CHARGE TO THE BIOHAZARD ADVISORY COMMITTEE

The problems of accidental infectious disease transmission have existed for many years. However, only within the last fifteen years have there been attempts to document numbers of laboratory-acquired infections. Also, recent developments in biomedical research have focused attention on the biohazard problem in laboratories. These have included the intensive studies of diseases with unknown etiologies (such as the search for oncogenic viruses), research on recombinant DNA molecules, and studies on exotic diseases entering the United States from other countries. Recently, the use of chemical carcinogens in laboratories has also come under closer scrutiny, often being considered along with the problems associated with biohazard control.

Also, there have been laws enacted at the federal and state levels which have created the need for attention to biohazard control. These include requirements of the Occupational Safety and Health Act, the National Environmental Policy Act, and, although not in the form of law, recommendations of the National Cancer Institute for Biohazard Programs for those research institutions with extramural cancer contracts.

The purpose of the Biohazard Advisory Committee will be to define the necessary steps which need to be taken within the University to prevent laboratory-acquired infections resulting from research involving hazardous and potentially hazardous microbial agents, and to define the necessary steps which need to be taken within the University to safely use chemical carcinogenic agents in laboratories. In carrying out this charge the committee should give consideration to the need for, the extent of, and the procedures for implementation of:

1. A medical surveillance program.

2. A program to provide the necessary consultation relating to and monitoring of the physical environment (the monitoring to see that policies regarding operations and physical facilities are met).

3. Establishment of policies relating to the required physical facilities and equipment for handling various risk categories of biological agents and carcinogens.

4. The necessary data which should be maintained and guidelines for management of the data base for the program (e.g. agent registry, personnel data, equipment data, proposal monitoring, etc.).

5. Guidelines for the amount of training for persons who are handling various risk categories of biological agents and carcinogenic agents.

6. Procedures which need to be established for enforcement of policies related to biohazard control.

7. Procedures which need to be established to meet the need for research proposal review prior to submission.

8. Steps which need to be taken to provide for review and update of policies on a continuing basis.

BIOHAZARD ADVISORY COMMITTEE

OPERATING POLICY AND PROCEDURE

I. Charge of the Committee:

This committee is advisory on matters relating to the safe handling, transport, use, and disposal of biohazards and carcinogens on the University campuses.

II. Meetings. Regular meetings shall be held as follows.

A. Dates

1. The committee shall meet every month at a predesignated time unless notified to the contrary. Additional meetings may be called at the discretion of the chairperson or scheduled by the Committee.
2. Minutes of the last meeting will be mailed to members at least one week prior to the next meeting.
3. Members shall be notified by phone one day prior to a meeting.

B. Quorum

1. A simple majority of members shall be present to make recommendations on any final proposals. Approved recommendations for submittal must have the vote of a majority of all voting committee members.
2. Consideration of tentative proposals and reviews may be conducted with less than a quorum at the discretion of the chairperson.

III. Assignment of proposals or requests. The committee chairperson will take the following action on each proposal or request that is accepted for review or action:

A. Assign a committee member or members to review the proposal, or

B. Call for action without an individual review.

IV. Final recommendations. The final recommendations shall reflect the concensus of the Committee. The recommendations of the Committee shall identify the individuals, departments, or other campus units that have provided inputs to the proposal; shall contain Committee suggestions of additional persons, department or campus units that should be given an opportunity to comment on the recommendations prior to adoption; shall contain any unresolved questions or concerns of the Committee; and shall indicate any widely differing views encountered within the Committee or from others.

UNIVERSITY OF MINNESOTA
Office of the Vice President for Student Affairs
Morrill Hall
Minneapolis, Minnesota 55455

September 24, 1975

Mr. Paul Maupin
Coordinator
Health Sciences Planning
4104 Powell Hall
East Bank Campus

Dear Mr. Maupin:

Because of some recent developments in: (1) types of biological and carcinogenic agents being studied in University research laboratories; (2) federal legislative mandates; and (3) changes in policies from federal agencies providing much of the grant money for this research, it is necessary that the University assess its policies and procedures regarding control of biohazards and carcinogens on campus. To accomplish this I am asking that the Department of Environmental Health and Safety convene an advisory committee to consider matters outlined in the attached charge. I would like to appoint you to serve on this committee. Please let me know if you cannot serve in this capacity.

We certainly look forward to the report of this committee with recommendations for implementation of a comprehensive program for control of biological agents and carcinogens on campus.

Sincerely,

Frank B. Wilderson, Jr.

Frank B. Wilderson, Jr.
Vice President for Student Affairs

Enc.

UNIVERSITY OF MINNESOTA
TWIN CITIES

University Health Service
Minneapolis, Minnesota 55455

November 7, 1975

Memorandum

To: Biohazards Advisory Committee Members

From: Walter Jopke, Assistant Professor & Senior Environmental Health Specialist, Department of Environmental Health and Safety, Boynton Health Service

Subject: Agenda for First Biohazards Advisory Committee Meeting on November 24, 1975, at 1:30 p.m., Boynton Health Service, Room N101, Library.

1. Introduction, Roger DeRoos, Ph.D., Associate Director for Environmental Health and Safety, Boynton Health Service

2. Review of present status of biohazards and carcinogenic programs on campus, by Walter Jopke and Professor George Michaelsen, Occupational Health Engineer, Department of Environmental Health and Safety, Boynton Health Service.

3. Review of the charge to the biohazards advisory committee which was sent by Dr. Frank Wilderson, Jr., Vice President of Student Affairs.

4. A review of the enclosed material:

   a. Policy Statement for the Control of Biohazards in Academic Institutions, 1975, American College Health Association.

   b. Safety Standards for Research Involving Oncogenic Viruses, October 1974, NCI.

   c. Classification of Etiological Agents on the Basis of Hazards, July 1974, MSPHS.

5. Open discussion for committee member interests and concerns.

BIOHAZARD AND CHEMICAL CARCINOGEN ADVISORY COMMITTEE MEETING

November 24, 1975

1:30 p.m. - 3:15 p.m.

Present: A. Elliott, Chairman, R. Anderson, H. Balfour, G. Ederer, M. Hannon, A. Jenkin, P. Maupin, L. Solomon, L. Wattenberg, W. Jopke, Ex-Officio

Absent: L. Henderson, P. Manning

Environmental Health and Safety Staff: R. DeRoos, G. Michaelsen

I. Introductions

The basic purpose of the committee is to develop a policy for the control of biohazards and carcinogens for all campuses of the Univeristy of Minnesota. It was noted that the committee is advisory to the Department of Environmental Health and Safety, with the objective of submitting a report on a recommended policy statement sometime within the next year. In the area of biohazard control, the committee will examine matters related to the control of laboratory acquired infections for University laboratories and adjunct facilities such as glassware washing areas. Similarly, the matters of chemical carcinogen control will be related to the University laboratories and adjunct facilities. It was suggested that consideration might first be given to those carcinogens on the Occupational Safety and Health restricted list.

There was a brief discussion of the need for this kind of policy statement and kinds of guidelines now available from the National Institutes of Health and Department of Labor.

II. Programs Already Established

A. Biohazard Shortcourse (NCI)
B. Review of Laminar Flow Cabinet Purchase Orders
C. Voluntary Requests for Information and Consultation
D. Laboratory Safety Course
E. Testing of Biological Laminar Flow Cabinets
F. Posting of Biohazard Signs

III. Major Problems

Two possibilities were considered for determining the problems facing our laboratories. One would be for the Committee to develop a questionnaire, possibly distributed through the health and safety coordinators.

Possible Inquiries for Questionnaire

1. Agent being used (chemical or biological)
2. Training (or experience) of employees
3. Control procedures
4. Physical facilities available

Another possibility would be to "re-write" the NIH Biohazard Safety Guide and make it applicable to our laboratory needs and specifications.

IV. Requested Before Next Meeting: Each member should review the NIH Biohazard Safety Guide.

Next Meeting: 1:30 p.m., January 5, 1976, Staff Library, N101, Boynton Health Service

Minutes Taken: P. Caryl

Biohazard Advisory Committee

Monday, January 5, 1976

Meeting Convened: 1:45 p.m.

Present: A. Elliott, G. Ederer, L. Henderson, P. Manning, S. Marker (for H. Balfour)
W. Jopke, Ex-Officio

G. Michaelsen, Staff

Absent: R. Anderson, M. Hannon, H. Jenkin, P. Maupin, L. Solomon, L. Wattenberg

It was suggested that applicable sections of the "NIH Guidelines: be used for the training of new employees.

Discussion included:

1. that medical surveillance be started for employees who are injured and to continue monitoring the employee after the injury or illness.

2. that the Health Service become involved in the monitoring of employee health.

3. that more new employees take the biohazard safety course. It was agreed that the more training an employee received, the less likely he is to cause or contract illness or injury.

4. that the education aspect of this committee be emphasized more than the "policing" aspect.

5. that a medical surveillance program be recommended to Vice President Wilderson for consideration.

6. that an employees' manual be developed; using the following information

   a. section 4 of NIH Biohazard Safety Guide (Identification and Classification of Biohazards)

   b. section 5 of NIH Biohazard Safety Guide (Procedures for Biohazard Control)

   c. general guidelines as established by the Committee

   d. section 6 of NIH Biohazard Safety Guide (Procedures for Storage and Handling)

The following members have agreed to review their particular section of the NIH Biohazard Safety Guide and report at the next meeting:

Microbiological - G. Ederer, S. Marker

Animal - P. Manning

Chemical - L. Henderson

Medical - A. Elliott

Enforcement & Policy - W. Jopke

Next Meeting: Monday, February 2, 1975, N101 Boynton Health Service, 1:30 p.m.
Meeting Adjourned: 3:00 p.m.
Minutes Taken: P. Carmel

UNIVERSITY OF MINNESOTA
TWIN CITIES

Boynton Health Service
Minneapolis, Minnesota 55455

Memorandum

To:

From: Environmental Health and Safety

Subject: Survey of Use of Biohazardous and Carcinogenic Substances

We need your assistance in developing data on the use of biohazards and chemical carcinogens on the campuses of the University. This information from the survey will be reviewed by the Biohazard Advisory Committee to; a) evaluate laboratory facilities and equipment, b) recommend policies and procedures for handling biohazardous material, c) appraise the degree of compliance with federal regulations governing chemical carcinogens, and d) provide information for research grants.

Your cooperation in completing the attached survey form will be appreciated. Please return the questionnaire to the Department of Environmental Health and Safety, Boynton Health Service, within two weeks. If you have any questions, please contact Mr. Walter Jopke at 373-5934.

WHJ:gam

Enclosure

Biohazard and Carcinogen Usage Questionnaire

Name _____

Location _____

Phone _____

Place a check mark in the appropriate column to indicate current and/or future use of agents and storage of substances where applicable. Please enumerate the specific microbial agents which you handle.

	Current	Storage	Future
I. Microbial agents			
1. Bacteria _____			
_____			
2. Fungi _____			
_____			
3. Mycoplasmas _____			
_____			
4. Chlamydiae _____			
_____			
5. Actinomycetes _____			
_____			
6. Rickettsiae _____			
_____			
7. Parasites _____			
_____			
8. Viruses _____			
_____			
II. Tissue Cultures			
1. Human			
2. Non-Human primate			
3. Mouse			

III. Carcinogens	Quantity Used	Quantity Stored	Future
1. N-Nitrosodimethylamine			
2. 2-Acetylaminofluorene			
3. 4-Dimethylaminoazobenzene			
4. beta-Propiolactone			
5. Ethyleneimine			
6. 3, 3^1 - Dichlorobenzidine			
7. 4, 4^1 - Methylene bis (2-chloroaniline)			
8. beta-Naphthylamine			
9. Benzidine			
10. 4-Aminodiphenyl			
11. bis-Chloromethyl ether			
12. Methyl Chloromethyl ether			
13. 4-Nitrobiphenyl			
14. Vinyl chloride			
15. Other suspected chemical carcinogens			
_____			
_____			

☐ I do not use or intend to use biohazardous or carcinogenic materials.

Hazard Assessment (Judgment Of Investigator)

	Low	Moderate	High	Does Not Apply
Carcinogens				
Health Hazard (toxic and pharmacologic effects)				
Physical Hazard (reactivity, stability, flammability, etc.)				

Operation Hazard Potential	Low	Moderate	High	Does Not Apply
1. Weighing				
2. Mixing				
3. Treatment of animals				
4. Analytical Procedures				
5. Synthesis Procedures				
6. Other (specify)				
_____				
_____				
BIOHAZARDS				
Processing of clinical specimen				
Use of laboratory animals				
Processing of animal materials				
Use of cell or organ culture				
Concentration of microbial agent				
Production of microbial agent in quantity				
Aerosol transmission				
DNA recombination experiments				

Disposal Procedures:

Comments:

BIOHAZARD ADVISORY COMMITTEE

Monday, February 2, 1976

Meeting Convened: 1:35 p.m.

Present: A. Elliott, G. Ederer, L. Henderson, P. Manning, S. Marker (for H. Balfour) P. Maupin, L. Solomon, L. Wattenberg, W. Jopke, ex-officio

G. Michaelsen, staff

Absent: R. Anderson, M. Hannon, H. Jenkin

Professor Ederer felt that the etiological classification was a good resource, but that parts 4 and 5 of the NIH Study Guide were more complete and it would be hard to up-grade this material.

Dr. Marker felt the information is good, but brought up the question of how and to whom this information should be distributed.

Through specific items on a questionnaire, developed by Professor Jopke, we should be able to establish a list of personnel who work with biohazards.

It was suggested that these forms be sent to the Department's directors and health and safety coordinators, with a sufficient number for all labs. This should be followed with a letter explaining how to complete the form.

A second follow-up letter should be developed requesting information on the type of work being done in the labs, the type of equipment found in their lab, etc.

It was reported by Dr. Jenkin (via Professor Jopke) that he felt sections of the NIH Student Guide should be explained.

Section 4, pages 10-13 of the NIH Study Guide has a possible list of agents. This list should be included in the lab survey form, so laboratory personnel can indicate which agents they use in the lab. This list should include suspected chemicals. It was brought up that the Department of Labor has a more complete list and additions should be made to the agents named by NCI.

Dr. Manning reported that further emphasis on the control of accidents involving infectious agents in the lab should be made. He also felt there should be definite recommendations for non-human primates.

Also further consideration should be given to defining the work area in a lab as to the low, moderate and high risk involved.

The question was raised as to whether the University should consider termination physicals.

It was suggested and agreed that each committee member would prepare a final draft of their assigned section. This would then be presented to the committee for final approval.

Meeting Adjourned: 3:00 p.m.

Next meeting: Monday, March 1, 1976, at 1:30 p.m., at Boynton Health Service

Minutes Taken: P. Caryl

university of minnesota

memo

to Mr Paul Mangan

from Roger DeBoer

- [x] For your information
- [ ] For your approval
- [ ] Approved
- [ ] For your attention
- [ ] Note and file
- [ ] Note and return
- [ ] Note and forward
- [ ] Please advise
- [ ] Please comment
- [ ] Please reply
- [ ] Please handle
- [ ] Send copy
- [ ] Please see me

Per our recent telephone conversation.

Date 2-20-1976

S92046

Duties for Staff of the Biohazards Control Program

The biohazards control staff have responsibility for rapidly expanding program efforts involving consultation on safe laboratory practices, review and approval of purchase orders for biological safety equipment (e.g. biological safety cabinets), testing and annual retesting of biological safety cabinets, posting of hazardous areas and operations, and short-term training of laboratory technicians in biohazards control. As this program develops, this staff will also: 1) survey laboratories to assure that they possess the necessary safety equipment; 2) develop and maintain an agent registry, divided according to risk categories for various agents; 3) formalize the procedures for monitoring the use of various biohazards signs and symbols; 4) develop appropriate standards unique to our facilities at the University of Minnesota, e.g. recent development of biological safety cabinet standard; 5) develop a mechanism for assuring safe procedures for transferring hazardous agents between laboratories on campus and shipment of agents intrastate; 6) serve as staff to the recently appointed Biohazards Advisory Committee; 7) develop and administer further training efforts for persons working with hazardous agents; 8) review plans for new facilities utilizing biologically hazardous agents, and also plans for modification of existing facilities; 9) periodic testing of ventilation systems to verify satisfactory operation; 10) give advice on decontamination of space and equipment for remodeling or modification of facilities; 11) respond to emergencies and investigate accidental exposures; 12) periodically test and certify sterilization equipment; and 13) provide consultation and surveillance relating to disposal of biohazardous wastes.

Biohazard Advisory Committee

Monday, April 5, 1976

Meeting Convened: 1:40 p.m.

Present: A. Elliott, Chairman, G. Ederer, S. Marker, (for H. Balfour), L. Wattenberg, W. Jopke, ex-officio

Absent: R. Anderson, M. Hannon, L. Henderson, H. Jenkin, P. Manning, P. Maupin, L. Solomon

G. Michaelsen, staff

Microbiological Section

Professor Ederer and Dr. Marker were asked to comment on Dr. Jenkin's letter as to whether or not the chemicals he mentions, in his letter, should be added to the present list of chemical carcinogens.

Medical Section

Approved

It was agreed that although the program may be slow in arriving, a medical surveillance program at the University will be developed in the future.

General Policy and Procedures Section

The proposed policy and procedure section will be further discussed at the next meeting.

Chemical Carcinogen Section

Dr. Wattenberg reported that the chemical aspect of the Committee's recommendations will be presented at the next meeting. He is awaiting comment on it from Dr. Fenton, of the Chemistry Department.

Laboratory Animal Section

Further discussion at next meeting

Professor Jopke reported on the results of the questionnaire, sent to laboratories using biological and chemical carcinogen agents. The results also included Duluth, Morris Crookston, Waseca, the Hormel Institute as well as the Twin Cities Campuses. It was felt that the questionnaire gives the Committee a source of information such as who to contact regarding the use of certain agents. A copy is enclosed for those members not present at the last meeting.

BIOHAZARD ADVISORY COMMITTEE

Monday, May 10, 1976

Meeting Convened: 1:50 p.m.

Present: A. Elliott, Chairman, G. Ederer, L. Wattenberg

G. Michaelsen, staff

W. Jopke, ex-officio

Absent: R. Anderson, M. Hannon, L. Henderson, H. Jenkin, P. Manning, S. Marker
P. Maupin, L. Solomon

I. Dr. Wattenberg reviewed his section of Chemical Carcinogens. He had divided compounds into three catagories: High (class I), Moderate (Class II), and Minimum (Class III). The chemical carcinogens were based on the list developed by NIH.

Professor Ederer suggested that Class I be changed to Class III and vice versa, so as to be consistent with the NIH Classifications.

It was also recommended that the following sentence by omitted. (see page 5). "In many laboratories, coffee is consumed with the laboratory."

II. Professor Jopke reviewed the results of the survey form sent to laboratories.

III. Professor Jopke also hoped that some time, in the near future, the Department of Environmental Health and Safety would be able to survey laboratories using biohazardous agents. Included in these surveys would be a check of each department's medical surveilance program, a discussion with employees about general safety practices, and an inspection of the safety equipment being used.

IV. It was reported that NIH is in the process of developing safeguards for laboratories using chemical carcinogens and DNA recombinants.

Agenda for next meeting

1. Dr. Marker and Professor Ederer will review and report on Dr. Jenkin's letter.

2. The Animal Care Section (Dr. Manning) is enclosed with these minutes and will be reviewed at next meeting.

Next Meeting: Monday, June 14, 1976, at 1:30 p.m., N101 Boynton Health Service

Meeting Adjourned: 2:25 p.m.

Minutes Taken: P. Caryl

SHIPPING ANIMAL PATHOGENS

The United States government has spent millions of dollars in recent years to eradicate foreign and domestic animal diseases. American livestock are among the healthiest in the world. To continue to protect our animal agriculture, the importation and interstate shipment of animal disease organisms and vectors are strictly regulated. If you work with these organisms, you should be familiar with regulations governing their shipment.

These regulations are contained in Parts 104 and 122 of Title Nine, Code of Federal Regulations. The Code states that no organism or vector may be brought into the United States, or moved from state to state, without permission. In applying for a permit, you must agree to take the necessary precautions to guard domestic livestock and the public against disease caused by the organism or carried by the vectors.

Organisms are all cultures or collections of organisms or their derivatives, which may introduce or disseminate any contagious or infectious disease of animals and poultry.

Vectors are all animals such as mice, pigeons, guinea pigs, rats, ferrets, rabbits, chickens, dogs, and the like, which have been treated or inoculated with organisms, or which are diseased or infected with any contagious, infectious, or communicable disease of animals or poultry or which have been exposed to any such disease.

Even though an organism is present in the United States, you have to get a permit before importing it. This regulation also applies to tissues, blood, serum, or diagnostic specimens which may unknowingly be infected with exotic disease agents. Again, USDA doesn't want to endanger humans or domestic livestock.

Permits are also required for interstate movement of organisms which were originally imported and some pathogens that are enzootic — such as bluetongue virus, scrapie, and vesicular stomatitis. Enzootic diseases are those routinely found in some parts of the country, but not in others.

However, some vectors or organisms may be moved between states without a permit. Examples are *E. coli, Staphylococcus aureus, Salmonella typhimurium,* and others. There are no restrictions on these because they are routinely found in all states.

Foot-and-mouth disease virus is excluded from the United States by law. The USDA bars the entry of 22 other disease-causing organisms into this country by policy. A list of these is at the end of this fact sheet.

To obtain a permit to import or transport these organisms and vectors, fill out VS Form 16-3, "Application for Veterinary Permit to Import or Transport Organisms or Vectors." These forms are available at Veterinary Services area offices. Or write to APHIS, Veterinary Services, Federal Building, Hyattsville, Maryland 20782. Send the completed forms to this address, too. Permits must be applied for at least 30 days prior to the shipping date.

Prior permission from the U. S. Public Health Service is required for importing or transporting organisms or vectors dangerous to humans. For appropriate forms, write Director of BioSafety, Center for Disease Control, Building Four, Room 232, Atlanta, Georgia 30333.

If you want to import or transport living plant pests, pathogens or disease vectors, you should apply for a permit from APHIS, Plant Protection and Quarantine Programs, Federal Building, Hyattsville, Maryland 20782.

Following is the list of animal disease organisms and vectors forbidden by USDA policy entry into the United States:

African horse sickness
African swine fever
Borna disease
Bovine infectious petechial fever
Contagious agalactic of sheep
Contagious bovine pleuropneumonia
Cutaneous besnoitisis
East Coast fever
Ephemeral fever
Exotic Newcastle disease
Fowl plague
Heartwater
Louping ill
Lumpy skin disease
Nairobi sheep disease
Pox disease of camels, goats and sheep
Pseudofarcy
Rift Valley fever
Rinderpest
Swine Vesicular disease
Teschen disease
Vesicular exanthema
Wesselsbron disease

Free copies of "How to Move Live Pests, Pathogens and Disease Vectors of Plants" are available from APHIS Information Division, USDA, Room 1154, South Building, Washington, D. C. 20250.

FINAL RESULTS OF SURVEY QUESTIONNAIRE

Use biohazard agents	60
Use chemical carcinogenic agents	109
Use both biohazard and chemical carcinogenic agents	28
Use no biohazard or chemical carcinogenic agents	80
Total replies	221

Most of the users of these agents either used the agents routinely, weekly or monthly and a few stored the agents for future intended use. This survey does not include intended future use, as indicated by several researchers.

Biohazard and Carcinogen Usage Questionnaire

Name _____

Location _____

Phone _____

PLEASE CHECK THE BIOLOGIC AND CARCINOGENIC AGENTS PRESENTLY IN USE

I. Classification of Agents[1]

A. Classification of Bacterial Agents

Class I

6 All bacterial agents not included in higher classes according to "Basis for Agent Classifications"

Class 2

3 Actinobacillus - all species except A. mallei, which is in Class 3
4 Arizona hinshawii - all serotypes
3 Bacillus anthracis
3 Bordetella - all species
1 Borrelia recurrentis, B. vincenti
6 Clostridium botulinum, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani
4 Corynebacterium diphtheriae, C. equi, C. haemolyticum, C. pseudotuberculosis, C. pyogenes, C. renale
7 Diplococcus (Streptococcus) pneumoniae
13 Erysipelothrix insidiosa
Escherichia coli - all enteropathogenic serotypes
3 Haemophilus ducreyi, H. influenzae
8 Herellea vaginicola
5 Klebsiella - all species and all serotypes
4 Leptospira interrogans - all serotypes
5 Listeria - all species
6 Mima polymorpha
4 Moraxella - all species
5 Mycobacteria - all species except those listed in Class 3
3 Mycoplasma - all species except Mycoplasma mycoides and Mycoplasma agalactiae, which are in Class 5
3 Neisseria gonorrhoeae, N. meningitidis
5 Pasteurella - all species except those listed in Class 3
11 Salmonella - all species and all serotypes
5 Shigella - all species and all serotypes
2 Sphaerophorus necrophorus
13 Staphylococcus aureus
1 Streptobacillus moniliformis
7 Streptococcus pyogenes
3 Treponema carateum, T. pallidum, and T. pertenue
4 Vibrio fetus, V. comma, including biotype El Tor, and V. parahemolyticus

Class 3

Actinobacillus mallei*
1 Bartonella - all species
3 Brucella - all species
1 Francisella tularensis
4 Mycobacterium avium, M. bovis, M. tuberculosis
1 Pasteurella multocida type B ("buffalo" and other foreign virulent strains*)
Pseudomonas pseudomallei*
1 Yersenia pestis

*USDA permit also required for import or interstate transport.

[1] From "Classification of Etiologic Agents On the Basis of Hazard" 1974 (4th Edition) USPHS, PHS.

B. Classification of Fungal Agents

Class 1

7 All fungal agents not included in higher classes according to "Basis for Agent Classifications."

Class 2

6 Actinomycetes (including Nocardia species and Actinomyces species and Arachnia propionica)
3 Blastomyces dermatitidis
3 Cryptococcus neoformans
1 Paracoccidioides brasiliensis

Class 3

3 Coccidioides immitis
3 Histoplasma capsulatum
2 Histoplasma capsulatum var. duboisii

C. Classification of Parasitic Agents

Class 1

All parasitic agents not included in higher classes according to "Basis for Agent Classification."

1 Toxoplasma gondii
3 Toxocara canis
2 Trichinella spiralis
2 Trypanosoma cruzi

Class 2

1 Endamoeba histolytica
3 Leishmania sp.
1 Naegleria gruberi

Class 3

2 Schistosoma mansoni

D. Classification of Viral, Rickettsial, and Chlamydial Agents

Class 1

Class 1 includes all viral, rickettsial, and chlamydial agents not included in higher classes according to "Basis for Agent Classification."
Specifically listed are:
2 Influenza virus A/PR8/34
2 Newcastle virus - strains licensed for vaccine use in U.S.
1 Parainfluenza virus 3, SF4 Strain

(These viruses are included because the Committee agreed that they are suitable for science experiments at a junior level.)

1 Mengo Virus

Class 2

1 Adenoviruses - human - all types
Cache Valley virus
1 Coxsackie A and B viruses
1 Cytomegaloviruses
1 Echoviruses - all types
2 Encephalomyocarditis virus (EMC)
Flanders virus
Hart Park virus
4 Hepatitis-associated antigen material
5 Herpes viruses - except Herpesvirus simiae (Monkey B virus) which is in Class 4
2 Corona viruses
3 Influenza viruses - all types except A/PR8/34, which is in Class 1
Langat virus
1 Lymphogranuloma venereum agent
3 Measles virus

Class 2 (con't.)

___ Mumps virus
2 Parainfluenza viruses - all types except Parainfluenza virus 3, SF4 Strain, which is in Class 1
3 Polioviruses - all types, wild and attenuated
1 Poxviruses - all types except Alastrim, Smallpox, Monkey pox, and Whitepox, which, depending on experiments, are in Class 3 or 4
1 Rabies virus - all strains except Rabies street virus, which should be classified in Class 3 when inoculated into carnivores
2 Reoviruses - all types
1 Respiratory syncytial virus
1 Rhinoviruses - all types
___ Rubella virus
1 Simian viruses - all types except Herpesvirus simiae (Monkey B virus) and Marburg virus, which are in Class 4
1 Sindbis virus
___ Tensaw virus
___ Turlock virus
1 Vaccinia virus
___ Varicella virus
___ Vole rickettsia
___ Yellow fever virus, 17D vaccine strain

Class 3

___ Alastrim, Smallpox, Monkey pox, and Whitepox, when used in vitro
2 Arboviruses - all strains except those in Class 2 and 4 (Arboviruses indigenous to the U.S. are in Class 3, except those listed in Class 2. West Nile and Semliki Forest viruses may be classified up or down, depending on the conditions of use and geographical location of the laboratory.)
___ Dengue virus, when used for transmission or animal inoculation experiments
___ Lymphocytic choriomeningitis virus (LCM)
2 Psittacosis-Ornithosis-Trachoma group of agents
___ Rabies street virus, when used in inoculations of carnivores (see Class 2)
___ Rickettsia - all species except Vole rickettsia when used for transmission or animal inoculation experiments
2 Vesicular stomatitis virus*
___ Yellow fever virus - wild, when used in vitro

Class 4

___ Alastrim, Smallpox, Monkey pox, and Whitepox, when used for transmission or animal inoculation experiments
___ Hemorrhagic fever agents, including Crimean hemorrhagic fever (Congo), Junin, and Machupo viruses, and others as yet undefined
___ Herpesvirus simiae (Monkey B virus)
___ Lassa virus
___ Marburg virus
___ Tick-borne encephalitis virus complex, including Russian spring-summer encephalitis, Kyasanur forest disease, Omsk hemorrhagic fever, and Central European encephalitis viruses
___ Venezuelan equine encephalitis virus, epidemic strains, when used for transmission or animal inoculation experiments
___ Yellow fever virus - wild, when used for transmission or ainmal inoculation experiments

II. Oncogenic Viruses

A. Low Risk

2 Adenovirus
7 Rous Sarcoma
6 Murine Leukemia
1 Bovine Leukemia
2 Polyoma
4 Simian - 40
1 Human Wart Virus
1 Lucke' Tumor Virus-Frog

B. Moderate Risk

1. RNA Tumor Viruses
___ Feline Sarcoma & Leukemia
2 Woolly Monkey Fibrosarcoma
___ Gibbon Ape Lymphosarcoma

2. DNA Viruses
___ Herpesvirus Saimiri
___ Herpesvirus ateles
___ Yabapox virus
1 Epstein-Barr Virus
___ Non-defective Adeno 2, SV-40 Hybrids

3. RNA and/or DNA virus isolates from man with possible oncogenic potential

C. 2 Other Viruses

III. Tissue Culture Use

	Current	Storage	Future
1. Human	14	15	15
2. Non-Human Primate	4	2	4
3. Mouse	10	11	10
4. Rat	4	3	1
5. Hampster	2	2	1
6. Rabbit	1	0	1
7. Guinea Pig	1	0	0

IV. List of Potentially Carcinogenic and Otherwise Hazardous Chemicals

Group 1. Nitroso Compounds

2 N-Nitrosodimethylamine (DOL)*
5 N-nitrosoguanadine
2 N-nitrosodiethylamine
3 Ethyl Nitrosourea
6 Methyl Nitrosourea
N-Nitrosodibutylamine
Methyl nitroso urethane
N-nitrosopiperidine
4 N-methyl, Nitroso guanadine
1,4 dinitrosopiperazine
15 Diazomethane

Group II.

8 Dimethylbenzanthracene
3 Benzo(a)pyrene
7 Methylcholanthrene
5 Beta propiolactone (DOL)
1 2-Acetylaminofluorene (DOL)
5 4-Dimethylaminoazobenzene (DOL)
3 Beta naphthylamine (DOL)
14 Benzidine (DOL)
4 3,3'Dichlorobenzidine and Salts (DOL)
1 o-Tolidine
4 Aflatoxin (U. Wash.)
3 Ethyl Methane Sulfonate
7 Urethane
3 Ethylenimine (DOL)
2 Methylchloromethyl ether (DOL)
1 4-Nitrobiphenyl (DOL)
Procarbazine
1 Nitroquinolineoxyide
2 Benzanthracene
55 Dioxane
2 Propylenimine
4-Aminodiphenyl (DOL)
4,4'Methylene bis (2-chloroaniline)(DOL)
22 Hydrazine
4 1,2-Dibromoethane
1 m-toluene diamine
72 Carbon Tetrachloride
bis-Chloromethyl ether
11 alpha-Naphthylamine
15 Other suspected chemical carcinogens

*DOL - Department of Labor Carcinogen List

80 I do not use or intend to use biohazards or carcinogenic materials.

Hazard Assessment (Judgment of Investigator)

V. Carcinogens	Low	Moderate	High	Does not Apply
Health Hazard (toxic & pharmacologic effects)	65	5	4	10
Physical Hazard (reactivity, stability, flammability, etc.)	52	11	3	12

Potentially Hazardous Operations	Low	Moderate	High	Does not Apply
1. Weighing	43	3	4	20
2. Mixing	36	10	5	14
3. Treatment of animals	24	5	2	29
4. Analytical procedures	39	7	1	18
5. Synthesis procedures	22	3	1	30
6. Other (specify) Killing Jar (Insects)				
Cutting epoxy resins				8
Aerosil (S_1O_2)				
Processing of tissue				
Histochemical staining				

VI. Biohazards

Processing of clinical specimen	35	4	1	27
Use of laboratory animals	36	4	1	23
Processing of animal materials	36	3	1	23
Use of cell or organ culture	28	1		28
Concentration of microbial agent	19	3		33
Production of microbial agent in quantity	14	4		32
Aerosol transmission	15	5		30
DNA recombination experiments	4	1		42

Disposal procedures for biohazardous material and/or chemical carcinogens:

Comments:

D R A F T

May 12, 1976

TO: Biohazard Advisory Committee

FROM: Patrick J. Manning, D.V.M.

SUBJECT: Safety Procedures for Use of Animals that Have Received Biohazardous Materials

Introduction. Procedures designed to prevent exposure to or transmission of biohazards from laboratory animals to human beings must take into account both naturally occurring diseases of laboratory animals transmissible to man and experimentally induced diseases which may be harmful to man. The ultimate responsibility for reducing or eliminating such risks lies with the principal investigator. Well-trained, properly informed employees represent the best defense against exposure to biohazards. A carefully conceived animal care program and properly designed and used animal facilities are also necessary to reduce biohazard exposure. The problem is extensive and complex; and precise, definitive procedures that encompass all potential exposure possibilities are not possible, but the reader should find the following guidelines of assistance in establishing policies for their laboratories.

Animal Procurement. Parties responsible for the procurement of laboratory animals must be familiar with zoonotic diseases common to the animal species and/or facility from which they originate. To that end diagnostic facilities should be available to periodically survey incoming animals for the presence of diseases transmissible from animals to man. Specific examples would include tapeworm infections of hamsters, such as Hymenolepis nana; ascarid infection of dogs and cats (larva migrans infection in man); ectoparasite infestation of dogs and cats; dermatomycoses of many species of laboratory animals; salmonellosis; shigellosis; tuberculosis; B virus; hepatitis virus; and endoparasite infections of nonhuman primates among numerous other zoonoses. Animals that arrive overtly ill, or become ill shortly after arrival, should be thoroughly examined and, if deemed necessary, complete necropsies should be done to aid in arrival at a definitive diagnosis. Animals with zoonotic diseases present a biohazard to all personnel in direct contact with them and as such are unsuitable for research. Vendors supplying such animals should be notified and appropriate procedures taken to prevent further recurrence of the disease.

Animals in Residence. Laboratory animals are often housed under high population density conditions in the laboratory, which is often conducive to the spread of infectious diseases. Additionally many such facilities have a higher than normal vermin population, and many such insects serve as vectors for various infectious agents. To reduce the risk of exposure to infectious agents, some of which are known to be transmissible to man, the design and use of the facility must minimize such hazards. To those ends the walls, floors and ceilings of such rooms should be constructed of impervious materials, such as sealed concrete, epoxy-coated concrete or cement, ceramic tile or quarry tile. The floor/wall and wall/ceiling junctions should be coved. Lighting should be fluorescent and provide at least 85 lumens per foot candles of light at waist level to discourage vermin; automatic timers are desirable. Floor drains should be disinfected daily and, if not in use, should be sealed with a metal cover and paraffin wax or other suitable sealant. Electrical outlets should be waterproof as must all electrical fixtures. There should be no exposed utility fixtures other than faucets and electrical outlets. Animal rooms should contain no cabinet work, shelves, or other paraphernalia. If a working surface is provided, it should be adjacent to a sink and be constructed of stainless steel with a marine edge and preferably attached to the wall with no supports extending to the floor.

Conventional Laboratory Animal Housing. Metal cages and racks should be of stainless steel with heliarc welded corners and no burrs or sharp corners. Cages should have barred doors and solid metal sides with perforations of various sizes (dpending upon species) to allow for ventilation. Floors may be mesh or flattened tubular steel. Waste pans should be constructed of stainless steel. Animals should be clearly visible in such cages. When plastic (shoebox) cages are used, clear polycarbonate plastic is preferred and cage lids should be of stainless steel and provide a food hopper and water bottle receptacle. In the event that automatic watering systems are used, care must be taken to be sure that they do not become contaminated with infectious agents.

Husbandry. Animal care routines which reflect the needs of the animal facility should be strictly adhered to by all personnel using or caring for the

animals. Personnel handling animals should wear disposable gloves. When known infectious agents or carcinogens have been given to the animal, a face mask, and in some instances a gown, should also be worn. On an enclosed supplemental sheet, a protocol for handling animals inoculated with various infectious agents provides further information for handling biohazardous material. Animals given infectious agents or carcinogens considered particularly hazardous should be housed separate and distinct from other animals, preferably in limited access rooms on a separate ventilation system. Animal room doors, as well as individual cages, should be conspicuously identified as to the agent used, date of exposure, names of the investigator and responsible technicians and their telephone number. Secretions and excretions of the animals so inoculated should be handled as infected animal carcasses.

Special Animal Housing and Biohazard Containment Facilities. When small numbers of animals receive biohazardous agents or compounds, it may be preferable to house them in a sealed biohazard enclosure such as a hood. When large numbers of animals are used, it would be appropriate to consider the use of laminar flow systems to reduce pathogens or to house animals behind specific barriers, such a filter top cages, laminar flow racks, or germfree housing conditions. In all these systems, the effectiveness of the barrier is determined by its design and the personnel using them and, as a consequence, employee education is of paramount importance.

Transfer of Animals. Extreme care must be taken in transferring animals from biohazard animal rooms to laboratories or other facilities. Personnel should be properly masked, gloved and gowned; and transport equipment must be sanitized or sterilized immediately after transport.

Animal Autopsy Facility. Animals exposed to various biohazards are often submitted for necropsy or necropsied by principal investigators or their technical staff. Necropsy rooms are generally multipurpose facilities, and extreme care must be taken to guard against contamination of these facilities. To that end, the prosector should be masked, gloved and gowned. The necropsy table should be of stainless steel and have suitable flushing devices, and appropriate disinfectants

should be on hand to completely and thoroughly disinfect all instruments and working surfaces that come into contact with animal tissues. Both animal rooms and necropsy room should regularly be surveyed microbiologically to determine the effectiveness of preventive sanitation and disinfectant procedures.

Cadaver Disposal. All animals that receive biohazardous agents and subsequently die should be placed in appropriate containers (at our University these containers are red plastic bags) and properly identified as to species, nature of biohazard, date, dose of biohazard, principal investigator and telephone number. If the animal has been inoculated with infectious agents, the carcass should be autoclaved at 250° F. for ~~40~~ 30 minutes. Final disposition of the carcass is usually by incineration.

Enclosure with Safety Procedures - Biohazards

UNIVERSITY OF MINNESOTA
TWIN CITIES

Research Animal Resources
Unit of Comparative Medicine
Box 351 Mayo Memorial Building
Minneapolis, Minnesota 55455
(612) 376-5097

February 3, 1976

TO: Animal Care Technicians

FROM: Patrick J. Manning, D.V.M.

SUBJECT: Procedure for Care of Infectious Disease Room

1. This room is to be kept locked at all times.

2. Put on disposable gloves, mask, and shoe covers before entering room and dispose of them in autoclavable bags just before leaving room.

3. All animal cages in this room are to be covered with a filter bonnet.

4. General care of room including replenishing food and water but excluding changing of animals from soiled to clean cages:

   a. Countertops and floors are to be disinfected daily.

      (1) Mop the floors with a disinfectant solution and rinse with clear, clean water. Contaminated disinfectant solution should be discarded in the room floor drain. Fill bucket with fresh clean water and rinse floors with damp mop. Clean countertop with disinfectant solution.

   b. Check food and water supply in each cage. Replenish either only when necessary. Do not attend to animals in cages with red cards. When water needs replenishing change entire bottle and autoclave old bottles. Attend to only one cage at a time - no more than one cage at a time is to have its filter bonnet removed. Change gloves between animals on different experiments.

   c. When leaving room discard gloves, mask and footwear in autoclavable plastic bags.

5. Care of animals in room.

   a. Assemble clean cages with bedding, food and water bottles in central supply area and bring items to room on a cart.

   b. Put on gloves, mask and disposable footwear and enter room.

   c. Change one cage at a time by removing filter from soiled cage, removing animals from cage and placing them in clean cage, replace old filter on soiled cage and put new filter on clean cage that has clean water, food and bedding. Store soiled cages and filters on a separate cart.

d. Cages with red cards are not to be handled at all.

e. Care for animals on one experiment and then change gloves before handling animals on another experiment.

f. When all animals have been transferred from soiled to clean cages, leave room after removing footwear, mask and gloves.

g. Put on new mask and gloves and transport soiled cages to autoclave and sterilize each cage with filter, water bottle and bedding at 250° F. for 30 minutes. Any cages that cannot be immediately autoclaved are to be stored in the infectious disease room and not in the autoclave room.

6. Handling of contaminated disposable clothing and dead animals.

a. Dead animals - animals in cages with red cards are not to be handled at any time. When you see a dead animal in these cages, contact the ~~office (Phyllis)~~ Animal Control Office who will in turn contact the investigator. Animals in cages that do not have red cards should be removed (be sure you are wearing disposable footwear, mask and gloves) and put into autoclavable plastic bags - these bags will be marked and stored in the room. Contact the office as to which animals were found dead, and the office will contact the investigator - leave animals in autoclavable bags in the infectious disease room. If requested by the investigator or your supervisor, these animals may then be autoclaved at 250° F. for 30 minutes. After autoclaving, animals may be discarded in the usual manner.

b. Contaminated disposable clothing (gloves, masks, and footwear) - these items are stored in the room in autoclavable plastic bags and, when other items are being autoclaved, these items should be autoclaved with other contaminated materials, such as animals or cage filter housing units.

7. Handling of cage filter units that have been autoclaved.

After these items have been sterilized, remove them from the autoclave and save the filters. Discard the bedding, food, and water in the cage washer room and send the cages, cage tops and water bottles through the cage or bottle washer for routine processing. Store the sterile filter tops in the storage room for future use.

Remember to always put on mask, gloves and footwear when entering the room and to remove these items when leaving the room. Also never handle cages prior to putting them in the autoclave unless you are wearing disposable gloves and a mask.

All carts, mop buckets and similar cleaning utensils are to be washed in the cage and rack washer every time they are used in the infectious disease room.

After servicing this room and removing gloves, wash your hands thoroughly with soap and water.

Enclosure with Safety Procedures - Biohazards

UNIVERSITY OF MINNESOTA
TWIN CITIES

Research Animal Resources
Unit of Comparative Medicine
Box 351 Mayo Memorial Building
Minneapolis, Minnesota 55455
(612) 376-5097

February 3, 1976

Procedure for Care of the Infectious Disease Room

Responsibility of the Investigator

1. Mark with a RED card cages you consider too infectious to be opened. Animals in these cages will not be fed or changed, and dead animals will not be removed.

2. On each cage card supply the following information:
   a. Pertinent animal identification - species, sex, age, number, etc.
   b. Infectious agent
   c. Person to be called for problem and his department and telephone number.

3. In the room leave the phone numbers of the people to be contacted for problems.

4. At the completion of the experiment, animals will be disposed of by the investigator. Place dead animals in sealed autoclave bags and have autoclaved for ~~1 hour~~ 30 min at 250° F.

Biohazard Advisory Committee Meeting

Monday, June 14, 1976

Meeting Convened: 1:40 p.m.

Present: A. Elliott, chairman, R. Anderson, G. Ederer, S. Katzmark (for P. Manning), S. Marker (for H. Balfour), L. Solomon, L. Wattenberg, W. Jopke, ex-officio

Absent: M. Hannon, L. Henderson, H. Jenkin, P. Maupin

Dr. Marker and Professor Ederer reviewed Dr. Jenkin's letter and included several changes into the section on microbiology.

In the review of Dr. Manning's section on Animal Care, a question was brought up as to whether 250° F. for 30 minutes was an adequate time and temperature for autoclaving animal carcasses before disposal. It was felt that such a short period of time would not take care of all biohazardous agents. It was mentioned that possibly time per weight might be a more appropriate measurement. This was in comparison to NIH that advises 8 hours at 250° for large animals.

When writing the final draft, it was recommended that a great responsibility be placed on the principle investigator, for health and safety matters.

A University-wide procedure for the disposal of potentially hazardous waste (effective June 15) was reported by Walter Jopke. Mr. Erland Brager (Env. Hlth. & Safety) will do the follow-up on this procedure and he should be contacted if questions arise.

Next Meeting:

September 13, 1976, 1:30 p.m., Room N101 Boynton Health Service

Agenda:

1. Review the first draft of the chemical carcinogen and biohazard safety manual.

2. Review the eight charges (November, 1975) to the Committee and consider new developments of chemical carcinogen and biohazard nature. For instance, where do we place DNA recombinants?

Meeting Adjourned: 2:15 p.m.

Minutes Taken: P. Caryl

Biohazard Advisory Committee

Monday, September 13, 1976

Meeting Convened: 1:40 p.m.

Present: A. Elliott, G. Ederer, L. Henderson, P. Manning, I. Rubinstein, W. Jopke, ex-officio

R. DeRoos, J. Krober, B. Spielman, F. Thompson, staff

Absent: R. Anderson, H. Balfour, M. Hannon, H. Jenkin, P. Maupin, L. Solomon, L. Wattenberg

Dr. Irwin Rubinstein of the College of Biological Sciences was introduced to the committee. Dr. Rubinstein is involved with the recombinant DNA research and will assist the committee in that regard.

Other introductions were staff: Ms. Janet Krober, who will assist with the development of the biohazard manual and Mr. Robert Spielman, who will be serving in an advisory capacity to the committee relative to chemical carcinogens.

It was suggested, in view of the fact that the guidelines for recombinant DNA research require a permanent institutional biohazard committee, that the present committee function in that capacity. In later discussion it was recommended that members will be contacted individually with regard to their willingness to serve on a permanent biohazard committee.

Professor Jopke reviewed progress on the biohazards control manual. One of the items of discussion was the title of the manual. It was decided that the title should be "Biohazards Control Policy and Procedures Manual." At this point in the discussion and in later discussion it was decided that this manual should include a section on recombinant DNA research, however, there was a general reluctance to print all of the material which is in the NIH guidelines. It was suggested that a general abstract of the guidelines be included in the biohazards policy and procedures manual, and that the NIH guidelines be referenced.

The remainder of the meeting consisted of a review of the charge to the committee. The following is a point-by-point review of that discussion (The order of the list being the same as the order of the list in the charge):

1. Matters related to the medical surveillance program are covered in the policy and procedures manual.

2. The Department of Environmental Health and Safety, with technical advice from the Biohazards Committee, will be responsible for consultation relating to, and monitoring of physical environment. It was emphasized, however, that it is the primary responsibility of the principal investigator to assure that policies regarding operations and physical facilities are met.

3. The proposed policy and procedure manual addresses the question of the required physical facilities and equipment for handling various risk catagories of biological agents and chemical carcinogens.

4. Data needs to be maintained in some central location on what biohazardous agents and chemical carcinogens are being used by what investigators (agent registry). Also there should be on file data regarding physical facilities and medical monitoring. This data will be maintained in the files of the Department of Environmental Health and Safety, and the University's appropriate Occupational Health Service.

5. The principal investigator should assure that persons working in the laboratory where there are biohazardous or chemical carcinogenic agents are adequately trained in regard to safety procedures. The possibility of a training program similar to that used in radiation protection, was discussed. When personnel begin work with a biohazardous agent or chemical carcinogen, they would be required to view video tapes pertaining to safety procedures in the laboratory. Efforts are beginning with the development of a series of these tapes for biohazards control at the University.

6. There was considerable discussion about matters relating to the enforcement of policies related to biohazard control and control of chemical carcinogens. It is anticipated, that in most instances, consultation relative to the policies and procedures containted in the "Biohazard Control Policy and Procedures Manual: would solve whatever safety hazards might exist. If there is an instance where there is a difference of opinion regarding a safety hazard, this could be brought to the Biohazard Committee for review. It would only be in the case of a very last resort that additional enforcement policies would be sought.

7. The Committee expressed a great deal of reluctance toward the idea of reviewing each proposal for safety procedures relating to biohazards control and chemical carcinogens. However it was noted that this would be necessary for recombinant DNA research, and it was suggested that there would probably need to be additional consultation with outside technical resources prior to submitting a committee decision.

The Office of Research Administration should be asked, in the revision of their form BA 23, to include questions about use of biohazardous agents and chemical carcinogens. Where these agents are used, the Department of Environmental Health and Safety would review the research proposal to be sure that adequate safety procedures and physical facilities will be available for conduct of the research. Only for recombinant DNA research would it be necessary that the proposal be reviewed by the Biohazards Committee prior to submission. In most cases, a technical review by the Department of Environmental Health and Safety with recommendations to the principal investigator would be sufficient. If in the Department of Environmental Health and Safety review it is found that there are unusually hazardous agents, or unusually hazardous conditions, the Biohazards Committee would be consulted for their advice. At least annually, the Biohazards Committee would review the proposal review process of the Department of Environmental Health and Safety.

CHARGE TO THE BIOHAZARD ADVISORY COMMITTEE

The problems of accidental infectious disease transmission have existed for many years, however, only within the last fifteen years have there been attempts to document numbers of laboratory-acquired infections. Also, recent developments in biomedical research have focused attention on the biohazard problem in laboratories. These have included the intensive studies of diseases with unknown etiologies (such as the search for oncogenic viruses), research on recombinant DNA molecules, and studies on exotic diseases entering the United States from other countries. Recently, the use of chemical carcinogens in laboratories has also come under closer scrutiny, often being considered along with the problems associated with biohazard control.

Also, there have been laws enacted at the federal and state levels which have created the need for attention to biohazard control. These include requirements of the Occupational Safety and Health Act, the National Environmental Policy Act, and, although not in the form of law, recommendations of the National Cancer Institute for Biohazard Programs for those research institutions with extramural cancer contracts.

The purpose of the Biohazard Advisory Committee will be to define the necessary steps which need to be taken within the University to prevent laboratory-acquired infections resulting from research involving hazardous and potentially hazardous microbial agents, and to define the necessary steps which need to be taken within the University to safely use chemical carcinogenic agents in laboratories. In carrying out this charge the committee should give consideration to the need for, the extent of and the procedures for implementation of:

1. A medical surveillance program.

2. A program to provide the necessary consultation relating to and monitoring of the physical environment (the monitoring to see that policies regarding operations and physical facilities are met).

3. Establishment of policies relating to the required physical facilities and equipment for handling various risk categories of biological agents and carcinogens.

4. The necessary data which should be maintained and guidelines for management of the data base for the program (e.g. agent registry, personnel data, equipment data, proposal monitoring, etc.).

5. Guidelines for the amount of training for persons who are handling various risk categories of biological agents and carcinogenic agents.

6. Procedures which need to be established for enforcement of policies related to biohazard control.

7. Procedures which need to be established to meet the need for research proposal review prior to submission.

8. Steps which need to be taken to provide for review and update of policies on a continuing basis.

Biohazard Advisory Committee

Monday, October 11, 1976

Meeting Convened: 1:40 p.m.

Present: A. Elliot, R. Anderson, G. Ederer, S. Marker, B. Powitz, I. Rubinstein, L. Wattenberg, W. Jopke, ex-officio

R. DeRoos, B. Spielman, staff

Introduction of Robert Powitz, who is replacing Larry Solomon on the committee.

Dr. Rubinstein briefly reviewed Part III of the NIH Recombinant DNA Research Guidelines, which included a NIH Environmental Impact Statement.

An abstract of the NIH Recombinant DNA Guidelines prepared by Janet Krober, was discussed in detail. This abstract of policies will be included in the Biohazards Manual. Questions on ethics, confidentiality, appeal process, and legal implications were covered. Additional revisions were made. Each member was asked to further review the abstract with final approval at next meeting. The question also arose concerning the process for informing the researcher of the Biohazards Committee and necessary approval process. It was stated that notification should be given by the Health and Safety Coordinators, Health and Safety Bulletin, letters to investigators.

Walter Jopke was asked to correspond with researchers at the University of Wisconsin and provide information to the University Attorney for interpretation of legal responsibility of the Committee and the appeal process.

Mr. Spielman reported on the progress being made with the chemical carcinogen manual and that it will be presented to the Committee as soon as it is approved by Drs. Wattenberg and Henderson.

Dr. Rubinstein felt another member was needed regarding DNA. Dr. Anderson felt that instead of another member, consultants could be used. After further disscussion, it was determined that the committee at the present time should remain as is, and use consultants to the committee when needed.

Meeting Adjourned: 2:45 p.m.

Next Meeting, Monday, November 8, 1976, at 1:30 p.m.

Minutes Taken: P. Caryl

Biohazard Committee
Policies Relating To
Recombinant DNA Research

Any recombinant DNA research supported by funding from the National Institutes of Health must comply with the guidelines published in the July 17, 1976 Federal Register and any updates issued by the National Institutes of Health. The guidelines will be considered as minimum requirements for recombinant DNA research conducted with or without NIH support at the University of Minnesota.

The responsibility for ensuring that research procedures and facilities comply with the guidelines is that of the principal investigator. Thus it is expected that any scientist working with genetic recombinants will familiarize her/himself with the document. In addition, however, the University has certain institutional responsibilities for ensuring the safe conduct of recombinant DNA research. The permanent Biohazard Committee as it pertains to recombinant DNA research, will function as follows:

1. To establish, review, and revise guidelines under which research involving recombinant DNA is conducted at the University of Minnesota.

2. To review all proposed recombinant DNA research, funded, or non-funded, in order to determine whether such research meets established guidelines.

3. To review periodically all ongoing recombinant DNA research to ensure that the guidelines continue to be met.

4. To advise the University of Minnesota about programs and facilities that may be necessary to establish and maintain conditions that conform to the established guidelines.

5. To maintain close and continuous association with the Department of Environmental Health and Safety, while relying on their staff for consultation, monitoring, record keeping, and training.

6. To approve or disapprove research involving recombinant DNA, taking into account matters related to biologic and ecologic of the proposed research. There will be an appeal process for proposals which are denied approval. Where the need arises for additional expert opinion, the Biohazard Committee will consult with individuals outside the committee. The person being consulted would be advised that the basic ideas of research are confidential. In cases where there are ethical concerns, the Biohazard Committee will consult with one of the Health Science panels of the Human Subjects Committee.

CHAPTER I

RECOMMENDATIONS

1. A permanent Recombinant DNA Research Committee should be appointed without delay in order to facilitate scientific research in a newly developing field in compliance with requirements of the National Institutes of Health and at the same time to assure that potential hazards of this endeavor are controlled.

2. The jurisdiction of the Committee should be University-wide and with delegated authority to carry out its responsibilities.

3. Initially, the membership of the Committee should include:

   a. Representation from each department conducting recombinant DNA research.

   b. Non-scientist representation from the History, Philosophy or similar "non-science" department.

   c. Governmental representation from outside the University (state, county or city officials).

   d. Representation from technical staff assisting with recombinant DNA research (e.g. senior laboratory technician).

   e. Representation from ASUW and GPSS.

   f. A clinical Microbiologist.

   g. Representation from the Attorney General's Division (ex-officio member).

   h. Representation from Environmental Health and Safety (ex-officio member).

4. The functions and responsibilities of the permanent Recombinant DNA Committee should be:

   a. To establish, review, and revise guidelines under which research involving recombinant DNA is carried out at the University of Washington; these guidelines to include such considerations as scientific value and appropriateness, socio-ethical ramifications and environmental impact. The NIH guidelines are to be considered minimum standards; guidelines adopted by the University of Washington may be more stringent. Meetings of this committee dealing with policy making matters should be open to the public.

   b. To review all proposed research on recombinant DNA at the University of Washington, regardless of funding source, in order to determine whether such proposals meet the established guidelines.

c. To approve or disapprove any proposal involving recombinant DNA, weighing the potential benefits of each project against the probable risk.

d. To periodically review all ongoing recombinant DNA research to ensure its conformity to established guidelines and to approve or disapprove its continuance on the basis of the review findings.

e. To advise the University of Washington with respect to such programs and facilities as are necessary to establish and maintain conditions that conform to the established guidelines.

f. To maintain close and continuous liaison with the Biohazard Safety Advisory Committee through the representative from Environmental Health and Safety Department.

5. An appeal process should be available to investigators whose proposals are disapproved or whose research is suspended by the Committee.

6. The permanent Recombinant DNA Committee should function within the University organizational structure in a manner essentially similar to the Human Subjects Review Committee. It should be provided similar administrative services, possibly by the existing office supporting the Human Subjects Review Committee.

7. Because this research field is potentially a highly sensitive political, social, and ethical issue, the President of the University and Board of Regents should be informed of these recommendations. They should further be urged to advise relevant governmental agencies and the community at large of these decisions along with the control measures being adopted.

8. Recognizing that some research involving recombinant DNA is already under way, and some additional is being contemplated, it is recommended that interim measures should be adopted immediately pending appointment of the permanent committee. These measures should include:

a. Immediate adoption of the NIH Guidelines as a <u>minimum</u> standard.

b. Charging all such departments that are now, or about to be, involved with such research with responsibility to comply with the NIH Guidelines.

c. Deferral of experiments falling into the P3 and P4 physical containment classification (as defined in the NIH guidelines) until a permanent committee is established.

9. The Environmental Health and Safety Department should be charged with the responsibility of technical staff support for the permanent Committee, surveillance of research activities including consultation and inspection services, maintaining records, verification and classification of research facilities, and establishing courses of instruction on biohazards associated with recombinant DNA research for investigators and staff.

CHAPTER II

BACKGROUND STATEMENT

1. Charge to ad hoc Committee

Because of the potential hazards that accompany research on recombinant DNA molecules and recognizing that the federal government was preparing guidelines concerning recombinant DNA research, the Vice President for Health Affairs appointed the ad hoc Recombinant DNA Committee on June 1, 1976. The Vice President requested the committee to address two major questions, namely, the appropriateness of the University engaging in recombinant DNA research and if it is conducted here, the controls and guidelines that should apply together with recommended procedures for implementing and extending the controls. (Appendix A)

2. Background Materials

Scientists engaged in Recombinant DNA research called for a moratorium in 1974 on certain kinds of experiments until an international meeting could be assembled to consider the potential hazards associated with recombinant DNA molecules. They also called upon the National Institutes of Health (NIH) to establish a committee to provide advice on recombinant DNA technology.

The international meeting was held at the Asilomar Conference Center, Pacific Grove, California in February 1975. The consensus of this meeting was that certain experiments should not be done at the present time, but that most of the work on construction of recombinant DNA molecules should proceed with appropriate physical and biological barriers. The Asilomar Conference Report also made interim assignments of the potential risks associated with different types of experiments. The NIH then assumed the responsibility for translating the broadly based Asilomar recommendation into detailed guidelines.

After extensive scientific and public airing of the issues, the NIH Recombinant DNA Advisory Committee debated the various points of view and developed recommended guidelines.

The NIH Guidelines, which were announced on June 23, 1976 (Appendix), establish carefully controlled conditions for conduct of experiments involving recombinant DNA molecules. These guidelines describe the role and responsibility of the institution. Included is a requirement for the institution to establish an institutional Recombinant DNA Committee with authority to approve or disapprove proposed research either because of the availability of adequate containment facilities or because of scientific appropriateness of the proposal.

CHAPTER III

SUMMARY OF COMMITTEE ACTIVITIES

1. Definition of Problem

Currently on campus, investigators from five departments are either actively engaged in recombinant DNA research or are considering research in this area (Appendix C). Those projects currently in progress are at P1 or P2 levels of physical containment as described in the NIH Guidelines. However, two investigators have proposed projects requiring P3 level physical containment. Several other investigators have informally proposed projects which would involve recombinant DNA molecules at P1 and P2 physical containment levels. Therefore, the ad hoc Committee recommended that a permanent Recombinant DNA Committee be appointed without delay.

2. Function and Responsibility of Permanent Committee

During the deliberation of the ad hoc Committee (Appendix D) suggestions were proposed regarding the function and responsibility of the permanent committee. The ad hoc Committee realized that the permanent committee would in the beginning have to take considerable time in making basic decisions on policies and establishing an administrative mechanism for a review process.

Any project must be reviewed first at the departmental level. Before beginning an activity which involves recombinant DNA, the investigator shall submit the proposal together with any appropriate supporting material to the department chairperson. The chairperson shall transmit the proposal and his recommendations for approval or disapproval through proper channels to the Recombinant DNA Committee. The review process should address the subjects of both safety and ethics of the proposed research.

The permanent committee must have the authority to approve or disapprove any research involving recombinant DNA. An appeal process should be developed for any proposal denied.

The ad hoc Committee discussed the position of the permanent committee within the University structure. It was suggested that the permanent committee function similar to the Human Subjects Review Committee. As a result, the ad hoc Committee chairman met with personnel from the Research Services Office to discuss the operations of the Human Subjects Review Committee. The group agreed that the permanent recombinant DNA committee could be provided similar administrative support, possibly by the same office as the Human Subjects Review Committee.

The major concern during the discussions was the competence and safety consciousness of the principal investigators and technicians. Training and refresher courses will be needed as well as a surveillance program to assure that proper procedures are followed.

The suitability and adequacy of physical containment facilities for recombinant DNA research must also be evaluated (Appendix E). The Committee should function to advise the University regarding the necessity of special facilities for such research.

3. Jurisdiction and Composition

The permanent committee should represent the entire University and not be restricted to the Health Sciences. Therefore, members of the committee would come from any department within the University involved with recombinant DNA research. Non-scientist representation was also recommended in order that ethical and moral considerations could be articulated in broad perspective. The permanent committee should have authority to recommend changes in the composition of the membership from time to time as circumstances dictate.

4. Community Concerns

Discussed at length was the concern about research involving recombinant DNA being a potentially explosive issue. Considerable controversy has taken place on the East Coast regarding such research. To minimize similar conflicts at this University the ad hoc Committee suggested that the President and Board of Regents be informed about the possible consequences of such research. It was advised that the Board of Regents decide as to the proper dissemination of information to appropriate governmental agencies and to the public at large.

To provide for input from outside the University the Committee suggested membership on the permanent committee also include non-University representation, particularly from governmental agencies with responsibility for public health and safety. Meetings of the committee which involve policy making decisions should be open to the public.

Recognizing the potential concerns, approval from the President and Board of Regents for such a committee was considered essential.

5. Technical Standards

The ad hoc Committee reviewed the NIH guidelines and suggested that these guidelines be adopted as the minimal requirements. Some Committee members had reservations about the adequacy of the NIH guidelines. Therefore, the Committee strongly recommended that the first order of business of the permanent committee be to review and, if necessary, develop more stringent local guidelines. Guidelines adopted by the permanent committee must be updated consonant with technological advances.

6. Interim Measures

As an interim measure before the permanent committee is appointed and has had sufficient time to develop review procedures, the Committee agreed that

APPENDIX A

University of Washington Correspondence

INTERDEPARTMENTAL

Vice President for Health Affairs
Health Sciences Center

June 1, 1976

To: Dr. Donald R. Peterson, Chairman
Mr. Kimball E. Jones, Secretary
Dr. Charles W. Boddener
GPSS Representative*
Dr. Neal B. Groman
Dr. Benjamin D. Hall
Dr. Charles D. Laird
Dr. Russell Ross
} ad hoc Recombinant DNA Committee

From: J. Thomas Grayston, M.D.
Vice President for Health Affairs

Subject: Appointment of a Committee to Evaluate the University's Needs for Safety Controls for Research on Recombinant DNA Molecules

Because of the potential hazards that accompany research on recombinant DNA molecules, I am asking you to serve on an ad hoc committee to make recommendations to me on this subject. Dr. Donald R. Peterson has agreed to serve as chairman. I am charging the committee to recommend the appropriate course of action for the University to take in this matter. In so doing, would you please address the following questions:

1. Is it appropriate for the University to engage in recombinant DNA research?

2. If recombinant DNA research is to be conducted at the University, what controls and guidelines should apply?

3. What procedures are recommended for implementing and extending these controls?

4. If a permanent committee is recommended, what should be the role, authority and structure of that committee? Consideration must be given to the NIH proposed guidelines and NSF guideline for research involving recombinant DNA molecules in responding to this question.

5. What responsibilities should be assigned the Department of Environmental Health and Safety in implementing and extending the recommended University guidelines and what should be that department's relationship to a permanent committee, if recommended?

Mr. Steve Milam, Assistant Attorney General, has been assigned as Counsel to the Committee and will advise on any legal questions raised during your deliberations.

university of minnesota memo

date Oct. 14, 19 76

to Mr. Walt Jopke

from Patrick J. Manning, D.V.M.

Please distribute to other members of the committee.

PJM/la

S-92050

RESEARCH ANIMAL RESOURCES

The primary role performed by the Research Animal Resources Department, as related to biohazards control, concerns the handling of animals brought to the University for research use. This includes procurement, receipt, distribution, housing, feeding, care, disease prevention, diagnosis and control, and personnel training and personnel health programs. Minimum standards have been established for quarantine, standards for animal maintenance, reporting of illness, and special instructions for employees responsible for care and use of animals. Current minimum standards for handling animals at the University are included in Appendix #___.

DRAFT

UNIVERSITY OF MINNESOTA
TWIN CITIES

Research Animal Resources
Unit of Comparative Medicine
Box 351 Mayo Memorial Building
Minneapolis, Minnesota 55455
(612) 376-5097

October 12, 1976

TO: Biohazard Advisory Committee

FROM: Patrick J. Manning, D.V.M.

SUBJECT: Safety Procedures for Use of Animals that Have Received Infectious or Other Biohazardous Materials

Introduction. Procedures designed to prevent exposure to or transmission of biohazards from laboratory animals to human beings must take into account both naturally occurring diseases of laboratory animals transmissible to man and experimentally induced diseases which may be harmful to man. The ultimate responsibility for reducing or eliminating such risks lies with the principal investigator. Programs for the safe handling and ultimate disposition of potentially contaminated animals and animal wastes must protect the health and well being of the employee, maintain the integrity of the experimental program and minimize the hazard to non-program personnel or animals within adjacent areas. Such programs are based upon an understanding and appreciation of the hazard potential of the work underway and the subsequent selection of procedures, equipment, or facilities needed to minimize or eliminate such risks. ~~Comprehensive reviews of information dealing with biological hazard assessment and/or control can be found in numerous publications, (1), (2), (4), (5), (10), (11).~~ The training of personnel in the fundamentals of animal care and disease control, as well as the implementation of appropriate pre-employment and periodic medical surveillance programs, must also be recognized as necessary prerequisites for program success. A carefully conceived animal care program and properly designed and used animal facilities are also necessary to reduce biohazard exposure. The problems are extensive and complex; and precise, definitive procedures that

encompass all potential exposure possibilities are beyond the scope of this document, but the reader should find the following guidelines of assistance in establishing policies for their laboratories.

PERSONNEL TRAINING.

In addition to basic information relating to the processing and disposition of wastes from normal animals, personnel working with infected animals, contaminated animal wastes, etc., must have an understanding of factors which influence the transmission and control of biohazardous agents carried or harbored by laboratory animals. Established training courses, which provide this type of information, are available from a number of scientific organizations, notably the American Association for Laboratory Animal Science. When dealing with animals harboring biohazards, individuals responsible for personnel training should also provide specific information on the biohazard (virus, bacteria, carcinogen, radioactive isotope, etc.), its host range, the ability of experimentally infected animals to infect non-exposed animals or to excrete the agent in urine or feces, the need for special caging or animal isolation systems, requirements relating to the need to autoclave isolation cages and their contents prior to processing, and the selection and use of appropriate personnel protective equipment for the work underway.

PERSONNEL HEALTH PROGRAMS.

Organizations or agencies conducting biomedical studies with laboratory or domestic animals should provide pre-employment and periodic medical surveillance programs for all employees assigned to animal facilities or having significant contact with animals or potentially contaminated animal wastes.

Preemployment medical examinations should include:

1. Compilation of employee's familial and medical history.
2. Basic physical examination and laboratory tests.
3. Obtaining and storing preplacement blood sera as a diagnostic reference source.
4. Tetanus immunization.
5. TB skin test.

Medical procedures detailed below should also be performed when warranted by potential biohazard of work assignment:

1. Sensitivity tests (skin) for histoplasmosis, blastomycosis, etc.
2. Full-plate chest x-ray for work involving potential exposure to tubercular, fungal, or mycotic agents.
3. Immunization programs appropriate to the animal care activities conducted (i.e. rabies, anthrax, encephaletic diseases, etc.)

Periodic medical surveillance programs are designed to assist in the early recognition of subclinical forms of disease, identify changes in the worker's serological profile or determine if any other changes have occurred in the medical status of employees assigned to high-risk areas or operations. Medical surveillance programs should include an extension of sensitivity, serological, x-ray and other diagnostic or laboratory procedures included in the pre-employment examination. Immunization programs should also be reviewed to assure that they are maintained in an acceptable state.

When funding is available, the physical examination and laboratory tests entailed in the pre-placement medical examination should be repeated annually.

ANIMAL PROCUREMENT.

Parties responsible for the procurement of laboratory animals must be familiar with zoonotic diseases common to the animal species and/or facility

from which they originate. To that end, diagnostic facilities should be available to periodically survey incoming animals for the presence of diseases transmissible from animals to man. Specific examples would include tapeworm infections of hamsters, such as Hymenolepis nana; ascarid infection of dogs and cats (larva migrans infection in man); ectoparasite infestation of dogs and cats; dermatomycoses of many species of laboratory animals; salmonellosis; shigellosis; tuberculosis; B virus; hepatitis virus; and endoparasite infections of nonhuman primates, among numerous other zoonoses. Animals that arrive overtly ill, or become ill shortly after arrival, should be thoroughly examined and, if deemed necessary, complete necropsies should be done to aid in a definitive diagnosis. Animals with zoonotic diseases present a biohazard to all personnel in direct contact with them and, as such, these animals are unsuitable for research. Vendors supplying such animals should be notified and appropriate procedures taken to prevent further recurrence of the disease. Within the University of Minnesota, Research Animal Resources is staffed and equipped to procure animals under conditions of the aforementioned criteria.

ANIMAL FACILITIES.

Laboratory animals are often housed under high population density conditions, which are often conducive to the spread of infectious diseases. Additionally, many such facilities have a higher than normal vermin population, and many insects serve as vectors for various infectious and noninfectious agents. To reduce the risk of exposure to infectious agents, some of which are known to be transmissible to man, the design and use of the facility must minimize such hazards

Animal areas in which biohazards are used should be characterized by:

1. Well-planned room arrangements which facilitate the movement of personnel and materials along a clean to potentially comtaminated area axis.

2. Air locks, ultraviolet chambers or pass-through sterilizers which separate areas having varying biohazard potentials (clean areas vs. contaminated areas).
3. Strategically located change rooms and shower facilities.
4. Steam and gas sterilizers including retorts for the sterilization of contaminated animal cages or containers of animal wastes.
5. Waste treatment systems for sterilization of contaminated liquid wastes.
6. Pathological or Class VI incinerators for the disposal of animal carcasses and other types of contaminated flammable wastes.
7. Refrigeration systems for the temporary storage of contaminated biodegradable wastes.
8. Air handling systems which provide fresh air at a rate of 15 or more changes per hour with no recirculation. Differential air pressure zones to control directional air flow and exhaust air filtration systems.

All surfaces in animal rooms should be constructed of materials which are easily disinfected or sanitized. To those ends, the walls, floors and ceilings of such rooms should be constructed of impervious materials, such as sealed concrete, epoxy-coated concrete or cement, ceramic tile or quarry tile. The floor/wall and wall/ceiling junctions should be coved. Lighting should be fluorescent and provide at least 85 foot candles of light at waist level. Automatic timers are desirable. Floor drains should be disinfected daily and, if not in use, should be sealed with a metal cover and paraffin wax or other suitable sealant. Doors should seal tightly and

and have a seal strip at the bottom. Electrical outlets and electrical fixtures should be waterproof. There should be no exposed utility fixtures other than faucets and electrical outlets. Animal rooms should contain no cabinets, shelves, or other storage items. Support equipment for the animal care staff or investigators, as well as food and bedding, should not be stored in animal rooms. If a working surface is provided, it should be adjacent to a sink and be constructed of stainless steel with a marine edge and preferably attached to the wall with no supports extending to the floor.

CONVENTIONAL LABORATORY ANIMAL HOUSING.

The most suitable metal cages and racks are constructed of stainless steel with heliarc welded corners and no burrs or sharp corners. Cages should have barred doors and solid metal sides with perforations of various sizes (depending upon species) to allow for ventilation. Floors may be mesh or flattened tubular steel. Waste pans should be constructed of stainless steel. Animals should be clearly visible in such cages. When plastic (shoebox) cages are used, clear polycarbonate is preferred; cage lids should be of stainless steel and provide a food hopper and water bottle receptacle. In the event that automatic watering systems are used, care must be taken to be sure that they do not become contaminated with infectious agents. Public laws, as well as Standards and Guidelines of funding agencies, specify minimum space requirements for laboratory animals. This literature is available in the offices of Research Animal Resources.

HUSBANDRY.

Animal care routines which reflect the needs of the animal facility should be strictly adhered to by all personnel using or caring for animals. Personnel handling animals should wear disposable gloves. When known infectious agents or carcinogens have been given to the animal, a face mask, and in some instances a gown, should also be worn. Two enclosed supplemental

sheets describe current protocols for handling animals inoculated with various infectious agents or radioactive compounds and provide further information for handling biohazardous material. Animals given infectious agents or carcinogens should be housed in separate animal rooms, preferably in limited access rooms on a separate ventilation system. Animal room doors, as well as individual cages, should be conspicuously identified as to the agent used, date of exposure, names of the investigator and responsible technicians and their telephone numbers. A "Procedures of Animal Care Manual" is available in the office of Research Animal Resources.

SPECIAL ANIMAL HOUSING AND BIOHAZARD CONTAINMENT FACILITIES.

When small numbers of animals receive biohazardous agents or compounds, it may be appropriate to house them in a sealed biohazard enclosure such as a hood. When large numbers of animals are used, it would be appropriate to consider the use of laminar flow systems to reduce exposure to pathogens or to house animals within specific barriers, such as filter top cages, laminar flow racks, or in germfree housing isolators. In all these systems, the effectiveness of the barrier is determined by its design and the personnel using them and, as a consequence, employee education is of paramount importance.

TRANSFER OF ANIMALS.

Extreme care must be taken in transferring animals from biohazard animal rooms to laboratories or other facilities. Personnel should be properly masked, gloved and gowned; the animals must be in sealed containers (or filter top cages) and transport equipment must be sanitized or sterilized immediately after transport.

ANIMAL AUTOPSY FACILITY.

Animals exposed to various biohazards are often submitted for necropsy or necropsied by investigators or their technical staff. Necropsy rooms are generally multipurpose facilities, and extreme care must be taken to guard

against contamination of these facilities. To that end, the prosector should be masked, gloved and gowned. The necropsy table should be of stainless steel and have suitable flushing devices, and appropriate disinfectants should be used to completely and thoroughly disinfect all instruments and working surfaces that come into contact with animal tissues. Both animal rooms and necropsy rooms should regularly be surveyed microbiologically to determine the effectiveness of preventive sanitation and disinfectant procedures.

WASTE HANDLING PROCEDURES.

Animal waste collection and disposal procedures should be scheduled on a regular and timely basis. When storage of animal wastes is required, the area selected should be physically separated from other storage facilities and free of insects and rodents. Refrigerated storage facilities are recommended when wastes must be held in excess of 4 to 6 hours. The various types of wastes encountered in animal isolation facilities should be segregated at the time of collection to facilitate disposal without rehandling. Subdivision of wastes from animal isolation facilities into the following categories has proven to be helpful.

1. Solid Wastes - Flammable

Flammable wastes, including animal carcasses, feces, bedding, feed, etc., should be collected in a safe and sanitary manner. Isolation cage systems used in the maintenance of animals infected with moderate-to-high-hazard agents should be autoclaved prior to processing. Appropriate work clothing and personnel protective equipment (i.e. rubber gloves, respirators, ventilated suits, etc.) should be worn when collecting and processing wastes from uncaged animals infected with hazardous microorganisms.

Leakproof metal or plastic containers equipped with tight-fitting lids should be used for the collection and transportation of all

animal wastes. The use of disposable plastic waste can liners is recommended. All cans should be identified (handle tags) in a manner which will indicate the area of origin (project-location) and detail the need for special handling (contaminated - to be autoclaved).

When waste containers must be moved through low-hazard areas of the facility (corridors in single corridor animal isolation units), the outer surface should be topically disinfected prior to removal from the room of origin.

Containers of waste which must be autoclaved (250° F/8 hrs. c̄ 15 minutes pre-vacuum of 27 in. Hg. NIH Biohazards Safety Guide) out of animal isolation areas for disposal at a remote cite must bear a converted thermal indicator which indicates that the material has been autoclaved. Personnel responsible for transportation of such material should be instructed to refuse to handle containers which are not tagged or do not satisfy the processing protocol (i.e., contaminated - to be autoclaved).

Flammable wastes from biohazard areas should be disposed of by incineration. Pathological incinerators equipped with mechanical charging devices should be used. Such units should be periodically evaluated to assure compliance with environmental quality standards.

2. Solid Wastes - Nonflammable

Broken glass, metal objects, and other non-flammable wastes should be collected in well-marked waste receptables with tight-fitting lids. Non-flammable wastes should never be mixed with reusable equipment. Containers of non-flammable wastes originating in diseased animal isolation rooms should be topically disinfected before being moved through low-hazard areas (corridors) of the facility and autoclaved prior to removal from the unit. Converted thermal indicators should accompany all such containers to minimize delay in transportation and

processing outside of the unit of origin. Non-flammable solid wastes are generally disposed of by on-station burial or at municipal waste disposal sites.

3. Liquid, Water Soluble or Water Dispersable Wastes

Liquid wastes from diseased animal isolation facilities generally contain infectious material to a greater or lesser degree. When working with agents which are exotic or not endemic within the general laboratory area, as well as agents having significant epidemic or epizootic potential, the need to consider on-station systems for the decontamination of liquid exfluent is essential.

Regardless of the ultimate decision with respect to the need for and type of system selected, the following procedures should be implemented in the handling of potentially contaminated liquid wastes.

a. Appropriate personnel protective equipment, including work clothing, rubber boots, gloves, respirators, and hair covering should be mandatory.

b. Personnel should be trained to recognize and avoid procedures capable of generating hazardous aerosols (high pressure cleaning devices, vigorous sweeping). Push brooms or rubber squeegees should be used to direct liquid wastes to gutters or floor drains.

c. The use of hot water (83° C.), disinfectants, and compatible detergent disinfection solutions, is recommended as a terminal procedure in the cleaning of floors and walls in animal isolation and potentially contaminated waste processing areas.

CADAVER DISPOSAL.

All animals that receive biohazardous agents and subsequently die should be placed in appropriate containers (at our University these containers are red plastic bags) and properly identified as to species, nature of biohazard,

Enclosure with Safety Procedures – Biohazards

UNIVERSITY OF MINNESOTA
TWIN CITIES

Research Animal Resources
Unit of Comparative Medicine
Box 351 Mayo Memorial Building
Minneapolis, Minnesota 55455
(612) 376-5097

February 3, 1976

TO: Animal Care Technicians

FROM: Patrick J. Manning, D.V.M.

SUBJECT: Procedure for Care of Infectious Disease Room

1. This room is to be kept locked at all times.

2. Put on disposable gloves, mask, and shoe covers before entering room and dispose of them in autoclavable bags just before leaving room.

3. All animal cages in this room are to be covered with a filter bonnet.

4. General care of room including replenishing food and water but excluding changing of animals from soiled to clean cages:

   a. Countertops and floors are to be disinfected daily.

      (1) Mop the floors with a disinfectant solution and rinse with clear, clean water. Contaminated disinfectant solution should be discarded in the room floor drain. Fill bucket with fresh clean water and rinse floors with damp mop. Clean countertop with disinfectant solution.

   b. Check food and water supply in each cage. Replenish either only when necessary. Do not attend to animals in cages with red cards. When water needs replenishing change entire bottle and autoclave old bottles. Attend to only one cage at a time – no more than one cage at a time is to have its filter bonnet removed. Change gloves between animals on different experiments.

   c. When leaving room discard gloves, mask and footwear in autoclavable plastic bags.

5. Care of animals in room.

   a. Assemble clean cages with bedding, food and water bottles in central supply area and bring items to room on a cart.

   b. Put on gloves, mask and disposable footwear and enter room.

   c. Change one cage at a time by removing filter from soiled cage, removing animals from cage and placing them in clean cage, replace old filter on soiled cage and put new filter on clean cage that has clean water, food and bedding. Store soiled cages and filters on a separate cart.

d. Cages with red cards are not to be handled at all.

e. Care for animals on one experiment and then change gloves before handling animals on another experiment.

f. When all animals have been transferred from soiled to clean cages, leave room after removing footwear, mask and gloves.

g. Put on new mask and gloves and transport soiled cages to autoclave and sterilize each cage with filter, water bottle and bedding at 250° F. for 30 minutes. Any cages that cannot be immediately autoclaved are to be stored in the infectious disease room and not in the autoclave room.

6. Handling of contaminated disposable clothing and dead animals.

a. Dead animals - animals in cages with red cards are not to be handled at any time. When you see a dead animal in these cages, contact the ~~office (Phyllis)~~ Research Animal Resource office who will in turn contact the investigator. Animals in cages that do not have red cards should be removed (be sure you are wearing disposable footwear, mask and gloves) and put into autoclavable plastic bags - these bags will be marked and stored in the room. Contact the office as to which animals were found dead, and the office will contact the investigator - leave animals in autoclavable bags in the infectious disease room. If requested by the investigator or your supervisor, these animals may then be autoclaved at 250° F. for 30 minutes. After autoclaving, animals may be discarded in the usual manner.

b. Contaminated disposable clothing (gloves, masks, and footwear) - these items are stored in the room in autoclavable plastic bags and, when other items are being autoclaved, these items should be autoclaved with other contaminated materials, such as animals or cage filter housing units.

7. Handling of cage filter units that have been autoclaved.

After these items have been sterilized, remove them from the autoclave and save the filters. Discard the bedding, food, and water in the cage washer room and send the cages, cage tops and water bottles through the cage or bottle washer for routine processing. Store the sterile filter tops in the storage room for future use.

Remember to always put on mask, gloves and footwear when entering the room and to remove these items when leaving the room. Also never handle cages prior to putting them in the autoclave unless you are wearing disposable gloves and a mask.

All carts, mop buckets and similar cleaning utensils are to be washed in the cage and rack washer every time they are used in the infectious disease room.

After servicing this room and removing gloves, wash your hands thoroughly with soap and water.

Enclosure with Safety Procedures - Biohazards

UNIVERSITY OF MINNESOTA
TWIN CITIES

Research Animal Resources
Unit of Comparative Medicine
Box 351 Mayo Memorial Building
Minneapolis, Minnesota 55455
(612) 376-5097

February 3, 1976

Procedure for Care of the Infectious Disease Room

Responsibility of the Investigator

1. Mark with a RED card cages you consider too infectious to be opened. Animals in these cages will not be fed or changed, and dead animals will not be removed.
2. On each cage card supply the following information:
   a. Pertinent animal identification - species, sex, age, number, etc.
   b. Infectious agent
   c. Person to be called for problem and his department and telephone number.
3. In the room leave the phone numbers of the people to be contacted for problems.
4. At the completion of the experiment, animals will be disposed of by the investigator. Place dead animals in sealed autoclave bags and have autoclaved for ~~1 hour~~ 30 min at 250° F.

Jerry Steiger

Radiation Protection Service
Division of Environmental Health and Safety
University Health Service
University of Minnesota
Minneapolis, Minnesota 55455

For information on Radiation Protection call 373-3167

In case of Radiation Emergency dial "0" OPERATOR

Radiation Protection Instructions for Animal Caretakers

1. The animal care supervisor or attendant must be informed and advised when animals under his care contain radioisotopes. This is the responsibility of the approved radioisotope user who is the director of the research project.

2. Cages or cage cards must be posted with an approved University of Minnesota "Caution Radioactive Material" sign, or "Radiation Area" sign as needed.

3. Radiation surveys must be made around the cages to determine levels of external radiation. If the Approved User cannot provide these surveys, contact the Radiation Protection Officer (RPO). A contamination survey must be made of all cage facilities following use.

4. Animals that have been irradiated by x-ray or external radiation from sealed sources of gamma rays, will not present a radiation hazard.

5. If the radioisotopes will be excreted in the urine or feces, absorbent material in a tray must be provided below each cage. The absorbent material must be changed periodically and disposed of as radioactive waste. If dogs or other large animals will excrete radioisotopes in the urine or feces, a metabolic cage must be used, and the excrement collected and properly stored prior to pick-up as radioactive waste.

6. Contact the RPO for cage washing instructions. Small animal cages may be washed in the laboratory sink, if this procedure is approved by the RPO. Prior to washing large cages suspected of being contaminated, contact the RPO. In centralized animal facilities animal care supervisors should be fully apprised of the radioisotopes in use so that an animal husbandry procedure, to include appropriate cage cleaning and sanitation, may be initiated.

7. Laboratory coats, appropriate eye protection, and disposable gloves must be worn during cage cleaning and when handling the animals.

8. Personnel radiation monitors may be required in some animal care situations. Contact the RPO for advice concerning this service.

9. Animal carcasses containing radioisotopes must be properly disposed of in accordance with the requirements of the RPO. Radioactive animal carcasses and associated waste must be placed in a sealed plastic bag, and the bag labeled with radiation caution tape. The bag must be labeled with the type and number of animals contained, the radioisotope(s) and the activity of each radioisotope. Any animal carcasses containing ^{131}I, ^{125}I, ^{86}Rb, ^{51}Cr, ^{85}Sr, or ^{45}Ca must be packaged separately and labeled. For disposal of the animals, call the RPO to request pick-up from the laboratory, phone 3-3167. In campus locations where immediate pick-up can not be provided, the animals may require temporary storage in a laboratory freezer or refrigerator to prevent biodegradation.

10. In case of radiation emergencies such as spillage of contaminated waste, contact the RPO in the Department of Environmental Health and Safety, Boynton Health Service, 373-316

UNIVERSITY OF MINNESOTA
TWIN CITIES

Health Sciences Planning Office
Physical Planning
Box 75 Powell Hall
4103 Powell Hall
Minneapolis, Minnesota 55455
(612) 373-8981

November 1, 1976

Mr. Frank B. Wilderson, Jr.
Vice President for Student Affairs
16 Morrill Hall
East Bank Campus

Dear Mr. Wilderson:

It has become increasingly clear to me that the initial charge of the Biohazard Advisory Committee has expanded to the extent that I feel I can no longer serve on the committee. Other commitments in my capacity as Health Sciences Planning Coordinator and my involvement with several other committees places demands on the majority of time that I have available, and I believe it would be in the best interest of the committee for you to appoint a new member who will have more time to devote to the issues at hand. It has been a pleasure working with the other members of the Biohazard Advisory Committee for this past year, and it is with regret that I submit my resignation to this committee.

Yours truly,

Paul J. Maupin
Health Sciences Planning Coordinator
Health Sciences Planning Office

Biohazard Advisory Committee

Monday, November 8, 1976

Meeting Convened: 1:50 p.m.

Present: A. Elliott, chairman, G. Ederer, L. Henderson, S. Marker, I. Rubinstein, L. Wattenberg, W. Jopke, ex-officio

R. DeRoos, F. Thompson, staff

Absent: R. Anderson, H. Jenkin, P. Manning, P. Maupin, B. Powitz, S. Sabo

Mr. John Diehl, University Attorney's Office

Mr. Jopke introduced Mr. John Diehl, University attnorney. Mr. Diehl stated that University insurance does cover the Committee members. Mr. Diehl felt that there is probably no chance of legal complications. He will develop a proposal by which the Committee can be protected.

Dr. DeRoos discussed the differences of the Ad Hoc Committee versus the permanent committee. It was suggested by Dr. Henderson that an appeal for a permanent committee would go to the Administration, rather than to another committee.

It was stated that the responsibility of a safe environment in each lab lies with the employer.

The question was raised as to "How does one enforce non-grant research?" Questions were brought up as to how to keep up on the research being done. It was felt that primary responsibility be placed on the researchers themselves. Research grants involving recombinent DNA research go through the Committee.

Mr. Jopke reviewed the permanent Charge to the Committee, including DNA recombinanct research.

Professional liability was discussed in connection to the Charge to the Committee.

The Committee was asked to approve the Charge. Dr. Elliott explained the need for approval as the Charge now reads. By unanimous vote, the Charge was accepted by the permanent Committee.

Dr. DeRoos discussed the medical surveillance program and how it will affect the Committee.

Dr. Henderson felt that a complimentary statement be added to the Charge to include mutigenic and taratogenic agents.

A reference library should be set up on the Minneapolis, St. Paul and Duluth campuses. This library would contain pertinent information and references regarding biohazardous material, chemical carcinogens and DNA recombinance. Locations of where these materials are should be included in the biohazard manual.

Professor Jopke reviewed the safety standard guidelines for biological cabinets. This standard is given to researchers as a suggestion on the type of cabinets to purchase. Discussion lead to ventilation and the use of HEPA filters. Recommendation should be made to the Purchasing Department regarding the requirements for exhaust hoods. A NFS "seal of approval" might be needed to acquire a proper hood.

Agenda for Next Meeting

- Dr. Manning's animal care section
- Mr. Diehl - legal implications and appeal process
- Safety standard regarding hoods

Meeting Adjourned: 2:45 p.m.

Next Meeting: Monday, December 13, 1976, at 1:30 p.m.

Minutes Taken: P. Caryl

UNIVERSITY OF MINNESOTA Office of the Vice President for Student Affairs
Morrill Hall
Minneapolis, Minnesota 55455

November 8, 1976

Mr. Paul J. Maupin
Health Sciences Planning Coordinator
Box 75 Powell Hall
4103 Powell Hall
University of Minnesota

Dear Paul:

I appreciate your service on the Biohazard Advisory Committee in the past and I am sorry that you will be unable to continue that involvement. We will attempt to find a replacement for you on the Committee, but it will be difficult to find someone with your background in the work we are trying to do with this Committee.

Sincerely,

Frank B. Wilderson, Jr.
Vice President for Student Affairs

/djs

cc: Paul Rupprecht