (mrem)
Cath Lab	50	15945	318.9
Nuclear Medicine	11	3272	297.45
Radiation Medicine	79	610	7.72
Radiology/Techs and	119	17241	144.88
Radiology/Residents			

ALARA Reviews

There are two notification levels for the ALARA program. Level I notifications involve a radiation worker receiving greater than 10 percent of the maximum allowable dose (prorated for a quarter exposure period). The recipient is notified in writing when their exposure meets this level's criteria. The notification requests that the worker review their work procedures in order to reduce exposure, if feasible.

Level II notifications involve a radiation worker receiving greater than 30 percent of the maximum allowable dose (prorated for a quarter exposure period). The recipient is notified when their exposure meets this level's criteria and is requested to complete an investigation form as to the probable cause and consideration of actions for reducing the probability of a recurrence.

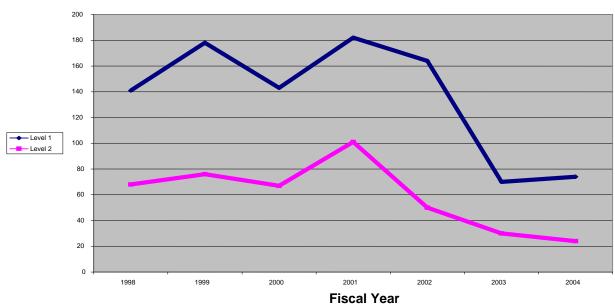
The ALARA notifications for FY 04-05 appear in Table 8 for each quarter. A trend graph is included. The number of ALARA Levels I and II notifications decreased significantly during the FY. The change in ALARA levels and EDE calculations has helped with this. The use of the EDE calculation provides a more realistic representation of the individual's dose by providing an allowance for protection given by wearing a lead apron.

Level I reports are down 57 percent and Level II reports are down 40 percent from last fiscal year.

Table 8 **ALARA Numbers for Each Quarter**

Quarter	Level I	Level II
3 rd 04	23	4
4 th 04	10	8
1 st 05	25	7
2 nd 05	16	5
Total for the Year	74	24





Bioassays

A thyroid scan is required on individuals who use certain quantities of I-125 and I-131 in both bound and volatile form. Thyroid scans or urinalysis is also done if there is skin contamination. Nuclear Medicine performs its own thyroid scans for staff directly involved in I-131 therapy administrations. The Radiation Safety Office conducted ninety-eight (98) thyroid scans in FY 04-05. All results were less than 0.12 uCi body burdens, indicating no greater than 10 percent of the annual limit of uptake.

Radioactive Material Purchases

All radioactive material must be purchased and received through the Radiation Safety Office, with the exception of radiopharmaceuticals for Nuclear Medicine. The Radiation Safety Office purchased 41.011 curies of radioactive material (down 70%) at a total of \$1,033,703 (up 16%) for Authorized Users in FY 04-05. The most commonly purchased radioisotopes were Ir-192, I-125, S-35, P-32, Sr-90 and H-3 (Table 9a).

Table 9a

<u>Quantity of Radioactive Material Ordered via</u>

<u>the Radiation Safety Office, FY 04-05</u>

Isotope	Amount (mCi)	Isotope	Amount (mCi)
Al-26	0.00006	Mn-54	0
C-14	15.02869	Na-22	.001
Ca-45	0	P-32	1290.10823
Cd-109	0.008	P-33	7.810796
Co-57	100	Pd-103	32.89233
Cr-51	38.10963	Rb-86	0
Cs-137	.005	S-35	888.92284
Ga-67	0	Sr-89	0
H-3	174.20988	Sr-90	131.03585
I-123	0	Tc-99m	0
I-125	413.25599	T1-201	0
In-111	0	Zn-65	0
Ir-192	106293.563		

Total Cost \$878,142.23 Total Amount (mCi) 109,384.9503

Table 9b

<u>Quantity of Radioactive Material Ordered via</u>

<u>Nuclear Medicine, FY 04-05</u>

Isotope	Amount (mCi)	Isotope	Amount (mCi)
C-14	.009	In-111	185.775
Co-57	.004	Sm-153	198.145
Cr-51	6.962	Tc-99m	157,283.531
Ga-67	455.040	Tl-201	175.549
I-123	52.040		
I-131	26960.843	Total	185317.88

Nuclear Medicine ordered 185318 millicuries at an estimated total of about \$602,400.

Table 9c indicates that as of June 30, 2005, the University had a total of 105,634.0651 mCi of radioactive material on hand (not including sealed sources).

Table 9c **Radioactive Material On-hand as of June 30, 2005**

Radionuclide	Activity (mCi)	Radionuclide	Activity (mCi)
Al-26	.001	H-3	105,224.498
Am-241	0.009	I-123	0
Ba-133	0.000	I-125	69.022
C-14	151.358	Ir-192	0
Ca-45	.025	Mn-54	.252
Cd-109	.023	Na-22	.086
Cl-36	0	Ni-63	1.854
Cm-244	0	P-32	60.862
Co-57	0	P-33	.967
Co-60	.001	Pu-239	0.001
Cr-51	1.75	S-35	123.129
Cs-137	.031	Sr-90	0
Fe-55	.176	T1-204	.017
Gd-153	.0001	Zn-65	.003
		Total	105,634.0651

Radioactive Waste

The Radiation Safety Office conducted seven hundred and fifty-four (754) pickups of radioactive waste in FY 04-05. Table 10 lists the radionuclides picked up and the total activity for each radionuclide for the fiscal year. The dry solid waste was either shipped out as long-lived radioactive waste or held in storage for at least ten (10) half-lives, surveyed, and disposed of as non-radioactive waste. H-3 and C-14 were the most common long-lived radionuclides, with I-131, P-32, and S-35 the most common short-lived radionuclides. Mixed hazard waste is segregated by half-life, radionuclide and concentration. It is then either decayed until it is only a chemical waste or shipped as a mixed waste (mixed waste is not included in Table 10). During FY 04-05, 3.00 cubic feet of animal waste was shipped.

Table 10

Total Radioactive Waste Received by Radionuclide

Activity	ın	mıl	licuries
----------	----	-----	----------

Isotope	Dry Solid Waste	Aqueous
Al-26	0.001	0
C-14	17.336	1.731
Ca-45	0.985	0
Co-57	10.2	0
Cr-51	2.000	1.53

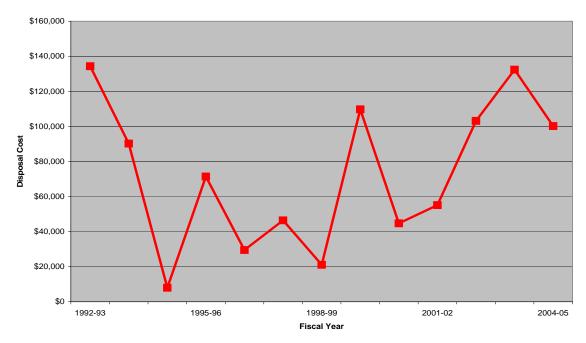
Eu-152	.030	0
H-3	73.048	124.780
I-125	95.444	39.039
I-131	2588.980	0
P-32	214.370	183.825
P-33	4.921	0.840
Pd-103	11.400	0
S-35	118.659	194.116
Zn-65	.200	.500
Total	3137.574	546.361

The release of liquid aqueous radioactive waste to the municipal sewerage system was eliminated during FY 02-03. These wastes are now shipped for commercial incineration. This eliminates the possibility of non-aqueous wastes from being mistakenly, and unlawfully, released.

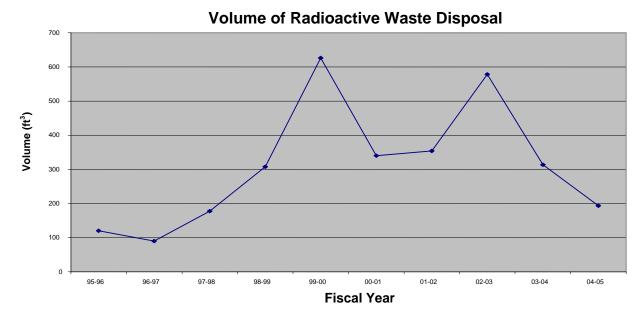
The annual Kentucky radioactive waste report was prepared and filed in Frankfort. The following graphs depict the total volume of waste generated and the associated disposal costs for the past ten years. In general, UK has been able to contain waste costs. However, fees are rising; special waste disposals occur and charges are being added such that the overall cost can be expected to increase.

Cost and Quantity Trend Report

Radioactive Waste Costs



Volume of dry solid radioactive waste, short and long-lived, including animal carcasses, and including sealed sources. Excluding mixed radioactive-hazardous waste and excluding liquids.



Meter Calibrations

Authorized Users working with radioactive material other than H-3, C-14 or S-35 are required to have an appropriate survey meter (commonly a Geiger counter with an end window or pancake type detector) in the laboratory. The Radiation Safety Office calibrates these survey instruments annually. The Authorized User must notify the Radiation Safety Office when he/she purchases a new Geiger counter. One hundred and Ninety Three (193) meters were calibrated during FY 04-05.

Patient Care Support

The Radiation Safety Office provides radiation safety support for patient's receiving therapeutic radiopharmaceuticals (>33 mCi I-131), Cs-137 implants, Ir-192 implants and seed implants. Upon administration of radiopharmaceuticals or brachytherapy implants, the Radiation Safety Office performs and documents a multi-point radiation survey. This data is used to determine the allowed time hospital staff and visitors are allowed to be adjacent to the patient. The hospital staff and visitors are then instructed on the radiation safety precautions to be followed when in or around the room containing the radioactive patient.

Table 11

Radiation Safety Services to Nuclear Medicine and Radiation Medicine

Brachytherapy Implants	1
Thyroid treatments	98
Total	99

Sealed Source Inventory and Leak Test

The Radiation Safety Office performs all sealed source leak tests. All beta/gamma and neutron sealed sources (greater than 100 microcuries) were tested for leakage at intervals not to exceed six months. All sealed sources (greater than 10 microcuries) designed for the purposes of emitting alpha particles were tested at intervals not to exceed three months. Ni-63 foil sources (greater than 100 microcuries) are tested at intervals not to exceed six months. If a leak test reveals removable contamination greater than 0.005 microcuries, the source is removed from use and decontaminated, repaired or disposed of as radioactive waste. During FY 04-05, the Radiation Safety Office conducted two hundred and sixty (260) leak tests (counted each therapy source individually). No activity greater than 0.005 microcuries was observed

Lasers

The Principal Investigator is responsible for safe use of lasers in his/her laboratory and to inform the Radiation Safety Office in the event of an accident. There are currently twenty (20) laser Authorized Users. All Class 3b and higher lasers must be registered with the Radiation Safety Office prior to use. During FY 04-05, sixty-five (65) laser inspections were completed. Consultations and preregistration guidance were provided. A web based training program is available, allowing users to complete the laser safety training requirements on line. Ten (10) laser users have completed the online web based training during FY 04-05.

Andy Miller, Director UK Radiation Safety Office August 12, 2005

Radiation Safety Committee Membership

2004-2005

Abercrombie, Sheryl, Diagnostic Radiology, <a href="state-st

Ex-Officio

Allen, Mary, University Relations, mlallen@email.uky.edu, 257-6398

Hibbard, David, Environmental Health & Safety, dwhibb0@email.uky.edu, 257-3241

Hughes, Patricia, Nursing Services, phugh2@email.uky.edu, 323-6154

Miller, Andy (RSO), Radiation Safety Office, mamillf@pop.uky.edu, 323-6308

Report of the University Fire Marshal

ANNUAL ACTIVITIES UNIVERSITY FIRE MARSHAL 2004-2005

TRAINING—(FIRE EXTINGUISHERS/FIRE PREVENTION)

>HRS Classes

• August 17th: 1 person

• May 17th: 4 people

• June 21st: 3 people

>Residence Hall

- H.D. fire/life safety training: August 5th; 33 people,
- RA's fire prevention training: August 16th, 120 people
- RA's fire extinguisher training: August 16th, 120 people
- Haggin fire prevention, Sept 14th, 21 people,
- Kirwan 2: fire safety, Sept 14th, 12 people,
- Donovan Hall; fire prevention, September 14th, 32 people,
- Boyd Hall: fire prevention, September 15th, 6 people,
- Kirwan 3: fire prevention, September 15th, 5 people,
- Blanding 2: fire prevention, September 22nd, 14 people,
- Blanding 1: evaluated fire drill and fire prevention, September 22nd, 65 people
- Boyd Hall: fire/life safety training; September 23rd, 17 people,
- Keeneland: fire/life safety training; September 29th, 19 people,
- Kirwan 1: fire/life safety training, October 4th, 34 people
- RA training for 2nd semester; January 10th; 12 people

>Hospital/Medical Center

- February 24th: two classes; 36 people
- March 22nd; two classes; 35 people
- May 13th: two classes; 24 people
- June 7th: two classes, 21 people

>Greek Chapters

- Greek Women: August 10th; 1800 people (all sorority members are required to attend)
- SAE fraternity: October 4th, 34 people
- Sigma Chi: October 25th, 16 people
- Phi Sigma Psi; April 4th 17 people
- Sigma Chi and SAE; total of 15 people. Special meeting with emphasis on responsibility and awareness. House Corp members were present,
- Sigma Chi and SAE (combined class): attendees included House Corporation, Vic Hazard, Jim Wims, and Ken Clevidence: 35 people; Strongly emphasized fire/life safety policies and that Chapters will be closed in serious violations continue to occur
- >Football Operations training: August 11th, 65 people; fire prevention and emergency operations (first time class—attendees were workers for the football games---is to become annual training
- >Integrated Biological Science: 30 people
- >Mines and Minerals: 75 people
- >Physics Dept: 20 people >Chemistry Dept: 33 people
- >101 Club: discussed fire prevention/life safety/emergency evacuation for upcoming football season, 75 people
- >Animal Diagnostics: August 30th; 17 people
- >Animal Diagnostics: September 21st, 13 people
- >Homecoming Parade fire prevention class: 25 people
- >Laboratory Fire Prevention; Hospital Clinical Lab (Sue Overman), 21 people
- >CAER, November 3rd; two classes, 26 people,

>HSRB

- Mary Maley; December 2nd; fire drill training for fire response officers; 20 people
- April 14th, 10 people
- May 23rd: 4 people
- >BBSRB: total of 193
- >Janitorial Training: 62 people; total of 3 classes
- >4-H Camp Counselors; 47 people (see New Programs)
- >Chemistry Physics graduate students; 17 people
- >Agricultural Regulatory Services; 14 people

EMERGENCY LIGHTING TESTS

- Whitehall Classroom, Patterson Office Tower, Miller Hall, Gillis Building, and "Main Building" were tested with the acceptance generator test for the Main Building. September 3rd,
- Main Building; October 4th, final emergency lighting acceptance test in conjunction with State
- Parking Structure #2, December 20th,
- Commonwealth Stadium

EVACUATION (TRAINING AND/OR PLAN REVIEW)

- Revised College of Medicine's evacuation plan to require evacuation immediately upon the activation of the fire alarm system. A fire drill was conducted to test the new plan,
- College of Dentistry Evacuation Plan: is considered to be a patient treatment facility. Revised Plan to include additional Fire Response Officers, posted evacuation routes and conducted a fire drill to test the plan,
- Reviewed and approved evacuation plan for Phi Delta Theta sorority,
- Reviewed and approved evacuation plan for Sigma Kappa sorority,
- Mines and Minerals: evaluation of fire drill
- Kirwan 4; fire drill with a "smoke-out"; conducted a practice fire drill utilizing a smoke filled exit corridor. This type of drill was a FIRST for a resident building. 45 students participated. Fire Department assisted to ensure personal safety of the students. SEE SPECIAL PROJECTS
- Reviewed and approved new design of evacuation routes for Cooperstown, Shawneetown, and Rose Lane Apartments,
- Reviewed and approved evacuation routes for the four new residential buildings,
- Reviewed and approved revised evacuation routes for Cooperstown "A" building,
- Fire drill: Regulatory Services

SPECIAL PROJECTS

- Conducted campus life safety/preattack tours of University buildings with the fire department,
- Conducted tour of "RED ROOMS" for fire department,
- Greg agreed to serve a 3 year term as a Review Council member for *MakeThe Difference*, a new suggestion program for UK faculty and staff,

- Revised the on-line fire alarm report form to improve the quality of information received on the report,
- Medical Center sprinkler replacement project: Central Sprinkler Company notified UK of a type of sprinkler head that has the potential to fail during a fire. The Medical Center/Hospital complex has 6000 of these heads.
 Participated in the "preconstruction meeting" for the replacement of the sprinkler heads,
- Mailed the mandatory Evacuation Policy" for fire alarms to Deans, Directories, and Department Heads. Attached were letters of support from the State Fire Marshal and the Lexington Fire Marshal,
- Kirwan 4 fire drill with a "smoke-out"; in conjunction with the Fire Department, an unannounced fire drill utilizing smoke in an exit corridor was conducted. Although Hall Directors and Resident Advisors are trained in fire drills utilizing smoke, this was the first attempt in having a resident hall using smoke during a drill. The evaluation of the drill definitely indicated that this type drill should be utilized for all residence halls but a lack of personnel at the current time prevents this from becoming a new program.
- Homecoming Parade (float safety): October 6th; (31 organizations/31 people)
- Rap concert in Memorial Coliseum: October 13th----fire prevention requirements
- Reviewed Rupp Arena emergency procedures for basketball games.
- Boyd/Patterson Halls Halloween haunted house,
- Added Space Heater Policy to web site,
- Revised Microwave Policy
- Reviewed specifications for gas fire place installation for new resident halls
- Reviewed and approved chair arrangement for program to be held in atrium lobby, Young Library,
- Participated with Christy Giles, Patty Bender, and Jake Karnes in developing a program for the physically handicap for fire emergencies,
- Greek life safety presentation to Frank Butler, Ken Clevidence, and Mike Nietzel: Emphasis on the need to place more responsibility for life safety on each chapter.
- Approved "Open Flame Policy" for the Singletary Center,
- Inspected Farm House, Lambda Chi, Phi Sigma Epsilon, Phi Kappa Alpha, Kappa Sigma, Alpha Tau Omega and Sigma Nu for summer occupancy,
- Reviewed and approved exit capacity and occupant capacity for Memorial Coliseum during construction of new practice facility. Reviewed and

approved exit capacity and occupant capacity for Memorial Coliseum during construction of new practice facility and after construction is completed,

INSPECTIONS

- State Fire Marshal Inspection (annually); September, 2004
- State Fire Marshal Inspection (annually); June, 2005
- Conducted cursory inspection of the Coldstream Research Facility (recently acquired by the University)
- Princeton sub-station and 4-H camp. Installed 36 new fire extinguisher units in student cabins
- Cursory inspections each semester of residence halls,

FIRE INVESTIGATIONS

- Cooperstown Building A, Apartment 207: food left on active burner of stove, occupants left apartment; grease on stove overheated; no actual fire but severe smoke. No physical damage to apartment other than firemen had to break-down the front door to gain entry. Power to stove disconnected until stove was cleaned.
- Taylor Education Building, Macintosh Computer Lab, room 240; HVAC motor burned out, no physical damage to room, heavy smoke in room, Fire Department and PPD vented through window,
- Donovan Hall, September 2nd; second floor bathroom; scorched clothing; no visible flame but smoke and strong odor (arson)
- Kentucky Utilities Building (leased space); September 14th; room 743; candle left burning
- Natural Gas odor investigations
 >September 29th: area between Boone Faculty Club and Mines and Minerals Building: received several calls. Caused not determined although possibly came from Chemistry Physics building,
 >October 4th: area between Boone Faculty Club and Mines and Minerals
 - Solution Sol
- Hospital: laundry dryer. December 9th. No injuries, dryer destroyed, heavy smoke.
- Medical Science Wing, room MN 472, electrical fire, no injuries or physical damage, minor smoke
- Parking Structure #4: Vehicle fire (non-university vehicle) March 21st, total loss (1986 dodge pick-up; \$500); potential gas leak near carburetor per fire department investigator,

• Service Building, April 6th: third floor; fan left activated in mechanical room and ignited combustibles near-by. Fire extinguisher used to suppress. No physical damage to room or building, but due to odor, occupants on 3rd floor permitted to go home.

PROFESSIONAL TRAINING

- Greg: April 4th and 5th, attended Disaster Planning and Business Continuity training sponsored by NFPA,
- Greg and Garry: completed the "National Incident Management System (NIMS) an Introduction to Managing Incident Command System,
- Garry: Campus Safety Form 6, October 26-28

NEW PROGRAMS

• 4-H Camps Counselors: on June 18th, went to Cumberland Lake Camp to train all counselors in fire prevention, fire extinguishers, and evacuation of campers should the need arise. This is a first time program of this nature but will become an annual program.

KEY INDICATORS

Fire extinguishers inspected	6686
Fire Extinguisher/Fire Prevention Training	3290
Fire alarms*	478
Actual fires*	38
Working fires (Required UK Fire Marshal Response)	8
Plan Review (New Constructions/Renovations)	110

*SUMMARY OF FIRE ALARM INCIDENTS: The method of evaluating and recording fire alarm incidents continues to be reviewed. Improvements and methods of recording incidents have been implemented for fiscal year 2005-06. For this report, 332 of the 478 fire alarms (incidents) were considered to be nuisance alarms. A nuisance alarm occurs when there is no fire danger present, but the detection device responded automatically as designed to a stimuli that is interpreted as a fire. These alarms can be caused by mechanical failure, malfunction, improper location, or causes that can not be determined.

An "Actual Fire" for this report was described as an incident that required a suppressant (water) to be applied to an area. This included 12 mulch fires and two dumpster fires all of which did not cause any damage to property. Refer to the Fire Investigation section of this report for "working fires".

Only eleven alarms were considered to be Malicious False Alarms. A malicious false alarm is caused by an unknown subject with the intent of disrupting activities within the building.

PICTORIAL ACTIVITIES OF THE FIRE MARSHAL'S OFFICE



Ag. Science North

Fire Pump Test

7/28/04

104



Ag. Science North

7/28/04

Fire Pump





Kentucky Utilities Building: leased property Hazards of an open flame (candles)





2004-2005 Hall Director Training—Simulated Evacuation with Smoke





Inspection of storage areas

Inspection of offices



Joint University Inspection with State Fire Marshal on existing buildings



Joint University Inspection of new construction with HB&C

Report of the Committee on Safety and Environmental Health

EH&S Certificates of Appreciation

In recognition of outstanding contributions to safety at the University of Kentucky, the Committee on Safety and Environmental Health has awarded the following certificates of appreciation.

2005 Ann Thomas College of Medicine – Dean's Office

Letitia Hollingsworth-Gray Campus Recreation/Athletics Sabire Ozcan Molecular & Cellular Biology

Changguo Chen General Surgery

2004 Debra Sipe Agriculture Regulatory Services

Pradeep Kachroo Plant Pathology Robert Yokel Pharmacy Susan Kraner Pharmacology

Charles Peyton Auxiliary Services - Housing

2003 Teri Strickland College of Pharmacy

Cabot Jahniger State Fire Marshal's Office
Linus Walton College of Agriculture
Ben Crutcher Auxiliary & Campus Services

Jason Pridemore Student Resident Advisor
David Kaiser Physical Plant Division

Orlando Chambers Tobacco Research & Development Center

2002 Lyle Morgan Auxiliary Services – Housing

Joe Crouch Capital Project Management Homer Walter Physical Plant Division

Jerry Tackett Robotics and Manufacturing Systems

Michael Jay College of Pharmacy
Pamela Jacobs Clinical Laboratories
Don Stone Parking and Transportation

Debra Ross Auxiliary Services – Apartment Housing

Kathy Rose Campus Recreation

Maelor Davies Tobacco Health Research Institute

Eva Kaplan Animal Sciences

2001 Gene Baber Physics & Astronomy

IACUC Committee Mike Bardo, Chair

John Anthony Chemistry

Mary Vickers Livestock Disease and Diagnostic Center

Jana Angel Rehabilitation Services

David Waldridge Medical Center Physical Plant Division

Gary Ginn Anatomy & Neurobiology

John Gurley Cardiology Jeanne Bouvier Nursing

Ali Meigooni Radiation Medicine
Don Hill Physical Plant Division
Richard Riedl Capital Project Management

2000 Bob Brashear Ag Management Operations

Chemistry Ted Jenkins Residence Life Steve Evans Tony Ralph Residence Life Marcia Shrout Residence Life Stephen Stauffer Residence Life Melanie Tyner-Wilson Residence Life Loretta Hill **Custodial Services** James Bryan Surplus Property

Brian Butler Pharmacy Norman Goodman Pathology

Joseph Mallek Medical Center Physical Plant Division

Janet Rodgers Lab Animal Resources

Oney Vanlandingham Center for Applied Energy Resources

1999 Donald Thornton Parking and Transportation

1998 Mary Ferlan Wellness

John Summersett Physical Plant Division

Ralph Christensen Allied Health, Clinical Sciences
Creighton Trahan Office of the University Veterinarian

Kenneth Dickey Laboratory Animal Resources
Larry Iten Laboratory Animal Resources

Susan Overman Serology and Virology Tomi Ross Hospital Safety Office

Carl Nathe Public Relations

1996 Herbert Strobel Animal Sciences
Thomas Vanaman Biochemistry

Robert Toreki Chemistry

Claude Cornelison Auxiliary Services
Greg Shiddell Auxiliary Services

Joseph Mallek Medical Center Physical Plant Division

Relon Hampton

Jerry Hensley

Mike Polashock

Rae Ann Egner

Maintenance Department

David Campbell

Whitesburg Community College

Paducah Community College

Paducah Community College

Paducah Community College

Henderson Community College

Judith Chabot Ashland Community College

Minutes of the Committee on Safety and Environmental Health FY 2004-05

Committee on Safety & Environmental Health Minutes of September 23, 2004

Members Present: Guests: Herb Strobel - Chair Garry Beach Patty Bender Woody Bottom David Hoke **Bob Cadle** Helene Lake-Bullock for Ada Sue Selwitz Rachel Eldridge Nicholas McLetchie Marcia Finucane Susan Pollack David Hibbard Janet Williams John Lowry Travis Manley Lee Poore Don Thornton John Summersett Richard Riedl Greg Williamson

I. Welcome

Herb Strobel welcomed the members and visitors.

II. Approval of minutes

The minutes from the March 24, 2004 meeting were approved.

III. Review of Administrative Regulation (Revised AR III-1.1-5)

A review of the revised AR was performed. Significant changes were the renaming of the committee from "Environmental Health and Safety Committee, to "Committee on Safety and Environmental Health," and the removal of the General Safety Committee (subcommittee).

IV. State of Environment FY 03-04 Annual Report

The committee is required to annually forward this report to the Associate VP for Campus Services. The committee had previously been emailed a web link to the report to allow review. David Hibbard presented an overview of the Annual Report. At the completion of the presentation it was determined that a voting quorum did not exist. To expedite approval of the report, David Hibbard will pursue an online web mechanism to allow members to vote outside of the meeting.

V. Old Business

a. 15-Passenger Van Training

Memo dated February 17, 2003, from Mark Meier, Chair, Environmental Health and Safety Committee, to Ben Carr, VP for Auxiliary and Campus Services was

reviewed. College of Agriculture is only unit requiring employee training. Committee consensus was to have David Hibbard revise memo, post on committee website for member input, obtain committee approval, and then forward to the Associate VP for Campus Services for action.

b. Lab Safety Compliance/Enforcement Initiative

Memo dated April 19, 2004, from Mark Meier, Chair, Environmental Health and Safety Committee, to Wendy Baldwin, Executive Vice President for Research was reviewed. David Hibbard will follow-up on status of recommendations.

VI. New Business

David Hibbard stated that the UK Fire Marshal's Office is initiating a survey of all UK campus buildings to identify those in need of written evacuation plans and evacuation route postings.

Susan Pollack raised the issue on how safety inspections of off-campus property and leased property could be conducted. Who should be responsible for performing these inspections?

Various members inquired as to how effective current online safety training was for individuals where English was a second language.

The aforementioned issues will be revisited at a subsequent committee meeting.

VII. Next Meeting Date

November 18, 2004, was proposed as next meeting date. Members will be notified via email.

VIII. Adjourn

The meeting adjourned at 3:35 PM

Committee on Safety & Environmental Health Minutes of March 23, 2005

Members Present:

Herb Strobel - Chair John Anthony Tom Chambers

Jody Ensman for David Hoke

Barbara Knutson Ed McClure

Nicholas McLetchie

Larry Piercy

Susan Pollack

Richard Riedl Wayne Ritchie Rodney Stiles

Janet Williams
J. W. Yates

Guests:

Garry Beach Woody Bottom

Rachel Eldridge Marcia Finucane

David Hibbard

Lee Poore

Ann Thomas Warren Denny

Letitia Hollingsworth-Gray

Sabire Ozcan Changguo Chen

VI. Welcome

Herb Strobel welcomed the members and visitors at 2:03 PM.

VII. Safety Awards

Ann Thomas, College of Medicine - Dean's Office

Recognized for her efforts in ensuring the Medical Science Building has free unobstructed means of egress and her collaboration with the Fire Marshal's Office in scheduling and executing fire drills

Letitia Hollingsworth-Gray, Office of the Dean of Students - Campus Recreation/Athletics

Recognized for her efforts in ensuring the safety of those attending swim meets at the Lancaster Aquatics Center. "Tish" asked the Fire Marshal's Office to come in and do an audit of the aquatics center. As a result of the audit, various recommendations were made. All recommendations have been responded to and changes made.

Sabire Ozcan, Ph.D., College of Medicine - Department of Molecular and Cellular Biochemistry

Recognized for her efforts in going 21 consecutive quarters (~5 years) with no radiation safety violations. Radiation Safety inspects labs on a quarterly basis.

Changguo Chen, Ph.D., College of Medicine - Department of General Surgery

Recognized for his efforts in going 21 consecutive quarters (~5 years) with no radiation safety violations. Radiation Safety inspects labs on a quarterly basis.

VIII. Approval of minutes

The minutes from the September 23, 2004, meeting were approved.

IX. Subcommittee Reports

A. Chemical Safety Committee

The committee reviewed and approved Standard Operating Procedures for the Chemical Hygiene Plan, and plans to focus future efforts on user friendliness and online availability. With regard to lab inspections, focus will be placed on educating PIs, user friendly guidelines for identifying and interpreting inspection violations, and on relaying information directly to the appropriate responsible lab supervisor. The committee is working with UK Stores to compile a list of suggested gloves. Information will be provided to laboratories regarding glove selection and chemical compatibility. The committee reviewed the inventory and storage of toxic compressed gasses on campus. It was suggested that the smallest size gas cylinders should be used. The cylinders should be continuously stored and used in hoods. Use of mercaptans on campus requires a flexible policy that provides prior notification to PPD if use will be mistaken for a natural gas leak. The committee reviewed chemical spill responses. Eleven out of 26 involved leaks from vehicles. In reviewing accident and injury reports, the associated cause was examined. The committee questioned whether current efforts at educating the PI are adequate, or is a change in policy/education of PIs necessary.

B. Institutional Biosafety Committee (IBC)

The committee reviewed and approved 41 protocols since April, 2004. Twenty were registration only. Two involved human gene transfer protocols. In conjunction with the Occupational Health Service, the IBC has addressed the issue of vaccinia vaccination and counseling for lab workers. The committee has been in contact with the Central Kentucky Blood Center which has agreed only to release blood to those who are registered with the IBC. A confidentiality agreement was implemented with IBC members. "No Flames" and "No UV Lights" policies were implemented for biological safety cabinets. New procedures have been implemented for human gene transfer clinical trials in conjunction with the IRB. New standard operating procedures have been established for adenovirus, lentivirus, hantavirus, and TAT fusion proteins.

C. Radiation Safety Committee

This committee meets quarterly, and approves protocols for a five year period. In October, an irradiator was repaired and is currently operational. Additional safety requirements will be brought to light within the next year. There will be some new regulations regarding irradiators. The committee expects a 6 month window to

implement these regulations, with inspections to occur approximately 18 months later.

X. Old Business

A. State of the Environment Annual Report

Because a voting quorum did not exist at the last meeting, the Annual Report was placed online and was approved via an electronic voting procedure so that it could be forwarded to the Associate VP for Campus Services.

B. Lab Safety Compliance/Enforcement Initiative

David Hibbard will continue to pursue a meeting with Dr. Wendy Baldwin concerning a memo dated April 19, 2004. The memo focuses on laboratory compliance issues and recommendations. The issue of repeat violations is of particular concern.

C. 15-Passenger Van Training

A revised memo will be sent to the Associate Vice President for Campus Services for action. Online training has been removed from the web temporarily but will be reposted soon. Training is still available in person. Currently the College of Agriculture is the only unit requiring training. One of the goals, however, is to require anyone who will drive these vans to have training. Although 15-passenger vans are no longer purchased, Lee Poore discussed the dangers of 12-passenger vans. These pose the same hazards as 15 passenger vans, but have one seat removed. Susan Pollack suggested that we bring this to the attention of the UK's Purchasing unit. Ed McClure suggested we work toward blocking the rental of these vans as well. The committee also discussed the idea of reminder hangtags in these vans and what should be listed on them.

IX. New Business

Discussion centered on issues of pedestrian safety. Discussion involved concerned individual human decisions and problematic areas on campus. Construction areas that block the sidewalk on both sides of the street were discussed. Some sort of temporary sidewalk should be constructed if the existing sidewalks will be blocked. The budget on which a project is working plays a big part in the safety precautions that can be provided. Lower bidders offer fewer alternatives. Also, placing a temporary sidewalk on a city street requires permission from the city. Sometimes the city does not want a street to be blocked or narrowed. Discussion also focused on whether a formal letter would influence the need for better pedways, or if a number of individual complaints would be more effective. Responsibility for problem areas falls first on the contractor. If this person fails to provide the necessary safety precautions, the project manager is responsible. The need for statistical information was recognized in determining how many accidents occur in a

given time, and what percentage is attributed to pedestrians jay-walking. Also, traffic patterns on streets that run through campus need to be examined. Bicycles were also discussed in assessing how many accidents occur and where they occur most. The Bicycle Committee and the Kentucky Transportation Cabinet were mentioned as possible sources of statistical information.

The aforementioned issue will be revisited at a subsequent committee meeting.

X. Next Meeting Date

The second or third week of September, 2005, was proposed for the next meeting date.

XI. Adjourn

The meeting adjourned at 3:30 PM

Minutes of the Chemical Safety Committee FY 2004-05

Chemical Safety Committee Minutes of October 20, 2004

Present Guests

Barbara Knutson Lee Poore (Ex-Officio) Jan Hamon

Robin Cooper Woody Bottom Todd Porter Thomas Vanaman

Audra Stinchcomb Jim Calvert

Absent

Stephen Testa

Barbara Knutson called the meeting to order at 12:50 PM.

- 1. **Bylaws review-** Lee Poore reported on updates that need to be made to the Administrative regulations to reflect changes in EHS.
- 2. **Toxic Compressed Gas Program-** Lee Poore reported on progress. Many building inventories have been reviewed. The actual number of toxic gases is very low. OHS is working to get handling information to PIs and also to get delivery information from suppliers. Lee Poore will contact Scott Gross and Matheson and determine if inventories can be obtained from them.
- 3. **Laboratory Inspection procedures-** Inspections are continuing. A special effort is being made to contact areas prior to the inspection so PIs that would like to be present can make arrangements. This has helped in our effort to better educate PIs about what is being looked at and why. The accountability aspect of the program is still undetermined. David Hibbard is setting up a meeting with Wendy Baldwin and David Watt to have this finalized.
- 4. **Mercaptan Use Policy Review-** Lee Poore- This issue was brought up due to several calls to the fire department for natural gas smells on campus near Young Library. From interviews, it appeared the odor was coming from the west in the direction of Chemistry/Physics or the Engineering Complex. For both of the most recent incidents, no source was determined. Garry Beach, UK Fire Marshal, requested that the use of mercaptans in laboratories be explored. Dr. Vanaman suggested making the policy very specific for only ethyl and methyl mercaptans. There are many mercaptans used in UK labs and these restrictions would be burdensome if not needed in all cases. Lee Poore will revise and have for review and approval a future meeting.
- 5. **Spill report-** Woody Bottom presented a report of this year's spills. Woody also told the committee of a training opportunity for shipping and receiving dangerous goods.
- 6. **Review of Chemical Hygiene Plan-** Hard copies of the current plan were made available at the meeting. The web copy is available at http://ehs.uky.edu/ohs/chp/welcome.html. All committee members are asked to review this plan and have changes ready for the next meeting...

<u>Chemical Safety Committee</u> Minutes of December 15, 2004

Present Guests

Barbara Knutson Lee Poore (Ex-Officio) Jan Hamon

Robin Cooper Ruth Adams

Todd Porter Thomas Vanaman

Audra Stinchcomb Jim Calvert

Absent

Stephen Testa

Woody Bottom (Ex-Officio)

Barbara Knutson called the meeting to order at 12:05.

- 1. Mercaptan Use Policy Review- Lee Poore- Last meeting the revisions were discussed and need for this policy to be adopted discussed. Final draft to be presented at the next meeting for approval.
- **2. Glove selection-** Lee Poore discussed the need for better selection of gloves from Stores. The ones offered now have not been tested for chemical use. A list of suggested gloves is being compiled so stores can have options listed on their web site and a price contract to reduce costs for labs.
- **3. Review of Chemical Hygiene Plan-** Changes to the plan were approved unless questions are raised before printing in January.

<u>Chemical Safety Committee</u> <u>Minutes of March 12, 2005</u>

Present Guests
Barbara Knutson Lee Poore (Ex-Officio) Jan Hamon

Barbara Knutson Lee Poore (Ex-Officio)
Robin Cooper Woody Bottom

Todd Porter Jim Calvert
Thomas Vanaman Stephen Testa

Absent

Audra Stinchcomb Ruth Adams

Barbara Knutson called the meeting to order at 11:35 PM.

- 7. **Approval of minutes-** Lee Poore passed out minutes and asked for approval of the draft. Minutes were approved as written.
- 8. **Mercaptan release-** Lee Poore reported on another release which caused the fire department to be dispatched. Changes to the proposed mercaptan use policy will be made to reflect information gained from the recent release. The policy will request users of thiols to contact PPD. This will allow PPD valuable information if calls are made to PPD about orders and also to assist LFD if they arrive on campus. It has also become apparent that even appropriate uses of ventilation and engineering controls still causes order to be detected across campus. Isolating experiments and passing thiols through filters or a scrubber.
- 9. **Piranha waste-** Woody Bottom reported on a hazardous waste container that exploded in the EQMC. The waste was part of a 4 bottle collection labeled Piranha (a mixture of sulfuric acid and hydrogen peroxide). Piranha is a glass cleaner used in the manufacture of electronics. Mr. Bottom is concerned that these two components are not compatible with one another and future accidents are bound to happen if its use is continued. The researcher using this chemical will be contacted. A suggestion of substitution or neutralization shall be suggested.
- 10. **Flash Fire-** There was a flash fire in ASTECC lab. From the investigation is appears to have been caused by static electricity. While pouring flammable waste into the container the static discharged and the vapors ignited. The graduate student was not hurt but procedures in the lab have changed. All dispensing for the waste will be done under the hood.
- 11. **THF Spill in Pharmacy-** A four liter container of tetrahydrofuran (THF) was dropped and spilled on the third floor of the Pharmacy building. The fire department was called. By the time responders were at the scene and entered the lab, all the THF had evaporated. No one was injured nor overexposed.
- 12. Chemical Hygiene Plan\Lab safety handbook- The 2005 plan has been updated on the website and copies have been printed. Anyone needing hard copies need to contact OHS and request them.

- 13. Waste floor wax dumping- Woody Bottom reported on the practice of janitorial personnel dumping used floor wax at loading docks. This practice causes waste to enter the storm sewer system, a violation of water quality regulations. Because the wax is labeled as biodegradable, some janitorial personnel believed that it could be safely dumped in such a manner. Mr. Bottom pointed out that this is not acceptable. Retraining of housekeepers and their supervisors has occurred but the committee was asked to look for these issues in their buildings.
- 14. **Adjourn-** Meeting adjourned at 1:00pm.

Minutes of the Institutional Biosafety Committee FY 2004-05

Institutional Biosafety Committee Minutes of July 14, 2004

Members Present

Thomas Chambers
Nader Hanna
Kenneth Dickey
Marcia Finucane
Glenn Telling
Jack Hiatt
Eric Smart
Robert Jacob
Richard Wheaton
Louis Hersh

Members Absent

Chuck Staben
Anthony Sinai
Peter Nagy
Brian Rymond
Kelly Breeding
Arthur Hunt

COMMITTEE BUSINESS

The meeting was called to order at 12:05 pm by Tom Chambers.

The minutes of June 9, 2004 IBC meeting were unanimously approved. Eric Smart moved. Louis Hersh seconded.

NEW BUSINESS

NEW PROTOCOL REVIEW

B04-328 Chambers, Thomas - Equine Influenza

Full Approval was granted. Kenneth Dickey moved. Eric Smart seconded. The vote was unanimous.

B04-329 DeSimone, Phillip – PANVAC-VF, phase III

Discussion only. No protocol had been submitted. Background documents were provided by Marcia Finucane.

COMMITTEE BUSINESS

Non-disclosure/confidentiality statements were signed by all present members. Copies of signed forms will be sent back to IBC members via campus mail.

Marcia Finucane updated the Committee as to the progress of the autoclave verification program scheduled to be implemented in the fall.

The Committee agreed that the present meeting time, the second Wednesday of every month from 12-2 was acceptable for the coming year.

The Committee agreed that annual/new member training for September should not be an evening event. The September training may be combined with the regular September IBC meeting if the meeting will not last over 1.5 hours. If needed, the training may occur as a separate meeting.

BSO UPDATE

PROTOCOLS MEETING FULL APPROVAL REQUIREMENTS

B04-322 Swerczek, Thomas - Evaluation of bacterial endophytes of grass- and legume-forages as emerging causes of reproductive loss disease in agricultural herbivores (horses, cattle and goats)

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-327 Schardl, Chris - Advanced Genetic Technologies

Motion to adjourn was made by Kenneth Dickey. Glenn Telling seconded. The meeting adjourned at 1:10 pm.

Institutional Biosafety Committee Minutes of August 11, 2004

Members Present

Thomas Chambers

Anthony Sinai

Kenneth Dickey

Marcia Finucane

Peter Nagy

Jack Hiatt

Eric Smart

Robert Jacob

Richard Wheaton

Brian Rymond

Kelly Breeding

Chuck Staben

Arthur Hunt

Members Absent

Louis Hersh Glenn Telling

COMMITTEE BUSINESS

The meeting was called to order at 12:00 pm by Tom Chambers.

The minutes of July 14, 2004 IBC meeting were unanimously approved. Richard Wheaton moved. Ken Dickey seconded.

NEW BUSINESS

NEW PROTOCOL REVIEW

B04-329 DeSimone, Phillip – A phase III randomized, controlled study to evaluate the safety and efficacy of PANVAC ™-VF in combination with GM-CSF versus best supportive care or palliative chemotherapy in patients with metastatic (stage IV) adenocarcinoma of the pancreas who have failed a gemcitabine-containing chemotherapy regimen.

Dr. Desimone attended the meeting for discussion.

The protocol was granted **provisional approval** pending the following Conditions be met: (See attached Recommendations for protocol)

A subcommittee assessed the room choice for the injections immediately following adjournment of this IBC meeting.

Kelly Breeding moved. Robert Jacob seconded. The vote was split 9-3 in favor of approval.

B04-335 Norris, Christopher – Recombinant adenoviral constructs for the study of calcineurin and brain aging

The protocol was **approved** with the following suggestions:

- 1. p.10: Paraformaldehyde will be used in the fume hood, not the Biological Safety Cabinet
- 2. p. 16: List cremation as standard DLAR protocol for carcass disposal

Ken Dickey moved. Peter Nagy seconded. The vote was unanimous

B04-334 Graf, Gregory – Lipid metabolism in obesity and its related diseases

The protocol was **approved**. Brian Rymond moved. Richard Wheaton seconded. The vote was unanimous.

B04-331 Bruemmer, Dennis - Mechanism of atherosclerosis and restenosis

The protocol was granted **provisional approval** pending the following conditions be met:

1. A table describing each and every construct to be used be submitted to M. Finucane Brian Rymond moved. Eric Smart seconded. The vote was unanimous.

B04-330 Leggas, Markos – The role of ABC transporters in tumor drug resistance and physiology

The protocol was **provisionally approved** for non-animal work only. The investigator was advised to remove the animal work from this protocol, and resubmit after IACUC approval. The room air handling system must be adjusted so that it is negative to the hallway. This is standard for laboratories and especially important when viral vector work is performed. Anthony Sinai moved. Peter Nagy seconded. The vote was unanimous.

COMMITTEE BUSINESS

The committee was invited to participate in the NIH Safety Symposium webcast, "Safety Considerations in Recombinant DNA Research with Pathogenic Viruses" September 21-22, 2004.

The newly created "Table of Principal Investigator Requirements" was discussed briefly and will be amended to include plants per Arthur Hunt's request.

BSO UPDATE

PROTOCOL MODIFICATIONS APPROVED

B04-337-M Perry, Robert - <u>Mechanisms of pathogenesis and discovery of antimicrobial therapies and vaccines (with aerosol inoculations)</u>

B04-333-M Asmis, Reto- Macrophages in atherosclerosis

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-332-BSL1 Palli, **Reddy -** <u>Molecular analysis of juvenile hormone action in *Heliothis* <u>virescens</u></u>

B04-336 Noonan, Daniel – <u>Targeting retinoic acid treatment of lung cancer/dissecting the molecular pathology of LAM disease</u>

<u>Institutional Biosafety Committee</u> <u>Minutes of September 8, 2004</u>

Members Present

Thomas Chambers

Marcia Finucane

Louis Hersh

Glenn Telling

Eric Smart

Robert Jacob

Richard Wheaton

Kelly Breeding

Chuck Staben

Arthur Hunt

Mark Farman

Doug Harrison

Daniel Kenady

Members Absent Kenneth Dickey

Jack Hiatt

COMMITTEE BUSINESS

The meeting was called to order at 12:01 pm by Tom Chambers.

The minutes of the August 11, 2004 IBC meeting were unanimously approved. Eric Smart moved. Chuck Staben seconded.

New IBC members for the 2004-2005 committee year were welcomed and introduced: Daniel Kenady, General Surgery, Mark Farman, Plant Pathology, and Douglas Harrison, Biological Sciences. They will each serve a three year term, ending August 31, 2007.

NEW BUSINESS

NEW PROTOCOL REVIEW

B04-341 Turco, **Salvatore** – <u>Glycosylation mutants of Leishmania</u>

The protocol was granted **provisional approval** pending the following conditions being met:

- 1. A description of the vector must be provided to the committee, to include the name of the vector and a diagram of the vector used to transfect the Leishmania with the gene of choice
- 2. Clarify the location of the experiments. Explicitly state which procedures will be done at UK and which will be done in St. Louis. Are the gene knockouts and transfections done in St. Louis?
- 3. On page 7, there is confusion about the concentration of the bleach/hypochlorite used to disinfect glassware. Since the MSDS on this organism recommends 1% sodium hypochlorite, use this for hard surfaces and glassware.
- 4. On page 10, wording change: remove "non-infective" from "non-infective promastigote" Tom Chambers moved. Kelly Breeding seconded. The vote was unanimous.

B04- 342 Kaetzal, David - Retrovirally Mediated Suicide Gene therapy using the enhancer region of PDGF

The protocol was approved with the following modification:

Replication competence will be monitored using the M. dunni test as described by Forestell, et al. 1996. <u>Improved detection of replication-competent retrovirus</u>. *J Virol Methods* 60:171-178. Glen Telling moved. Chuck Staben seconded The vote was unanimous.

B04-340 Van Zant, Gary – Retroviral Transduction of Stem Cells in Young and Old Mice The protocol was **provisionally approved** pending the following condition met: Completion of the laboratory audit by the Biological Safety Officer, and negative airflow into the laboratory from the hallway.

Chuck Staben moved. Robert Jacob seconded. The vote was unanimous.

COMMITTEE BUSINESS

• During the course of reviewing B04- 342 Kaetzal, David - Retrovirally Mediated Suicide Gene therapy using the enhancer region of PDGF, the committee discussed the necessity of testing for replication competence of retroviral/lentiviral vectors. The committee voted to require investigators using retroviral or lentiviral vectors to use the M. dunni test, or PCR to test for replication competence prior to injecting the vector for in vivo testing, regardless of the source of the vector system. In vitro experiments do not require this testing. Chuck Staben moved, Louis Hersh seconded. The vote was split 10-3.

Marcia Finucane updated the group on several issues:

- The Central Kentucky Blood Center will notify M. Finucane when investigators from UK purchase blood. She will make sure the investigator has a current IBC approval for working with human blood. If the investigator does not have approval, the request for purchase will be denied. This measure was implemented following an investigation in RGAN of an engineering lab using human blood without bloodborne pathogens training, IBC registration, or proper PPE.
- Marcia Finucane, Ed McClure, and Dave Hibbard have negotiated with state and local authorities
 concerning acceptance of autoclaved waste at the landfill. The state has given formal notice that
 there is no requirement for the autoclaved waste to be hauled separately or the transfer station to
 register as a medical waste hauler. The transfer station and the city had previously proposed an
 additional charge (~\$45,000/year) to haul autoclaved waste to a different landfill site. Finucane,
 McCormick, and Hibbard have lobbied for this charge to be dropped, and are awaiting word from
 the city and transfer station.
- M. Finucane has provided guidance to the Occupational Health Service regarding a new program
 providing vaccinia vaccinations to employees who may be potentially exposed to vaccinia virus.
 A final draft was not available in time for this meeting. She will forward the final draft to
 committee members via email for comments and vote when available.
- M. Finucane proposed adding a new IBC member from Microbiology & Immunology since two
 members from this department will leave the committee next year. Committee members
 suggested George Luo as a candidate.
- An adverse event report was distributed to the committee concerning IBC protocol B04-316: Greenberg, Richard- The safety, tolerability,and immunogenicity of three dose levels of ACAM3000 modified vaccinia ankaara (MVA) smallpox vaccine in adults without previous smallpox vaccination: A Double-blind, Placebo-controlled, Dose-Ranging, Phase I Study Followed by a Challenge with Dryvax® Smallpox Vaccine.

- The protocol initially reviewed and provisionally approved at the August 11, 2004 IBC meeting: B04-329 DeSimone, Phillip "A phase III randomized, controlled study to evaluate the safety and efficacy of PANVAC ™-VF in combination with GM-CSF versus best supportive care or palliative chemotherapy in patients with metastatic (stage IV) adenocarcinoma of the pancreas who have failed a gemcitabine-containing chemotherapy regimen," has not met the approval requirements. M. Finucane will meet with the protocol representatives (J. Garrison, J. Clark, W. Lingerfelt) to facilitate proper completion of the application. A subcommittee (K. Breeding, T. Chambers, R. Jacobs, D. Kenady, and M. Finucane) will meet with Dr. DeSimone to review the training presentation, date TBD)
- M. Finucane advised the committee that the biological safety office will be focusing on preventing explosions or fires in the Biological Safety Cabinet by urging investigators to replace traditional Bunsen burners with "Touch-o-matic" bunsen burners. M. Farman suggested the Fireboy burners would also be good alternative to traditional bunsen burners as they have a foot pedal and no pilot light. Both will be recommended to investigators who insist on using flames in the Biological Safety Cabinets.

BSO UPDATE

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-339 Cambi, Franca - PLP Splicing: In vivo analysis in a mouse model

Chuck Staben made the motion to adjourn. Richard Wheaton seconded. The meeting was adjourned at 1:35 pm.

<u>Institutional Biosafety Committee</u> Minutes of October 13, 2004

Members Absent

Robert Jacob

Jack Hiatt Eric Smart

Members Present

Thomas Chambers
Marcia Finucane

Marcia Finucane

Louis Hersh

Glenn Telling

Kenneth Dickey

Richard Wheaton

Kelly Breeding

Chuck Staben

Arthur Hunt

Mark Farman

Doug Harrison

Daniel Kenady

COMMITTEE BUSINESS

The meeting was called to order at 12:05 pm by Thomas Chambers.

Vote to accept the minutes of the September 8, 2004 meeting was postponed pending corrections and additions as discussed by the Committee. Revisions will be sent to IBC members via email for consideration and email vote.

NEW BUSINESS

MODIFICATION

B04-341 Turco, Salvatore: <u>Glycosylation mutants of Leishmania</u>

The protocol was granted **provisional approval** pending the following conditions be met:

- 1. The first page of the original application is amended to reflect animal work, noting IACUC protocol number
- 2. Acceptable transport of infectious agent and animal specimens is incorporated into the SOP. Tom Chambers will send a letter to the investigator describing acceptable transport.

Ken Dickey moved. Arthur Hunt seconded. The vote was unanimous.

NEW PROTOCOL REVIEW

B04-346 Geddes, James: Strategies for Calpain Inhibition

The protocol was granted **provisional approval** pending the following conditions are met:

- On page 12, amend application to reflect that up to 1 liter of culture may be produced
- 2. A summary or citation of the PCR procedure (see page 16) to test for replication competence is submitted to the committee.

Glenn Telling moved. Douglas Harrison seconded. The vote was unanimous.

B04-349 Smiley, **Jeffrey**: Influence of rat cytomegalovirus (RCMV) on *Porphyromonas gingivalis* induced periodontitis in rats.

The protocol was granted **provisional approval** pending the following conditions are met:

- 1. Attachment A is submitted for for the CMV and Porphyromonas gingivalis
- 2. Clarify the location of the second lab
- 3. Transport of infectious agents from the lab to DLAR and of animal specimens from DLAR to reflect standard procedures (see attachment).

Chuck Staben moved. Daniel Kenady seconded. The vote was unanimous.

B04-347 Horohov, David: Production of antibodies to equine cytokines

The protocol was **returned to the investigator** with the recommendation that he resubmit the protocol pending the following changes:

- 1. A paragraph is added to the application to describe the function of equine cytokines and a statement as to the need for the research.
- 2. A paragraph or more describing the rationale for use of adenovirus for antibody production rather than traditional methods for production of hybridomas.
- 3. The investigator must complete the UK specific training courses for lab safety & bloodborne pathogens, available on-line at HTTP://EHS.UKY.EDU/CLASSES.HTML
- 4. Dates of personnel training should be included in the application (page 5)
- 5. Adenovirus should be tested for replication competence because it is going into live animals; give method or citation
- 6. A description of safety precautions used during virus harvesting from the gradient should be included.
- 7. Bleach concentrations should be standardized throughout the application to 0.5% NaOCI
- On page 2, George Allen, not Roy Leach is responsible for the autoclaves; no validation methods are in use at this time, chemical integrators and biological spore testing will be used soon.
- Transport of agents should be described; both infectious agents to DLAR and specimens returning to the laboratory should be addressed (see attachment). Describe method of transport (on foot, state owned vehicle, etc.)
- 10. Attachment TC should be completed for Vero cells.
- 12. BBP attachment, the person responsible for lab safety and for the BSC certification must be someone in the lab, not the business manager for the department.
- 13. Change **expiration** of BSC certification to 2005,
- 14. Property tag numbers should be added to the protocol where listed (page 2, 2nd centrifuge)
- 15. If mixed biohazardous and radioactive materials will be generated, please describe how spills and waste of these materials will be handled (page 13, Section H)

Mark Farman moved. Glenn Telling seconded. The vote was unanimous.

B04-343 Greenberg, Richard: A Phase I/II Clinical Trial Evaluating the safety and immunogenicity of LC16m8, A modified vaccinia vaccine, in health volunteers The protocol was granted **full approval**.

Chuck Staben moved. Louis Hersh seconded. 4 committee members abstained from voting, 7 members voted in favor of approval.

B04-348 Lin, Yi-Ling: Transcriptional Regulation of Osteoclasts by Mitf

The protocol was granted **provisional approval** pending the following changes:

- 1. Name of personnel and training should be listed on page 2.
- 2. Clarify the maximum amount of paraformaldehyde to be present in the BSC. It should be less than 5ml to meet the CDC guidelines for use of volatile chemicals in BSCs.
- On page 7, check "vacuum" and "inoculation of culture media" as procedures to be done in the BSC.

4. A double trap vacuum line with inline HEPA/hydrophobic filter should be used, see CDC guidelines for BSC at

HTTP://WWW.CDC.GOV/OD/OHS/BIOSFTY/BSC/BSC.HTM

- 5. Attachment A: symptoms of exposure: replace "not being reported" with "unknown" and list symptoms of exposure to those of wild type virus.
- 6. Attachment R: Please refer to vendor specifications regarding probability of generating replication competent viruses. Probability is very low.
- 7. Attachment R: State that the source of the envelope protein is VSV.
- 8. Attachment R: Expand description of genes listed to describe purpose of each for this experiment (expressed, probe, etc)
- 9. Attachment R: Recombinant cell lines will be produced.

COMMITTEE BUSINESS

B04-329 DeSimone, Phillip: A phase III randomized, controlled study to evaluate the safety and efficacy of PANVAC ™-VF in combination with GM-CSF versus best supportive care or palliative chemotherapy in patients with metastatic (stage IV) adenocarcinoma of the pancreas who have failed a gemcitabine-containing chemotherapy regimen (UPDATE)

The committee voted to review Human Gene Transfer Trial protocols prior to IRB review. The consent form will be reviewed as part of the risk assessment. Kelly Breeding moved. Richard Wheaton seconded. The vote was unanimous.

The committee voted to require Human Gene Transfer Trial protocols to meet applicable Scientific Review Committee requirements prior to consideration by the Institutional Biosafety Committee.

Louis Hersh moved. Chuck Staben seconded. The vote was unanimous.

BSO UPDATE

M. Finucane reported on discussions with the UK IRB on the sequence of approvals for human gene transfer clinical trials. The recommended sequence is: 1) Medical/Scientific Review Board approval, then 2) IBC: require SRB approval, review and approve of risk assessment & exposure control plan, provisional approval until IRB review 3) IRB requires IBC provisional approval and IBC approved risk assessment/exposure control plan; IRB reviews and approves consent document, etc.; approval granted 4) IBC final approval granted after receiving copy of IRB approved consent form, patient information materials, & approval letter. The IBC voted to approve this procedure.

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-345 Creamer, Trevor: Structural characteristics of pancreatic polypeptide

<u>Institutional Biosafety Committee</u> <u>Minutes of November 10, 2004</u>

Members Absent

Kelly Breeding

Members Present

Thomas Chambers

Marcia Finucane

Louis Hersh

Glenn Telling

Kenneth Dickey

Richard Wheaton

Jack Hiatt

Chuck Staben

Arthur Hunt

Mark Farman

Doug Harrison

Daniel Kenady

Robert Jacob

Eric Smart

The meeting was called to order at 12:07 pm by Thomas Chambers.

The minutes of the September 8, 2004 IBC meeting were unanimously approved. Glenn Telling moved. Eric Smart seconded.

The minutes of the October 14, 2004 meeting were unanimously approved. Glenn Telling moved. Daniel Kenady seconded.

NEW BUSINESS

NEW PROTOCOL REVIEW

B04-347 Horohov, **David**: Production of antibodies to equine cytokines

The committee discussed use of 3H-thymidine in the biosafety cabinet (page 8). It was determined that the Radiation Safety Committee would make determinations as to the safety of this work. A phone call to the investigator confirmed he had Radiation Safety Committee approval for this work, he will fax a copy of the approval letter and verification that the BSCs have been certified to the Biological Safety Officer.

The **protocol was approved**. Richard Wheaton moved. Mark Farman seconded. The vote was unanimous.

B04-351 Esser, Karen: Beta-catenin effects on skeletal muscle growth

The protocol was **provisionally approved** pending the following changes:

- 1. Paraformaldehyde will not be used in the biological safety cabinet.
- 2. Karen Esser will be added as personnel handling agents in Part 5 of the application.
- 3. The povidone iodine solution (Betadine) listed in the spill procedure is the scrub formulation, not the surgical prep.
- 4. The investigator clarifies procedure for examining animal urine and feces for adenovirus contamination as mentioned in the scientific summary. Appropriate attachments should be included for this work.

Chuck Staben moved. Daniel Kenady seconded. The vote was unanimous.

B04-353 Shao, Jianhua: Molecular mechanisms of obesity and type 2 diabetes

The protocol was granted **provisional approval** pending the following changes:

- 1. C/EBPb is added to attachment A and Attachment R.
- 2. Page 9: Do not spray pipet tips with bleach.
- 3. p. 10: Check infected animal carcass as biohazardous waste generated
- 4. Send a copy of the IACUC form and IACUC approval letter to the Biological Safety Officer. Robert Jacob moved. Louis Hersh seconded. The vote was unanimous.

B04-356 Black, Esther: Gene expression predictors of lung cancer

The committee **declined to vote** on this protocol. The investigator is urged to resubmit after completing the forms with enough detail that the committee may assess the biosafety of the work.

B04-357 Black, Esther: Functional activity of Rb family members p107 and p130. The committee **declined to vote** on this protocol. The investigator is urged to resubmit after completing all the forms with enough detail that the committee may assess the biosafety of the work.

COMMITTEE BUSINESS

- Marcia Finucane requested the committee consider adding Randy Dinkins from USDA labs as an Ex Officio member. M. Finucane recommended Dinkins for his plant forage expertise and Arthur Hunt also cited his animal work as possibly an asset to the committee. Jim Strickland and Randy Dinkins will be invited to the next meeting to explain the mission of the USDA labs on campus and the research which will be conducted there. The committee will decide after this presentation whether M. Finucane should request that president Lee Todd appoint Dinkins to the committee.
- Marcia Finucane announced that she will be a guest lecturer in Wermeling spring '05 course PHR 760 008: Topics in Pharmaceutical Science: Drug Development, Regulation, and Clinical Research
- Marcia Finucane asked the committee if she should complete forms for investigators who refused for various reasons and whether different projects which are quite similar and involve the same organisms, could be consolidated into one application. The committee assured M. Finucane that it is the investigator's responsibility to complete the forms, not hers. The committee also agreed to the consolidation of projects into one application if the various projects are outlined as to aims, procedures and personnel. The committee also referred her to appropriate personnel regarding a specific investigator group.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B04-348 Lin, Yi-Ling: Transcriptional Regulation of Osteoclasts by Mitf

B04-346 Geddes, James: Strategies for Calpain Inhibition

B04-341 Turco, Salvatore: Glycosylation mutants of Leishmania

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-354 Cassis, Lisa: Regulation of adipocyte differentiation by angiotensin II

B04-344 Ko, Chemyong: Steroid/thyroid hormone action in the ovary

Motion to adjourn was made by Glenn Telling. Richard Wheaton seconded. The vote was unanimous. The meeting adjourned at 1:05 pm.

<u>Institutional Biosafety Committee</u> <u>Minutes of December 8, 2004</u>

Members Absent

Glenn Telling Jack Hiatt

Members Present

Thomas Chambers

Marcia Finucane

Louis Hersh

Kenneth Dickey

Richard Wheaton

Kelly Breeding

Chuck Staben

Arthur Hunt

Mark Farman

Doug Harrison

Daniel Kenady

Robert Jacob

Eric Smart

The meeting was called to order at 12:10 pm by Thomas Chambers.

The minutes of the November 10, 2004 IBC meeting were unanimously approved. Chuck Staben moved. Richard Wheaton seconded.

NEW BUSINESS

NEW PROTOCOL REVIEW

B04-360 Mumper, **Russell**: Nanoparticle formulations for improved tumor uptake and targeting The protocol was **provisionally approved** pending the following changes:

- 1. Strike BSL-1 references pertaining to human cell lines from the protocol. The Institutional Safety Committee and the BMBL recognize human cell lines and human tumorigenic cell lines as BSL-2 agents, and all personnel working with such are covered under the OSHA Bloodborne Pathogens Standard (29 CFR Part 1910.1030).
- 2. The current IACUC approval does not include the use of plasmid DNA. Please modify the IACUC application and submit a copy of the IACUC approval letter to Marcia Finucane. Completion of the laboratory audit with Marcia Finucane.

Robert Jacob moved. Eric Smart seconded. The vote was unanimous

B04-356 Black, Esther: Gene expression predictors of lung cancer

The protocol was **provisionally approved** pending College of Pharmacy Tissue Culture Room completion and the following modifications:

- 1. The investigator should wear a fit-tested respirator when manipulating constructs outside of biological safety cabinet and when cleaning a spill.
- 2. Page 13 should be completed.
- 3. Completion of laboratory audit.

Richard Wheaton moved. Mark Farman seconded. The vote was unanimous.

B04-357 Black, Esther: Functional activity of Rb family members p107 and p130. The protocol was **provisionally approved** pending College of Pharmacy Tissue Culture Room

completion and the following modifications:

- 1. Clorox should not be placed in the autoclave. Autoclaving is an acceptable means of decontaminating the waste mentioned on page 8. Please do not disinfect with Clorox and then autoclave any materials.
- 2. Fit-tested respirator does not have to be worn when just moving stocks from freezer to biological safety cabinet.
- 3. Attachment R: Mark that these agents are oncogenes (this is indicated on Part 5, Section C). and make sure the entire form is completed for each.
- 4. Centrifuging was not indicated as an aerosol generating procedure in Part 5, Section C. Please mark if this is applicable.
- 5. Change moi to pfu/ml (or other more appropriate concentration for titers).
- 6. Attachment BBP: please check "preparing or handling primary cell cultures" as a task and procedure.

Eric Smart moved. Douglas Harrison seconded. The vote was unanimous.

B04-364 D'Orazio, Sarah: MHC-lb restricted T cell responses during bacterial infection The protocol was **provisionally approved** pending the following minor revisions:

- Describe homogenization of tissue. This work should be done in the biological safety cabinet.
- 2. Add a paragraph to elaborate on rDNA constructs and describe knock-out plasmid.
- 3. Add Homo sapiens and OTCC source.
- 4. Add a sentence about mice disposal.
- 5. Send a copy of the IACUC approval letter to Marcia Finucane.
- 6. Complete laboratory audit.

Arthur Hunt moved. Chuck Staben seconded. The vote was unanimous.

COMMITTEE BUSINESS

The Dec. 6, 2004 memo from Amy P. Patterson, M.D., Director of NIH Office of Biotechnology Activities was distributed.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B04-351 Esser, Karen: Beta-catenin effects on skeletal muscle growth

B04-353 Shao, Jianhua: Molecular mechanisms of obesity and type 2 diabetes

Ken Dickey moved to adjourn the meeting at 1:15 pm. Mark Farman seconded. The vote was unanimous.

<u>Institutional Biosafety Committee</u> <u>Minutes of January 12, 2005</u>

Members Present

Thomas Chambers

Marcia Finucane

Louis Hersh

Jack Hiatt

Richard Wheaton

Kelly Breeding

Chuck Staben

Arthur Hunt

Doug Harrison

Daniel Kenady

Robert Jacob

Eric Smart

Members Absent Glenn Telling Mark Farman Kenneth Dickey

The meeting was called to order at 12:10 pm by Thomas Chambers.

Jim Strickland, PhD, gave a brief overview of the USDA-Agricultural Research Service.

The minutes of the December 8, 2004, 2004 IBC meeting were unanimously approved. Chuck Staben moved. Daniel Kenady seconded. The vote was unanimous

NEW BUSINESS

NEW PROTOCOL REVIEW

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until audit is performed, and any inadequacies are corrected as verified by the BSO.

B04-372 Carlyon, Jason: Anaplasma phagocytophilum pathogenesis

The protocol was granted provisional approval pending the following CHANGES:

- 1. A formal medical exposure plan for exposure to bacterium should be submitted to the Biological Safety Officer. Please refer to attached sample of exposure plan.
- 2. Revise with a description of procedures using animals in scientific summary...
- 3. Satisfactory completion of laboratory audit.

Louis Hersh moved. Richard Wheaton seconded. The vote was unanimous.

B04-362 Esser, Karyn: Stretch and mTOR signaling in skeletal muscle

The protocol was granted provisional approval with the following minor revisions:

- 1. All employees should complete lab safety training.
- 2. Respirators are required for manipulating virus outside of the Biological Safety Cabinet only.
- 3. Indicate that rDNA will be used in the secondary lab: Room MS533 where centrifuge is
- 4. In part 5: Biosafety Issues, Section B:Biosafety and handling considerations, check aerosol generating procedures as a potential for amplifying the risk of exposure (centrifugation).
- 5. Include description of use of NIH/3T3 cells.
- 6. Describe the use of animals in this protocol
- 7. Satisfactory completion of laboratory audit.

Douglas Harrison moved. Eric Smart seconded. The vote was unanimous.

B04-366 Ozcan, Sabire: Glucose regulation of metabolism and transcription in the pancreas

The protocol was approved pending satisfactory completion of the laboratory audit.

The committee was concerned that the biological safety cabinet certification would expire soon.

The Biological Safety Officer will confirm certification at audit.

Robert Jacob moved. Arthur Hunt seconded. The vote was unanimous.

B04-365 Dutch, Becky: SV5 and Hendra F protein

The protocol was granted **provisional approval** pending the following:

- 1. Clarification as to the strain of vaccinia and whether it requires vaccination of lab personnel manipulating it
- 2. Staff using HeLa cells added to BBP exposure control plan and obtain BBP training
- 3. Satisfactory completion of laboratory audit.

Chuck Staben moved. Eric Smart seconded. The vote was unanimous.

B04-363 Straley, Susan: Pathogenesis Studies

The protocol was granted **provisional approval** pending the following changes:

- 1. Attachment A completed for all infectious agents used
- 2. Description (short) of experiments using Shigella and Listeria included in BSL-2 summary
- 3. Volumes listed in protocol be corrected (milliliter listed instead of microliter in some places)
 4. The investigator completes lab specific safety training
- 5. At least one employee must complete the DOT/IATA training for shipping infectious agents
- 6. Satisfactory completion of full laboratory biosafety audit.

Eric Smart moved. Arthur Hunt seconded. The vote was unanimous.

B04-349 D'Angelo, Elisa: Fate and ecological effects of livestock antibiotics in manureamended soils

The protocol was **approved** pending submission of rDNA form to BSO.

Laboratory audit has been performed.

Arthur Hunt moved. Eric Smart seconded. The vote was unanimous.

COMMITTEE BUSINESS

DLAR request for IBC to recommend ABSL containment levels after introduction of infectious agent was supported by Eric Smart. Official vote postponed until February meeting.

The committee declined to discuss ABSL containment levels for animals infected with third generation Lentiviral vectors pending scientific recommendation from expert investigator not collaborating on G. Smith protocols. M. Finucane will request recommendation from other experts/journal articles. This will be discussed at February meeting. (see handouts: UK Fact Sheet: Biosafety Level 2+ (Lentiviral/Retroviral Vectors) and CDC information sheet: Agent: Retroviruses, including Human and Simian Immmunodeficiency Viruses (HIV and SIV)

The IBC will meet on the first Wednesday in February, and will return to regular schedule (second Wednesday) in March.

Room 308, Combs Cancer Research building is no longer available. Room 208 Combs is reserved for future meetings. Other locations were discussed and M. Finucane will determine if Room 208 will be the best choice for future meetings.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B04-360 Mumper, Russell: Nanoparticle formulations for improved tumor uptake and targeting Laboratory audit was performed, no inadequacies found.

PROTOCOL MODIFICATIONS

B04-351 Esser, Karen: Beta-catenin effects on skeletal muscle growth

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO) **B04-370 Perry, Sharyn**: Mechanism of gene regulation by the embryo MADS-factor AGL15, and roles in Glycine max somatic embryogenesis. Laboratory audit was performed, no inadequacies found.

B04-369 Perry, Sharyn: Regulation of gene expression by AGL15, an embryo MADS factor

B04-368 Harrison, Douglas: Roles of JAK signaling in drosophila Laboratory audit was performed, no inadequacies found.

Douglas Harrison moved to adjourn the meeting at 1:35 pm. Richard Wheaton seconded. The vote was unanimous.

<u>Institutional Biosafety Committee</u> Minutes of February 2, 2005

Members Present

Thomas Chambers

Marcia Finucane

Louis Hersh

Jack Hiatt

Richard Wheaton

Kelly Breeding

Chuck Staben

Arthur Hunt

Doug Harrison

Daniel Kenady

Kenneth Dickey

Eric Smart

Mark Farman

Glenn Telling

Tom Chambers called the meeting to order at 12:07 pm.

Members Absent Robert Jacob

OLD COMMITTEE BUSINESS

The minutes of January 12, 2005 were unanimously approved. Richard Wheaton moved. Kelly Breeding seconded.

NEW BUSINESS

NEW PROTOCOL REVIEW

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B05-377 Cohen, Donald A: Conditional depletion of macrophages in transgenic mice

The protocol was granted **full approval** pending the following minor modifications:

- 1. The investigator should update his BBP training (yearly)
- 2. The vector listed in Attachment R does not contain the elements listed. Correct the form and submit to BSO for approval.

The lab audit was found to be adequate.

Douglas Harrison moved. Eric Smart seconded. The vote was unanimous.

B05-376 Gong, Ming: <u>Vascular smooth muscle function under normal and diabetic conditions</u>
The protocol was granted **provisional approval** pending the following changes:

- 1. Include a description of infected tissue disposal in the scientific summary.
- 2. Explain acronyms of gene names listed in Attachment R.
- 3. Some corrections indicated in e-mail to Kathy Sandford dated 1/25/05 were not included in final IBC revision. Please ensure these changes are included in final copy submitted to BSO.

4. Satisfactory completion of lab audit.

Mark Farman moved. Glenn Telling seconded. The vote was unanimous.

COMMITTEE BUSINESS

The committee discussed and agreed that animals should be housed/handled at ABSL-2 following adenoviral vector and lentiviral/retroviral vector exposure. The UK fact sheet, BIOSAFETY LEVEL 2+ (LENTIVIRAL/RETROVIRAL VECTORS)² will be updated to reflect that work with third generation lentiviral vectors may safely be conducted at BSL-2, and animals will be housed at BSL-2 following exposure.

IRB/IBC agreement (handout in packet) Richard Wheaton moved to approve the IRB/IBC Standard Operating Procedures signed by Marcia Finucane on January 25, 2005 and Ada Sue Selwitz (signed January 20, 2005). Douglas Harrison seconded. The vote was unanimous.

The proposed IBC Bylaw changes (see attachment) were approved pending the following changes:

- 1. Change wording in section 2.1, Special members: to an individual with plant expertise, etc.
- 2. Section 1.3: replace "vice-president for Administration" with "the President or his/her designee."
- 3. Section 8.0 should be renamed as Section 2.7.
- 4. Delete "private" in section 2.7 (previously Section 8.0).

Eric Smart moved. Kenneth Dickey seconded. The vote was unanimous.

Marcia Finucane provided a brief overview of wildlife trap/count/release program to be developed in conjunction with faculty members of the Biology Department.

Marcia Finucane announced that a job has been posted for a biological safety specialist. In preparation for expanding the department, new policies will be developed to standardize biological safety office protocol review prior to IBC review.

Motion to adjourn was made by Kelly Breeding. Douglas Harrison seconded. The vote was unanimous. The meeting was adjourned at 1:13pm.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B04-372 Carlyon, **Jason**: Anaplasma phagocytophilum pathogenesis

B04-362 Esser, Karyn: Stetch and mTOR signaling in skeletal muscle

B04-365 Dutch, Becky: SV5 and Hendra F protein

B04-363 Straley, Susan: Pathogenesis Studies

B04-349 D'Angelo, Elisa: <u>Fate and ecological effects of livestock antibiotics in manureamended soils</u>

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B05-371BBP Bernard, Andrew: <u>Subcellular localization of human arginase, arginine</u> metabolism in patients with SIRS, arginine metabolism in abdominal sepsis (mouse model)

<u>Institutional Biosafety Committee</u> <u>Minutes of March 9, 2005</u>

Members Present

Thomas Chambers Marcia Finucane Louis Hersh

Jack Hiatt

Richard Wheaton

Robert Jacob

Chuck Staben

Arthur Hunt

Doug Harrison

Kenneth Dickey

Eric Smart

Mark Farman

Glenn Telling

Members Absent Kelly Breeding Daniel Kenady

Tom Chambers called the meeting to order at 12:08 pm. He noted a quorum was present. Lou Hersh conducted the meeting.

OLD COMMITTEE BUSINESS

The minutes of February 2, 2005 were unanimously approved. Eric Smart moved. Doug Harrison seconded.

NEW BUSINESS

NEW PROTOCOL REVIEW

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B05-384 Wilson, Melinda: Non-reproductive actions of estrogen

BBP on file with BSO

Laboratory biosafety audit has been performed and found to be satisfactory

Arthur Hunt and Louis Hersh were primary reviewers for this protocol.

- 1. noted that relevant human cell lines are used
- 2. noted no problems with the protocol
- 3. noted safety procedures are sufficient.

Arthur Hunt moved to grant **full approval** to the protocol as submitted. Louis Hersh seconded. The vote was unanimous.

B05-375 Timoney, John: Equine strangles

Doug Harrison, Kenneth Dickey, and Robert Jacob were primary reviewers for this protocol

- 1. results of the laboratory biosafety audit were satisfactory
- 2. noted that no lab employees had taken the bloodborne pathogen (BBP) training they are not using human cell lines so no BBP training is required
- 3. the committee questioned about the need to secure the laboratory

it was agreed that this is an important issue.

the investigator indicated that the lab was not locked when personnel not present.

- 4. the BSO will ensure that the lab is locked when personnel are not present.
- 5. questioned if *Strep. equii* produces a toxin and if the toxin may be cloned during the experiment.

the committee discussed that the PI is cloning cell surface proteins not secreted exotoxins

6. it was noted that the PI stated that these procedures carry no risk but that the ATCC classifies *S. equii* to be handled at BSL2

the PI will be required to handle all live cultures with BSL2 procedures

- 7. noted that some questions on page eleven were left blank
 - it was commented that the answer was unknown at this point in the research so the omission was appropriate.
- 8. noted there is a new post-doc in the Timoney lab who should be added to the personnel list for this protocol.
- 9. noted a deficiency in the description of how the proteins will be purified request the investigator elaborate on sonication methods.
- 10. noted the investigator included an IACUC protocol approval letter that covered the rabbit work but did not list the approval number on the form.

request that this number be added to page 1.

11. the committee agreed that the investigator could send these modifications to BSO for final approval.

The protocol was granted **provisional approval** pending modifications submitted to the BSO. Robert Jacob moved. Eric Smart seconded. The vote was unanimous.

B05-378 Estus, Steven: Molecular studies of neurodegeneration BBP on file with BSO.

Chuck Staben, Mark Farman, and Tom Chambers were primary reviewers for this protocol.

 noted that the investigator implied that genes other than the LDLR receptor would be used in the research.

the BSO will call to confirm.

the committee agreed that if other genes are used in the research that they would not represent a biosafety concern since the research is being conducted with BSL2

- 2. asked whether working with RNA isolates in the fume hood was appropriate containment noted that the fume hood is appropriate because the chemical hazards supersede the biological hazards
- 3. requested a new "attachment R" if oncogene was found and used in research. noted that even if using an oncogene, BSL2 containment would be appropriate.
- 4. noted on page 11 that the investigator indicated a "neighboring lab" as supplying HEK cells requested the investigator be more specific as "neighboring lab" is not specific

Louis Hersh moved to grant **full approval** pending minor changes. Eric Smart seconded. The vote was unanimous.

B04-367 Artiushin, Sergey: PCR 7 ELISA for detection of Leptospira in the Horses Glenn Telling and Richard Wheaton were primary reviewers on this protocol.

- 1. The laboratory biosafety audit was satisfactory.
- 2. noted that BBP training was not necessary since they are not using human body fluids for the protocol.
- 3. noted that the investigator did not mention "next steps" for the project, but that they would be addressed in future protocol submissions.
- 4. expressed concerns that the investigator did not list the proteins to be expressed in E. coli.

noted attachment R listed the proteins. the information was found to be acceptable

- 5. noted the form does not allow an answer of "Not applicable" so leaving the two questions unmarked was acceptable.
- 6. questioned if the lab needed an exposure control/treatment plan since the agent is readily

treated with doxycycline.

- 7. this is not needed as they are processing diagnostic specimens which are lower exposure risk than culturing in large amounts
- 8. questioned the use of 1% sodium hypochlorite.

commented that this is not the same as 1% bleach, but would be a stronger concentration that what is usually required.

- 9. noted a typographical error on page 7
- 10. requested that 106 cfu/ml and 102 cfu/ml be replaced with 10⁶ and 10².

Glenn Telling moved that the protocol be granted **full approval**, pending correction of the typographical errors. Richard Wheaton seconded. The vote was unanimous.

B05-380 Gu, Liya: <u>DNA mismatch repair deficiency and leukemia relapse</u> BBP on file with BSO

Daniel Kenady and Eric Smart were primary reviewers on this protocol.

- 1. laboratory biosafety audit was satisfactory
- 2. noted that human cells and human blood would be manipulated at BSL2.
- 3. no concerns with the protocol
- 4. all safety precautions were adequately addressed

Eric Smart moved that it be granted **full approval** as submitted.

Chuck Staben seconded. The vote was unanimous.

COMMITTEE BUSINESS

Minimum guidelines for TAT protein use

Guidelines from IUPUI were included in the IBC packet for review. Marcia Finucane proposed writing similar guidelines for UK. The committee agreed there is a difference between the TAT protein and TAT fusion protein. The TAT fusion protein can penetrate cells and therefore any proteins attached to it may readily enter cells. The recommendation was made to change the title to "Minimum guidelines for TAT Fusion protein use" and to list commercially available TAT fusion proteins in the guidelines.

Biologicals Response Modifiers Advisory Committee Meeting #31 Briefing Document for October 25-26, 2001. Lentivirus Vectors in Gene Transfer Clinical Trials

- 1. This document was included in the IBC packet for review.
- 2. BSO explained that it supports statements made to the committee concerning third generation lentiviral work being conducted at BSL2.
- 3. The committee agreed that there should be no requirement for an assay for the generation of replication competent virus for third generation lentivirus
- 4. It was noted existing IBC guideline calls for testing for replication competence when the recombinant viral vector is placed into animals
- 5. It was suggested to post a few "do's/don'ts" on the website for work with lentivirus vectors.
- 6. It was pointed out that UK already has guidelines on working with Lentivirus posted on the website
- 7. It will be determined if additional information about third generation lentiviral vectors should be added to the policy.

Institutional Implications of the Boston University Incident

some points were outlined to discuss (hey were included in the IBC packet for review)

summarized the BU incident.

asked if it would be appropriate to require attenuated strains to be registered noted that the OSPA Internal Approval form does not distinguish between biological hazards or chemical hazards.

noted that that form will go online sometime next year and that would be a good time to ask to have the form amended.

The committee tabled the issue for future discussion.

A Phase I, Open-Label Clinical Trial of the Safety and Tolerability of Single Escalating Doses of Autologous CD4 T Cells Transduced with VRX496 in HIV Positive Subjects (Powerpoint Presentation)

presentation was passed out

preparation for reviewing Richard Greenberg's protocol at a future meeting

Motion to adjourn was made by Eric Smart. Chuck Staben seconded. The vote was unanimous. The meeting was adjourned at 1:14pm.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B05-377 Cohen, Donald A: Conditional depletion of macrophages in transgenic mice

B05-376 Gong, Ming: <u>Vascular smooth muscle function under normal and diabetic conditions</u>

Dr. Gong has completed all requested changes/amendements to her application. Her laboratory is under positive pressure to the hallway and requests have been made to PPD to make it negative to the hallway.

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B05-391P Zhu, Hongyan: Accessing RNAi as a reverse genetic tool for global analysis of NBS-LRR gene function in *Medicago truncatula*

Institutional Biosafety Committee Minutes of April 13, 2005

Members Present

Kelley Breeding
Thomas Chambers
Kenneth Dickey
Marks Farman
Marcia Finucane
Louis Hersh
Arthur Hunt
Daniel Kenady
Eric Smart
Chuck Staben

Members Absent

Doug Harrison Jack Hiatt Robert Jacob

Tom Chambers called the meeting to order at 12:10pm. Derek Adams was introduced to the committee as the new Biological Safety Specialist.

OLD COMMITTEE BUSINESS

Glen Telling Richard Wheaton

The content of the minutes of March 9, 2005 were unanimously approved with minor modifications. Eric Smart moved. Louis Hersh seconded.

NEW BUSINESS

Marcia Finucane proposed changing the meeting day to Tuesdays or Thursdays for 2005-2006. No decision was made. The suggestion was tabled.

New Protocol Review

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B05-396 Yannelli, John: Dendritic cell generation in non-small cell lung cancer (NSCLC) BBP on file with BSO

Laboratory biosafety audit has not been performed, pending renovation of lab space Thomas Chambers, Chuck Staben, Glenn Telling, Eric Smart, and Kenneth Dickey were primary reviewers.

- 1. Dendritic cells are injected into patients.
- 2. The lab has had contamination problems in the past. This is not a biosafety issue; it is due to other lab factors.
- 3. Pipette disposal should be in a cardboard box or other puncture resistant box, not red trash bags.
- 4. Red trash bags should only be used for items to be incinerated. This lab should use orange or clear bags and autoclave solid waste.
- 5. The investigator is conducting two separate projects: clinical and research. rDNA use for each should be clearly indicated, as well as where the rDNA is being used.

The protocol was **approved with minor modifications**. Kenneth Dickey moved. Eric Smart seconded. The vote was unanimous.

B04-352 Luo, Guangxiang: Genetic analysis of RNA virus replication (Hepatitis C virus)

Louis Hersh, Doug Harrison, and Arthur Hunt were primary reviewers.

Laboratory biosafety audit was performed and deficiencies have been corrected.

- 1. It was noted the project possibly involves using concentrated HCV and transgenic models to express HCV or mutated HCV in mice.
- 2. Part three should be expanded to include description of transgenic mouse model and types of mutants, and properties of mutants, and to identify any hazards with each.
- 3. Attachment R should be completed separately for each class of construct/mutant
- 4. The committee discussed the IACUC issue of injection and animal housing.
- 5. If using concentrated HCV, biosafety level 3 is appropriate.
- 6. Guangxiang Luo should be added to personnel list.
- 7. Although no vaccine is available, interferon treatment may be an option for persons exposed/infected with HCV. The committee recommends a medical surveillance plan be adopted and testing offered to personnel potentially exposed to HCV in the course of this research.
- 8. Several questions were identified by the committee to be answered by the investigator in a revised protocol:
 - a. Describe the mutants and properties they might have.
 - b. Will host range of virus be altered? If yes, please explain the risks involved.
 - c. Describe explicitly any mutational studies with infectious clones.
 - d. When will virus replicate in mouse models? Will it be immediately after injection or later?
 - e. Is virus shed from mouse? Please describe. What is possible transmission route to humans?
 - f. Clarify personnel and tasks (i.e. who is doing what).
 - g. Describe risk attenuation.
 - h. Will virus be used at high concentrations? If so, under what conditions?
 - i. Will the plasmid(s) be infectious?
 - j. Is there a possible biosafety issue with transfers? If not, why not?

The protocol was **returned to the researcher**. Arthur Hunt moved. Louis Hersh seconded. The vote was unanimous.

B05-395 Ranjan, Dinesh: Oxidative Cellular Signaling in EBV-Lymphoproliferation

Daniel Kenady, Robert Jacob, and Kenneth Dickey were primary reviewers. BBP on file with BSO.

- Daniel Kenady summarized the research methods. They were found to be well described in the protocol.
- 2. The question was raised whether the 1% disinfectant concentration referred to bleach or to hypochlorite. 1% sodium hypochlorite (i.e. 20% bleach) is acceptable.
- 3. A new lay summary should be submitted that is written at a lay level.

The protocol was **approved with modification**. Daniel Kenady moved. Glenn Telling seconded. The vote was unanimous.

B05-392 Howe, Daniel: Biology of coccidian parasites

Mark Farman and Richard Wheaton were primary reviewers.

Laboratory biosafety audit was performed and found to be satisfactory.

- 1. Bloodborne pathogens training and an exposure plan are required for this research.
- 2. A statement describing efficacy of the protocol for heat-killing parasites should be included.
- 3. The Toxoplasma SOP should include information pertaining to the risk associated for immunocompromised individuals working with live organisms.
- 4. Constructs for the DNA vaccine should be diagrammed and included with the application.

The protocol was **provisionally approved**. Chuck Staben moved. Richard Wheaton seconded. The vote was unanimous.

OTHER ITEMS FOR DISCUSSION

Institutional Implications of the Boston University Incident. Pl's testing of attenuated strain

Article: Inadvertent Laboratory Exposure to Bacillus anthracis---California, 2004

Marcia Finucane referred to the article: "Inadvertent Laboratory Exposure to Bacillus anthracis--- California, 2004" and suggested the IBC set policy on testing of attenuated strains to ensure they are indeed attenuated. The IBC asked her to draft a policy for review.

Article: Rules, Regs, and Red Tape (handout at meeting)

Marcia Finucane distributed this article which discusses the implications of the Final Rule for the Select Agent Program.

Intellectual Property (email from Katherine Adams, handout at meeting)

This email was distributed by Marcia Finucane. The committee discussed MTAs at UK.

Kelly Breeding made the motion to adjourn the meeting. Mark Farman seconded. The vote was unanimous. The meeting adjourned at 1:33pm.

BSO UPDATE

PROTOCOLS MEETING REGISTRATION REQUIREMENTS

B05-378 Estus, Steven: Molecular studies of neurodegeneration

B05-375 Timoney, John: <u>Equine strangles</u>

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO) B05-388 Rymond, Brian: Function of snRNP particles in pre-mRNA splicing

B05-385P Maiti, Indu: Expression of glucocerebrosidase gene in transgenic tobacco

B05-383P Maiti, Indu: Expression of genes in tobacco to enhance seed germination

B05-390 Webb, Bruce: Enhancement of insect expression systems

B05-387P Maiti, Indu: Expression of a synthetic gene encoding xylanase from Clostridium

thermocellum in transgenic tobacco plants

B05-389 Webb, Bruce: Selection and optimal expression of insect anti-growth proteins

Institutional Biosafety Committee Minutes of May 11, 2005

Members Present

Kelley Breeding Thomas Chambers Kenneth Dickey Mark Farman Marcia Finucane Louis Hersh Arthur Hunt

Daniel Kenady Chuck Staben

Glen Telling

Richard Wheaton

Doug Harrison

Robert Jacob

Members Absent

Eric Smart Jack Hiatt

Tom Chambers called the meeting to order at 12:09pm. He noted a quorum was present.

OLD COMMITTEE BUSINESS

The minutes from the April 13, 2005 meeting were unanimously approved. Arthur Hunt moved. Kenneth Dickey seconded.

NEW BUSINESS

New Protocol Review

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B04-363M Straley, Susan: Pathogenesis Studies Modification

Primary Reviewers: Chambers, Harrison, Hunt, Farman, Jacob, Telling, Wheaton, Dickey Biosafety Audit will be performed 5/13/05.

- 1. The investigator cited articles that were not attached to the application
- 2. Please send electronic or hard copies of the articles cited in reference to the vector description.

The protocol was **provisionally approved** pending completion of the listed items. Robert Jacob moved. Doug Harrison seconded. The vote was unanimous.

B05-401 Stevenson, Brian: Borrelia burgdorferi genes and proteins

BBP on file with BSO

Primary Reviewers: Chambers, Hunt, Dickey

The committee was impressed with the description of biosafety precautions/procedures and found them to be acceptable. However, the committee did not find enough information about the actual science of the protocol to evaluate its safety. Therefore, the investigator is asked to resubmit the application with more specific details as follows:

- 1. Will proteins be expressed?
- 2. Is there any potential to change the pathogenicity of the organism?
- 3. Explain gene acronyms listed on rDNA form

- 4. Please send the lay and scientific summaries from the grant proposals for this work, to give the committee more details about what is proposed
- 5. Clarify on Attachment TC source of hybridomas (hybridomas are not covered on IACUC protocol)

The investigator was asked to **resubmit** the protocol with the above information included. Arthur Hunt moved. Mark Farman seconded. The vote was unanimous.

B05-373 Fannon, Michael: Role of Antiangiogenic Agents in Physiological and Pathological Processes

The lab audit has not been completed

BBP on file with BSO

Primary Reviewers: Harrison, Telling, Wheaton

- 1. A description of eye bank testing should be submitted to BSO.
- 2. Needs rDNA attachment form submitted describing the transfection procedure.
- 3. A discussion on the biosafety level of this work determined that BSL2 would be sufficient as these are not high risk CJD or BSE tissues.

The protocol was **provisionally approved** pending completion of the above items. Glenn Telling moved. Richard Wheaton seconded. The vote was unanimous.

B05-397 Greenhagen, Bryan: Production of Terpenoids in Yeast

The laboratory audit is completed.

Primary Reviewers: Farman, Jacob

- 1. Attachment R lists different numbers for plasmid. If this is a typographical error, please Correct. If different plasmids are used, provide information for each
- 2. The autoclaving protocol should be more specific (time, temperature, pressure)
- 3. Describe specific procedures in place to prevent large spills

The protocol was **provisionally approved** pending modifications. Robert Jacob moved. Mark Farman seconded. The vote was unanimous.

B05-405 Greenberg, Richard: A Phase II, Open-Label, Multicenter Study to Evaluate the Safety, Tolerability, and Biological Activity of Repeated Doses of Autologous T Cells Transduced with VRX496 in HIV-Positive Subjects

Primary Reviewers (receive additional information in packet): Smart, Staben, Kenady, Hersh

- 1. What action the sponsor and investigator will take if VSV-G DNA is confirmed and the follow-up biological RCL assay confirms the presence of a RCL?
- The IBC also requests that the consent form contain a statement cautioning the patient
 that even if symptoms improve, the patient may still be infectious for HIV/AID and that
 they should continue to refrain from unprotected sexual relations, sharing of needles,
 blood donation or any other behavior considered contributing to the transmission of this
 infection.

The protocol was **provisionally approval** pending completion of the above items. Chuck Staben moved. Louis Hersh seconded. The vote was unanimous.

OTHER ITEMS FOR DISCUSSION

Minors in the Lab Policy and Registration Forms

For IBC review and Approval

Committee will individually review again and submit suggestions for changes by May 16.

Article: Heightened security after flu scare sparks biosafety debate (in packet)

Time did not allow for discussion of the article.

Article: Ethical Guidelines for embryonic stem cell research: A newsmaker interview with Richard O. Hynes. PhD, FRS

Time did not allow for discussion of this article.

The meeting was adjourned at 2:15pm. Louis Hersh moved. Mark Farman seconded. The vote was unanimous.

BSO UPDATE

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B04-320-FT-M Slack, Charles: Benefits of the roundup ready alfalfa weed control program 2004

B03-249-M Westneat, David: <u>Studies of Social and Reproductive Behavior in House Sparrows</u> <u>Carrying West Nile Virus(modification)</u>

B04-325-FT-M Bessin, Ricardo: <u>Evaluation of Transgenic Corn for Southwestern Corn Borer Resistance</u>

Institutional Biosafety Committee Minutes of June 8, 2005

Members Present

Kelley Breeding Thomas Chambers Kenneth Dickey Mark Farman Marcia Finucane Doug Harrison Louis Hersh Jack Hiatt Daniel Kenady Robert Jacob **Members Absent**

Eric Smart Arthur Hunt Chuck Staben Richard Wheaton

Tom Chambers called the meeting to order at 12:05pm. He noted a quorum was present.

OLD COMMITTEE BUSINESS

Glen Telling

The minutes from the May 11, 2005 meeting were unanimously approved. Kelly Breeding moved. Mark Farman seconded.

NEW BUSINESS

New Protocol Review

IBC approval is granted only when biosafety containment and procedures are reviewed and found to be adequate for the research being undertaken and when the laboratory biosafety audit is adequate. If provisional approval is granted pending the audit, full approval is not granted until the biosafety audit is performed, and any inadequacies are corrected as verified by the BSO or designee.

B05-410 Issel, Chuck: <u>Equine Infectious Anemia</u> Attachment BBP on file with BSO

Primary Reviewers: Tom Chambers, Glenn Telling, Eric Smart, Ken Dickey Tom Chambers presented the protocol.

- 1. Respective parts of the protocol must include specific location of "research farm". (i.e. UK's Main Chance Farm barn # .)
- 2. Issue of the stall mucking must be addressed. Who and when?
- 3. Discuss the precise protocol used for transporting animal carcasses if necessary.
- 4. Is the Adenovirus tested for replication competency? Explain. Adenovirus constructs should be tested for replication competent adenovirus prior to inoculating animals. Please include in protocol.
- 5. The Biological Safety Cabinet in room 436 should be added to the protocol.

The protocol was **provisionally approved pending revisions**. Ken Dickey moved. Glen Telling seconded. Tom Chambers abstained. The vote was unanimous.

B05-414 Timoney, Peter: <u>Virulence and immunity of equine arteritis virus</u>
Primary Reviewers: Tom Chambers, Doug Harrison, Eric Smart, Ken Dickey
Tom Chambers presented the protocol.

- Respective parts of the protocol must include specific location of "research farm".
 (i.e. UK's Main Chance Farm barn # __.)
- 2. Discuss the precise protocol used for transporting animal carcasses if necessary.
- 3. Rocal must be listed on the disinfectant list with the appropriate dilution.

4. Does virus modification and passage through HeLA cells change the host range? Are these viruses pathogenic to humans?

The protocol was **provisionally approved pending revisions**. Doug Harrison moved. Mark Farman seconded. Tom Chambers abstained. The vote was unanimous.

B05-408 Moscow, **Jeffery**: Role of drug and vitamin transport genes in cancer etiology and treatment

BBP on file with BSO

Primary Reviewers: Doug Harrison, Robert Jacob

Doug Harrison presented the protocol.

- 1. An elaboration is needed on the transporter genes being used. More description of the specific functions is needed.
- 2. Consistency on Section 2 B, rDNA will be used in room MN 469 if DNA cloning will be performed.
- 3. The certification of the Biological Safety Cabinet is out-of-date. Documentation of the certification is required. It may be faxed to 257-8787, Attn: Marcia Finucane, BSO.
- 4. On Attachment TC: An explanation is needed regarding the origin the cancer cells. Describe cell line origin and give name of commercial source, etc.
- 5. Describe how many and details of plasmids on Attachment R.
- 6. Personnel must complete Bloodborne Pathogen Training.

The protocol was **provisionally approved pending revisions**. Robert Jacob moved. Doug Harrison seconded. The vote was unanimous.

B05-409 Kraner, Susan: Regulation of Na[±] channel gene expression and Calcium regulation in brain aging and Alzheimer's disease (3 year renewal)

BBP on file with BSO

Primary Reviewers: Robert Jacob and Glenn Telling

Robert Jacob presented the protocol.

1. While the investigator supplied adequate details of standard biosafety procedures (for example

spill procedures, the use of personal protective clothing etc.), the protocol in its current form

lacks sufficient scientific context to enable the committee to adequately assess the potential for

biosafety-related issues. The investigator therefore needs to supply more details of the

proposed experiments (but not the detailed SOP or entire grant request).

- 2. More details of the AAV system and its planned use must be supplied if the investigator really plans to use this as a delivery system.
- 3. Where and when will the SA toxins be used? Describe use of saxitoxin and tetrodotoxin in this protocol.
- 4. What animals will be used? Will animal use include only uninfected tissue harvest? Please explain.

The investigator was asked to **resubmit the protocol** with the above information included. Kelly Breeding moved. Glenn Telling seconded. The vote was unanimous.

B05-415 Greenberg, Richard: 04-ID-168: A multicenter, open-label phase I/II study to evaluate safety and immunogenicity of MVA-BN[®] smallpox vaccine in HIV infected subjects (CD4 counts >350 / µI) and healthy subjects with and without previous smallpox vaccination - POX-MVA-010 Primary Reviewers: Louis Hersh, Chuck Staben, Daniel Kennady

Louis Hersh presented the protocol.

Overall, the committee members were satisfied and deemed the protocol reasonably safe. The protocol was **approved**. Louis Hersh moved. Mark Farman seconded. The vote was unanimous.

B05-412 Greenberg, Richard: A Double-Blind, Placebo-Controlled, Dose-Finding, Phase 2
Study to Assess the Safety, Tolerability, and Immunogenicity of Three Dose Levels of ACAM3000
Modified Vaccinia Ankara (MVA) Smallpox Vaccine in Adults With and Without Previous Smallpox
Vaccination

Primary Reviewers: Lou Hersh, Chuck Staben, Daniel Kennady, Marcia Finucane

1. A spill protocol should be included in the application.

Overall, the committee members were satisfied and deemed the protocol reasonably safe. The protocol was **approved pending revisions**. Louis Hersh moved. Mark Farman seconded. The vote was unanimous.

B05-407P Hartman, John: Sudden Oak Death Kentucky Forest Survey

Primary Reviewers: Farman, Hunt

Mark Farman presented the protocol.

- 1. Training date for John Hartman is supplied.
- 2. A list of disinfectants to be used is supplied.
- 3. Information on the location and certification of the Biological Safety Cabinet should be included in application. (Certifying company and date)
- 4. The scientific summary should include information about the DNA extractions/manipulations being performed in a biological safety cabinet.

The protocol was **provisionally approved pending revisions**. Mark Farman moved. Glenn Telling seconded. The vote was unanimous.

B05-416 Zaitlin, David: Characterization and isolation of disease resistance genes from Nicotiana

Primary Reviewers: Arthur Hunt, Mark Farman

Mark Farman presented the protocol.

- 1. Your proposed use of ethanol for decontaminating sporangia needs to be clarified. If this is a standard, effective method in decontaminating blue mold sporangia and spores, please supply a standard reference. If that is not available, the committee would accept 10% bleach as a generally effective decontaminant. If no standard reference is available regarding ethanol, and bleach is not appropriate in your protocol, please supply the committee data that demonstrate the effectiveness of your decontamination procedure. These should include time and effectiveness data with sufficient numbers of sporangia and spores as well as a range of exposure times and concentrations to evaluate effectiveness.
- 2. Clarify the rDNA work: What are the plans if resistant plants are found? If plant transformations are planned for later experiments, they should be explained in this protocol or added as a modification at a later date.
- HEPA filters in the growth chamber should be routinely checked and certified.
- 4. How will the effectiveness of the containment procedures be tested? Will proper PPE be used? Please describe in detail.
- 5. Work with plant pathogens which could affect crops in KY is considered at least BSL2-P, not hazardous to human but to plants.

The protocol was **provisionally approved pending revisions**. Mark Farman moved. Lou Hersh seconded. The vote was unanimous.

B05-417 Tannock, Lisa: Serum Amyloid A and vascular proteoglycans in atherosclerosis Primary reviewers were not assigned. The protocol was emailed to the committee for review on 6/8/05.

Marcia Finucane presented the protocol.

- 1. Attachment R: rDNA should be completed for the construct proposed.
- 2. Information about personnel training should be included in protocol.
- 3. Rooms should be described.
- 4. Prior to injection into animals, the adenovirus should be assayed for replication competent virus. This should be described in the protocol.

The protocol was **provisionally approved pending revisions**. Marcia Finucane moved. Glenn Telling seconded. The vote was unanimous.

OTHER ITEMS FOR DISCUSSION

Dr. Guangxiang Lou was approved to attend the next IBC meeting to answer questions.

Minors in lab policy (vote)

The policy was discussed and changes were suggested. The committee declined to vote on the policy

pending revisions. The Minors in Research Proposal will include Dr. Farman's comments. The Biosafety

department will also incorporate any suggestions from the committee submitted be June 15th. The draft

policy will be emailed to IBC members for review and vote.

Non-voting administrators on the IBC. Marcia Finucane suggested amending the by-laws to state that administrators may serve on the IBC but may not vote.

Ken Dickey suggested amending the by-laws to name current ex-officio members (Ken Dickey, Marcia Finucane, and Martin Evans) as standing members to avoid confusion as to their voting status.

ASM News magazine letters: Another Leukemia case tied to viral vectors in French gene therapy trial; Nanoemulsions destroy pathogens, deliver vaccines; Elusive Hepatitis C virus propagated in vitro.

These articles were not discussed.

The meeting was adjourned at 2:03 pm. Glenn Telling moved. Mark Farman seconded. The vote was unanimous.

BSO UPDATE

Protocols meeting registration requirements

B04-363M STRALEY, SUE: PATHOGENESIS STUDIES MODIFICATION

B05-401 STEVENSON, BRIAN: BORRELIA BURGDORFERI GENES AND PROTEINS

B05-395 Ranjan, Dinesh: Oxidative Cellular Signaling in EBV-Lymphoproliferation

B05-398BBP Greenhagen, Bryan: Production of Terpenoids in Yeast

B05-373 Fannon, Michael: Role of antiangiogenic agents in physiological and pathological processes

PROTOCOLS ISSUED REGISTRATION NUMBERS

(These protocols do not require review by IBC and are registered with the BSO)

B05-413 Matthews, James: Molecular Mechanisms of Nutrient Absorption and Metabolism

B05-386 Crofford, Leslie: Microsomal prostaglandin E synthase-1 in rheumatoid [arthritis]

B05-402FT Wagner, George: Studies of cadmium accumulation in plants

B05-403 Wagner, George: Studies of plant trichome secretion

Minutes of the Radiation Safety Committee FY 2004-05

Radiation Safety Committee Minutes of August 10, 2004

Members Present:

Sarajane Doty Sheryl Abercrombie

Members Absent:

Ralph Christensen (Chair)
David Hibbard (Ex-Officio)
Robert Yokel
James Matthews
Angela Lehr (Ex-Officio)
David Orren
Robert Zwicker
Harry Enoch (Ex-Offico, Administration)
Bob Wilson (Ex-Officio, RSO)
William St. Clair
Tim Gorringe
Mary Allen (Ex-Officio)
Guy Simmons

Guest(s):

Jerry Schlenker; Assistant RSO, William Garner, RHT, Fred Rawlings, Assistant RSO

Chairman Christensen called the meeting to order at 3:00 P.M. A quorum was present.

Bob Wilson informed the committee that his last day at UK would be October 29th. Harry Enoch informed the committee that his last day at UK would be August 31st. Dr. Christensen asked for volunteers from the committee to join and advisory committee for

Dr. Christensen asked for volunteers from the committee to join and advisory committee for interviewing RSO candidates.

- 1. Minutes for the May 11, 2004 meeting: The Minutes were reviewed. Dr. Simmons moved to accept the minutes as written, seconded by Dr. Enoch. The Minutes were approved by an 11 to 0 vote.
- 2. Quarterly Report, Including the ALARA and Trends Reports: The report review was led by Mr. Wilson. There was a question about training in the departments. Cardiology department had requested and received further training. Fetal level 1 and level 2 notifications were discussed. Counseling for the level 2 notifications was described by the RSO. Mary Allen moved to approve the quarterly and ALARA reports, provided that subsequent reports will list fetal notifications by department. It was seconded by Dr. Yokel. The motion was approved by a 13 to 0 vote.

- 3. The Form for Departmental requests to add clinical Authorized Users was reviewed. Dr. Simmons recommended that any authorization listed on a Radioactive Materials License in the last 5 years be noted.
- **4. Application Process Revision** This is still pending.
- 5. Annual Report Review Mary Allen suggested that a review of offsite facilities in Bereah, Hazard, etc be included in future reports. A correction added 'not' to the sentence, 'Final training has been completed, but the system is not in use.'
 Page 3, line 5. There was a discussion of the tracking in the annual Alara numbers. Mary Allen moved to accept the report. Dr. Matthews seconded the motion. The report was approved by a 12 to 0 vote.
- **RSO Report:** Mr. Wilson presented the RSO Report. Elements of the written report, provided, were discussed.
 - **1. Incidents/Misadministrations** There have been no radiological incidents or misadministrations in the past quarter.
 - **2.** License Inspections Activities conducted under the Broad Medical and Teletherapy / Gamma knife licenses were inspected on May 25 and 24 by the Kentucky Radiation Control branch. No items of noncompliance were noted. The final report has not been received.
 - **3. Medical Center / Hospital Radiation Safety Program** Safety inspections for all 118x-ray units were completed in FY 2003-04. Twenty-seven brachytherapy and 114 I-131 therapy patients were attended in the year. Thirteen machines had been removed, and 17 machines had been added. There was a discussion about what regulation requires inspections of the X-Ray equipment. JCHO specifies it and the regulations prohibit using a machine that does not meet the standards.
 - Dr. Zwicker volunteered to join the RSO hiring advisory committee.

There being no other business items, Dr. Gorringe made a motion to adjourn. Dr. St. Claire seconded the motion. Chairman Christensen adjourned the meeting at 4:30 P.M.

Radiation Safety Committee Minutes of November 9, 2004

Members Present:

Ralph Christensen (Chair)
David Hibbard (Ex-Offico, Administration)
Robert Yokel
James Matthews
Angela Lehr (Ex-Officio)
David Orren
Bob Wilson (Ex-Officio, RSO)
Mary Allen (Ex-Officio)
Sarajane Doty
Sheryl Abercrombie
Guest(s):

Members Absent:

Guy Simmons Tim Gorringe William St. Clair Robert Zwicker

Jerry Schlenker; Assistant RSO, William Garner, RHT, Fred Rawlings, Assistant RSO

Chairman Christensen called the meeting to order at 3:00 P.M. A quorum was present.

David Hibbard announced that the search for a new RSO was ongoing. There should be resolution before Christmas. Bob Wilson would continue in a part-time basis to address license issues.

- 1. Minutes for the May 11, 2004 meeting: The Minutes were reviewed. Dr. Matthews moved to accept the minutes as written, seconded by Ms. Allen. The Minutes were approved by an 10 to 0 vote.
- **2. Quarterly Report, Including the ALARA and Trends Reports:** The report review was led by Mr. Rawlings. Dr. Yokel moved to approve the quarterly and ALARA reports. It was seconded by Dr. Matthews. The motion was approved by a 10 to 0 vote.
- 3. Irradiator Incident: Mr. Rawlings described the mechanical failure of the safety interlocks that enabled operators to open the chamber door with the source in the ON position. Mr. Wilson stated that he felt that performing the live test was the best way to determine any extraneous dose to members of the public. There was a discussion about several points. There should be a hard wired alarming monitor. Joe Fink coordinates a program that provides annual money grants for preventive maintenance contracts. There should at least be a repair schedule if this is not available. The Chair of MMI should be tapped to write a letter in support of providing a grant for this irradiator. What kind of audit can detect if users are trained and using the irradiator correctly? Does the logbook need to be redesigned? Can a core group or one paid person be made operators? How many keys are the optimum number for secure operations?

- **4.** Ms. Allen made a motion that if the State Office of Radiation Control sent a citation letter regarding the event, that the RSO should negotiate a response and keep the Radiation Safety Committee informed. Dr. Yokel seconded the motion. It was approved 8-0.
- **5.** Dr. Yokel made a motion to pursue funding party for a maintenance service contract by the owner of the irradiator or other involved. Dr. Orren seconded the motion. It was approved 8-0.
- **6.** Mr. Wilson discussed the RSO report.

There being no other business items, Ms. Allen made a motion to adjourn. Mr. Hibbard seconded the motion. Chairman Christensen adjourned the meeting at 4:30 P.M.

Radiation Safety Committee Minutes of February 8, 2005

Members Present:

Ralph Christensen (Chair)
David Hibbard (Ex-Officio, Administration)
William St. Clair
Guy Simmons
Patricia Hughes (Ex-Officio)
David Orren
Andy Miller (Ex-Officio, RSO)
Tim Gorringe
Sarajane Doty

Members Absent:

James Matthews Mary Allen (Ex-Officio) Robert Yokel Robert Zwicker Sheryl Abercrombie

Guest(s):

Fred Rawlings, Assistant RSO, Jerry Schlenker, Assistant RSO, William Garner, RHT, UK Health Physics Class members.

Chairman Christensen called the meeting to order at 3:00 P.M.

Dr Christensen introduced Andy Miller as new RSO to the Committee. -.

- 1. **Minutes for the November 9, 2004 meeting:** The Minutes were reviewed. A date correction was noted. Ms. Doty moved to accept the minutes with corrections. Dr. St.Clair seconded. The Minutes were approved by a 9 to 0 vote.
- 2. **Quarterly Report, Including the ALARA and Trends Reports:** The report review was led by Mr. Rawlings. Dr. Simmons noted that at the August meeting, there had been a discussion about listing departments for Fetal Alara notices. After a discussion about what the limits were, Andy Miller stated that he would review the fetal Alara criteria and address it as an action item at the next meeting. Dr. St. Clair moved to approve the quarterly and ALARA reports. It was seconded by Ms. Doty. The motion was approved by a 9 to 0 vote.

3. RSO Report-

- a) Incidents/Misadministrations There have been no misadministrations and no incidents in the past quarter.
- b) License Inspections The State visited the irradiator in November 2004 and performed a reciprocity inspection on the vendor repairing the irradiator. Commitments for irradiator safety were made to the State in letters dated December 7, 2004 and December 21, 2004. The RSO visited with the State in January. A letter was received in January authorizing restart of the irradiator subject to the commitments of these letters.

- c) A Notice of Violation dated November 17, 2004 was received for the May 24, 2004 inspection of the hospital. Corrective actions were implemented. A response was sent December 29, 2004. The State acknowledged our return to compliance on January 10, 2005.
- d) License Amendments Amendment requests were made to change the RSO for the Academic, Medical, GammaKnife and Irradiator licenses. Additional information was provided on January 28, 2005. As of February 1, 2005, no amended licenses have been received.
- 4. Mr. Miller is investigating the report of a CT scan of a pregnant patient and a fluoroscopy burn of another patient.
- 5. A spill in a research lab in HSRB in January contaminated a technician's pants and shoes. Radiation Safety was called in responded appropriately. The RSO and Assistant RSO followed up with an interview.

There being no other business items, Ms. Doty made a motion to adjourn. Mr. Hibbard seconded the motion. Chairman Christensen adjourned the meeting at 4 PM.

Radiation Safety Committee Minutes of May 10, 2005

Members Present:

Ralph Christensen (Chair)
David Hibbard (Ex-Officio, Administration)
Guy Simmons
Sheryl Abercrombie
Robert Zwicker
Patricia Hughes (Ex-Officio)
Sarajane Doty
Mary Allen (Ex-Officio)
Andy Miller (Ex-Officio, RSO)
David Orren

Members Absent:

James Matthews Tim Gorringe Robert Yokel William St. Clair

Guest(s):

Jerry Schlenker, Assistant RSO

Chairman Christensen called the meeting to order at 3:00 P.M.

- 1. **Minutes for the May 8, 2005 meeting:** The Minutes were reviewed. The Minutes were approved by a 7 to 0 vote.
- 2. **Quarterly Report, Including the ALARA and Trends Reports:** The report review was led by Mr. Miller.
- 3. **Authorized Users Medical:** A presentation on the status of Authorized Users for medical use of licensed materials was led by Mr. Miller. Current regulations and regulations that take effect in October 2005 were reviewed. Mr. Miller provided a copy of a proposed letter reaffirming the RSC approval status of each Authorized User. After a brief discussion, Committee members made suggestions for improvements in the letter. The letter serves to document the approval of each Authorized User by the RSC. The committee agreed that future Authorized Users would be approved by a quorum and approvals could be sent to members via e-mail. A motion was made and seconded to reaffirm the approval of the Authorized Users. The motion was approved by a 7 to 0 vote.
- 4. **ALARA for fetal doses:** A discussion was held about the current limits for ALARA for fetal doses. After discussion, a motion was made and seconded to accept the NCRP 91 limits of 50 mrem per month of gestation for fetal doses as the ALARA limit. The motion was approved by a 7 to 0 vote.

5. RSO Report-

- a. Incidents/Misadministrations There have been no misadministrations and no incidents in the past quarter.
- b. License Inspections There were no inspections of any licenses by the State during the last quarter.
- c. License Amendments An amendment to the Broad Scope license was submitted and approved to increase the Tc-99m possession limit.
- d. GammaKnife computer monitor incident A break in occurred at the GammKnife suite. Computer monitors were stolen. All radioactive materials were accounted for by the Medical Physicist.
- e. The Teletherapy and GammaCell units are scheduled for disposal in June.

There being no other business items, a motion was made and seconded to adjourn. Chairman Christensen adjourned the meeting at 4:30 PM.