IC Safety and Health Committee Manual

IC Safety and Health Committee Manual

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18. IC Occupational Safety and Health Committee Worksite Surveys Standardized Reporting Format

Occupational Safety and Health Protection for Federal Employees

The Occupational Safety and Health Act of 1970, Executive Order 12196, and Title 29 Code of Federal Regulations part 1960 require the heads of federal agencies to establish programs to protect their employees from occupational safety and health hazards.

The designated safety and health official for the Department of Health and Human Services
is
Shirl A. Eller
Acting Director for the Office of Research Services
Building 31, Room 4B54

Responsibilities of management are as follows:

1. To comply with safety and health standards issued under Section 6 of the Occupational Safety and Health Act of 1970, or develop alternate standards.
2. To develop procedures for responding to employee reports of unsafe and unhealthful working conditions.
3. To furnish approved personal protective and other safety equipment and enforce compliance with requirements for its use.
4. To inspect all workplaces at least annually with employee representatives and supervisors responsible for the workplaces.
5. To establish and enforce procedures to assure that employees are not subjected to restraint, interference, coercion, discrimination, or reprisal for exercising their rights under the provisions of the Occupational Safety and Health Program of the Department of Health and Human Services and its suborganizations.
6. To ensure that notices of serious unsafe or unhealthful working conditions found during Inspections are posted near the locations where the conditions exist.
7. To establish procedures for the elimination of hazardous conditions, and to inform exposed employees of the plans for elimination the hazards. Imminent danger hazards will be corrected promptly.
8. To establish and maintain a management information system to record occupational accidents, injuries, illnesses, and their causes. The data contained in this system will be used to develop annual summaries of injuries, illnesses and useful preventive data. Summaries will be posted for a minimum of 30 days.
9. To establish and provide occupational safety and(health training programs for employees as appropriate.
10. To establish occupational safety and health committees.

Responsibilities of employees are as follows:

1. To comply with occupational safety and health standards, rules, regulations and orders issued by the Department of Health and Human Services and its suborganizations which are applicable to their actions and conduct.
2. To use personal protective and other safety equipment provided for their protection.
3. To report all work-related accidents and illnesses to their supervisors.

Rights of employees and their representatives are as follows:

1. Employees shall be authorized and granted official time to participate in the Occupational Safety and Health Program.
2. Employees shall have access to safety manuals and records covering occupational safety and health standards and injury and illness statistics.
3. Employees shall be afforded the opportunity to comment on alternate occupational safety and

health standards proposed by the Department of Health and Human Services and its suborganizations.

4. Employees shall have the right to report unsafe or unhealthful working conditions and to request to appropriate officials that safety and health Inspections be conducted.
5. Additional information pertaining to the Occupational Safety and Health Program, its standards and procedures, the Federal Law, and other information on safety and health shall be available for review by employees through the NIH Division of Occupational Health and Safety.

Division of Occupational Health and Safety…….. (301) 496-2960
Division of Emergency Preparedness… (301) 496-1985
To report an emergency (on campus)……. 911
Using a TTY……..(301) 496-0063
To report an emergency (off campus)……..9-911
Division of Environmental Protection…..(301) 496-3537
Division of Radiation Safety…….(301) 496-5774
Occupational Medical Service……..(301) 496-4411

To report unsafe acts or conditions notify:

- Your supervisor
- The NIH Division of Occupational Health and Safety (301-496-2960)
- NIH Occupational Safety and Health Committee Executive Secretary (301-496-3353)
- NIH BioSafety Committee Executive Secretary (301-496-3353)
- NIH Radiation Safety Committee Executive Secretary (301-496-5774)

Discrimination

Employees who exercise their rights under the provisions of the Occupational Safety and Health Program shall be protected from discrimination, restraint, interference, coercion or reprisal.

For additional information on Occupational Safety and Health at the NIH, please refer to Manual Issuance chapter #1340- Occupational Safety and Health Management.

NIH POLICY MANUAL

1340 - NIH Occupational Safety and Health Management
Issuing Office: ORS/DOHS 301-496-2960
Release Date: 2/27/06

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1. **Explanation of Material Transmitted:** This chapter establishes the scope and objectives of the Occupational Safety and Health Program and details the responsibilities of NIH personnel to foster a safe work environment.

2. **Filing Instructions:**

   Remove: NIH Manual 1340, dated 11/29/96
   Insert: NIH Manual Chapter 1340 dated 2/27/06

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- On-line information, enter this URL: http://www1.od.nih.gov/oma/manualchapters/
- To sign up for e-mail notification of future changes, please go to the NIH Manual Chapters LISTSERV Web page.

A. Purpose:

This chapter outlines the scope, objectives, and responsibilities of employees for the National Institutes of Health (NIH), Occupational Safety and Health Management Program. It represents the NIH commitment to actively promote a comprehensive and effective Occupational Safety and Health Program and provides the foundation for the development and maintenance of the various program components. **B. Policy:**

The objective of the Program is to assign responsibility to support the development, implementation, maintenance and improvement of a comprehensive Occupational Safety and Health Program that reflects the NIH policy to:

Provide the highest practical degree of safety and health for employees in all activities of the NIH;

Minimize losses in property damage and human resources due to accident, injury, or illness; and

Comply with Public Law 91-596 (The Occupational Safety and Health Act of 1970), Executive Order 12196, and other regulations, standards, and guidelines governing the occupational safety and health of HHS employees.

C. Scope:

The objectives and responsibilities set forth in this manual are applicable to all NIH employees and are directed toward providing a comprehensive and effective Occupational Safety and Health Program. Institute and Center (IC) Directors and Supervisors will actively support the Occupational Safety and Health Programs within their respective areas of responsibility and comply with the specified directives and responsibilities. NIH employees will comply with applicable regulations and guidelines; perform their duties in the safest possible manner and report hazards, accidents, injuries and illnesses to the appropriate NIH authorities.

D. References:

1. Executive Order 12196 of February 26, 1980, Occupational Safety and Health Programs for Federal Employees

2. Public Law 91-596, Williams-Steiger Occupational Safety and Health Act of 1970, Federal Agency Safety Programs and Responsibilities

3. Title 10 CFR Part 21, Reporting of Defects and Noncompliance; Section 21.21, Notification of failure to comply or existence of a defect and Section 21.61, Failure to notify; Nuclear Regulatory Commission

4. Title 29 CFR Subpart G, Part 1910.96, Ionizing Radiation; Occupational Safety and Health Administration (OSHA), Department of Labor

5. Title 29 CFR Part 1960, Basic Program Element for Federal Employee Occupational Safety and Health Programs and Related Matters; OSHA, Department of Labor

6. Health and Human Services (HHS) Transmittal No. 88.01 Safety Management Manual, Issue Date 09/23/88. **E. Responsibilities:**

The Office of Research Services (ORS), through the Division of Occupational Safety and Health (DOHS), the Division of the Fire Marshal (DFM) and the Division of Radiation Safety (DRS), have overall responsibility for Occupational Safety and Health at NIH. The promotion of safety and health policies, practices and procedures is the responsibility of each member of the NIH Community. Employees are expected to perform their work in a safe

manner and to ensure that they do not place themselves, co workers, visitors or support services personnel at risk of injury or illness due to unsafe or unhealthful conditions, actions or infractions. When operating a government or public vehicle, employees are expected to wear seatbelts and obey traffic regulations. When representing the NIH on official business, employees should ensure that their contributions exhibit safety and health concerns.

1. **Director, NIH:**

    a. Through the ORS, DOHS and DRS, provides executive leadership in the development, promulgation and implementation of occupational safety and health policies, standards and procedures applicable to the NIH.

    b. Supports a staff necessary to effectively administer a comprehensive occupational safety and health program for NIH.

2. **NIH Safety Committees**: (See Appendices 1-4 for charters for the: 1) Occupational Safety and Health Committee, 2) IC Safety and Health Committees, 3) Institutional Biosafety Committee and 4) Radiation Safety Committee, at the National Institutes of Health.

    a. Assist the Director, NIH, the Division of Occupational Health and Safety, Division of the Fire Marshal and the Division of Radiation Safety in providing oversight required for compliance with applicable safety and health laws and regulations.

    b. Assist with the organization and administration of the NIH Occupational Safety and Health Program.

    c. Provide technical advice, assistance, and management-level support; recommend and set policies regarding occupational safety and health as authorized by the Director, NIH.

    d. Provide the foundation for the development and maintenance of a Safety and Health Committee in each IC.

e. Provide a means by which employees can use their knowledge of workplace operations to assist management in the improvement of policies, conditions, and practices.

3. **Office of Research Services**:

a. Serves as the primary operational component in developing and implementing NIH-wide safety and health programs through surveillance, consultation, training, and education.

b. Provides administrative management for the comprehensive Occupational Safety and Health Program in compliance with NIH policy and applicable federal, state, and local regulations.

c. Prepares and coordinates the NIH position on proposed legislation and regulations pertaining to safety and industrial hygiene, fire safety, occupational safety and health, education, training, promotion, etc., that are applicable to the NIH. Activities for engineering and environmental hazards control are provided through the Office of Research Facilities Development and Operations.

d. Monitors, investigates, prepares reports and maintains records of NIH work related injuries and illnesses. Develops and implements methods to prevent these work related losses. Conducts and/or assists in the conduct of investigations of hazardous conditions. Engineering issues pertinent to the NIH are managed by the Office of Research Facilities Development and Operations.

e. Performs workplace reviews as are considered appropriate to evaluate compliance with occupational safety and health policies and procedures.

f. Provides technical assistance to NIH employees at all levels of responsibility on matters pertaining to the Occupational Safety and Health Program. Assesses the need for and develops training programs to promote occupational safety and health.

4. **Supervisors (all levels throughout NIH):**

a. Ensure and promote safety in the work area under their jurisdiction.

b. Comply with and enforce all applicable occupational safety and health standards, rules, regulations and orders by competent authority pertaining to the activities under their jurisdiction.

c. Ensure that employees are instructed and/or trained in safe practices and methods of job performance as such pertain to their assignments. Ensure that all visitors and support services personnel are appropriately informed about the existence of hazards present and special precautions required to prevent adverse exposure to these hazards. Acquire the knowledge and information needed to recognize and control hazardous conditions in the workplace. Select and employ standard operating procedures that reduce the potential for injury or illness to the lowest practicable level.

d. Ensure that employees performing official duties and who become ill or are injured on the job have access to appropriate first aid and/or medical attention.

e. Investigate and report each accident and/or injury in accordance with established procedures. Initiate within the limit of their authority and capability, such actions necessary to correct unsafe or unhealthful working conditions determined to exist and promptly advise management when such conditions require corrective actions beyond their jurisdiction.

f. Review work practices to ensure compliance with such standards, codes, regulations, rules, and orders identified by occupational safety and health personnel as being applicable to the work area concerned.

g. Obtain assistance from the appropriate occupational safety and health personnel on the

interpretation and application of specific standards, codes, regulations, or rules.

h. Ensure that employees under their supervision are aware of their responsibilities and follow the appropriate procedures for conducting their work safely.

5. **Employees**:

a. Comply with all occupational safety and health standards, rules, regulations, orders, and safe operating procedures applicable to the NIH.

b. Promptly advise the supervisor regarding all work related accidents resulting in personal injury, illness, and/or property damage.

c. Promptly report to the supervisor, appropriate occupational safety and health personnel and/or IC Safety and Health Committee Members, any unsafe or unhealthful conditions in the work environment.

F. Reporting Occupational Safety and Health Concerns:

1. Employees are encouraged to report legitimate concerns for their occupational safety and health and may do so without fear of any form of reprisal.

2. Employees may request an inspection of their workplace by giving notice of alleged unsafe or unhealthful conditions directly to the Division of Occupational Safety and Health. Employees may request such an inspection anonymously.

3. NIH employees shall report any unsafe or unhealthful condition to their Supervisor, the Division of Occupational Health and Safety, Division of Radiation Safety, Division of the Fire Marshall, and/or IC Safety and Health Committee Members. Reports involving physical, chemical, or biological hazards shall be reported to the Division of Occupational Health and Safety. Reports involving radiation hazards shall be reported to the Division of Radiation Safety (see the NIH Telephone and Service Directory for information). Employees will be notified by their supervisor, Division of Occupational Health and Safety, Division of Radiation Safety, or Division of the Fire Marshall personnel of the

actions taken in response to their report of unsafe or unhealthful conditions.

4. All reports of job-related accidents, personal injury, or illnesses are initiated through the Occupational Medical Service (OMS), Division of Occupational Health and Safety, when the injured party presents to the OMS. The OMS will ensure that appropriate accident report forms are completed, filed, and appropriately distributed.

5. Employees may also report alleged unsafe and unhealthful conditions to the Health and Human Services (HHS) designated Safety and Health Official or applicable agencies outside the HHS (Department of Labor, Nuclear Regulatory Commission, Occupational Safety and Health Administration).

G. Additional Information:

For further information on this manual chapter, contact the Division of Occupational Health and Safety, Office of Research Services on 301-496-2346.

H. Records Retention and Disposal:

All records (e mail and non e mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743 "Keeping and Destroying Records," Appendix 1, NIH Records Control Schedule, Item 1300B and 2300-792 Safety and Health Programs.

NIH e mail messages. NIH e mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e mail messages. E mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e mail systems have back up files that are sometimes retained for significant periods of time, e mail messages and attachments may be retrievable from a back up file after they have been deleted from an individual's computer. The back up files are subject to the same requests as the original messages. **I. Management Controls:**

The purpose of this manual issuance is to outline the scope, objectives, and responsibilities of employees for the NIH, Occupational Safety and Health Management Program.

1. **Office Responsible for Reviewing Management Controls Relative to this Chapter (Issuing Office):** Through this manual issuance, the Division of Occupational Health and Safety (DOHS) is accountable for the method used to ensure that management controls are implemented and working.

2. **Frequency of Review (in years):** Annual Review

3. **Method of Review:** Other Review: The DOHS will maintain oversight and ensure effective implementation and compliance with this policy through annual IC worksite safety surveys and the OSHA annual Agency report on occupational safety and health issues.

4. **Summary Reports are sent annually to:** Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Administration and Management.

Appendix 1. Charter for the NIH Occupational Safety and Health Committee:

The NIH Occupational Safety and Health Committee (OSHC) provides safety policy recommendations to the Director of the NIH, or his/her designee, in matters pertaining to occupational health, accident control and fire prevention.

Duties of the Committee:

1. Meets quarterly, or more often as required, to identify substantive biomedical research areas and institutional support programs where occupational health, safety and fire hazards may exist.

2. Recommends policies regarding occupational health, accident control, and fire prevention.

3. Provides technical advice, assistance and management-level support to the Directors of the Division of Occupational Health and Safety (DOHS), Division of Radiation Safety (DRS) and the Division of Fire the Marshal (DFM) in matters regarding occupational health, accident control and fire prevention.

4. Encourages the development of and supports the activities of IC Safety and Health Committees and maintains liaison with these committees.

5. Monitors and reviews inspection reports, safety and health training programs; plans for abating hazards, medical surveillance initiatives, reports of occupationally acquired illnesses and injuries, responses to reports of hazardous conditions, safety and health program deficiencies and complaints regarding safety and health programs.

6. Provides to the Director, NIH, or his/her designee a summary report reviewing the results of the annual workplace inspections of all NIH facilities.

7. Conducts annual reviews of the NIH Chemical Hygiene Plan and performs Committee responsibilities as specified in the Plan.

8. Establishes working groups and appoints ad hoc members to the Committee, as necessary, to effectively carry out its duties.

Membership and Organization of the Committee:

The Committee is composed of 10 or more voting members appointed by the Director of the NIH or his/her designee.

All members should be recognized as persons of good judgment and should represent the diversity of occupational areas and accident experience of the NIH. The disciplines of chemistry, toxicology and medicine must be represented on the Committee. At least 5 members are selected from among the current chairpersons of established IC Safety and Health Committees. One member should be an Intramural Principal Administrative Officer, to provide an administrative perspective and approach. One member is the American Federation of Governmental Employees (AFGE) Health and Safety Officer from the NIH Local. The Director, Division of Occupational Health and Safety or his/her designee, serves as Executive Secretary. The Director, Division of Environmental Protection, Director Division of Fire Marshal, Medical Director, Occupational Medical Service, DOHS, and a representative appointed by the Director, Office of Research Facilities Development and Operations, serve as permanent, non-voting, resource members of the Committee. The Director of the NIH or his/her designee selects the Chairperson from among the Committee membership. The Chairperson serves a two- year term. The members serve overlapping terms of three years duration. The Chairperson and members may be reappointed for additional terms.

Appendix 2. Charter for the IC Safety and Health Committees:

A. Purpose:

The promotion of safety and health policies, practices and procedures is the responsibility of each member of the NIH Community. Employees are expected to perform their work safely and not place themselves or others at risk of injury or illness due to unsafe or unhealthy conditions, actions or infractions. This policy establishes guidelines to assist each Institute and Center (IC) in conveying NIH occupational safety and health regulations to ensure compliance with NIH Manual 1340. It represents the NIH commitment to actively promote a comprehensive and effective Occupational Safety and Health Program and provides the foundation for the development and maintenance of a Safety and Health Committee in each IC. Each IC is required to establish an IC Safety and Health Committee.

B. References:

1. NIH Manual 1340, NIH Occupational Safety and Health Management.

2. Public Law 91-596, Williams-Steiger, Occupational Safety and Health Act of 1970, Federal Agency Safety Programs and Responsibilities.

3. Title 10 Code of Federal Regulations (CFR) Part 21, Reporting of Defects and Non-compliance; Section 21.21, Notification of failure to comply or existence of a defect and Section 21.61, Failure to notify; Nuclear Regulatory Commission.

4. Title 29 CFR Subpart G, Part 1910.96, Ionization Radiation; Occupational Safety and Health Administration (OSHA), Department of Labor.

5. Title 29 CFR Part 1960, Basic Program Elements for Federal Employee Occupational Safety and Health Programs and Related Matters; Occupational Safety and Health Administration, Department of Labor.

6. Health and Human Services (HHS) Transmittal No. 87.01, Safety Management Manual, Issue Date 9/18/87.

7. Executive Order 12196 of February 26, 1980, Occupational Safety and Health Programs for Federal Employees.

C. Scope:

The objectives and responsibilities set forth in this policy are applicable to all NIH employees and are directed toward providing a comprehensive and effective IC Safety and Health Committee Program. IC Directors and Supervisors will actively support the IC Safety and Health Committee within their respective areas of responsibility and comply with the specified directives and responsibilities. NIH employees will perform their duties in the safest practical manner and report hazards, accidents, injuries and work-related illnesses to the appropriate NIH authorities as detailed in Manual 1340.

D. Policy:

The IC Safety and Health Committee serves as a conduit for communication between the IC employees, management, the Division of Occupational Health and Safety (DOHS) and the Division of Radiation Safety (DRS) concerning occupational safety and health matters. The objective of the IC Safety and Health Committee is to support the development, implementation, maintenance and improvement of a comprehensive Occupational Safety and Health Program that reflects NIH policy to:

- provide the highest practical degree of occupational safety and health for employees in all activities of the NIH;
- minimize losses in human resources and property damage due to accident, injury or work-related illness; and
- comply with Public Law 91-596 (The Occupational Safety and Health Act of 1970), Executive Order 12196, and other regulations, standards and guidelines governing the occupational safety and health of HHS employees.

E. Responsibility:

The IC Safety and Health Committee will report to the IC Director through the Scientific Director. In those ICs that do not have a Scientific Director, a senior administrator, appointed by the IC Director, will serve to facilitate safety related communication between the Committee and the IC Director. The IC Safety and Health Committee in an effort to monitor and assist in the execution of the NIH's safety and health policies and programs shall:

1. Meet at least on a quarterly basis and report through the Scientific Director to the IC Director.

2. Keep minutes of all IC Safety and Health Committee meetings, distribute the minutes to all members and the IC Scientific Director, and make copies available upon request, to IC employees.

3. Monitor performance of safety and health activities of the IC and make recommendations to the IC Scientific Director on the effectiveness of these activities.

4. Develop policies and programs in coordination with the DOHS and the DRS specific to the IC in regard to occupational safety and health matters.

5. Perform annual workplace surveys with the assistance of the DOHS to assure compliance with NIH and OSHA safety and health policies and standards. These surveys will be conducted using standardized criteria developed by the DOHS. A corrective action plan will be prepared and implemented, addressing any deficiencies found during the survey. The IC will disseminate the results of these surveys and corrective actions to the IC Scientific Director, NIH Occupational Safety and Health Committee (OSHC) and the Director of the Office of Intramural Research, as appropriate.

6. Develop procedures for handling occupational safety and health suggestions, recommendations and reports of hazardous conditions from IC employees.

7. Review and comment on proposed NIH policies, guidelines and standards concerning occupational safety and health as requested by the OSHC.

8. Assist in the development of prevention strategies for work related accidents resulting in personal injury, illness and/or property damage.

9. Assist the Office of Intramural Research, the DOHS and the DRS in the dissemination of safety information in the event of an emergency or on an as-needed basis.

F. Membership and Organization of the Committee:

The Committee is composed of IC employees selected by the IC Scientific Director or his/her designee, who represent the diverse occupational areas of the organization. Membership shall include (where applicable), but not be limited to the following individuals.

- Senior research personnel
- Principal Administrative Officer
- Facilities management staff
- A representative from each IC operating component (branch, laboratory, etc.)
- Occupational Safety and Health Specialist
- Health Physicist

The IC Scientific Director or his/her designee shall select the chairperson from among the Committee membership. The chairperson serves a two-year term. The members serve overlapping terms of three years duration. The chairperson and members may be reappointed to serve additional terms.

Appendix 3. Charter for the NIH Institutional Biosafety Committee:

The NIH Institutional Biosafety Committee (IBC) provides recommendations for safety policy to the Safety and Health Council for approval by the Director, NIH, or designee, in matters pertaining to the control of hazards associated with the intramural use of microbiological agents and their vectors and serves as an advisory body to the Division of Occupational Health and Safety (DOHS), Office of Research Services (ORS).

Committee functions include those designated for the Institutional Biosafety Committee in the *NIH Guidelines for Research Involving Recombinant DNA Molecules.*

Duties of the Committee:

1. Recommends policies regarding biosafety to the Deputy Director Intramural Research and the Director, NIH.

2. Provides technical advice, assistance, and management-level support to the DOHS, ORS, and to the NIH Biosafety Officer in matters regarding biosafety.

3. Identifies substantive biomedical research areas where biohazards may exist.

4. Recommends procedures for approving operations involving microbiological agents and their vectors that require maximum containment for biosafety and for agents that, in the judgment of the Committee, may constitute unique or serious hazards.

5. Performs function of an Institutional Biosafety Committee as specified in the *NIH Guidelines for Research Involving Recombinant DNA Molecules.*

6. Reviews accidents resulting in personnel exposures to hazardous microorganisms or widespread area contamination and reports of noncompliance with established national and NIH policies regarding the safe conduct of research involving hazardous microorganisms.

7. Establishes working groups and appoints ad hoc members to the Committee, as the Committee deems it necessary, to effectively carry out its duties.

8. Annually reviews the NIH Exposure Control Plan for Non-Hospital Personnel.

9. Can initiate reviews of emerging biosafety issues of particular interest or concern to the NIH and the surrounding community. Membership and Organization of the Committee:

Membership and Organization of the Committee:

The Committee is composed of ten members appointed by the Director, NIH, or designee. Six members are nominated from among the intramural research community; five are scientists representing a diversity of disciplines relevant to biomedical research, infectious diseases, and recombinant DNA technology and one is a non doctoral employee from a biomedical research laboratory. Intramural research community members must be senior, tenured researchers within their respective Institutes. The NIH Biosafety Officer is a member and serves as the Executive Secretary. Members are also selected from the general public who are not affiliated with the NIH apart from their membership on the Committee. One member who is nominated by the Director, Office of Research Facilities Development and Operations, shall have expertise pertaining to design, operational capability, and maintenance of NIH research facilities. The

Director, NIH, or designee selects the chairperson from among the Committee membership. The chairperson serves a two year term. The members serve overlapping terms of three years duration. The chairperson and members may be reappointed for additional terms.

Appendix 4. Charter for the NIH Radiation Safety Committee:

A. Mission Statement:

The Radiation Safety Committee (RSC) is responsible to the Director, NIH for oversight of the NIH Radiation Safety Program to ensure the safe use of radioactive materials and all sources of ionizing radiation throughout NIH and those NIH-occupied buildings included in the NIH Radiation Safety Program. The RSC is responsible for formulating policy with regard to radiation protection matters in the intramural research program that involve NIH employees and members of the general public, routine clinical and clinical research programs, and protection of the environment to ensure compliance with Federal regulations, including those of the U.S. Nuclear Regulatory Commission. The Radioactive Drug Research Committee is a subcommittee of the NIH Radiation Safety Committee. The Radiation Safety Officer (RSO) is responsible to the Director, NIH, for management and operation of the Radiation Safety Program as well as policy directives of the RSC. The RSO and RSC shall be provided sufficient authority, organizational freedom, and management prerogative to accomplish these goals. These responsibilities and authorities are limited to the NIH's intramural research program and client agencies served under USNRC license 19-00296-10.

B. Duties of the Committee:

1. Ensures the safe use of all radioactive materials and sources of radiation throughout NIH and those NIH-occupied buildings included within the NIH Radiation Safety Program, for the Director, NIH.

2. Delegates to the NIH Radiation Safety Officer the authority to implement the Radiation Safety Program and enforce applicable Federal regulations and NIH radiation safety policies and procedures to ensure the radiation safety of persons and protection of the environment.

3. Provides technical advice, assistance, and management-level support to the Radiation Safety Officer in implementing the Radiation Safety Program and the NIH program for maintaining radiation exposures to employees, patients, and research subjects as low as reasonably achievable (ALARA).

4. Reviews the Radiation Safety Program at least annually to determine that all activities involving radioactive materials and sources of radiation are being conducted safely and in accordance with applicable Federal regulations and NIH radiation safety policies.

5. Reviews the qualifications of licensed physicians and grants approval for the use of radioactive materials in human subjects. If a Committee member is an investigator who may participate in the research being proposed in an application to the Committee, he or she shall abstain from voting on the approval or disapproval of the application.

6. Performs functions of the Radioactive Drug Research Committee in accordance with applicable regulations of the Food and Drug Administration, DHHS.

7. Approval of the RSC is required before the initiation of approved clinical research studies involving exposure of human subjects to ionizing radiation for research purposes from which the subject does not benefit, i.e., when normal volunteers or patient volunteers are involved and the use of radiation or radioactive materials is not a standard medical procedure which is required for the clinical management of the patient. Research uses subject to this review shall include all studies involving normal volunteers and experimental procedures for diagnosis or treatment, including uses for which an Investigational New Drug (IND) application is required by the FDA and radioactive research drugs regulated under FDA regulations contained in 10 CFR 361, §361.1.

8. The Chairperson of the Radiation Safety Committee acts for the Director, NIH, in all matters relating to Federal or state radioactive material or radiation source licensing.

9. Establishes and revises radiation safety policies, consulting with the Office of the Director through the Management Representative on issues that require involvement of upper level management, e.g., in cases when there is significant potential for impact on the NIH mission.

10. Establishes working groups and appoints ad hoc members to the Committee, as the Committee deems necessary.

C. Membership and Organization of the Committee:

The membership of the Committee shall include the following: The Radiation Safety Officer; a representative of the Office of the Director of the NIH who is not an Authorized User (this person serves as the "management representative"); a physician who is Authorized by the RSC for clinical use of radioactive materials; a person who is Authorized by the RSC for the use of radioactive

materials in laboratory research; a representative of the nursing service. Members are appointed by the Director of the NIH or his designee. The Medical Board may be consulted to identify nominees for membership on the RSC to represent clinical care areas; the Board of Scientific Directors may be consulted to identify nominees for other positions. Membership shall include representation of the various types of users of radioactive materials and radiation sources at NIH. Additional members may be added to the RSC, upon recommendation of its Chair to enable effective action by the Committee. The following are highly recommended: the Chair of the RDRC; a health or medical physicist with training and experience in radiation dosimetry of radioactive materials administered to humans, a radiopharmacist; physicians with expertise in diagnostic radiology, nuclear medicine, and radiation therapy; individuals with these qualifications in the list of mandatory members may serve the RSC in these areas of expertise. Members shall serve three-year terms, with staggered terms to provide for continuity. With the member's consent, the Chairperson may renew a member's appointment. The Chairperson's appointment shall be effective until the Chairperson resigns or until another Chairperson is appointed by the Director, NIH. When members are replaced, new appointees shall be chosen to maintain the balance of members required under 10 CFR 35.

The Division of Radiation Safety shall provide administrative support to the Committee and shall maintain the official Committee files.

Meetings shall be conducted at a frequency sufficient to meet the requirements of 10 CFR 35. A majority of Committee members shall constitute a quorum for the conduct of official Committee business.

ICD Safety and Health Committees: Charter

A. Purpose

The promotion of safety and health policies, practices and procedures is the responsibility of each member of the NIH Community. Employees are expected to perform their work safely and not place themselves or others at risk of injury or illness due to unsafe or unhealthy conditions, actions or infractions. This policy establishes guidelines to assist each Institute, Center and Division (ICD) in conveying NIH occupational safety and health regulations to ensure compliance with NIH Manual Issuance #1340-NIH. It represents the NIH commitment to actively promote a comprehensive and effective Occupational Safety and Health Program and provides the foundation for the development and maintenance of a Safety and Health Committee in each ICD. Each ICD is required to establish an ICD Safety and Health Committee.

B. References

1. NIH Manual Issuance #1340, NIH Occupational Safety and Health Management.
2. Public Law 91-596, Williams-Steiger, Occupational Safety and Health Act of 1970, Federal Agency Safety Programs and Responsibilities.
3. Title IO Code of Federal Regulations (CFR) Part 2 1, Reporting of Defects and Noncompliance; Section 21.2 1, Notification of failure to comply or existence of a defect and Section 21.6 1, Failure to notify; Nuclear Regulatory Commission.
4. Title 29 CFR Subpart G, Part 1910.96, Ionization Radiation; Occupational Safety and Health Administration (OSHA), Department of Labor.
5. Title 29 CFR Part 1960, Basic Program Elements for Federal Employee Occupational Safety and Health Programs and Related Matters; Occupational Safety and Health Administration, Department of Labor.
6. Health and Human Services (HHS) Transmittal No. 88.01 Safety Management Manual, Issue Date 9/23/88.
7. Executive Order 12196 of February 26, 1980, Occupational Safety and Health Programs for Federal Employees.

C. Scope

The objectives and responsibilities set forth in this policy are applicable to all NIH employees and are directed toward providing a comprehensive and effective ICD Safety and Health Committee Program. ICD Directors and Supervisors will actively support the ICD Safety and Health Committee within their respective areas of responsibility and comply with the specified directives and responsibilities. NIH employees will perform their duties in the safest practical manner and report hazards, accidents, injuries and work-related illnesses to the appropriate NIH authorities as detailed in Manual Issuance #1340-NIH.

D. Policy

The ICD Safety and Health Committee serves as a conduit for communication between the ICD employees, management and the Division of Safety concerning occupational safety and health matters. The objective of the ICD Safety and Health Committee is to support the development, implementation, maintenance and improvement of a comprehensive Occupational Safety and Health Program that reflects NIH policy to:

- provide the highest practical degree of occupational safety and health for employees in all activities of the NIH;
- minimize losses in human resources and property damage due to accident, injury or work-related illness; and
- comply with Public Law 91-596 (The Occupational Safety and Health Act of 1970), Executive Order 12196, and other regulations, standards and guidelines governing the occupational safety and health of HHS employees.

E. Responsibility

The ICD Safety and Health Committee will report to the ICD Director through the Scientific Director. In those ICDs that do not have a Scientific Director, a senior administrator, appointed by the ICD Director, will serve to facilitate safety related communication between the Committee and the ICD Director. The ICD Safety and Health Committee in an effort to monitor and assist in the execution of the NIH's safety and health policies and programs shall:

1. Meet at least on a quarterly basis and report through the Scientific Director to the ICD Director.
2. Keep minutes of all ICD Safety and Health Committee meetings, distribute the minutes to all members and the ICD Scientific Director, and make copies available upon request, to ICD employees.

3. Monitor performance of safety and health activities of the ICD and make recommendations to the ICD Scientific Director on the effectiveness of these activities.
4. Develop policies and programs in coordination with the Division of Safety if specific to the ICD in regard to occupational safety and health matters.
5. Perform annual workplace surveys with the assistance of the Occupational Safety and Health Branch (OSHB) to assure compliance with NIH and OSHA safety and health policies and standards. These surveys will be conducted using standardized criteria developed by the OSHB. A corrective action plan will be prepared and implemented, addressing any deficiencies found during the survey. The ICD will disseminate the results of these surveys and corrective actions to the ICD Scientific Director, NIH Occupational Safety and Health Committee (OSHC) and, the Director of the Office of Intramural Research, as appropriate.
6. Develop procedures for handling occupational safety and health suggestions, recommendations and reports of hazardous conditions from ICD employees.
7. Review and comment on proposed NIH policies, guidelines and standards concerning occupational safety and health as requested by the OSHC.
8. Assist in the development of prevention strategies for work related accidents resulting in personal injury, illness and/or property damage.
9. Assist the Office of Intramural Research and the Division of Safety in the dissemination of safety information in the event of an emergency or on an as-needed basis.

F. Membership and Organization of the Committee

The Committee is composed of ICD employees selected by the ICD Scientific Director or his/her designee, who represent the diverse occupational areas of the organization. Membership shall include (where applicable), but not be limited to the following individuals.

- Senior research personnel
- Principal Administrative Officer
- Facilities management staff
- A representative from each ICD operating component (branch, laboratory, etc.)
- Occupational Safety and Health Specialist
- Health Physicist

The ICD Scientific Director or his/her designee, shall select the chairperson from among the Committee membership. The chairperson serves a two-year term. The members serve overlapping terms of three years duration. The chairperson and members may be reappointed to serve additional terms.

NIH POLICY MANUAL

1361 - CORRIDOR UTILIZATION
Issuing Office: ORS/DS 496-2960
Release Date: 4/29/98

1. **Explanation of Material Transmitted:** This manual chapter establishes the NIH policy for the safe use of corridors in buildings occupied by NIH personnel.

1. **Material Superseded:** NIH Manual Chapter 1361, dated 7/31/91

1. **Filing Instructions:**

   Remove: NIH Manual 1361 dated 7/31/91
   Insert: NIH Manual Chapter 1361 dated: 4/29/98

1. **Distribution:** F-401 and F-402

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- On-line information, enter this URL: http://www3.od.nih.gov/oma/manualchapters/
- To sign up for e-mail notification of future changes, please go to the NIH Manual Chapters LISTSERV Web page.

A. Purpose:

Established under this chapter is the NIH policy for the safe use of corridors in buildings located on the NIH Bethesda reservation and at the NIH Animal Center (NIHAC) in Poolesville. **B. Background:**

The NIH Corridor Utilization Policy applies only to buildings located on the NIH Bethesda reservation and the NIHAC in Poolesville and is based on the judgement that certain uses for the corridor, in addition to the safe movement of people, can be accommodated without compromising the safe and adequate means of egress. **C. Policy:**

It is the policy of the NIH that all corridors of buildings located on the Bethesda reservation and at the NIHAC provide for: (1) a readily apparent, safe and adequate means by which building occupants may exit a building in the event of a fire or other serious emergency; (2) adequate access and use by emergency personnel; (3) the safe movement of people during normal daily use of the building; and (4) the safe transportation of goods and materials. The NIH Corridor Utilization Policy details specific allowances, restrictions and requirements for corridor use.

Newly constructed or renovated buildings shall be designed with clear and unobstructed corridors. Corridor storage shall not be permitted in these buildings. Limited storage of items in the corridors of existing buildings shall be allowed only as defined by the NIH Corridor Utilization Policy.

Buildings occupied by NIH employees which are located outside the Bethesda/NIHAC sites shall conform to the requirements of the local authority having jurisdiction. **D. Additional Information:**

To obtain copies of this policy or for further information, contact the NIH, Division of Safety, Occupational Safety and Health Branch at 496-2960. **E. Records Retention and Disposal:**

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records, Appendix 1, *NIH Records Control Schedule*," Item 1300, Station Management.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

F. Management Controls:

The purpose of this manual issuance is to provide guidance to NIH personnel for the safe use of corridors in buildings located on the NIH Bethesda reservation and at the NIHAC in Poolesville.

1. Office Responsible for Reviewing Management Controls Relative to this Chapter (Issuing Office):

   Through this manual issuance, the Division of Safety (DS), Occupational Safety and Health Branch (OSHB) is accountable for the method used to ensure that management controls are implemented and working.

2. Frequency of Review (in years): On-going review.

3. Method of Review:

Other Review (describe): The OSHB will maintain oversight and ensure effective implementation and compliance with this policy through annual worksite safety surveys of all corridors of buildings located on the Bethesda reservation and at the NIHAC. These worksite surveys will be conducted by the IC Safety Committee responsible for the area, with the assistance of OSHB personnel. OSHB staff will also conduct periodic walkthroughs of these buildings, handling exigent corridor problems. Worksite safety surveys will be reviewed annually by the NIH Occupational Safety and Health Committee and an Executive Summary will be forwarded to the Deputy Director for Intramural Research (DDIR).

4. Review Reports are sent to : DDIR (Executive Summary)

Foreword:

This policy represents the combined effort of the Division of Safety, NIH management and the occupants of various NIH buildings. Requirements for providing safe and adequate means of egress have been balanced with routine building use needs and the continuing shortage of space. The degree to which this policy successfully achieves such a balance may be seen differently by various groups; in all probability it will not be seen as totally satisfying to any group. However, adherence to these provisions will provide for an acceptable level of safety to building occupants and emergency and service personnel, while still accommodating utilization of the corridors for specific purposes.

Introduction:

Fire codes and building regulations establish requirements for safe and adequate means of egress from buildings during emergencies. A fundamental principle of these codes and regulations is to maintain an exit path (i.e., corridors) which is free of obstructions and hazards. The NIH policy is based on the judgment that certain uses for the corridor, in addition to the safe movement of people, can be accommodated without compromising the safe and adequate means of egress.

In order to assist building occupants and those responsible for the implementation of this policy, explanatory comments are provided in the right hand column, adjacent to the policy. The policy is printed in the left hand column in bold type.

Purpose:

This issuance establishes the NIH policy for the safe use of corridors in buildings occupied by NIH employees. The intent of this policy is to ensure that corridors provide for: (1) a readily apparent, safe and adequate means by which building occupants may exit a building in the event of a fire or other emergency; (2) adequate access and use by emergency personnel; (3) the safe movement of people during normal daily use of the building; and (4) the safe transportation of goods and materials.

Responsibility:

A. Each NIH Institute/Center (IC) is responsible for ensuring compliance with this policy in building areas that it occupies.

It is anticipated that such direction will be provided by individual Scientific Directors who may choose to utilize their internal safety committees to monitor compliance, inform new staff members and/or provide advice to IC management.

B. NIH personnel are responsible for understanding both the need for maintaining a readily apparent and adequate means by which personnel may safely exit a building in the event of an emergency and the needs related to the daily use of the corridor. Staff members are expected to become familiar with this policy and to adhere to its provisions.

C. The Division of Safety is responsible for providing additional guidance or interpretation of the provisions of this policy; conducting periodic inspections of NIH corridors for the purpose of advising each IC of conditions requiring corrective action and taking immediate action to bring about the removal of items that would prevent safe egress of building occupants.

Although every attempt has been made to identify and explain the various requirements associated with the safe utilization of NIH building corridors, some unique situations may not appear to have been adequately addressed. The Division of Safety will provide advice and interpretation of such situations as needed. The Safety Operations Section, Occupational Safety and Health Branch may be contacted on 4962346 for advice and guidance.

Policy:

1. Minimum Corridor Width

The minimum corridor width prescribed below shall be maintained:

A. Corridors required for emergency evacuation in patient care areas of Building 10 shall be at least eight feet in clear and unobstructed width. Patient-use corridors in the ACRF shall be clear and unobstructed the full constructed width.

This requirement for corridors in patient care areas is specifically stated in both the National Fire Protection Association's Life Safety Code (NFPA 101) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Standards. It is based on the need to provide for the transport of patients in beds, litters or similar equipment. The restriction is not intended to prohibit the temporary parking of small wheeled carts or similar mobile equipment required for patient care which would not impede evacuation. Corridor widths in the ACRF are subject to a different section of the applicable codes and meet the necessary minimum widths as constructed.

B. Other corridors of Building 10 and the ACRF shall be at least five feet (60 inches) in clear and unobstructed width. In buildings where constructed corridors are five feet in width, occupants shall maintain the entire width free of any material or equipment.

A minimum 54 inch width of clear and unobstructed egress must be maintained in all corridors of other buildings. No exceptions to reduce the corridor width from the stated dimensions shall be allowed.

As in 1.A above, this requirement is not intended to prohibit the temporary parking of an occasional laboratory cart which may be quickly moved by the occupants in order to provide full access. Locations for such equipment shall be provided on the side of the corridor authorized for equipment or storage (see Section 3.D).

Bulletin or chalkboards or similar items may extend into the clear space; however, displays which extend into the clear space by more than 4 inches are not permitted.

This Policy prohibits the use of the clear width for temporary storage of construction material, equipment scheduled for installation, supplies pending movement into labs or offices, surplus materials or similar items which would serve to jeopardize area occupants.

C. Corridors of buildings located outside the Bethesda/NIHAC sites shall conform to the requirements of the local authority having jurisdiction.

From a practical standpoint, this prohibits the use of the corridor for any storage and/or operation of equipment. For example, Montgomery County Fire Codes require that corridors be kept clear from wall-to-wall regardless of width. NIH is not in a position to grant exceptions to this requirement.

2. Stairwells, Horizontal Exits and Designated Areas of Refuge

Materials and equipment not required for emergency response shall not be located or used in stairwells, horizontal exits or designated areas of refuge.

This restriction is specifically stated in the Life Safety Code. While everyone may recognize that stairwells require absolutely clear access, few understand that certain corridors, known as "horizontal exits," have similar requirements because they are designed to provide increased protection to occupants under emergency conditions.

Typically, horizontal exits are provided instead of additional stairwells which would be required to meet the travel distance requirements of the codes. Horizontal exits are separated from the balance of the building by a 2-hour-rated fire wall. Thus, persons reaching a horizontal exit are provided similar protection as in a stairwell. Consequently, use restrictions for horizontal exits are identical to those imposed on stairwells. It should be understood that the concept of horizontal exits anticipates that occupants will move from an area of immediate danger through an area protected by

fire walls to a low-risk area. Generally, once reaching a horizontal exit, the urgency for exiting the building via the stairwell is diminished.

"Areas of refuge" are intended to serve as safe marshaling locations for controlled evacuation of personnel. At NIH they are provided in Buildings 10, ACRF and Lister Hill. In addition to providing a level of fire protection similar to stairwells or horizontal exits, such areas are also equipped with automatic mechanical means to prevent smoke from entering the area.

3. Allowances, Restrictions and Requirements for Corridor Use

Materials or equipment may be located in a corridor whose width is greater than the minimum prescribed in 1.A and 1.B above provided that:

A. The minimum prescribed width is maintained clear and unobstructed.

See comments under 1.A and 1.B above.

B. Such use is restricted to one side of the corridor. The same side should be utilized on all floors throughout the building.

This practice is generally intended to permit storage and/or operation of certain equipment on the side of the corridor opposite the stairwell door to ensure that, under emergency conditions, there will be no impediments to reaching the stairwell. However, in some corridors, utility modifications have resulted in enclosed chases projecting from the side of the corridor normally preferred as the "clear" side. Where this condition exists, utilization is limited to the side with the projecting utility chases.

In buildings where access to a stairwell or horizontal exit is in the end wall of the corridor, the primary or lead Institute/Center shall establish which side will be used for materials or equipment. The selected side shall be uniform throughout the building to enable the occupants to become familiar with a clear path pattern regardless of the floor they occupy at the time of an emergency. This uniformity will also allow the Emergency Management Branch, Division of Public Safety (DPS), to plan emergency response patterns.

C. Such use does not involve the storage or use of:

Nothing in Section 3.C prohibits the incidental use of the corridor for delivery of restricted materials, the movement of such items from room to room or similar activities. Manipulative procedures involving the restricted items listed below (weighing, processing, etc.) are prohibited.

Flammable or combustible liquids (except as noted).

The restriction on the storage or use of flammable and combustible liquids in corridors is intended to eliminate fuel sources which, if ignited, could involve a large area and

would be difficult to contain. With the presence of liquid materials, there also is the potential for the accumulation of flammable vapors since ventilation rates in corridors are substantially lower than those in laboratories.

This restriction does not prohibit the use of properly located scintillation counters in corridors in which the scintillant containing a flammable solvent is confined in sealed vials. However, the storage of bulk flammable containing scintillants is prohibited. It is recommended that consideration be given to using non-flammable scintillants and locating the counter in the laboratory.

Hazardous chemicals.

The manipulation or storage of the following types of chemicals in the corridor is prohibited: (1) chemicals that are reactive (e.g., sodium or potassium) or may become reactive (e.g., picric acid); (2) explosive compounds (e.g., tetranitromethane); (3) compounds that are capable of creating a single, acute toxic exposure if released (e.g., phosgene or nitrogen mustard); (4) highly corrosive or strong oxidizers that may react violently with other materials; (5) known chemical carcinogens that could easily contaminate an area or unnecessarily expose personnel; (6) temperature sensitive compounds which may become autoreactive (e.g., acrolein); and (7) waste chemicals of any nature due not only to the type of hazards noted above but also to the impossibility of identifying unknown compounds or obtaining information once such material leaves the laboratory.

Compressed gas cylinders - all sizes.

Cylinders containing compressed gases present a particular hazard because of their high pressure. A single cylinder can reach a speed of 35 mph in 1/10th of a second if the valve mechanism breaks. In addition, some cylinders are not provided with a means of venting the contents if the internal pressure exceeds the design limits of the cylinder. While the same hazards exist within a laboratory, their consequences are more likely to be confined. Provisions for acceptable storage of compressed gases in authorized locations outside individual laboratories or work areas are set forth in Section 4.

Liquified gases (except as noted).

Although liquified gases (e.g., cryogenic liquids) often present equal or greater hazards than compressed gases, the typical equipment using liquid nitrogen as a freezer supply or serving as a refrigerator backup is considered to represent minimal risk and would be permitted if properly located in the corridor.

Radioactive materials (except as noted).

The use or storage of radioactive materials in corridors is specifically prohibited, except for the amount of radioactive material in actual use within a scintillation counter or film cassettes in a locked freezer. Radioactive wastes are not to be placed in corridors in preparation for pick up by disposal personnel. Nothing in this section

would preclude the transportation of sources or radioactive specimens through the corridors; however, such activities are to be conducted in a manner which minimizes the chances of contamination through spillage or breakage and maintains radiation levels within acceptable limits.

Failure to adhere to these provisions may compromise the NIH license to use radionuclides issued by the U. S. Nuclear Regulatory Commission. Users found in violation of these provisions are subject to temporary or permanent loss of their authority to use radionuclides. Further information is available in the *NIH Radiation Safety Guide* and from the Radiation Safety Branch, DS, 496-5774.

Biological agents at or above Biosafety Level 2 or those requiring BL2 or higher physical containment.

Equipment which, by design or use, would present significant hazards under routine or emergency conditions.

Some classes of equipment may be safely operated in the corridor. The intent of this policy is to restrict equipment which, by design, operation or use, may present undue risk. For example, centrifuges normally are designed to safely contain the physical hazard associated with a disintegrating rotor. However, they are not normally designed to contain chemical or biological agents. Centrifuges used for procedures with nonhazardous materials are permitted.

Refrigerators or freezers containing only non-restricted material do not present any unique hazards and are permitted. However, the user should consider the potential risk associated with the material stored, the frequency of access (regular and frequent access increases the probability of accidental breakage) and the consequences of electrical or equipment failure (e.g., internal temperature rise resulting in vapor overpressure, exothermic reaction, etc.).

Equipment designed to operate under either positive or negative pressure shall be located in the laboratory. There is a clear risk of pressure-related explosions or implosions in addition to the risks that may be associated with the agents or compounds used in such equipment. At NIH, there have been several instances where the cover of a lyophilizer has fractured under normal operations and a lyophilizer was the source of a serious fire loss.

Incubators, used in compliance with this Section, are permitted in corridors since their normal operating temperatures do not pose undue risks. However, drying ovens, which operate at far higher temperatures, are not permitted in the corridor.

Other types of equipment not permitted in corridors are those utilizing high voltage (e.g., some equipment used for electrophoresis) or those posing mechanical hazards such as unguarded belts, pulleys or gears.

Normally, duplicating or copy machines which do not utilize flammable liquids are permitted, provided that excess paper stock is not stored in the open corridor.

Live Animals.

Construction Items.

Construction materials may be stored *temporarily* in the corridor during the workday, as long as the minimum prescribed clear corridor width is maintained. Construction materials shall not remain in the corridor overnight. Equipment and supplies shall not, under any circumstances, be stored in stairwells.

Surplus Property.

Equipment and supplies cannot be abandoned in corridors, horizontal exits, designated areas of refuge or stairwells. Dispose of unneeded property by contacting the appropriate IC Property Custodial Officer. Refer to the *NIH Personal Property Management Guide* (NIH Manual 26101-25-2) for additional information.

Waste Containers.

Containers for the storage/disposal of waste materials shall not be left in the corridor. The *NIH Waste Disposal Guide* describes specific disposal procedures for the following types of waste: general, medical pathological, chemical, radioactive and mixed.

D. Location of material or equipment does not prevent emergency access to exit doorways, emergency equipment or utility panels, and an adequate clear space is provided on one or both sides of all doorways serving occupied space.

In Building 10, 200 Series, North Corridor, the north wall shall be clear, with STORAGE ONLY on the south wall. A 10-foot clear space shall be maintained on each side of the principal (central) entrance from the South Corridor and a 2-foot clear space provided on each side of all other door openings in the south wall.

All emergency equipment; including safety showers, eyewashes, sprinklers and fire extinguishers, must be maintained with full and unobstructed access at all times. Storage or equipment placement shall not block fire alarm system equipment (fire alarm pull stations, fire alarm panels, etc.), utility panels or closets. A **36 inch** clear space must be provided on each side of the panel or device. All exit doors, including stairwell doors, shall be clear of storage to a distance of **five feet** on either side of the door.

That portion addressing clear space adjacent to doorways serving occupied space is primarily intended to provide a measure of protection for emergency personnel to safely observe or gain access to a room during an emergency. The preferred method is to provide an 18-inch clear space on the latch side of the door jamb. An alternative

method is to provide a 12-inch clear space on each side of the door jamb. Both methods meet the access provisions for persons with disabilities of the Architectural Barriers Act, which NIH is required to follow. Some buildings presently do not have access provisions for people with special needs.

The restrictions applicable to Building 10 are related to emergency plans which call for this portion of the North Corridor to be used for emergency evacuation of patients. Door opening clearances are necessary to accommodate patients who may be transported in beds or litters.

E. All material storage shall be contained within suitable metal cabinets with metal doors. Material storage outside of metal cabinets or on open shelves is prohibited.

This requirement also permits storage in standard file cabinets and similar metal furnishings. Storage on top of cabinets is not allowed in order to eliminate potential injury from material or equipment that may become accidently dislodged. Combustible materials (e.g., paper, wood, plastic or similar materials) are to be stored within the cabinets, since they constitute a fuel source which would serve to spread fire through the corridor. Combustible furniture and cabinets can also serve as a fuel source and shall not be stored or used in the corridor.

The requirement for metal doors is intended to eliminate the risk of personal injury should someone fall against a glass door.

F. Electrical service to authorized equipment shall be provided by permanent installation of an easily accessible protected outlet located adjacent to the equipment. Extension cords shall not be used.

The use of extension cords or equipment power cords passing through doorways or walls is prohibited. Modifying a fire rated building component (wall, door or door frame) so that an electrical cord will pass through, negates the fire rating of the component. The user should request that the Division of Engineering Services determine the availability of additional power and whether the additional heat load generated by the equipment can be accommodated. Since the cooling capacity for corridors is limited, elevated ambient temperatures may adversely affect equipment operation.

4. Compressed and Liquified Gas Cylinder Storage Locations

Authorized locations for full and empty cylinders have been identified for all buildings. All stored cylinders shall conform to the restrictions posted at each location, shall be chained in the racks, shall not exceed the capacity of these chain racks, shall have protective caps in place, and shall identify the responsible investigator.

Posted restrictions prohibit the storage of flammable and oxidizing gases adjacent to one another and restrict toxic or corrosive gases to individual laboratories or work areas. Other restrictions may be posted in specific buildings due to the nature of the occupancy.

5. Local Policies and Restrictions

An IC that occupies an entire building or the lead IC in a multi-IC building may establish additional policies and restrictions for corridor use in buildings under its control, providing such policies and restrictions do not conflict with this NIH policy. A draft copy of local policies and restrictions must be forwarded to the Division of Safety, Occupational Safety and Health Branch, for review and approval.

An IC may establish additional requirements for the space it occupies in a building as provided in this Section.

Last Updated: 08/26/99 NIH

Fire Prevention

A comprehensive laboratory safety survey will take into account all aspects of workplace safety, and while not the primary focus of the survey, fire prevention must be considered. Fire prevention issues are of concern since approximately 6,000 people die and millions of dollars in property damage is suffered each year in fires in the United States. The NIH has been fortunate in not suffering a fatality due to fire. However, fires have and do occur. Typically the fires have been electrical in nature, and in sprinkler equipped laboratories, damage is confined to the immediate area.

> In one NIH laboratory, an electrophoresis apparatus overheated and the electrical leads reached a temperature hot enough to ignite combustible materials adjacent to the unit. Two sprinkler heads were activated and contained the fire. No injuries occurred, and the laboratory was operational the next day with a damage estimate of $4,000.
>
> Conversely, another electrically related equipment fire caused damages of over $250,000 to the laboratory module and the loss of valuable research data. The laboratory had to be completely renovated, and the staff was displaced for almost one year. This second laboratory was not equipped with automatic sprinklers.

Contact the Division of the Fire Marshal, Office of Research Services at (301) 496-0487 for questions concerning fire safety issues.

Fire Safety Components

Ensure that all exits are clearly marked and free of clutter. A fire extinguisher should be available in the adjacent corridor and all fire alarm pull stations marked and accessible. Verify that all telephones in the area have the emergency phone numbers posted.

Automatic Sprinklers

Laboratories in newly constructed buildings are provided with automatic sprinklers. Older laboratory buildings are being retrofitted as renovations occur. If a fire emergency occurs in the laboratory, only the individual sprinkler heads which reach their activation temperature (typically 135 - 165 F) will deliver water to the fire. When a sprinkler head activates, the NIH Fire Department is notified through the building fire alarm system that a "water flow" is occurring. Ensure that sprinklers are able to operate effectively in a fire emergency by keeping all stored items a minimum of 18 inches below ceiling mounted sprinkler heads. This will allow for proper water distribution at the fire site when sprinklers are activated.

Heat Detectors

Laboratories which do not have automatic sprinkler protection are provided with heat detectors. Heat detectors are small, round, ceiling mounted devices which detect either rapid temperature increases or sustained high temperatures in the laboratory. If they become activated, the NIH Fire Department will be notified through the building fire alarm system that a potential fire emergency is in progress. Through renovations, all heat detectors will eventually be replaced with automatic sprinklers which will deliver water to control or extinguish a fire before it has a chance to grow and cause more damage.

Fire Doors

Fire doors are typically of steel or solid wood construction and are provided with specially tested components including closers, latching hardware and wired fire-rated glass windows. The corridor door which is used to enter the laboratory is a fire door. Individual laboratory and office doors

shall be kept closed at all times to maintain both directional airflow within the building and the fire resistive integrity of the fire walls. Keeping the doors closed assists in the control of nuisance odors and, in the event of a fire, provides smoke and flame containment. Equipment power cords or any type of wire or tubing passing through or under doorways is prohibited. Don't nail or screw signs or other items to a fire door. Modifying a fire rated building component (wall, door or door frame) negates the fire rating of the component.

Open Penetrations

All penetrations through fire barriers (e.g., wall and floor slab penetrations, etc.) must be sealed with an approved fire stopping material which meets the requirements of applicable fire and building codes. The integrity of these barriers must be maintained in order to provide smoke and flame containment thereby preventing loss of life and property. Sealed penetrations help maintain the proper air balance in an area and assist in the control of nuisance odors. If open penetrations exist in the laboratory, notify the Building Facility Manager.

Passage and Aisle Widths

A minimum 36 inch free and clear passage width shall be maintained in all doorways and aisles within each office and laboratory. Equipment, furniture, or materials which reduce these passageways to less than 36 inches must be relocated.

Combustibles

The storage of combustible material (e.g., cardboard boxes, paper, plasticware, catalogs, etc.) in the laboratory and office should be minimized. These materials should be kept in metal cabinets with metal doors. The cabinet doors should be closed when not in use. Do not store these items on upper shelves where they might restrict the flow of the automatic sprinkler in the event of a fire.

Flammable Liquid Storage Cabinets

In all laboratory renovations, at least one flammable liquid storage cabinet is provided. These cabinets are constructed of heavy gauge steel, labeled or identified as a flammable liquid storage cabinet, designed with a raised sill to contain any spills within the cabinet and have a three-point latch to keep the doors closed. Contact your IC Safety and Health Specialist (301) 496-2960 for information on obtaining a cabinet.

References

National Institutes of Health Manual Chapter 1361. Corridor Utilization Policy, revised 1998.
NFPA 101 Life Safety Code. ANSI/NFPA I01. American National Standards Institute, National Fire Protection Association, 2003 edition.

Updated 4/24/2006

Electrical Safety

BACKGROUND

Laboratories are often heavily furnished with different types of electrical equipment and instrumentation. Laboratory personnel should be familiar with the equipment and instrumentation on hand and with the electrical hazards they may present.

Occupational electrocutions continue to be a serious problem throughout the United States. Data obtained from the Bureau of Labor Statistics' Annual Survey indicate that approximately 10% of all occupational fatalities are due to electrocutions. This data, as well as other information collected by the National Institute of Occupational Safety and Health (NIOSH), demonstrate that fatalities due to electrocutions occur in a variety of ways. NIOSH Alerts have described cases in which workers have been electrocuted as a result of contacting improperly grounded equipment. These investigations also demonstrate that careful routine inspection and aggressive maintenance might well prevent such fatalities.

Laboratory workers may not recognize the hazard of electrocution associated with the use of worn or damaged receptacles, connectors, extension and power cords, or the equally hazardous condition presented by electrical equipment placed in wet or damp areas. Electrical hazards of this sort are particular concern because of the large number of users of electrical equipment in all kinds of workplaces at the NIH. Caution should be used around ALL electrical circuits and equipment. The potential for electric shock should never be underestimated. Employers and other groups should regularly emphasize the safe use of electricity in the workplace. A continuous effort must be made to prevent electrical injuries and deaths due to electrical contact with moisture and because of damaged receptacles and connectors.

The Division of Occupational Health and Safety (DOHS) strongly urges periodic inspection and maintenance of electrical systems to assure compliance with applicable sections of the National Electrical Code, Occupational Safety and Health Administration (OSHA) standards, and NIH requirements. Electrical components should be used only when in accordance with the manufacturers' specifications, and should be tested and approved by a nationally recognized laboratory (such as Underwriters Laboratory, Factory Mutual, etc.).

THREE MAJOR HAZARDS OF ELECTRICITY

Shock

The majority of occupational regulatory guidance directed at electrical hazards is based on the potential for shock or electrocution. More fatalities occur from exposure to 120 VAC than any other voltage, and an electric shock with a current as low as 30mA may be fatal. Essentially, the normal electrical signal of the heart is disrupted by the current passing through it, resulting in fibrillation and arrest. Tissue damage, both as the exit point and in internal organs, may occur if the shock is severe enough or if the duration of the shock is prolonged. The third component of electrical shock injuries is the effect of muscle contraction. Contraction of the hand often prohibits a shock victim form releasing an energized line or mechanical part, exposing the body to the shock effects for a longer period of time.

Arc

One estimate states that one half of all serious electrical injuries involve burn from electrical arcs. Even though electrical arcs and arc blast are usually associated with high voltages, the severity of an arc blast is not voltage sensitive. The occurrence of this phenomenon in a NIH laboratory under normal operational conditions is highly unlikely, although not impossible. An arc is most likely to develop where a phase to phase, or phase to ground cross connection can occur with exposed energized equipment. The heat generated from an electrical arc is intense, and is more likely to cause a fatality than the subsequent arc blast.

Blast

An arc blast results from the rapid expansion of air following the occurrence of an electrical arc. Physical trauma to the body and to the surrounding property is the greatest hazard associated with an arc blast, but again, is an unlikely event in the NIH laboratory.

RECOMMENDATIONS FOR LABORATORY PERSONNEL

Proper utilization of electrical systems

All receptacles and connectors should be used only when in accordance with the manufacturers' specifications, and the specific listing for the item as set forth by nationally recognized testing laboratories. **Users should be advised of the importance of using receptacles and connectors only for applications for which they have been designed.** Physical abuse and stress on these components must be minimized by the selection of a safe location and by exercising prudent care and maintenance practices for laboratory equipment. Immediate corrective action should be taken when damaged components of safety hazards are encountered.

Extension cords, outlets, electrical connections, and damaged wiring

The use of extension cords, including multi-outlet extension cords, is discouraged. If additional outlets are needed, the responsible person should submit a Delpro/ADB work order for additional wall outlets to be installed. If a sufficient number of outlets already exists in a laboratory, but accessibility is limited to a particular instrument or a piece of equipment, then a specialist from ORS, Division of Scientific Equipment and Instrumentation may replace the instruments' power cord with a longer more accommodating cord. If multi-outlet extension cords (also called a **power strip**) are necessary, they must be equipped with a circuit breaker and should be mounted off the floor or bench-top. The use of multiple tap cheater plugs is prohibited.

Equipment with damaged electrical cords shall be taken out of service immediately and electrical cords replaced prior to returning equipment to service.

Fuses in raceways
Only fuses with an appropriate rating shall be used. Never attempt to substitute a fuse with a higher rated fuse. If there is any question concerning fuse selection, contact the Building Engineer of assistance.

Ground-fault circuit interrupters
Ground fault circuit interrupters (GFCIs) shall be installed on all outlets located within one (1) meter of any water source (e.g. sink, eyewash, safety shower). Contact the Building Engineer to have GFCI's installed where outlets are within one meter of a sink, or to remove the outlet if it is not required.

Space heaters
Space heaters are not allowed in NIH laboratories. Difficulties in regulating a comfortable temperature shall be directed to the appropriate Office of Research Facilities Maintenance Unit by calling (301) 435-8000.

Compliance
OSHA Standards
General Industry
1910.137 – Electrical protective devices.
Design safety standards for electrical systems
1910.302 – Electrical utilization systems.
1910.303 – General requirements.
1910.304 – Wiring design and protection.
1910.305 – Wiring methods, components, and equipment for general use.
1910.306 – Specific purpose equipment and installations.
1910.307 – Hazardous (classified) locations.

1910.308 – Special systems.

Industry Standards

National Research Council. 1995. Prudent Practices for Handling Hazardous Chemicals in the Laboratory. National Academy Press, 2 101 Constitution Ave.. NW, Washington, DC 20418

National Electrical Safety Code. 70. 2005

National Electrical Code 70B, 2006

National Electrical Code. 70E-2004

Technical Assistance Branch Surveillance Programs

Anesthetic Gases Program

The NIH has established a surveillance program to evaluate employee exposures to various anesthetic gases. The program is maintained by the Division of Occupational Health and Safety (DOHS), Technical Assistance Branch (TAB).

The program operates by identifying and quantifying the exposure levels of workers who through the cause of their work use and thus are potentially exposed to the various anesthetic gases (nitrous oxide, halothane, isoflurane and metophane) used at the NIH for two or more continuous hours. The surveillance results provide information on the effectiveness of the controls being used to minimize employee exposures. In addition, these surveys provide documentation of NIH surveillance activities to be reviewed by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International and other similar entities.

In evaluating employee exposures to waste anesthetic gases, the NIH uses a modification of the 1977 National Institute of Occupational Safety and Health (NIOSH) criteria. These criteria recommend the following time-weighted-average (TWA) exposure limits as measured over the period of anesthesia administration: a) halogenated anesthetics (isoflurane, halothane, metophane) 2 parts per million (ppm) when used alone, and 0.5 ppm when used in combination with nitrous oxide; b) nitrous oxide, 25 ppm. Contact DOHS, TAB at (301) 496-3353

Ergonomics

Individual workstation ergonomic evaluations, consultations, and self-diagnostic training sessions are conducted either through the direct request of NIH employees, or at the request of Occupational Medical Service (OMS) health care professionals on behalf of an NIH employee. If practical, on-the-spot corrections and adjustments are made to workstations and recommendations for future improvements are offered. Group consultations and self-diagnostic training sessions are also conducted for NIH employees upon request, with the approval of that group's administrative component. Written ergonomic evaluation reports are prepared only at the request of an OMS health care professional. Contact DOHS, TAB at (301) 496-3353.

Ethylene Oxide Surveillance Program

In accordance with OSHA Regulation 29 CFR 1910.1047, Ethylene Oxide, the NIH has established an Ethylene Oxide Surveillance Program. The Division of Occupational Health and Safety (DOHS), Technical Assistance Branch (TAB) maintains the Ethylene Oxide Program. Medical surveillance of NIH employees is provided by the Occupational Medical Service (301) 496-4411.

Potential ethylene oxide exposures at the NIH are typically associated with using ethylene oxide sterilizers or handling materials removed from the sterilizers. There are three types of ethylene oxide gas sterilizers used at the NIH:

1. Automatic or general purpose sterilizers that are supplied by compressed-gas cylinders and vented to a sanitary sewer,
2. Single-dose cartridges which are exhausted through a ventilation system,
3. Andersen Anprolene Sterilization Systems which use glass ampules.

All ethylene oxide sterilization facilities at the NIH are routinely surveyed to determine if the workers that operate the sterilizers and those that work in the immediate area are exposed to

excessive levels of ethylene oxide. These surveys also serve to provide documentation of surveillance activities to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International and other similar entities.

In evaluating employee exposures to ethylene oxide, the NIH complies with the exposure levels set by OSHA. These are: **1.0 ppm** as an "8- hour time-weighted average", **5.0 ppm** as a "short term exposure limit", and **0.5 ppm** as an "action level." Contact DOHS, TAB at (301) 496-3353.

Formaldehyde Surveillance Program

In accordance with OSHA Regulation 29 CFR 1910.1048, Formaldehyde, the NIH has established a Formaldehyde Surveillance Program. The Division of Occupational Health and Safety (DOHS), Technical Assistance Branch (TAB) maintains the Formaldehyde Program. Medical surveillance of NIH employees is provided by the Occupational Medical Service (OMS) (301) 496-4411.

The Formaldehyde Program operates by identifying and quantifying the exposure levels of workers potentially exposed to formaldehyde. All NIH employees who work with formaldehyde gas, its solutions, and materials that release formaldehyde should be identified and their location and job activity supplied to TAB. Personnel in the following laboratories are covered by the regulation: pathology, gross anatomy (human and animal), clinical pathology and histology. All other laboratories where formaldehyde exposure results from the handling and preparation of preserved specimens, the use of formaldehyde in experimental procedures (animal infusion) and where formaldehyde is used as chemical reagent or intermediate are covered by the Laboratory Standard, 29 CFR 1910.1450. These surveys also serve to provide documentation of surveillance activities to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) International and other similar entities.

In evaluating employee exposures to formaldehyde, the NIH complies with the exposure levels set by OSHA. These are: **0.75 ppm** as an "8-hour time-weighted average", **2 ppm** as a "short term exposure limit", and **0.5 ppm** as an "action level". Contact DOHS, TAB at (301) 496-3353.

Glutaraldehyde Program

A surveillance program for glutaraldehyde has been established at the National Institutes of Health to evaluate Clinical Center employee exposures. The program is maintained by the Division of Occupational Health and Safety (DOHS), Technical Assistance Branch (TAB). Medical Surveillance of NIH employees is provided by the Occupational Medical Service (OMS) (301) 496-4411. Personnel in the Clinical Center are covered by this protocol. All other laboratories where glutaraldehyde exposure results from the handling and use of glutaraldehyde are covered by the Laboratory Standard, 29 CFR 1910.1450.

Glutaraldehyde is widely used as a microbiocidal agent for the disinfection and/or cold sterilization of medical and surgical equipment. It is also used in some X-ray developers, in electron microscopy, as a tissue fixative agent and in some embalming agents. The program operates by identifying and quantifying exposure levels of workers potentially exposed to glutaraldehyde, and providing information on the effectiveness of the controls that are being used to minimize exposures. These surveys also serve to provide documentation of surveillance activities to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

For evaluating employee exposures to glutaraldehyde, the NIH uses exposure criteria established by the American Conference of Governmental Industrial Hygienists (ACGIH). ACGIH has adopted a ceiling threshold limit value (TLV-C) of **0.05 ppm (0.2 mg/m_3)** as an airborne exposure level that should not be exceeded at anytime during any part of the work shift. Contact DOHS, TAB at (301) 496-3353.

Hearing Conservation Program

In accordance with OSHA Regulation 29 CFR 1910.95, Occupational Noise Exposure, the NIH has established a Hearing Conservation Program (HCP). The Division of Occupational Health and Safety (DOHS), Technical Assistance Branch (TAB) is responsible for implementing all elements of the Hearing Conservation program at the NIH, except for audiometric testing, that is conducted and managed by the NIH Occupational Medical Service (OMS) (301) 496-4411.

All areas where noise levels exceed 80 dBA are identified. Areas where noise level equal or exceed 85 dBA are posted with noise “caution” warning signs that recommend the wearing of hearing protection. Employees who work in areas that have noise levels equal to or exceed 85dBA are monitored. If the dosimetry monitoring meets or exceeds the dose exposure limit of 100%, which corresponds to an 8-hour time-weighted average (TWA) sound level at 85 dBA, then the employees are referred to OMS for inclusion in the HCP.

Inclusion into the HCP entitles the employees to annual audiometric testing and hearing conservation training that includes proper usage of hearing protection and assistance on all relevant aspects of the HCP. They are required to wear hearing protection when in posted “caution” areas. Contact DOHS, TAB at (301) 496-3353.

Indoor Air Quality

Indoor air quality evaluations on the NIH campus and Poolesville facility are conducted by the Division of Occupational Health and Safety (DOHS), Technical Assistance Branch (TAB) personnel with the assistance of Building Engineers and Facility Managers from the Office of Research Facilities. Privately owned off-campus facilities are evaluated with the assistance of NIH Facility Managers and the property management company. Indoor air quality complaints are initially referred to the Building Engineers and Facility Managers, since most concerns can be alleviated through the use of simple environmental controls. On-campus odor complaints must be referred immediately to the NIH Fire Department, their response is discretionary.

Comprehensive indoor air quality surveys are conducted at the request of Building Engineers and Facility Managers only after the use of environmental controls, or adjustments in the building's operations and maintenance plan have failed to achieve positive results. Comprehensive surveys are also conducted at the request of Occupational Medical Service health care professionals with specific medical guidance. Contact DOHS, TAB at (301) 496-3353.

Primary Barrier Equipment

The Division of Occupational Health and Safety (DOHS), Technical Assistance Branch (TAB) provides various services regarding certification, maintenance, and decontamination of specific primary barrier equipment. Chemical fume hoods and other ventilation systems known as local exhaust ventilation systems or LEVs (down draft tables and sinks, slot hoods, and canopy hoods) are certified when installed and on an annual basis. The certification of these systems includes inspection, adjustment, and verification of air flow velocities and direction.

Another type of primary barrier equipment is the biological safety cabinet. Most types of these cabinets at the NIH provide product, environmental, and personnel protection. Biological safety cabinets are maintained and certified according to the National Sanitation Foundation Standard 49, which is the accepted standard for the biological safety cabinet industry. Various tests are performed to verify air flows, air filter integrity, containment of contaminated cabinet air, and that the cabinet is safe to operate regarding other cabinet operational features. Whenever cabinets are to be moved, internal repairs are to be made, or when filters are to be replaced, these cabinets must be decontaminated.

Services are provided for other types of primary barrier equipment, such as, vertical clean benches, cage change stations, animal racks, and animal isolators. Contact DOHS, TAB at (301) 496-3353.

Respiratory Protection Program

The NIH has established a Respiratory Protection Program in accordance with OSHA Regulation 29 CFR 1910.134, Respiratory Protection. The program provides NIH-wide procedures for the proper selection, use and care of respiratory protective equipment and is maintained by the Division of Occupational Health and Safety (DOHS), Technical Assistance Branch (TAB).

The NIH program covers all NIH employees with the exception of the NIH Clinical Center (potential exposure to tuberculosis) and building 41A, Maximum Containment Laboratory. All NIOSH approved respirators are covered by the NIH Respiratory Protection Program.

Work site evaluations, respirator selection, respirator training and fit testing are done by the Technical Assistance Branch. Medical clearance to wear a respirator is done through the Occupational Medical Service (OMS) (301) 496-4411. Appropriate respirators are provided to employees by the NIH at no cost to the employee. Employees and/or supervisors are not permitted to purchase or supply their own area. Contact DOHS, TAB at (301) 496-3353.

Safety Shoe Program

The Division of Occupational Health and Safety (DOHS), Technical Assistance Branch (TAB) administers the NIH Safety Shoe Program. This program has been established to protect NIH employees from possible foot injuries due to occupational foot hazards. Any NIH employee who may encounter a potential foot injury on the job can obtain safety shoes upon approval of the individual's supervisor. At present, most shoes are purchased from a shoe-mobile which comes to the NIH campus at the Building 13 Loading Docks on the first and third Wednesday of each month from 1:00 pm to 4:00 pm. All safety shoes made available to NIH employees have met the general requirements for impact and compression resistance required by the ANSI Standard Z41. Employees requiring safety footwear must bring a completed "Request for Safety Footwear, NIH-1980," which is signed and completed by their supervisor. The supervisor indicates what types of shoes are required by that particular employee. NIH employees are authorized to obtain a new pair of safety shoes when the current shoes are no longer serviceable (generally about every 12 months). Any medical problems requiring special footwear for an individual must be documented by a private physician or by the Occupational Medical Service. Contact DOHS, TAB at (301) 4963457.

Community Health Branch

Food Safety and Sanitation Program

The NIH Food Safety Program provides periodic comprehensive environmental hygiene inspections of all NIH affiliated cafeterias, snack bars, beverage stations/carts, child care facilities and the Clinical Center Nutrition Kitchen, both on- and off-campus. These inspections are conducted by a certified food safety professional. Inspections of these facilities include reviews of the physical structure, food protection practices, food service employee hygiene behavior, equipment cleanliness, solid and liquid waste disposal procedures, pest management protocols and general sanitation.
Food service facility plan reviews, employee training activities, enforcement procedures, and consultative sessions relating to food hygiene and public health sanitation are conducted by the NIH Food Safety Program Manager.

Reports on food protection and other public health consultations are furnished to Division of Employee Services (DOES). Food complaints and possible food borne disease outbreaks associated with NIH facilities are investigated and evaluated. Compliance with current acceptable food safety practices is achieved through enforcement meetings and re-inspections.

The NIH Food Safety Program assures that facilities comply with the current US Public Health Service, Food and Drug Administration recommended Food Code and the Code of Maryland, Health Department Regulations 10.15.03, governing Food Service Facilities.

For more information contact the Food Safety Program Manager in the Division of Occupational Health and Safety, Community Health Branch at (301) 496-4294.

Water Analysis for Lead

The Division of Occupational Health and Safety (DOHS), Community Health Branch CHB supports Office of Research Facilities (ORF) in maintaining the quality of drinking water in NIH buildings by sampling drinking water for concentrations of lead as needed. The branch also maintains records of previous samples and their corresponding locations to aid in responding to inquires concerning drinking water quality.

For the evaluation of acceptable lead levels, the NIH uses the EPA trigger level of **20 parts per billion (ppb)** as set forth in the EPA Document "Lead in Drinking Water in Schools and NonResidential Buildings," April 1994 (EPA 812-B-94-002). In areas where the lead in drinking water levels is found to be greater than 20 ppb, the ORF will supply bottled water until such a time as the lead levels are reduced to below 20 ppb. Typical control measures to reduce lead concentrations can include: flushing the system or the water fountain, cleaning the strainers, repiping, and replacing the entire water fountain.

Contact DOHS, CHB at (301) 496-4294

Pest Management

The Division of Occupational Health and Safety (DOHS), Community Health Branch (CHB), is responsible for providing integrated pest management services and consultation to the NIH research and support services community. The CHB uses the integrated pest management (IPM) method of pest control in all areas where it is responsible for pest management, i.e., the Bethesda campus and Clinical Center, the NIHAC at Poolesville, and off-campus (rental and lease) facilities. IPM programs focus on managing the environment to prevent pest problems

through the use of surveys and reports on issues such as structural repair, sanitation and housekeeping, in addition to education and training of facility personnel, and the use of “least toxic” pest control methods. IPM programs and services help ensure the safe and hygienic operation of NIH facilities and support AAALAC and JCAHO accreditation, Occupational Medical Services, food safety and protection, child care programs, and the occupational health and safety program at the NIH. In order to accomplish its mission, the CHB performs the following activities:

- The CHB is the principal organization responsible for the development and implementation of integrated pest management programs at the NIH. These programs are designed to meet the specific needs of NIH personnel, research programs, and the facilities. CHB staff also evaluate, oversee, and administer all contracted IPM services at the NIH.
- Conduct field surveys and pest identifications to provide technical advice, recommendations, and guidance on issues pertaining to the safe and effective control of pests in and around NIH facilities.
- Review plans, drawings, and specifications for the design, construction or renovation of buildings in order to incorporate integrated pest management concepts and requirements in all NIH occupied facilities.
- Collaborate with and support other ORS components, and their programs, in areas related to IPM, i.e., animal feed and bedding operations, solid waste management, building and grounds maintenance, housekeeping services, etc.
- Evaluate new pest management technologies and specialized methods for preventing or controlling pests in the biomedical research environment and to improve the efficiency of ongoing programs.
- Serve as the primary liaison to the extramural research community, federal and state agencies, universities, and the private sector on integrated pest management issues.

  Contact DOHS, CHB at (301) 496-4294

AED

The Occupational Safety and Health Administration (OSHA) estimates 13 percent of all workplace fatalities occur annually as the result of cardiac arrest. When used by trained personnel, Automatic Emergency Defibrillators (AEDs) and Cardiopulmonary Resuscitation (CPR) can assist persons experiencing some types of cardiac arrest. Applied electrical shocks from a portable emergency AED can restore normal cardiac rhythm in some instances. According to the American Heart Association “Chain of Survival” concept, the efficacy of defibrillation and overall survivability is directly tied to how quickly emergency action is administered.

The Community Health Branch (CHB), Division of Occupational Safety and Health (DOHS), Office of Research Services (ORS), is responsible for management of a Public Access Defibrillation (PAD) program for off-campus NIH leased-buildings. The objective of the PAD program is to provide AEDs for use by trained lay-responders in the event of a cardiac emergency involving employees, students or visiting associates.

At this time, surveys are ongoing at off-campus buildings regarding the placement of the AEDs. Additional information regarding the program, including how to volunteer as a lay-responder, will be posted in the future. An aggressive advertising program is planned to introduce the program and provide opportunities for off-campus personnel to become trained in CPR and AED.

This page will be updated as more information is available

For more information contact the DOHS, CHB at 301-496-4294.

Radiation Safety Information

ACTIVITY	SECTION	DESCRIPTION
Radiation Safety Officer	Office of the Chief	Maintains NIH radiation safety program and Nuclear Regulatory Commission (NRC) licenses
Executive Secretary, NIH Radiation Safety Committee (RSC)	Office of the Chief	Provides support to NIH Radiation Safety Committee
Records Management/Privacy Act/FOIA	Office of the Chief	Manages RSB database and information
Radiation Safety Training	Technical Services	Coordinates radiation safety training program
Building 21 "hot lab" facility	Technical Services	Manages the Building 21 facility used for iodinations and work with high activity sources
Dosimetry ("film badges")	Technical Services	Provides dosimeters and exposure histories to researchers
Human Use Dosimetry	Technical Services	Internal/external dosimetry support to RSC, IRP, RDRC
Bioassay program	Technical Services	Schedules and performs thyroid counts, whole body counts, urine bioassays
Ordering, shipment, transfer and receipt of radioactive materials to/from NIH	Radioactive Materials Control	Receives and delivers radioactive materials in accordance with NRC regulations
Radioactive waste disposal	Radioactive Materials Control	Manages radioactive waste disposal and provides guidance on policies and procedures for waste disposal
Radioactive waste/mixed waste pickups, waste containers	Radioactive Materials Control	Collects, processes, manages, and disposes of radioactive waste
Laboratory radiation safety surveys and surveillance	Radiation Safety Operations	Conducts radiation safety surveys of research laboratories
Survey meter	Radiation Safety Operations	Calibrates survey calibrations meters for contamination or exposure rate
Radiation safety consultation	Radiation Safety Operations	Addresses radiation safety questions, counsels Declared Pregnant Women, analyzes shielding needs

Radiation exposure investigations	Radiation Safety Operations	Investigates internal and external radiation exposures of NIH personnel
Radiation surveys of radiation producing equipment	Radiation Safety Operations	Surveys x-ray machines, irradiators, and electron microscopes
Laboratory clearances	Radiation Safety Operations	Performs radiation safety clearances of laboratories for construction/non-radioactive materials use

Introduction to NIH Hazard Communication Program

The National Institutes of Health's comprehensive Occupational Safety and Health Program has been established to provide NIH employees with places and conditions of employment in which the risk of exposures to potential hazards is minimized.

The NIH Hazard Communication Program (NIH-HCP) described in this booklet is an integral part of the NIH Occupational Safety and Health Program. The NIH-HCP uses a comprehensive approach to inform employees of the potential chemical hazards to which they may be exposed. Additionally, it provides individuals with information concerning protective measures that can be used to minimize these hazards. By having such information available to each employee at the worksite, users of chemicals will be able to recognize potential health hazards and to use the recommended protective measures, thus minimizing the risk of occupational exposures to hazardous chemicals. The ultimate goal of these efforts is to reduce, to the lowest practical level, the incidence of chemically related injuries and illnesses of NIH employees. The NIH-HCP complies with the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard, 29 CFR 1910.1200.

The NIH-HCP has been established to provide information about chemical hazards. This information is communicated in three primary ways:

1. Material safety data sheets (MSDSs),
2. Warning labels and signs, and
3. Training programs.

Part I of this booklet describes the responsibilities that NIH management, supervisors, and employees have in developing, implementing, and maintaining the NIH-HCP. Part I also describes how each of the above three mechanisms is used to inform employees of both the hazardous properties of the chemicals they work with and the measures they can take to protect themselves from exposure to these chemicals.

Part II of this booklet includes a summary of the NIH-HCP along with a checklist on how to implement the program.

PART I. THE NIH HAZARD COMMUNICATION PROGRAM (NIH-HCP)

Policy Statement

It is the policy of NIH that all employees who are potentially exposed to hazardous chemicals in their assigned jobs shall be fully informed of both the hazardous properties of the chemicals and the protective measures that are available to minimize exposures to these chemicals. This type of information will be made available to employees by means of labels on chemical containers, material safety data sheets and training. Employees will be informed of any known hazards associated with chemicals to which they may be potentially exposed before their initial assignment and whenever the hazards change. The goal of the NIH-HCP is to reduce employee exposure to

hazardous chemicals and thus reduce the overall incidence of chemicallyrelated injuries and illnesses.

Responsibility for Program Implementation

Effective hazard communication can be realized when responsible management and responsive employees work together in developing and implementing an integrated hazard communication program. The NIH-HCP is performance-based, allowing for flexibility in implementing the program components depending on the needs of the employees within the various work environments. The roles and responsibilities of NIH management and employees are outlined below.

Responsibilities of the Director, NIH

The Director, NIH, is ultimately responsible for the health and safety of all NIH employees. The Director establishes health and safety policies and delegates the responsibility for design and implementation of safety and health programs. The Director is responsible for assuring that an effective Hazard Communication Program is administered for all NIH employees.

Responsibilities of the Non-Laboratory Supervisor

Supervisors in support (e.g., housekeeping, animal care, engineering services, etc.) and administrative areas provide the necessary direction and support to ensure the effective implementation of the NIH-HCP for their work locations. The supervisor is responsible for providing the information and training specific to the employees' specific needs and work environment.

The supervisor(s) of each section or work location is responsible for:

1. Identifying chemicals that pose a potential health or physical risk to employees in their work area;
2. Ensuring that employees are made aware of the potential hazards associated with those chemicals, including the availability of chemical specific information (e.g., MSDSs);
3. Maintaining a listing of hazardous chemicals in the workplace;
4. Ensuring that employees minimize any potential exposure through the use of safe work practices, necessary or assigned protective equipment, and the use of available engineering or facility design features (e.g., specialized ventilation devices such as hoods, physical barriers, etc.);
5. Providing employees, under their supervision, guidance and training specific to their work;
6. Coordinating employee medical consultation and/or surveillance if overexposure to a hazardous chemical is suspected; and
7. Reporting to the NIH Division of Occupational Health & Safety or the NIH Occupational Safety and Health Committee problems pertaining to the implementation of the NIH-HCP.

Responsibilities of the Laboratory Supervisor

Because the use of potentially hazardous chemicals in laboratories is governed by the NIH Chemical Hygiene Plan (NIH-CHP), the laboratory supervisor is exempt from some of the provisions of the Hazard Communication Program. Laboratory supervisors do not have to inventory or keep a listing of all hazardous chemicals used in the laboratory, nor do they have to have a written hazard communication program specific for the laboratory worksite. The laboratory supervisor is responsible for:

1. Ensuring that employees minimize any potential exposure by using appropriate work practices, as specified in the NIH-CHP;
2. Ensuring that employees are aware of the potential hazards associated with those chemicals used in their work area, and have access to chemical specific safety information (e.g., labels, MSDSs);
3. Ensuring that the labels on incoming chemical containers are not removed or defaced;
4. Providing employees, under their supervision, guidance and training specific to their work environment and encouraging employees to attend basic laboratory safety training available through the Division of Occupational Health & Safety;
5. Coordinating employee medical consultation and/or surveillance if overexposure to a hazardous chemical is suspected; and
6. Reporting to the NIH Division of Occupational Health & Safety or the NIH Occupational Safety and Health Committee problems pertaining to the implementation of the NIH-HCP.

Copies of the OSHA Laboratory Standard and the NIH Chemical Hygiene Plan (NIHCHP) are available from the IC Safety and Health Specialist (301-496-2346).

Responsibilities of the Employee

Employees have the opportunity to affect their work environment by gaining knowledge about the chemical hazards associated with their work and applying this knowledge to reduce the risk of injury and adverse health effects to themselves, coworkers, and visitors in their work area.

Each employee is responsible for:

1. Performing his/her work in a safe manner;
2. Complying with all applicable provisions of the NIH-HCP;
3. Following all standard operating procedures or research protocols for their worksite; and
4. Reporting the existence of health and safety hazards associated with the use of chemicals to his/her supervisor, the NIH Division of Occupational Health & Safety, or the NIH Occupational Safety and Health Committee.

Responsibilities of the Division of Occupational Health & Safety (DOHS)

The Division of Occupational Health & Safety provides administrative management for the NIH-HCP. The DOHS is responsible for:

1. Monitoring federal regulations and updating the NIH-HCP to reflect any changes;
2. Providing basic training in hazard communication for NIH employees;
3. Providing technical guidance and policy interpretation to personnel at all levels of responsibility on matters pertaining to the NIH-HCP; and
4. Providing assistance to supervisors and employees in the implementation of the NIH-HCP. The DOHS employs specialists in industrial hygiene, chemical hygiene, and occupational health and safety to assist all NIH employees in developing effective safety programs for implementation at their worksite. An Occupational Safety and Health Specialist is assigned to each IC to provide support and assistance in addressing the safety and health concerns of NIH employees.

Responsibilities of the NIH Occupational Safety and Health Committee

The NIH Occupational Safety and Health Committee serves in an advisory role to the Director, NIH, and to the directors of the institutes and centers (ICs), and to the DOHS. As it relates to the NIH-HCP, the committee is responsible for:

1. Periodically reviewing and monitoring the status of compliance with the NIH-HCP to evaluate program development, implementation and resources, and
2. Making recommendations for program improvement.

The NIH-HCP Components

The NIH Hazard Communication Program consists of three components:

1. The identification of hazardous chemicals;
2. The maintenance of current hazard information at the worksite including warning labels and signs and material safety data sheets; and
3. The training of employees. The purpose of each of these components, as well as the requirements for implementing them, are provided below.

Identification of Hazardous Chemicals

The NIH-HCP applies to all persons who are potentially exposed to hazardous chemicals in their work. The first step that each non-laboratory supervisor must take in their work areas is to identify and inventory the hazardous chemicals present. All supervisors must determine which chemicals may present a hazard to their employees based on the physical and chemical properties of the substance, its potential health effects and how it is used. The identification and inventory of hazardous chemicals should also consider which employees are at risk of exposure. The hazardous chemical inventory and assessment provides the basis for determining what additional controls, safe work practices and training will be needed.

In identifying hazardous chemicals in the work area, attention should be given to:

1. The quantity of the chemical used;

2. The physical properties of the chemical (e.g., volatility, flammability, etc.);
3. The potency and toxicity of the chemical;
4. The manner in which the chemical will be used; and
5. The means available to control release of or exposure to the chemical. It is important that written operating procedures or research protocols for each work area are periodically reviewed to ensure that appropriate safety precautions are included. Protocols should be updated to reflect changes that may affect the chemical hazard assessment of ongoing work.

The chemical listing serves as an index for MSDSs that must be readily available at the worksite, and helps determine how containers must be labeled as well as which employees are in need of training. A complete and current hazardous chemical listing benefits employees who need to select appropriate safeguards to reduce their risk of exposure on a daily basis, as well as those who respond to emergencies or who need to repair equipment that is potentially contaminated with a chemical.

Material safety data sheets should be consulted for important physical and health hazard data. Supervisors may contact the Safety and Health Specialist assigned to their IC (301-496-2346) for assistance in performing a hazardous chemical assessment or to obtain copies of the OSHA Hazard Communication Standard or additional copies of this document.

Hazard Information at the Worksite

Employees must be provided with information about the potential hazards of chemicals before beginning their initial assignment, in order that the potential for harmful exposures is minimized. This hazard information must be made available to employees at the worksite. Two readily available resources for this type of information are the label on the chemical container (see exhibit 1) and the MSDS available from the manufacturer, distributor or importer of the chemical (see exhibit 2).

Labels

Labels on containers of hazardous chemicals serve as an *immediate* warning of the hazards associated with the chemical and as a reminder that more detailed safety and health information is available elsewhere, particularly in an MSDS. For these reasons, manufacturers, distributors, and importers are required to provide labels that include both the chemical name and all appropriate hazard warnings.

Labels, signs, placards, and other forms of warnings provide *visual* reminders of specific hazards not only to employees working directly with the chemical, but also to others such as visitors, service representatives, housekeeping personnel, and emergency personnel who may encounter these chemicals.

Supervisors must establish procedures to assure that containers of hazardous chemicals are labeled, tagged or marked with:

1. The identity of the hazardous chemical and

2. The appropriate hazard warnings signifying the primary health and physical hazards of the contents.

The chemical identity on the label must correspond to that used in the MSDS. The supervisor must ensure that labels or other forms of warning are legible, in English, and prominently displayed on the container or readily available in the work area. Users of hazardous chemicals should ensure that labels on purchased or supplied chemicals are not removed or defaced unless the container is relabeled with the required information.

Material Safety Data Sheets

MSDSs identify the physical and chemical properties of hazardous chemicals (e.g., flash point, vapor pressure), their physical and health hazards (e.g., potential for fire, explosion, signs and symptoms of exposure), and precautions for safe handling and use. Information in the MSDS covering the physical and chemical properties of a chemical (e.g., volatility, flammability, reactivity), its toxic properties (e.g., carcinogen or reproductive hazard), and routes of exposure can be used to define what potential hazards the material presents to users.

Employees must have access to the MSDS (or the safety-related information contained therein) for each chemical that the supervisor has identified as potentially hazardous within their worksite.

All manufacturers, distributors, and/or suppliers of hazardous chemicals are required to provide an MSDS with each chemical purchased. If shipments of chemicals are received without an MSDS, the recipient should contact the manufacturer/supplier for a copy. If a potentially hazardous chemical is purchased through the Central Store, a copy of the MSDS for that chemical may be obtained from the IC Safety and Health Specialist.

It is important to ensure that MSDSs (or information contained therein) maintained at the worksite provide up-to-date, complete, and accurate information. Supervisors and employees may wish to consult with the DOHS or the National Library of Medicine for access to additional chemical information databases (see appendix B).

Employee Information and Training

All employees working with, or who may be potentially exposed to, hazardous chemicals should receive information and training that will enable them to work safely with those chemicals. Employees should receive training about the nature of the known hazards associated with the chemicals they handle, as well as the measures that are available to protect themselves. By receiving training in a timely manner, employees are better able to make use of the information contained in an MSDS and on labels, to recognize potential hazards to their own health, as well as those for fellow employees or visitors in

their work area, and to make informed judgments regarding the appropriate safeguards to use in minimizing their exposures to hazardous chemicals.

Employee training should focus on the following:

1. The known physical and health hazards associated with the chemicals in their workplace;
2. Methods that can be used to detect the presence or release of the chemicals; and
3. Available protective measures to minimize exposures including engineering controls, safe work practices, personal protective equipment, and emergency procedures.

Supervisors must provide this information before employees begin their initial assignment and whenever a new hazardous chemical is introduced into the workplace. This information must be provided for both routine and non-routine tasks.

In addition to job-site specific training provided by the supervisor, the DOHS offers a variety of safety training, industrial hygiene and surveillance programs, and information resources to promote employee health and safety. Information regarding the training opportunities offered by the DOHS can be obtained by contacting the IC Safety and Health Specialist (301-496-2346).

PART II. GUIDANCE IN IMPLEMENTING THE NIH-HCP

A summary of the key requirements for implementing the NIH-HCP is provided in checklist form. More detailed information on each of these requirements is provided on the pages referenced in parentheses. Additional guidance for implementing the program requirements can be obtained by consulting the answers to the questions found on pages 8-10. Supervisors are encouraged to collaborate with the DOHS staff to implement the plan at their specific worksites.

Checklist for Implementing the NIH-HCP

- Identification of Hazardous Chemicals by Work Area
- Obtain and Maintain MSDSs of Hazardous Chemicals from Manufacturers/Distributors
- Devise Method to Ensure that MSDSs (or information contained therein) are Accessible to Employees
- Ensure Labels are Legible and List Chemical Name and Necessary Hazard Warning Information
- Inform Employees of NIH-HCP
- Inform Employees of Job-site Specific Chemical Hazards and Available Protective Measures for Reducing Potential Exposure
- Provide New Information on Chemical Hazards as It Becomes Available

Answers to Questions on Program Implementation

1. What is a hazardous chemical?

OSHA's Hazard Communication Standard (29 CFR 1910.1200) broadly defines a hazardous chemical as any chemical whose presence or use is a physical hazard or a health hazard.' Chemicals defined as "physical hazards include:

- combustible liquids, compressed gases, explosives, flammables. organic peroxides, oxidizers, pyrophorics, and unstable or water-reactive chemicals.

Chemicals defined as "health hazards" include those that:

- cause either acute or chronic health effects due to exposure by inhalation, ingestion or direct skin or eye contact. The term health hazard includes chemicals which are carcinogens, reproductive toxins, irritants, corrosives, sensitizers, and chemicals that damage a specific organ or system (e.g., hepatotoxins, nephrotoxins).

Supervisors and employees may wish to consult the OSHA Hazard Communication Standard for more detailed definitions of both physical and health hazards. Additional information can be obtained by attending DOHS training programs or calling the Safety and Health Specialist assigned to your IC at (301) 496-2346.

The NIH-HCP uses OSHA's broad definitions to refer to the hazardous properties which may be associated with chemicals. However, to determine whether certain chemicals pose physical or health risks to employees and require inclusion in the NIH-HCP, specific attention should be given to the exposure potential of chemicals present in the work area. Exposure potential is dependent on the following:

1. The quantity of the chemical used;
2. The manner in which the chemical is used; and
3. The means available to control release of or exposure to the chemical.

Additional factors that may influence the effects of chemicals on the health of employees are the potency or toxicity of the chemical and any characteristics of the persons using the chemical that may place them at increased risk (e.g., medical conditions, sensitivity to the chemical).

2. How can I get a copy of OSHA's Hazard Communication Standard?

A copy of the standard is available by contacting your IC Safety and Health Specialist at (301) 496-2346.

3. What sources of information are available for compiling a list of hazardous chemicals?

As an aid in determining substances which are considered to be hazardous, supervisors should consult OSHA's Hazard Communication Standard for detailed explanations and definitions of categories of hazardous chemicals. Manufacturer's MSDSs can be used to identify important physical and health hazard data. Information on developing and maintaining chemical listings and performing chemical hazard assessments can be obtained by contacting the IC Safety and Health Specialists in the DOHS.

4. Why can't I simply rely on the manufacturer's/ supplier's MSDS to determine whether a chemical is hazardous?

While the chemical and physical properties of the material (e.g., its volatility, flammability, reactivity), as well as its toxic properties (e.g., carcinogen or reproductive hazard), can be used to define the hazard potential the material presents to employees, the risk of experiencing harmful health effects varies with the degree of exposure in a given work operation. Therefore, the determination of what constitutes a hazardous chemical needs to be made by the supervisor for his/her work area. Factors influencing the degree of exposure include the quantity of chemical, the manner in which it is used, and the means available to control the release of, or exposure to the chemicals.

5. *What information must be maintained and made accessible to employees at the worksite?*

A current list of chemicals identified as potentially hazardous to employees, MSDSs (or information contained within) for those chemicals, and labels that identify the chemical and list the critical hazard information must be maintained and made accessible at the worksite. In certain cases, the information in the MSDS section covering precautions and safe handling and use may apply more to chemical usage in *industrial processes.* Therefore, NIH users of chemicals should factor in their own working requirements and conditions of use when selecting appropriate work practices, personal protective equipment, and engineering controls.

Laboratories do not have to maintain chemical listings under the hazard communication standard.

6. What if I find that the manufacturer's/supplier's MSDS provides incomplete information or is missing critical information?

Two additional sources of information are available. The National Library of Medicine (NLM) has several databases that can be used to access additional information (see appendix B). The DOHS also maintains an MSDS database for a large number of chemicals. If you need information, contact your IC Safety and Health Specialist at (301) 496-2346.

7. What if the manufacturer's/supplier's MSDS does not include the names or identity of the chemical component(s)?

Information relating to the chemical identity or name of a hazardous chemical may be withheld by the chemical manufacturer, importer or employer if it is deemed a trade secret. However, information about its harmful properties can not be withheld and must be included in the MSDS. Also, the chemical identity must be made available to health professionals and certain designated individuals to render medical treatment, to bring about protective measures in an emergency or, when requested in non-emergency situations, to protect employees who may be potentially exposed.

For such disclosures, a written statement of confidentiality may be required prior to release of the chemical identity or, in an emergency situation, as soon as circumstances permit.

8. If an employee works with several hazardous chemicals in a process, is it necessary to maintain an MSDS for each hazardous chemical present?

Employees must have access to information related to potentially hazardous chemicals identified in each work area. This information may be the manufacturer's MSDS or some other source that contains pertinent health and safety information. The supervisor, however, may choose to develop safe operating procedures for processes that cover groups of hazardous chemicals designed to identify and control the collective hazards associated with these chemicals. In these cases, individual MSDSs do not have to be maintained.

9. Do I have to re-label all incoming containers of hazardous chemicals?

Manufacturers and suppliers of hazardous chemicals are required to label their containers with the identity of the chemical and the appropriate hazard warnings. Therefore, in most cases, incoming containers will not have to be relabeled, if the majority of employees in a work area speak a language other than English, supervisors may add the necessary information in that language as long as the information is presented in English as well.

10. Do I need to label processing equipment?

For stationary process containers (including automated processing equipment such as auto-analyzers or DNA synthesizers, signs, placards, or other written operating procedures may be used in place of labels as long as it is clear to which containers these instructions refer.

11. Do I need to label transfer containers?

When transferring hazardous chemicals from a labeled container to another the portable or transfer container does not have to be labeled if only one person handles the

container and the container is filled and emptied by that person during the workday. In situations where other persons may be exposed to the chemicals present in the portable or transfer container, it is always prudent to label the container to inform those who are potentially exposed about the hazards associated with the chemical and the necessary precautions to minimize their exposure.

12. Does laboratory glassware need to be labeled?

Laboratory containers such as beakers, test tubes, etc., do not have to be labeled with hazard information since they are usually intended for immediate use. However, it is good laboratory practice to identify the contents of all containers.

13. In addition to labels, what other forms of warning should be used to identify the presence of hazardous chemicals?

In some cases, warning signs on doors should be used to alert persons not to enter the work area unless they are aware of the necessary safeguards. Door signs should also provide the name and telephone number of the person(s) to contact in case of emergency. This information is especially important for visitors or employees not assigned to that area.

14. If MSDSs and labels are maintained at the worksite, why is it necessary to train employees?

MSDSs and labels have limited value unless the employees understand how to use the information and are aware of actions to be taken to avoid or minimize hazardous exposures and thus the occurrence of adverse health effects Training provides this opportunity and allows supervisors to assess their employees' level of understanding of the material and their use of written operating procedures or protocols.

15. What additional training programs covering chemical safety are available?

The DOHS offers a program entitled Laboratory Safety at the National Institutes of Health." Contact your IC Safety and Health Specialist for a course announcement. Additional training in Hazard Communication for supervisors, support, and administrative personnel is provided by the DOHS on an as needed basis. An introduction to the general topic of hazard communication is included in the NIH Training Center Course entitled "Introduction to Supervision."

16. What if I believe that I have not been provided with the required hazard information?

All NIH employees have the right to discuss their safety and health concerns with their supervisor, the DOHS, and the Occupational Safety and Health Committee without fear of reprisal for expressing their concerns.

17. Are contract employees covered under the NIH-HCP?

Employees working under contract at the NIH are subject to their employer's Hazard Communication Program to the extent that hazardous chemicals are being supplied and used by the contractor. Contract employees potentially exposed to chemicals present at the NIH facility can obtain NIH-HCP information from the NIH project officer for the contract. NIH contractors must submit a listing of hazardous chemicals they bring into NIH facilities and provide corresponding MSDSs to the NIH project officer for the contract.

18. Who can I contact if I have questions on implementing any of the requirements of the NIH-HCP?

A toxicologist within the DOHS provides technical guidance on matters pertaining specifically to the NIH-HCP. In addition, the DOHS has assigned Safety and Health Specialists to each IC to assist NIH employees with safety and health concerns. Contact your IC Safety and Health Specialist at (301) 496-2346 to obtain the necessary assistance.

APPENDIX A -General References

American Conference of Governmental Industrial Hygienists (Issued annually). *Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices.* 2005. Cincinnati, Ohio.

Bretherick, L. *Handbook of Reactive Chemical Hazards.* 3rd ed. 1985. Butterworths, Boston.

Bretherick, L. *Hazards in the Chemical Laboratory.* 4th ed. 1986. Royal Society of Chemistry, London.

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National Institutes of Health (NIH). *NIH Occupational Safety and Health Management.* 2/27/2006. NIH Manual Issuance No. 1340.

National Institutes of Health (NIH). *NIH Guidelines for the Laboratory Use of Chemical Carcinogens.* 1981. NIH Pub. No.81-2385.

National Research Council. *Prudent Practices for Handling Hazardous Chemicals in Laboratories.* 1981. National Academy Press, Washington, D.C.

NIOSH Pocket Guide to Chemical Hazards. June, 1997 (or subsequent editions). National Institutes for Occupational Safety and Health (NIOSH), Cincinnati, Ohio, Government Printing Office (GPO), Washington, D.C., GPO Stock No. 017-03300483-8.

Patty's Industrial Hygiene and Toxicology. Vol. 1 - General Principles, Vol. II – Toxicology, Vo I . III - Theory and Rationale of Industrial Hygiene Practice. 4th ed. 1991. Wiley-Interscience, New York.

Sax, N. I. *Dangerous Properties of Industrial Materials.* 7th ed. 1989. Van Nostrand Reinhold Company, New York.

Steere, N.V., (Fd.) *CRC Handbook of Laboratory Safety.* 3rd ed. 1990. CRC Press, Boca Raton, Florida.

U.S. Department of Labor. *Chemical Hazard Communication.* 1992. Occupational Safety and Health Administration (OSHA), Washington, D.C., OSHA Publication No. 3084.

U.S. Department of Labor. *Hazard Communication Guidelines for Compliance.* 1988. Occupational Safety and Health Administration (OSHA), Washington, D.C., OSHA Publication No. 3111. U.S. Government Printing Office (GPO), Washington, D.C., GPO Stock No. 929022-00000-9.

U.S. Department of Labor. Title 29 Code of Federal Regulations (CFR) Parts 1910, 1915, 1917, 1918, 1926, and 1928 - *Hazard Communication. 1989. U.S. Government* Printing Office, Washington, D.C.

U.S. Department of Labor. Title 29 Code of Federal Regulations (CFR) Part 1960 - *Basic Program Elements for Federal Employee Occupational Safety and Health Programs and Related Matters.* 1991. U ,S. Government Printing Office (GPO), Washington, D.C.. GPO Stock No. 869-013-00113-3.

World Health Organization (WHO). *Handling Chemical Carcinogens in the Laboratory - Problems of Safety.* 1979. International Agency for Research on Cancer (IARC) Lyon, France. IARC Scientific Publication
No. 33. WHO Publication Centre, 49 Sheridan Avenue, Albany, NY 12210.

APPENDIX B - National Library of Medicine (NLM) Databases for Chemical Hazard Information

The NLM collection of databases can be directly accessed through the "Grateful Med" software package. For more information about the databases listed below, as well as to receive an application package for "Grateful Med." Contact (301) 496-6193 and ask for the service desk.

1. Registry of Toxic Effects of Chemical Substances (RTECS)

RTFCS is a database file containing toxic effect data on 90,000 chemicals. Both acute and chronic effects are covered including data on contact irritation, carcinogenicity, mutagenicity, and potential reproductive hazards. Federal regulatory requirements and exposure levels also are included.

2. Toxicology Information Online (Toxline) and Toxicology Literature from Special Sources (Toxlit)

Toxline and Toxlit are the NLM's online, interactive collection of toxicological information containing references to published material and research in progress.

3. Toxicology Data Network (Toxnet)

Toxnet is a computerized system of toxicologically oriented factual data banks managed by the National Library of Medicine. Many NIH facilities with NLM accounts may access this database directly, those facilities which do not have access to the NLM can request assistance from the NLM.

4. Medlars Online (Medline)

The Medline is the NLM file of bibliographic citations from approximately 3,400 medical and biomedical journals.

APPENDIX C - NIH-HCP Resources

Use this space for your personal record of resources
that are available in implementing the NIH-HCP.

APPENDIX D - Glossary of Terms

Acute Effect:
An adverse effect on a human or animal which has severe symptoms developing rapidly and coming quickly to a crisis.

Carcinogen:
A substance or agent capable of causing or producing cancer in mammals, including humans. A chemical is considered to be a carcinogen if it is listed by either the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP) or by the Occupational Safety and Health Administration (OSHA).

Chronic Effect:
An adverse effect on a human or animal body, with symptoms which develop slowly over a long period of time or which recur frequently.
Combustible Liquid. Any liquid having a flashpoint at or above 100° F (38° C), but below 200° F (93° C).

Corrosive:
A chemical that causes visible destruction of, or irreversible alterations in, living tissue by chemical action at the site of contact.

Engineering Control:
A mechanical or design feature intended to remove or isolate potentially harmful substances in the work place. Common engineering controls include local exhaust ventilation systems such as hoods and physical barriers to contain potential hazards.

Explosive:
A chemical that causes a sudden, almost instantaneous release of pressure, gas and heat when subjected to sudden shock, pressure, or high temperature.

Flammable:
A solid, gas, liquid or aerosol that will ignite and burn according to specific tests and definitions. A flammable liquid is defined as any liquid having a flashpoint below 100° F (38° C).

Flashpoint:
The minimum temperature at which a liquid gives off a vapor in sufficient concentration to ignite and burn according to specific tests and definitions.

Hepatotoxin:
A substance that causes injury to the liver.

Irritant:
A chemical, which is not corrosive, but which causes a reversible inflammatory effect on living tissue by chemical action at the site of contact.

Nephrotoxin:
A substance that causes injury to the kidneys.

Non-Routine Task:
A specific task or activity that is not part of the employee's assigned duties. A non-routine task includes work which the employee may not have specific training or requisite experience to do the work safely.

Organic Peroxide:

An organic compound that contains the bivalent -0-0 structure and may be considered to be a structural derivative of hydrogen peroxide where one or both of the hydrogen atoms has been replaced by an organic radical.

Oxidizer:
A chemical other than a blasting agent or explosive that initiates or promotes combustion in other materials, causing fire either by itself or through the release of oxygen or other gases.

Personal Protective Equipment:
Devices worn by the worker to protect against potential hazards. Typical examples include chemically resistant gloves, eye and face protection, hard hats, impermeable aprons, etc.

Pyrophoric:
A chemical that will ignite spontaneously in air at a temperature of 130° F (54.4) C) or below.

Reproductive Toxin:
Substances that affect either male or female reproductive systems and may impair the ability to have children.

Sensitizer:
A chemical that causes a substantial proportion of exposed people or animals to develop an allergic reaction in normal tissue after repeated exposure to the chemical.

Target Organ Toxin:
A toxic substance that attacks a specific organ of the body

Vapor Pressure:
The pressure exerted by a saturated vapor above its own liquid in a closed container. These values are usually expressed in millimeters of mercury (mmHg). The higher the vapor pressure, the more easily it will enter the atmosphere when left exposed.

Water Reactive:
A chemical that reacts with water to release a gas that is either flammable or presents a health hazard.

EXHIBIT I

Examples of Labels

The NIH-HCP requires that all containers of hazardous chemicals be labeled, tagged or marked with the identity of the material and appropriate hazard warnings. For chemicals purchased from a manufacturer, importer or distributor, the original label on the container is required to provide the necessary identification and hazard warning

information. In most work locations at the NIH, the original container label will be adequate in meeting the NIH-HCP labeling requirement.

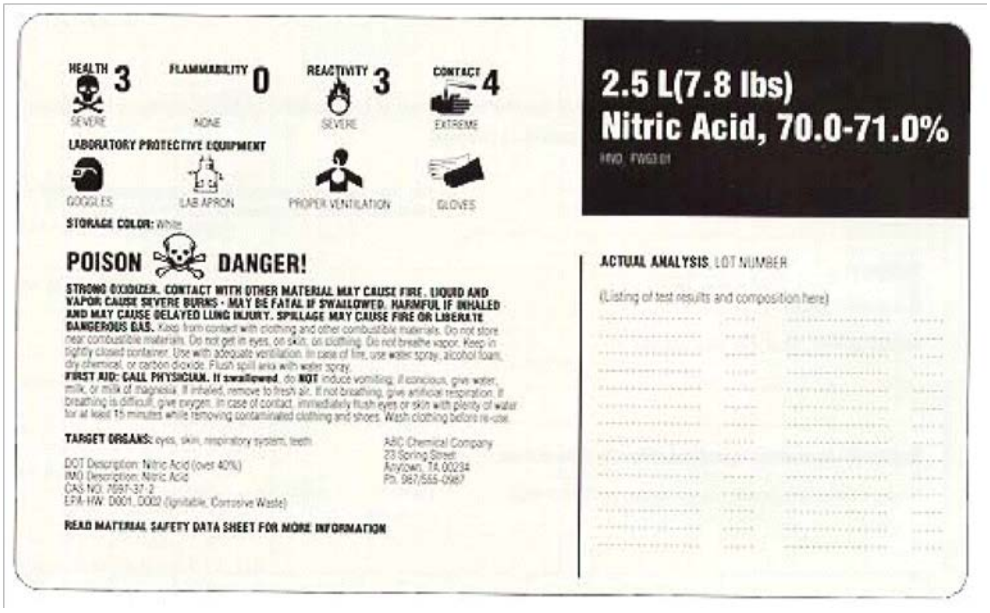
The layout and format of the information presented on a chemical container labels may vary. Chemical container labels may use words, pictures, color codes or various combinations of words and symbols to convey hazard identification and warning information. Label A provides an example of a container label for a typical laboratory chemical. Label B provides an example of a container label for a typical industrial chemical.

The specific words and symbols used on chemical container labels indicate the type of hazard present. The use of the word

- DANGER indicates that a serious potential hazard is present.
- WARNING indicates that a moderate potential hazard exists.
- CAUTION is typically used when the chemical presents a low potential hazard.

Additional information on labels and other forms of warnings is provided in the training programs offered by the DOHS.

Label A



Label B

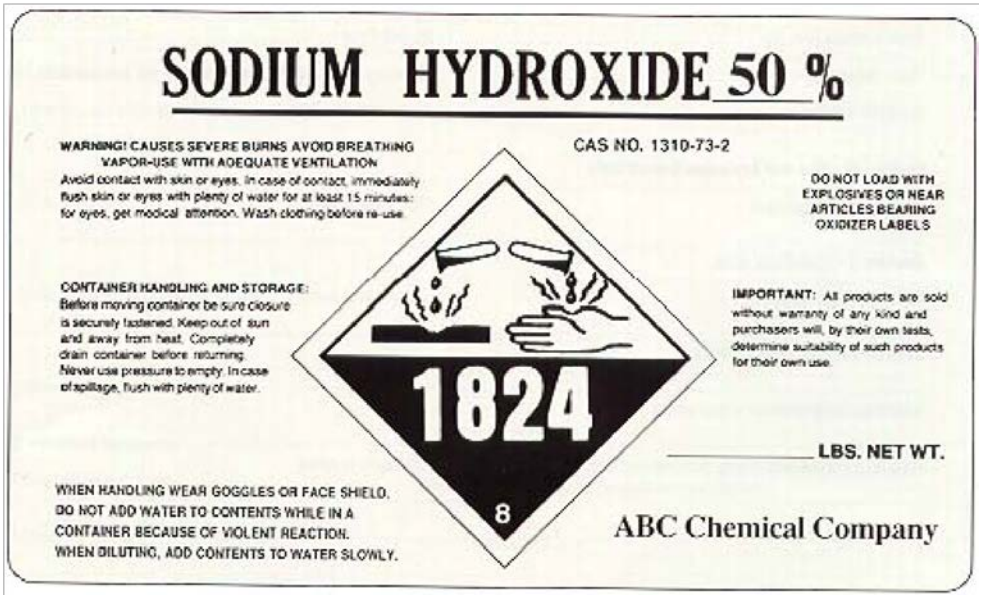


EXHIBIT 2

Material Safety Data Sheet Form

This sample MSDS identifies the key categories of information that need to be included in an MSDS whether it is developed in-house or by the manufacturer/supplier/importer of the hazardous chemical.

Note: Blanks spaces are not permitted. If any item is not applicable or no information is available, the space must be marked to indicate that.

Identity (as used on label and chemical list)

Section I

Manufacturer's Name

_____

Address (number, street. city, state, and zip)

_____

_____

_____

_____

Emergency Telephone Number

_____

Information Telephone Number

_____

Date Prepared:_____

Signature of

Preparer (Optional)_____

Section II - Hazardous Ingredients/Identity Information

Hazardous Components (specific chemical OSHA ACGIH Other Limits % identity- common name(s))
PEL TLV Recommended optional

_____

_____

_____

Section III - Physical/Chemical Characteristics

Boiling Point_____ Specific Gravity (H,O =1)_____

Vapor Pressure (mm Hg)_____ Melting Point_____

Vapor Density (air =1)_____ Evaporation Rate (butyl acetate =1_____

Solubility in Water_____ Appearance and Odor_____

Section IV - Fire and Explosion Hazard Data

Flash Point (method used) Flammable Limits LEL UFL **Section V - Reactivity Data**

Stability (unstable/stable) Conditions to Avoid

Incompatibility (materials to avoid)

_____

Hazardous Decomposition or Byproducts

_____

Hazardous Polymerization (may occur/will not occur) Conditions to Avoid

_____

_____

_____

Section VI - Health Hazard Data

Route(s) of Entry (inhalation/skin/ingestion)

_____

Health Hazards (acute and chronic)

_____

Carcinogenicity (NTP/IARC monographs/OSHA -regulated)

_____

_____

Signs and Symptoms of Exposure

_____

_____

Medical Conditions Generally Aggravated by Exposure

_____

_____

Emergency and First Aid Procedures

_____

_____

Section VII - Precautions for Safe Handling and Use

Steps To Be Taken in Case Material is Released or Spilled

_____

_____

Waste Disposal Method

_____

_____

Precautions To Be Taken in Handling and Storing

_____

_____

Other Precautions

_____

_____

Section VIII - Control Measures

Respiratory Protection (specify type):
Ventilation (local exhaust/general mechanical/other):
Protective Clothing/Equipment (gloves/eyewear/other):
Work/Hygienic Practices:

NATIONAL INSTITUTES OF HEALTH
DIVISION OF OCCUPATIONAL HEALTH & SAFETY

NIH Chemical Hygiene Plan

Introduction

The use of hazardous chemicals in the laboratory is a necessary part of modern biomedical research science. In an effort to ensure the protection of laboratory personnel from the risks associated with the use of hazardous chemicals, the Occupational Safety and Health Administration (OSHA) has promulgated a standard entitled *Occupational Exposures to Hazardous Chemicals in Laboratories* (29 CFR 1910.1450), referred to as the Laboratory Standard. Traditionally, OSHA health standards have been established to help protect industrial and manufacturing workers who may be exposed to significant quantities of only a few hazardous chemicals over a working lifetime. In laboratories, the use of hazardous chemicals is generally limited to small quantities used on a short-term basis and in operations where the chemicals and procedures change frequently. The Laboratory Standard demonstrates that OSHA has recognized the need for a standard that focuses on the unique nature of laboratory work.

The Laboratory Standard requires the development and implementation of a formal, written, and employee-accessible program, referred to as a Chemical Hygiene Plan. This plan, as defined by OSHA, must be "capable of protecting employees from health hazards associated with hazardous chemicals used in the laboratory."

The Laboratory Standard complements the provisions of the OSHA *Hazard Communication Standard* (29 CFR 1910.1200). In accordance with the *Hazard Communication Standard*, the NIH has established a written program, the *NIH Hazard Communication Program* (NIHHCP). The NIH-HCP provides for the identification and inventory of hazardous chemicals, the availability of Material Safety Data Sheets (MSDSs) for these chemicals to employees, chemical container labeling, and employee training in hazard communication.

The NIH Chemical Hygiene Plan is consistent with the *NIH Hazard Communication* Program. Additionally, the Laboratory Standard supersedes the provisions of all other OSHA health standards, except for the permissible exposure limits found within the OSHA *Air Contaminants Standard* (29 CFR 1910.1000) and the substance-specific limits found in Subpart Z, *Toxic and Hazardous Substances*.

I. Purpose

This plan outlines the information and services provided by the Division of Occupational Health and Safety (DOHS) and the Division of Environmental Protection (DEP) on the safe use, storage, and disposal of hazardous chemicals in the laboratory.

This program is written to meet the specific safety and health requirements outlined in 29 CFR 1910.1450, *Occupational Exposure to Hazardous Chemicals in Laboratories*.

II. Scope

This plan applies to all laboratories and laboratory personnel of the NIH that use, store, or handle hazardous chemicals.

Selected Definitions

Action Level: A concentration designated in 29 CFR part 1910 for a specific substance, calculated as an eight hour time-weighted average, that initiates certain required activities such as exposure monitoring and medical surveillance.

Chemical Hygiene Officer: A qualified individual who provides technical guidance in developing and implementing a chemical hygiene plan. At the NIH, the Director of the DOHS serves in this capacity.

Chemical Hygiene Plan: A written plan that establishes procedures and policies to protect laboratory personnel and other support staff from the potential adverse health effects associated with exposure to hazardous chemicals.

Designated Area: A predetermined and well labeled area in which carcinogens, reproductive toxins (teratogens/embryotoxins), or other chemicals with significant acute or chronic toxicity are used/kept in the laboratory.

Hazardous Chemical: A substance that is recognized to have a measurable potential for adverse (acute or chronic) health effects in humans. The *Hazard Communication Standard* provides additional guidance in determining the extent of the hazard presented by a chemical. For additional information, please refer to the *NIH Hazard Communication Program*.

IC: Institutes and Centers. An acronym used at the NIH that refers to organizational and management structure.

Laboratory/Laboratory Scale/Laboratory Use: A workplace in which relatively small quantities of hazardous chemicals are used in a nonproduction basis and in which the tasks performed are designed to be easily and safely manipulated by one person.

Laboratory Personnel: Any person working in an NIH laboratory who handles or uses potentially hazardous chemicals. At the NIH, visiting scientists, guest researchers, special volunteers, students, and other similar personnel are included in the scope of the *Chemical Hygiene Plan.*

Particularly Hazardous Substances: These include "select carcinogens," reproductive toxins, and substances which have a high degree of acute toxicity.

Permissible Exposure Limits (PELs): An exposure limit for OSHA regulated substances specified in 29 CFR part 1910.1000, Subpart Z, *Toxic and Hazardous Substances*.

Reproductive Toxins: Chemicals that affect an individual's reproductive ability including chromosomal damage (mutations) and/or have an adverse effect on a fetus (teratogenesis).

Select Carcinogen: A substance regulated by OSHA and designated by the National Toxicity Program (NTP) or the International Agency for Research on Cancer (IARC) as having a moderate to high potential for causing cancer in animal models. This designation separates moderate-to-high risk carcinogens from those with slight to minimal risk when viewed in the context of their use in a laboratory.

Threshold Limit Value (TLV): An airborne concentration of a specific substance under which it is believed that nearly all workers may be repeatedly exposed day after day without adverse health effects. TLVs are exposure guidelines established by the American Conference of Governmental Industrial Hygienists (ACGIH).

III. Responsibilities

NIH Manual Issuance 1340, *NIH Occupational Safety and Health Management*, outlines the scope, objectives, and responsibilities of NIH staff in implementing the NIH Occupational Safety and Health Management Program. Additional information on the safe use of hazardous chemicals is provided in the *NIH Hazard Communication Program*.

The laboratory supervisor is responsible for providing health and safety information to his or her staff on the specific hazards found in the laboratory. In addition, a DOHS Safety and Occupational Health Specialist is assigned to each IC to assist laboratory workers in matters relating to chemical safety.

IV. Information and Training

The DOHS provides information and training for laboratory researchers by providing three training courses that address chemical hazards in the laboratory.

A web based training course, "Introduction to Laboratory Safety", covers basic laboratory safety in NIH research laboratories. This course introduces laboratory personnel to common hazards and exposure risks; including chemical, biological, radiological and physical hazards that are found in NIH research laboratories. All researchers complete this course upon arrival at the NIH. The web-based training program is available at http://www.ors.od.nih.gov/labsafety.

A three-hour classroom course, titled "Laboratory Safety at the National Institutes of Health", is also provided by the DOHS. Researchers attend this classroom course after completing the web-based course. This course provides additional training on the recognition and control of chemical, biological, and physical hazards and provides information on NIH policies and procedures for working safely in research laboratories.

The DOHS also provides a course, titled "Laboratory Safety Refresher Course" that reviews and provides updates for safety procedures and policies that govern laboratory safety at the NIH. NIH laboratory personnel, including summer students and summer research associates, are required to complete this annual refresher course.

Contact the DOHS at 301-496-3353 for a list of upcoming program dates or check the website at http://www.ors.od.nih.gov/labsafety/ and click on the current year brochure.

V. Safe Work Practices with Hazardous Chemicals

Laboratory supervisors should ensure that all personnel under their direction possess the requisite knowledge, training, and education to safely handle hazardous chemicals in the laboratory. All laboratory personnel are responsible for following the appropriate work practices when using hazardous chemicals.

- Minimize all chemical exposures and avoid underestimating the risk. Avoid unnecessary exposure to chemicals by any route.

- Keep food, beverages, cosmetics, and medication outside the lab.

- Protect your clothes and exposed skin by wearing laboratory coats and gowns. Open-toed shoes, sandals, shorts, and other apparel that leave skin exposed are not appropriate when handling potentially hazardous chemicals. Laboratory coats must not be worn outside the laboratory.

- Wear the appropriate gloves and eye/face protection whenever handling hazardous chemicals. These items should not be worn outside the laboratory.

- Ensure unimpeded access to safety showers and eyewash stations. Test flush eyewash stations weekly.

- Remove gloves carefully; thoroughly wash hands and forearms upon completion of work and before leaving the laboratory.

- Use a chemical fume hood when opening, pouring, or handling hazardous chemicals.

- Conduct all work within the chemical fume hood at a distance of at least six inches behind the face opening and position the vertical sliding sash at the height specified on the certification sticker. Avoid blocking the airfoil, baffles, and rear ventilation slot. Support large items with legs to minimize airflow disruption across the work surface. Minimize foot traffic around the hood during use, since passing in front of the hood during operation disrupts the airflow and may pull contaminants out of the hood. Do not use the fume hood for storage. By following these steps, the hood provides adequate containment for most chemical operations.

- Keep all doors to the laboratory closed when using the fume hood to ensure proper hood operation. Open laboratory doors can adversely affect hood performance.

- Avoid the release of toxic substances in work spaces, especially in cold rooms and warm rooms since they have contained, recirculated atmospheres.

- Never pipet by mouth.

- Transport laboratory chemicals using bottle carriers and suitable carts.

- Follow the established procedures for the decontamination and safe movement of scientific and medical equipment (*NIH Personal Property Management Guide, NIH Manual 26101-25-2*).

- Maintain continuous oversight of inexperienced personnel (high school students, etc.) working with potentially hazardous chemicals.

- Contact DOHS (301-496-2346) for clearance of the workspace when personnel have to enter laboratories to perform required services (i.e., maintenance). Remove hazardous materials from equipment/facilities to be serviced and forewarn personnel of the need for protective equipment or work practices, etc. Decontaminate the equipment when possible. Provide the appropriate personal protective equipment.

- Follow the hazardous material spill procedure immediately in the event of a hazardous chemical spill.

Hazardous Material Spill Procedure

1. Close the windows and doors and have everyone leave the room.

2. Call the Fire Department: 911 on-campus and 9-911 off-campus. The Fire Department provides medical attention/transportation to any exposed/injured employees and assists with the spill clean-up.

3. Wash all parts of the body that may have come in contact with the material with copious amounts of water and wait for the Fire Department to respond. Eyes should be flushed for 15 minutes. For minor exposures, rinse the area thoroughly and report to the Occupational Medical Service, Building 10, Room 6C306 (301-496-4411).

4. Do not reenter the room until the Fire Department or appropriate authorities determine that the area is safe.

Suggested Guidelines on the Safe Storage of Hazardous Chemicals in a Biomedical Research Laboratory

The use of chemicals is an essential part of modern biomedical science. Many of the chemicals commonly used in the laboratory are not especially hazardous, but clearly there are exceptions.

In the laboratory, hazardous chemicals can be divided into four general categories: corrosive, flammable, reactive, and toxic. Usually, it is the immediate or obvious hazard that determines the classification of a particular chemical.

The safe storage of chemicals in the research laboratory and the cost associated with the proper disposal of chemical wastes are inextricably linked. According to the American Chemical Society, the cost associated with chemical disposal is an average of ten times the purchase price. In some cases, there are no acceptable waste disposal options. Controlling the increasing cost of proper chemical waste disposal and the inherent hazards of storing and working with hazardous chemicals requires rethinking many of the ways that we purchase, handle, and store laboratory chemicals.

General Principles for the Purchase and Storage of Hazardous Chemicals in the Laboratory

- Purchase only what you can reasonably expect to use during the next six months.
- Buy what you specifically need. It is often possible to buy premade molar and normal solutions, thereby reducing the likelihood of waste.
- Purchase containers in the smallest practical size. Although the cost may be slightly greater, significant savings are realized in reduced disposal cost and safer storage.
- Avoid glass containers. Purchase chemicals in plastic containers. If this is not possible, purchase shatter resistant plastic coated bottles.
- Read labels. Most of the information that you will need to handle and store the chemical is found on the manufacturer's label.
- Obtain and read the Material Safety Data Sheet (MSDS) for each of the chemicals that you use. DOHS will provide copies upon request (301-496-3353). In addition, Laboratory Chemical Safety Summaries for each specific chemical can be viewed at http://www.hhmi.org/about/labsafe/lcss.html .

- Rotate your chemical inventory. Indicate the date received and the date opened. Pay particular attention to the expiration date. Stored chemicals should be inspected periodically for deterioration and container integrity. For example, ether must be dated twice, once when it is received and again when it is opened. It should be discarded as chemical waste six (6) months after opening.

- Label all chemical containers in the laboratory with the following information:

- The name of the chemical or stock solution o The date of preparation o Concentration o Your initials
  The identification and disposal of unlabeled chemical containers is very expensive.

- Keep all chemical containers off floors, carts, and electrical equipment.

- Segregate your chemicals into their respective hazard categories: corrosive, flammable, reactive, or toxic. Physically separate incompatible chemicals.

- Label the secondary storage containers and areas in which particularly hazardous chemicals may be used. These substances must be kept in a designated area.

- Store all hazardous laboratory chemicals below eye level. This simple task greatly reduces the likelihood of something falling from above, breaking, and contaminating the laboratory or causing injuries.

- Avoid placing any chemical container in direct sunlight, underneath a sink, or near heat sources.

- Store hazardous chemicals in cabinets with doors rather than on open shelves. Do not store on laboratory bench tops or in chemical fume hoods.

- Use and manage your chemical fume hood wisely. Do not store chemicals or equipment in the hood since these items can block the air slots and compromise the operation of the hood. Shelving units specifically designed to be used in chemical fumes hoods are available and can be used in your hood. Contact DOHS for information about these products, 301-496-2346.

- Keep temperature-sensitive, volatile or flammable chemicals only in explosionsafe or explosion-proof refrigerators.

- Store all flammable chemicals in an approved flammable storage cabinet. If you need a flammable storage cabinet, call your IC Safety and Health Specialist for assistance (301-496-2346). Flammable storage cabinets come in various sizes.

- Follow the disposal guidelines provided by the NIH Waste Disposal Guide. Do not dispose of chemicals down the drain or by evaporation.

- Properly collect, tag, and date waste. Keep chemical waste containers closed/sealed. Use drip pans under waste collection containers to prevent spills.

Additional information on the safe storage of laboratory chemicals and assistance in determining chemical incompatibility is available from your IC Safety and Health Specialist by calling 301-496-2346.

VI. Control of Exposure to Hazardous Chemicals

Hazardous chemicals may be used only in laboratory facilities specifically designed and engineered for such work. They may not be used in areas including (but not limited to) offices, storage rooms, shared equipment areas, cold rooms, and other areas lacking the appropriate facilities and a proper means of ventilation.

Local exhaust ventilation systems such as fume hoods and slot hoods are the primary method of controlling exposures to hazardous chemicals in the laboratory. All fume hoods used at the NIH must meet the NIH fume hood design specification. ICs may purchase fume hoods only through the Office of Research Facilities Development and Operations (ORFDO). Any alteration affecting a local exhaust ventilation system or associated ductwork must be approved by the DOHS prior to the system's modification.

Ductless chemical fume hoods are not to be used in NIH laboratories. Captured organic vapors begin to desorb from ductless chemical fume hood charcoal filters shortly after adsorption occurs, and some degree of breakthrough or failure to capture occurs during introduction of vapor into the hood.

The need for regular monitoring of airborne contaminants in the laboratory is not usually justified or practical, assuming that fume hoods and other appropriate methods of containment are used properly, safe work practices are followed judiciously, and all laboratory and support personnel practice good personal hygiene.

Contact the IC Occupational Safety and Health Specialist at 301-496-2346 for assistance when a concern arises over potential exposure to a laboratory chemical. Specialized monitoring and chemical exposure determination is available from the Industrial Hygienists of the DOHS.

The Laboratory Standard requires that exposures to OSHA regulated chemicals in the laboratory must not exceed the Permissible Exposure Limits (PELs) or the recommended Threshold Limit Values (TLVs) when there is no PEL.

Special Note on Pregnancy

Personnel who are pregnant or considering becoming pregnant may have special concerns about working with chemicals that have potential reproductive hazards. Such concerns can be discussed with her supervisor, the DOHS IC Safety and Health Specialist (301-496-2346), and/or the staff of the Occupational Medical Service (301-496-4411).

VII. Personal Protective Equipment

Personal protective equipment (PPE) is an essential means of worker protection and can be used in combination with physical containment devices such as fume hoods. The DOHS IC Safety and Health Specialist can perform a workplace hazard assessment to identify any hazards that are present, or likely to be present, during a particular operation and provide information and guidance on the selection and use of personal protective equipment. Information on the selection and use of PPE is also presented in the NIH Laboratory Safety training courses.

Various types of protective equipment, including chemical resistant gloves, aprons, eye and face protection, etc., are available from the NIH Self Service Stores and numerous vendors. Consult the *NIH Supply Catalog* for more information or call your IC Safety and Health Specialist for additional advice (301-496-2346).

Disposable gloves are one of the most commonly used types of PPE. The proper use of disposable gloves provides protection to the wearer by providing a barrier to potential hazards and product protection by protecting experimental materials from enzymes or DNA on the glove wearer's hands. Select the correct glove for the task. Certain gloves do not afford appropriate chemical protection. All laboratory personnel are responsible for following the appropriate work practices when using disposable gloves.

- Remove your gloves carefully; thoroughly wash your hands and forearms upon completion of work and before leaving the laboratory. Do not reuse disposable gloves.

- Disposable gloves that become visibly contaminated or are suspected of being contaminated with hazardous materials should be replaced as soon as possible. Gloves

contaminated with hazardous materials should be disposed of in accordance with the *NIH Waste Disposal Guide*. All used disposable gloves should be treated as potentially contaminated and disposed of appropriately.

- Gloves should not be worn in common-use areas except in emergency situations or in rare situations when conditions warrant their use. Common-use areas are those areas outside laboratory rooms and animal holding and procedure areas.

Some types of gloves are reusable. These gloves should be inspected prior to each use and replaced as necessary. Reusable gloves include those designed to protect the user from the temperature extremes encountered when handling materials that are either hotter or colder than the normal laboratory environment.

Shatter proof prescription safety glasses that provide protection from flying objects are available through the Occupational Medical Service (301-496-4411). Goggles and a face shield should be worn if there is a potential for a chemical splash.

Respirators must not be used in the laboratory without prior approval by the DOHS. Laboratory supervisors are not authorized to select or recommend the use of respiratory protection, regardless of the type. Call your IC Safety and Health Specialist if you feel that you may need respiratory protection. It is the policy of the NIH to provide, at no cost to the employee, respiratory protection when: the best available engineering controls fail to adequately reduce employee exposure to respiratory hazards; substitution of respiratory hazards with less hazardous elements is not feasible; modifications in hazardous operations fail to reduce exposures to below regulated or acceptable levels.

The criterion for the selection, fitting, and use of respirators is described in the OSHA *Respiratory Protection Standard* (29 CFR 1910.134).

VIII. Precautions to be Taken When Working with Particularly Hazardous Substances

These substances include select carcinogens, reproductive toxins, and chemicals that have a high degree of acute toxicity. Substance specific information is contained in Material Safety Data Sheets and is also available through the Technical Assistance Branch of the DOHS (301496-3353).

The laboratory supervisor is responsible for ensuring that appropriate precautions are taken when working with hazardous chemicals.

Safe Work Practices with Particularly Hazardous Substances

- Control access to the laboratory through the use of appropriate signs that warn of the hazards and indicate the precautions or approvals necessary for entry. Contact your IC Occupational Safety and Health Specialist for assistance.

- Contact the Occupational Medical Service at 301-496-4411 to determine if medical surveillance may be warranted if toxicologically significant quantities of a particularly hazardous substance are used on a routine or frequent basis.

- Maintain an accurate record of the workers who use these substances and the amounts used and stored in the laboratory.

- Contact the Division of Environmental Protection at 301-496-7990 for assistance with specialized waste disposal.

- Keep particularly hazardous substances in a secondary container to help prevent breaks and spills. This secondary container should be opened only inside a chemical fume hood.

- Attach a suitable hazard warning label to this secondary container to alert others of the chemical contained therein and the need for special precautions, for example: "Warning - Cancer Hazard" or "Highly Toxic."

- Protect work surfaces from contamination through the use of disposable, absorbent, plastic backed paper. Replace contaminated paper as necessary and handle as hazardous waste.

- Use additional containment devices (such as shielding or protective filters) to safely handle, store or protect equipment and workers when using these chemicals.

- Wear appropriate personal protective equipment including; gloves, eye/face protection, and other protective apparel or equipment as needed. Examples include: impervious gowns, aprons or gauntlets.

- Remove all protective apparel and thoroughly wash hands, forearms, face and neck upon completion of work and before leaving the laboratory.

IX. Prior Approval for Work with Certain Hazardous Chemicals

Prior approval is required when working with certain hazardous chemicals and when there is a significant risk of exposure. This oversight process is followed when the proposed work involves hazardous chemicals that meet one or more of the following criteria. The chemicals to be used:

- Can cause severe, acute, or lethal effects upon exposure by any route in quantities of 50 ug/kg or less.

- Are highly unstable or, when combined with other compounds in the procedure, are explosive.

- May undergo chemical or physical changes during routine use and generate byproducts that may overcome standard control measures or may penetrate available personal protective equipment to cause severe acute or lethal injuries.

- Have been determined by the DOHS to present a unique hazard or are used in an operation that requires approval above the level of the laboratory supervisor.

When one or more of the criteria above are met, the project Principal Investigator (PI) must develop a specific written safety protocol and submit it to the DOHS IC Safety and Health Specialist for review prior to beginning work. This safety protocol should include: (1) a thorough description of the chemical(s) to be used - including the potential physical and health effects, (2) a step-by-step review of the work to be performed, (3) a list of the available engineering controls and personal protective equipment, (4) provisions for proper labeling, storage, and waste disposal, and (5) decontamination procedures. Evidence of employee training on the established safety protocol must be provided to the DOHS. This information shall include a review of the safety protocol described above, expected actions in the event of an emergency, the date the training was provided, and the name and last four digits of the social security number of personnel trained. Assistance in laboratory safety training is available from the DOHS Safety Training Officer at 301-496-3353. The oversight process for work with hazardous chemicals ensures that the proposed activities are conducted by specifically trained personnel in accordance with an approved safety protocol.

If the Principal Investigator (PI) and the DOHS fail to resolve a significant issue regarding a protocol, the matter will be referred to the IC Scientific Director and/or the NIH Occupational Safety and Health Committee, as appropriate.

X. Chemical Hygiene Plan Evaluation and Record Keeping

The NIH Chemical Hygiene Plan is reviewed annually and updated as needed by the DOHS and the NIH Occupational Safety and Health Committee. Comments and suggestions on the improvement of this document should be directed to the Director, DOHS (301-496-2960).

Training records are maintained by the DOHS. Individuals may request their training records by contacting the DOHS Training Officer (301-496-3353).

XI. Services Provided by the Office of Research Services (ORS) and the Office of Research Facilities Development and Operations (ORFDO)

The DOHS, ORS conducts a number of programs focusing on laboratory safety and the proper handling of chemicals. Contact the DOHS IC Safety and Health Specialist for additional information regarding these programs or go to the DOHS website http://www.nih.gov/od/ors/ds/dohs.

Division of Occupational Health and Safety 301-496-2346

The DOHS offers a number of laboratory support functions:

- Reviews safety protocols for work involving certain hazardous chemicals to ensure that the proposed activities are conducted by trained personnel using the proper safety equipment.

- Conducts surveys of work locations to identify practices or procedures that may pose potential hazards to the health and safety of personnel.

- Identifies potentially hazardous situations in work areas and recommends appropriate control measures.

- Reviews designs/drawings of all local exhaust systems considering every component of the system, including the shape and placement of hoods, size and

length of ductwork, size and position of the exhaust fan, and the sitting of the exhaust system in the laboratory and building. All applications employing local exhaust ventilation must be reviewed by DOHS.

- Provides expert advice and guidance on the proper selection, use, and functioning of protective equipment.

- Oversees a comprehensive testing and certification program for safety related ventilation equipment including: chemical fume hoods, local exhaust systems, biological safety cabinets, and other containment systems.

Division of Environmental Protection 301-496-7990

The Division of Environmental Protection, ORFDO, offers a number of services related to the treatment and disposal of non-radioactive waste:

- Provides technical support and guidance in proper disposal of waste.

- Oversees all NIH non-radioactive chemical, medical, and solid waste handling, treatment, and disposal activities.

- Conducts research regarding alternate systems for the management of chemical waste.

- Monitors NIH activities for compliance with Federal, State, and Local environmental regulations and the impact of those activities on the environment.

Occupational Medical Service 301-496-4411

The NIH Occupational Medical Service, DOHS, offers a comprehensive occupational medical care program to NIH employees:

- Provides emergency medical treatment in the event of a spill or other unusual event resulting in an acute chemical exposure.

- Evaluates any employees who develop signs or symptoms associated with a possible physical or chemical exposure in the laboratory.

- Provides periodic medical surveillance when chemical exposure monitoring data reveal an exposure at or above the action level for an OSHA regulated substance.

- Maintains employee medical records.

NIH POLICY MANUAL

3015 - ADMITTANCE OF CHILDREN TO HAZARDOUS AREAS

Issuing Office: ORS/DS/OSHB 496-3353
Release Date: 02/14/96

1. **Explanation of Material Transmitted:** This chapter sets forth NIH policy on the admittance of children to Clinical Center areas and work areas that may contain inherently or potentially hazardous chemicals, radioactive materials, biohazards or hazardous equipment.

1. **Filing Instructions:**

   Remove: NIH Manual 3015 dated 05/15/87
   Insert: NIH Manual Chapter 3015 dated: 02/14/96

1. **Distribution:** NIH Manual Mailing Keys F-401 and F-405

PLEASE NOTE: For information on:

- Content of this chapter, contact the issuing office listed above.
- On-line information, enter this URL: http://www3.od.nih.gov/oma/manualchapters/
- To sign up for e-mail notification of future changes, please go to the NIH Manual Chapters LISTSERV Web page.

A. Purpose:

This chapter sets forth NIH policy on the admittance of children to NIH Clinical Center, hazardous buildings, trade, craft or laboratory work areas that may contain inherently or potentially hazardous chemicals, radioactive materials, biohazards or hazardous equipment. This policy shall apply to all children who are not employees at the NIH, but come to the campus for tours, day care or visit. Persons who are formally registered as Normal Volunteers, Student Volunteers or Special Volunteers are considered "employees" for purposes of this policy. **B. References:**

1. Exposure of Minors, U.S. Nuclear Regulatory Commission, Rules and Regulations, Title 10, Chapter 1, Code of Federal Regulations - Energy,

   Standards for Protection Against Radiation, Part 20, Section 104.

2. Biosafety in Microbiological and Biomedical Laboratories, U.S. DHHS, Centers for Disease Control and National Institutes of Health. HHS Publication No. (CDC) 84-8395. 3rd Edition, May 1993.

3. NIH Manual Chapter 1340 - "NIH Occupational Safety and Health Management." **C. Responsibilities:**

NIH employees have a continuing responsibility to assure a safe work environment for themselves, their co-workers, Clinical Center patients and their guests. Supervisors are specifically responsible for the safety of all employees and visitors in their work areas. The Division of Safety provides support to employees and supervisors in meeting these responsibilities. **D. Definitions:**

1. Laboratory Director - Used in the same context as in "Biosafety in Microbiological and Biomedical Laboratories" (CDC/NIH, HHS, 1993) to mean the officially designated Supervisor (Branch Chief, Section Chief, Laboratory Chief or Principal Investigator) who has responsibility for all activities within a laboratory. A laboratory director contemplating a visit by his/her own children will obtain written authorization from his/her supervisor.

2. Office - Shall be a room which is physically separated from a laboratory. An office that is an integral part of a laboratory room will be considered to be "laboratory" rather than "office" space. **E. Policy:**

1. Laboratories - Visiting children under 12 years of age will not be allowed into any laboratory area except with the specific written permission of the laboratory director.

   Visiting children under 18 years of age will not be allowed into areas posted with radiation warning signs, or into any animal facility, except with the specific written permission of the laboratory or animal facility director.

   Furthermore, visiting children under 18 years of age are never allowed into the following areas: laboratories posted at Biosafety Level 3 or Biosafety Level 4; laboratories in which infectious agents are being actively manipulated; laboratories in which chemical carcinogens or other acutely toxic chemicals are actively handled; areas of high radiation or airborne radioactivity (as defined in 1O CFR 20.104).

2. Hazardous Building, Trade or Craft Areas - Specific written permission of the appropriate supervisor is required before visiting children under 12 years of age will be allowed into any shop, mechanical space or construction site. All children must be continually supervised while in such areas. Furthermore, children will not be allowed into areas posted with restrictive warning signs. Examples are: "Danger - Asbestos," "High Voltage," "Caution - PCBs," "Danger - High Noise Hazard," "Authorized Personnel Only."

3. Clinical Center - Nonpatient children under 12 years of age will not be allowed into any Clinical Center laboratory, treatment room, patient isolation room, operating or recovery room, ICU or other "restricted" area, except with the specific written permission of the attending physician, head nurse or other

appropriate supervisor. All children must be continually supervised while in such areas.

Last Updated: 09/21/99 NIH

NIH POLICY MANUAL

3034- WORKING WITH HAZARDOUS MATERIALS
Issuing Office – Phone: ORS/DOHS (301) 496-2960 Release Date: 03/21/2006

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1. **Explanation of Material Transmitted:** This release establishes NIH policy and procedure governing work with hazardous chemicals as described in the NIH Hazard Communication Program and the NIH Chemical Hygiene Plan, U.S. Department of Labor, Occupational Safety and Health Administration regulations that require such programs, (29 CFR 1910.1200, 29 CFR 1910.1450).

2. **Filing Instructions:**

   Remove: NIH Manual Chapter 3034 dated: 03/01/93

   Insert: NIH Manual Chapter 3034 dated: 03/21/2006

PLEASE NOTE: For information on:

- Content of this chapter, contact the Division of Occupational Health and Safety on (301) 496-2960.

- NIH Manual System, contact the Office of Management Assessment, OM, on (301) 496-2832.

- On-line information, enter this URL: http://www1.od.nih.gov/oma/manualchapters

Replaces: 3034 dated 03/01/93
Issuing Office: ORS/DOHS (301) 496-2960

WORKING WITH HAZARDOUS MATERIALS

A. PURPOSE:

This chapter establishes the NIH policy for working with hazardous chemicals described by the *NIH Hazard Communication Program* and the *NIH Chemical Hygiene Plan.*

B. BACKGROUND:

The *NIH Hazard Communication Program* applies NIH-wide where potentially hazardous chemicals are used in the workplace. Additionally, the *NIH Chemical Hygiene Plan* applies to all laboratory areas. These programs were established in accordance with the U.S. Department of Labor, Occupational Safety and Health Administration regulations.

C. POLICY:

It is the policy of the NIH that all employees potentially exposed to hazardous chemicals while performing their jobs be fully informed of both the hazardous properties of these chemicals and the protective measures that are available to minimize chemical exposures. The *NIH Hazard Communication Program* consists of three major components:

1. Identification of hazardous chemicals;
2. Maintenance of current hazard information at the worksite, including warning labels and signs and material safety data sheets; and 3. Training of employees.

The *NIH Chemical Hygiene Plan* complements this program and consists of procedures to be used in all laboratory locations when working with potentially hazardous chemicals.

Policy and procedures are described in the *NIH Hazard Communication Program* and the NIH Chemical Hygiene Plan. Copies of the *NIH Hazard Communication Program* and the *NIH Chemical Hygiene Plan* can be obtained by calling the Division of Occupational Health and Safety (DOHS) at 301-496-2960 or on the DOHS website at :
http://www.nih.gov/od/ors/ds/pubs/index.html

D. REFERENCES:

29 CFR 1910.1200-“Hazard Communication” and 1910.1450-“Occupational Exposure to Hazardous Chemicals in Laboratories”

E. RECORDS RETENTION AND DISPOSAL:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and

disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records," Appendix 1, Item 1300-B-3.

NIH e-mail messages (messages, including attachments that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational values are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property and, if requested for a legitimate Government purpose, must be provided to the requester. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of the Inspector General may request access to or copies of e-mail messages. E-mail messages must also be provided to Congressional oversight committees, if requested, and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same request as the original messages.

F. MANAGEMENT CONTROLS:

The purpose of this Manual Chapter is to establish the NIH policy for working with hazardous material.

1. **Office Responsible for Reviewing Management Controls Relative to this Chapter**:
   Through this manual issuance, the Division of Occupational Health and Safety (DOHS), Office of Research Services (ORS) is responsible for the method used to ensure that management controls are implemented and working.

2. **Frequency of Review**: Annual review.

3. **Method of Review**: The DOHS will maintain oversight and ensure effective implementation and compliance with this policy through awareness training incorporated into DOHS sponsored training courses including, "Laboratory Safety at the NIH" and the annual "Laboratory Safety Refresher Course".

4. **Review Reports**: Are sent to the Deputy Director for Management, the Deputy

Director for Intramural Research, and the Director, Office of Management Assessment. Reports should indicate that controls are in place and working well or include any management control issues that should be brought to the attention of the report recipient.

The Code of Federal Regulations, Title 29, Volume 6 can be viewed here:

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

Retrovirus Exposure Surveillance Program

Table of Contents

I. Purpose

The Retrovirus Exposure Surveillance Program is intended:

1. to provide serologic monitoring of participants for antibodies to the retrovirus(es) used in their laboratory and for which a licensed test is commercially available;
2. to provide serologic monitoring for antibodies to HIV-1 for participants with potential occupational exposure to human body fluids;
3. to provide clinical evaluation, laboratory testing, counseling, chemoprophylaxis, and periodic follow-up for individuals experiencing a known or suspected occupational exposure to a retrovirus; and
4. to provide updated epidemiologic and safety information in conjunction with occupational safety and health consultants on avoidance of potential worksite exposures to retroviruses.

II. Relevant OMS Procedure Manual Sections

A. Preplacement Medical Evaluation. Chapter III, Section 2.
B. Human Pathogen Surveillance Program Humans. Chapter IV, Section 5.
C. Injuries Involving Human Body Fluids. Chapter III, Section 7.
D. Wound Care Guidelines. Chapter III, Section 9.
E. Occupational Injuries and Illnesses. Chapter III, Section 5.

III. Attachments

A. Laboratory Testing and Interpretation - Attachment I
B. Consent Form; HIV-1, HTLV I/II Testing - Attachment II
C. Consent Form; Research Lab Worker, HIV-2/SIV Testing - Attachment III
D. HIV-2/SIV Questionnaire - Attachment IV

E. Procedure for Specimen Collection and Processing - Attachment V
F. Notification Memorandum; Negative Test Results - Attachment VI
G. Initial Report of Exposure/Injury; Research Lab Worker - Attachment VII
H. Medical Questionnaire and Physical Examination Form - Attachment VIII
I. Open Trial of Zidovudine Post-Exposure Chemoprophylaxis in Health Care Workers with Occupational Exposures to HIV - Attachment IX
J. Report of Illness Form - Attachment X
K. Fact Sheet; HIV-1 - Attachment XI
L. Fact Sheet; HIV-2 - Attachment XII
M. Fact Sheet; SIV - Attachment XIII
N. Fact Sheet; HTLV-I/II - Attachment XIV

IV. Eligibility

A. All NIH employees who work with known or suspected live primate retrovirus(es) or who work with human body fluids are eligible for participation in this program.

B. Non-federal employees working on the NIH campus are eligible for that portion of the surveillance program related to evaluation and treatment for known or suspected exposures as detailed in Section XI.

V. Identification of Eligible Employees

A. Supervisors identify potential workplace health hazards, including retroviruses and human body fluids, as part of the preplacement medical evaluation process. Position applicants are offered enrollment in the RESP during the preplacement medical evaluation.

B. Principal Investigators identify workers who may have contact with human pathogens when they complete the registration form listing Materials (potentially) Infectious for Humans. OMS contacts and offers enrollment to eligible workers not previously enrolled.

C. The Hospital Epidemiology Service (HES) describes the RESP to Clinical Center employees during their orientation and encourages eligible employees to enroll.

D. OMS staff offer enrollment in this program to any NIH employee, not previously enrolled, who reports an occupational injury involving a human body fluid.

VI. Definitions

A. ***Research lab worker (RLW)*** - an NIH employee who intentionally works with a primate retrovirus in a laboratory or an animal care setting.

B. ***Health care worker (HCW)*** - an NIH employee who is at risk for an occupational exposure to human body fluids, but does not intentionally work with a primate retrovirus in a laboratory or an animal care setting.

C. ***Seronegative*** - a serum sample which is non-reactive on enzyme immunoassay (EIA) testing. See Attachment I for additional details.

D. ***Indeterminate*** - a serum sample which is repeatedly reactive on EIA testing and has at least one significant band on the Western blot testing, but does not have sufficient additional bands to be positive. See Attachment I for additional details.

E. ***Seropositive*** - a serum sample is positive if it is repeatedly reactive on EIA testing and there is a diagnostic pattern of bands on Western blot testing. See Attachment I for additional details for specific retroviruses.

F. ***Overt exposure*** - an injury involving material which is from a source known or suspected to be infected with a retrovirus and the material contacts or penetrates the employee's mucous membrane or skin.

VII. Coding/Confidentiality

A. Coding
    1. A unique two digit laboratory identification number (LID) is assigned to each work group intentionally working with a primate retrovirus.
    2. Each blood specimen drawn is assigned a unique computer generated sample identification number (SID) by the OMS coordinator.
        a. The SID is the only identifier provided to the facility testing the serum sample.

B. Confidentiality
    1. OMS strictly protects the privacy of individuals participating in this program by withholding their names and other identifying information (e.g., work sites, date of birth) from all persons not directly connected with the conduct of this program.
    2. Linking the SID and the participant's name can only be done by the program director and program coordinators.
    3. Others can access an individual's RESP medical record only with the participant's written authorization.

VIII. Consequences of Declining to Participate in the Program

A. Declination to participate in the RESP does not adversely affect an employee's employment status.
B. Refusal to participate neither precludes participation at a later date, nor affects an employee's treatment in the event of an occupational injury involving a retrovirus.
C. Declining participation does not compromise an employee's benefits under the Federal Employees Compensation Act.

IX. Program Enrollment

A. Administration of the consent form(s)
    1. Following a brief presentation and discussion of the RESP by an OMS clinician, a research lab worker who elects to participate reads and signs the specific program consent form(s) for the virus(es) with which he/she works and for which testing is desired. A LID is assigned and the data is entered into the computer by the OMS clinician.
        a. Attachment II - the consent form for testing for antibodies to HIV-1 and HTLV-I/II.
        b. Attachment III - the consent form for testing for antibodies to HIV-2/SIV.
    2. Following a similar presentation, health care workers electing to participate sign a consent form (Attachment II) for testing for antibodies to HIV-1.
    3. Each participant indicates on the consent form the address (other than work location) to which program related information is mailed.

B. Administration of the questionnaire

1. As part of the enrollment process the research lab worker working with HIV-2/SIV completes a self-administered questionnaire (Attachment IV). This questionnaire identifies:
    a. types of nonhuman primates used in past and present research, and
    b. more detailed information on past exposures.
2. A program coordinator reviews the completed form for missing or inconsistent entries on key items, and resolves them with the participant.

C. Laboratory studies

1. Sample collection and processing - 7.5 ml. of blood is obtained. The serum is separated into two samples and a unique SID is assigned to each sample. One sample is sent to the repository for storage. The stored sera will be discarded after ten years. The other sample is sent for EIA testing. Detailed information on specimen collection and processing is provided in Attachment V.
2. Interpretation of results - the program director is responsible for interpreting test results and initiating appropriate action.
3. Notification of results - the participant is informed of negative laboratory results by mail (Attachment VI). An employee with an indeterminate or positive test result is contacted by telephone by the program director within two weeks of specimen collection.
    a. A research lab worker with an indeterminate or positive test result is notified before coworkers tested the same day are mailed their negative test results.

X. Periodic Visits

A. Notification for subsequent testing Individuals are notified by mail two weeks before the anticipated periodic visit.
    a. Research lab workers' periodic visits are scheduled every 6 months.
    b. Health care workers' periodic visits are scheduled every 12 months.

B. Laboratory studies
    1. Specimen collection/processing, interpretation, and notification of results are accomplished as outlined in Section IX.C.

XI. Overt Exposure/Illness Visit

A. Identification
    1. A participant who experiences an overt exposure or symptoms suggestive of infection with a retrovirus is identified by self report.
    2. Enrollees are reminded in writing of the importance of promptly reporting injuries, through the consent form and the notification letter with their laboratory test results.

B. Report of overt exposure
    1. First aid - percutaneous injuries are vigorously scrubbed and soaked for 15 minutes with a 10% povidone iodine solution (e.g., Betadine); contaminated mucous membranes are irrigated for 15 minutes with normal saline or water.
        a. First aid should be administered immediately following the injury at the work station.Health care workers' periodic visits are scheduled every 12 months.
        b. If an injury is reported to OMS within one hour of its occurrence, first aid is promptly administered regardless of whether or not it was performed previously.
    2. History - in addition to completing the standard federal injury report (refer to the Medical Management of Occupational Injury and Illnesses), the OMS program director or designee completes:
        a. the Initial Report of Exposure/Injury (Attachment VII) for injuries involving a primate retrovirus in a research lab, or

b. the Report of Injury Involving Human Body Fluids (refer to the Medical Management of Injuries Involving Human Body Fluids for additional details).

3. A medical history questionnaire is administered and a targeted physical examination is performed (see Attachment VIII).
4. Systemic chemoprophylaxis (i.e., zidovudine, lamivudine, and possibly indinavir - is considered on an individual basis for significant exposures involving HIV-1 and HIV-2/SIV. See Attachment IX for additional details.
5. Laboratory studies

a. Retrovirus antibody testing - 7.5 ml. of blood is drawn at the time of report and at six weeks, and three and six months from the date of injury; if chemoprophylaxis is initiated retrovirus testing is performed as specified in Attachment IX.
b. the Report of Injury Involving Human Body Fluids (refer to the Medical Management of Injuries Involving Human Body Fluids for additional details).

6. Follow-up - each participant offered chemoprophylaxis is given an appointment to return for follow-up counseling, ideally with their significant other(s), within three days of the initial report. The employee is advised to report to the program director or designee, any acute febrile illness that occurs within three months of an overt exposure/injury.
7. Notification of safety officials - all significant injuries involving a retrovirus are reported to the designated safety expert for the employee's work area. The safety specialist conducts a confidential accident assessment.
    a. The Clinical Center Safety Officer is informed if the injury involves an individual in a clinical area.
    b. The Occupational Safety and Health Branch (OSHB) Branch Chief is informed if the injury involves an individual in a non-clinical area.

C. Report of illness
1. History - the OMS program director or designee completes the Initial Report of Illness (Attachment X); this report identifies the employee's: a. chief complaint,
    b. associated symptoms,
    c. recent occupational history (for research lab workers this includes the retrovirus(es) utilized in the lab), and
    d. possible overt exposures.
2. A medical questionnaire is administered and a targeted physical examination is performed (Attachment VIII).
3. Laboratory studies - appropriate serologic testing is performed for the suspected etiologic agent.
4. Follow-up - is determined on an individual basis and is influenced by the initial serologic test results.

XII. Indeterminate/Seropositive Visit

A. Confirmation - the program director attempts to clarify/confirm the test results utilizing a previously stored serum sample prior to notifying the employee.
B. Notification - the program director contacts individuals with indeterminate or positive test results by phone to inform them of their need for further evaluation and to arrange a time for the initial visit. C. Initial visit.
1. Discussion of results - the program director personally explains the test results to the employee.
2. Exploring possible exposures - the program director reviews the known routes of virus transmission and inquires about possible occupational and personal exposure(s).
3. Targeted medical history - includes a signs and symptoms inventory and review of general systemic problems.

4. Focused physical examination - the program director performs a physical exam based upon the employee's medical history. The findings are recorded on Attachment X.
5. Laboratory studies - at the initial visit blood is drawn for repeat retrovirus antibody testing as necessary to confirm the prior laboratory findings.
6. Counseling - is provided by the program director and a supplemental, retrovirus specific, fact sheet is distributed: a. HIV-1 - Attachment XI,
   b. HIV-2 - Attachment XII,
   c. SIV - Attachment XIII, or
   d. HTLV I/II - Attachment XIV.
7. Follow up - the employee is asked to return to OMS within three days for additional counseling. In addition, the program director and coordinator are available for consultation as deemed necessary by the participant.
   a. Employees with confirmed positive results are referred to available community resources.

D. Periodic visit

1. Participant with indeterminate results
   a. Periodicity - as noted in Section XII.C.7. and monthly from the date of the initial indeterminate result for three months and again at six months from that date.
   b. An interval medical history is obtained at each visit and a targeted physical exam is performed as indicated by the interval medical history.
   c. Counseling - focuses on the participant's emotional status and use of support systems and community resources.
   d. Laboratory studies - retrovirus antibody testing and potentially other testing as clinically indicated.
   e. Worksite investigation - if a suspected work associated seroconversion is documented, the program director contacts a safety expert (see Section XI.B.7.) who initiates a review of work practices. This expert protects the identity of the participant and worksite location involved throughout the investigation.
2. Participant with positive test results
   a. Periodicity - as noted in Section XII.C.7.; additional office visits are arranged on an individual basis as needed.
   b. Discussion of test results - the program director explains the results from the tests done at the initial visit.
   c. Counseling - see Section XII.D.1.c.
   d. Worksite investigation - see Section XII.D.1.e

XIII. Medical Records

A. Retrovirus surveillance file
   1. Medical records consist of:
      a. the signed program consent form(s),
      b. all laboratory results related to the RESP,
      c. any adverse exposure/injury and illness reports, and
      d. all related progress notes.
   2. Maintenance of records - the file is maintained in a secured cabinet in OMS and only the program director and selected coordinators have access. The records are retained for thirty years.
   3. Access to medical records - information contained in the RESP file is available only to a program participant and with the participant's signed consent, to his/her personal physician following:
      a. provision of identifying documentation (e.g., a drivers license) to the OMS program director or the coordinator, and
      b. completion of a Release of Medical Information Form by the participant.
      c.

XIV. Program Review and Evaluation

A. The RESP is reviewed and updated by the program director and coordinators at least annually and more frequently as indicated based on the following:
    1. technological advances in laboratory testing for retroviruses; and
    2. new health and safety information related to occupational exposures to retroviruses.

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Attachment I. Laboratory Testing and Interpretation

I. Definitions

A. Enzyme immunoassay (EIA) threshold value (TV) - the manufacturer's recommended threshold value for a positive (reactive) test.
   1. Positive EIA - test result greater than or equal to the TV.
   2. Negative EIA - test result less than the TV.

B. Positive HIV-1 Western blot - clearly exhibits any two of the following bands:
   1. p24,
   2. gp41, or
   3. gp120/160.

C. Positive HIV-2/SIV Western blot - clearly exhibits the following bands:
   1. A gag or pol band and
   2. gp36, 105 [trimer], or 120.

D. Positive HTLV-I/II Western blot - clearly exhibits the following bands:
   1. p24 and
   2. gp46 and/or gp61/68.

E. Positive SRV/D Western blot - clearly exhibits the following bands: 1. p24 or p27 and
   2. gp20 or gp70.

F. Indeterminate Western blot - a blot with a significant band which is at least as intensely reactive as the weakly reactive control strip, but with no other bands to known retroviral antigens.

G. HTLV I/II positive radioimmunoprecipitation assay (RIPA) - demonstrates immunoreactivity to gp68.

II. Serum is separated from each blood specimen obtained at any visit and divided into two samples of equal volume. One is submitted for EIA testing. Based upon the EIA results additional testing is performed as follows: A. EIA negative - no further testing.

B. EIA positive - EIA testing is repeated.

1. If the sample is positive on repeat testing, it is submitted for Western blot testing.
   a. In the case of HIV-2/SIV testing - the sample is submitted for HIV-2/SIV Western blot testing and HIV-1 EIA testing, as HIV-1 antibodies can react with the HIV-2/SIV EIA.
   b. Any sample which is subsequently determined to be HIV-1 EIA positive is submitted for HIV-1 Western blot testing.

III. For each sample which is tested by Western blot the following information is reported:

A. which bands are present, including none if appropriate, and

B. the intensity of reactivity of each recorded band.

IV. Indeterminate Western blot samples are sent with at least three negative controls for radioimmunoprecipitation assay (RIPA) or other relevant assay.

Attachment II. Informed Consent for Serologic Testing and Follow-up for Employees Working with Human Blood and Body Fluids, HIV-1, HTLV-I/II

The Occupational Medical Service (OMS), part of the Division of Safety at the National Institutes of Health, offers this medical surveillance program to NIH personnel who work with retroviruses and/or human blood and body fluids. The program consists of:

- serologic monitoring for antibodies to the retrovirus(es) (e.g., HIV-1, HTLV-I/II) to which you may be exposed and for which a licensed commercial test is available; and
- provision of updated epidemiologic and occupational safety information on worksite exposure to retroviruses.

As part of my participation in this program, I agree to have a blood sample (7.5 ml) taken from a vein in my arm. The risk of serious physical injury is negligible although there may be some pain at

the site on entry of the needle, and a small bruise may develop. There is also a very small risk of fainting or of infection at the needle entry site. The blood will be tested for antibodies to the retrovirus(es) to which I may be exposed and for which a licensed commercial test is available. Other tests, including other related antigen assays, may also be done on my blood. Routine testing will be offered every six (6) months for laboratory workers intentionally working with these viruses and every twelve (12) months for health care workers.

The confidentiality of my medical records and any information collected as a result of my participation in this surveillance program are fully protected from unauthorized disclosure by the Federal Privacy Act of 1974. To protect my identity my serum sample will be identified only with a code number. All medical records related to my participation in this program are stored separately from my general OMS medical record in a secured file. Access to these records is strictly limited to the surveillance program director and coordinators, to myself, and others only with my written authorization. There is a possibility that data gathered from this surveillance program may be used in a medical publication. In case of such an event, I will not be personally identified by name or any other means.

As part of my participation in this program, I agree to have the program director serve as my physician in interpreting and communicating the results of the laboratory tests. Negative test results will be mailed as soon as one week but no later than three weeks from the date the blood is drawn to the address (other than my work location) that I will designate on this form.

Indeterminate or positive test results will be communicated directly to me within two weeks by the program director. At that time, I will be advised by the program director to return for further evaluation and counseling. Because the virus may be transmitted in several ways, it is important that I inform sexual and needle sharing partner(s) that any, or all, of them may have been exposed to the HIV-1 or HTLV-I/II virus and encourage them to be tested. The program director will help me and my partner(s) to obtain information regarding the meaning of the test results and the means to be used to prevent the spread of this infection. If I am unwilling or unable to notify my partner(s), the program director is responsible for attempting to contact and inform them of their possible exposure to the virus. Reasonable attempts will be made to protect my identity including withholding my name when notifying any partner(s) of their possible exposure. Some notification or counseling of current and/or ongoing partners may be carried out through arrangements with, or referral to, local public health agencies.

In the event of an overt work exposure to one of these retroviruses or human blood and body fluid, I will contact OMS as soon as possible. Additional blood testing, information collection, physical examination, and incident investigation will be done. Chemoprophylaxis (i.e., zidovudine, lamivudine, and possibly indinavir) will be considered for an exposure involving a retrovirus. Follow-up for these cases will be performed at two weeks, four weeks, six weeks, three months, six months and twelve months from the date of exposure.

Participation in this surveillance program is voluntary. If I choose not to participate, my refusal will not affect my current position. Refusal to participate in the program will neither preclude participation at a later date nor will it affect my treatment in the event of an exposure. I may withdraw from the program at any time for any reason, upon written notification to the RESP program director.

My declining to participate does not compromise whatever benefits may be available to me under the Federal Employees Liability Act under circumstances where it is demonstrated that my infection has been acquired during the performance of my official duties.

I have read this consent form, have been given the opportunity to ask questions relevant to my participation, and agree to participate in the surveillance program. I will contact the program director

or coordinator (301-496-4411) if I have any concerns or questions related to the program. Please sign and complete the following:

_____ _____
Participant's Signature Date

_____ _____ Participant's name - Printed Date of Birth

_____-_____-_____Social Security Number _____ Female _____Male

_____
P.O. Box/Street Address (MAILING, NOT work address)

City_____ State _____ Zip _____

_____ _____ Home Telephone Number Work Telephone Number

_____ _____
Witness' Signature Date

Attachment III Informed Consent for Questionnaire, Serologic Testing, and Follow-up for Employees Working with Human Immunodeficiency Virus-Type 2 (HIV-2) and/or Simian Immunodeficiency Virus (SIV)

The Occupational Medical Service (OMS), part of the Division of Safety at the National Institutes of Health, in collaboration with the Centers for Disease Control and Prevention (CDC), offers this medical surveillance program to NIH personnel who work with the Human Immunodeficiency Virus-Type 2 (HIV-2) or the Simian Immunodeficiency Virus (SIV) or animals which may be infected with either of these viruses. The impetus for this survey stems from an understanding that HIV-2 and SIV can be transmitted by exposure to blood infected with these agents. The purpose of this survey is to use information on work practices and exposures and sensitive laboratory tests to effectively evaluate the possible association between occupational experiences and the presence of antibodies to HIV-2 or SIV. Participation in this program is voluntary. The program consists of:

- collection of information related to daily work practices and overt exposures to either of these genetically similar retroviruses or to animals infected with these agents;
- laboratory testing for antibodies to HIV-2/SIV and other related antibody/antigen tests; and
- provision of updated epidemiologic and occupational safety information on work site exposure to HIV-2/SIV.

Description of Program

To provide information on work practices and exposures, I will complete a short, self- administered questionnaire.

As part of my participation in this program, I agree to have a blood sample (7.5 ml) taken from a vein in my arm. The risk of serious physical injury is negligible although there may be some pain at the site on entry of the needle, and a small bruise may develop. There is also a very small risk of fainting or of infection at the needle entry site. The blood will be tested at the CDC for antibodies to HIV-2/SIV utilizing a SIV-transmembrane-derived peptide. Other related tests, including tests for HIV-1 (the virus associated with AIDS), will be performed on my blood if it tests positive for either HIV-2 or SIV. Routine testing will be offered every six (6) months.

The confidentiality of my medical records and any information collected as a result of my participation in this survey are fully protected from unauthorized disclosure by the Federal Privacy Act of 1974. My serum sample and questionnaire will be identified only with a code number. All medical records related to my participation in this program are stored separately from my general OMS medical record in a secured file. Access to these records is strictly limited to the RESP program director and coordinators, to myself, and to others only with my written authorization. There is a possibility that data gathered from this survey may be used in a medical publication. In case of such an event I will not be personally identified by name or any other means.

As part of my participation in this program, I agree to have the program director serve as my physician in interpreting and communicating the results of the laboratory tests. Negative test results will be mailed as soon as three weeks but no later than six weeks from the date the blood is drawn to the address (other than my work location) that I will designate on this form.

Indeterminate or positive test results will be communicated directly to me within eight weeks by the program director. At that time, I will be advised by the program director to return for further evaluation and counseling. If my test is positive for HIV-2 or SIV, further steps will be required. Because the virus may be transmitted in several ways, it is important that I inform sexual and needle sharing partner(s) that any, or all, of them may have been exposed to the HIV-2 or SIV virus and encourage them to be tested. The program director will help me and my partner(s)

obtain information regarding the meaning of the test results and the means to be used to prevent the spread of this infection. If I am unwilling or unable to notify your partner(s), the program director is responsible for attempting to contact and inform them of their possible exposure to the virus. Reasonable attempts will be made to protect my identity including withholding my name when notifying any partner(s) of their possible exposure. Some notification or counseling of current and/or ongoing partners may be carried out through arrangements with, or referral to, local public health agencies.

In the event of an overt work exposure, I will contact OMS as soon as possible. Additional blood testing, information collection, physical examination, and incident investigation will be done. Chemoprophylaxis (e.g., zidovudine) will be considered following a significant exposure. Post exposure follow-up will be performed at two weeks, six weeks, three months and six months from the date of exposure.

Participation in this survey is voluntary. If I choose not to participate, my refusal will not affect my current position. Refusal to participate in the survey will neither preclude participation at a later date nor will it affect my treatment in the event of an exposure. I may withdraw from the survey at any time for any reason, upon written notification to the program director.

My declining to participate does not compromise whatever benefits may be available to me under the Federal Employees Liability Act under circumstances where it is demonstrated that my infection has been acquired during the performance of my official duties.

I have read this consent form, have been given the opportunity to ask questions relevant to my participation, and agree to participate in the survey. I will contact the program director or Coordinator (301-496-4411) if I have any concerns or questions related to the survey.

I work with, and wish to be tested for antibodies to, (check those that apply):

_____ HIV-2 _____ SIV.

Please sign and complete the following:

_____ _____
Participant's Signature Date

_____ _____
Participant's name -Printed Date of Birth

_____-_____-_____ _____ Female _____Male
Social Security Number

_____
P.O. Box/Street Address (MAILING, NOT work address)

City_____ State _____ Zip _____

_____ _____
Home Telephone Number Work Telephone Number

_____ _____
Witness' Signature Date

Attachment IV
National Institutes of Health
Occupational Medical Service

Retrovirus Exposure Surveillance Program

Primate Workers/SIV Researchers Questionnaire

Name: _____

Today's Date ___ ___ / ___ ___ / ___ ___

Lab Number ___ ___

A1. Which one of the following best describes your current occupation or job title? (CIRCLE ONE)

1. Veterinarian 2. Research scientist 3. Animal caretaker 4. Research technician

Other (SPECIFY)

A2. Have you ever worked with HIV-2? (CIRCLE ONE)

1. YES 2. NO 3. DON'T KNOW

B1. Have you ever worked with nonhuman primates?

1. YES (GO TO B2.) 2. NO (SKIP TO C1.)

B2. Which of the following activities have you performed on or for nonhuman primates? (CIRCLE ALL THAT APPLY)

1. Fed
2. Cleaned cages
3. Caught and restrained
4. Administered medications
5. Obtained blood samples
6. Cleaned or extracted teeth
7. Surgery
8. Autopsies
9. Inoculated with infectious agents (SPECIFY AGENTS)

B3. What is the total number of years that you have worked with nonhuman primates? (CIRCLE ONE)

1. One year or less
2. More than 1 year but less than 3 years
3. More than 3 years but less than 5 years
4. More than 5, 10, 15, 20 years

B4. How many of those years did you work with nonhuman primates known to be infected with SIV?

1. None
2. One year or less
3. More than 1 year but less than 3 years

4. More than 3 years but less than 5 years
5. More than 5 years

B5. Which one of the following best describes the most recent time you worked with nonhuman primates? (Circle One)

1. Within the last year
2. More than 1 year but less than 2 years
3. More than 2 years

B6. Which one of the following best describes the most recent time you worked with nonhuman primates known to be infected with SIV?

1. Within the last year
2. More than 1 year but less than 2 years
3. More than 2 years
4. Never

B7. Please refer to the Show Card attached to the back of this questionnaire. Using List 1, record the code letter(s) that correspond to the types of nonhuman primates you ever worked with.

____ ____ ____ ____ ____ ____ ____ ____ ____

B8. In your work with nonhuman primates, have you ever sustained a NEEDLE STICK OR OTHER SHARP (NON-BITE/SCRATCH) INJURY involving nonhuman primate blood, body fluids, or unfixed tissue where the SIV status of the source was either NEGATIVE or UNKNOWN? (Circle One)

1. YES (GO TO B8a.) 2. NO (SKIP TO B9.)

B8a. Approximately how many times have you sustained such an injury? _____ times

PLEASE ANSWER THE FOLLOWING QUESTIONS FOR UP TO THREE OF YOUR MOST SEVERE INJURIES OF THIS TYPE.

	Injury #1	Injury#2	Injury #3
B8b. Please indicate the date of each injury. (mm/yy)	___ /___	/___	___ /___

B8c. Again, referring to List 1 on the attached Show Card, record the letter that corresponds to the type of animal _____ involved _____ _____in each injury.

B8d. Using List 2 on the attached Show Card, record the code number(s) that describe the course of action(s) you took for_____ each injury.

B9. IN YOUR WORK WITH NONHUMAN PRIMATES, HAVE YOU EVER BEEN BITTEN OR SCRATCHED AND THE SIV STATUS OF THE ANIMAL WAS EITHER NEGATIVE OR UNKNOWN?

1. YES (GO TO B9a.) 2. NO (SKIP TO B10.)

B9a. Approximately how many such injuries have you had? _____ Times

PLEASE ANSWER THE FOLLOWING QUESTIONS FOR UP TO THREE OF YOUR MOST SEVERE BITE INJURIES.

	Injury #1	Injury #2	Injury #3
B9b. Please indicate the date of each injury. (mm/yy)	___ /___	/___	___ /___

B9c. Again, referring to List 1 on the attached Show Card, record the code letter that corresponds to the type of animal _____ _____ _____ involved in each injury.

B9d. Using List 2 on the attached Show Card, record the code number(s) that describe the course of action(s) you took for _____ _____ _____ each injury.

B10. IN YOUR WORK WITH NONHUMAN PRIMATES, HAVE YOU EVER SUSTAINED A NEEDLE STICK OR OTHER SHARP INJURY INVOLVING NONHUMAN PRIMATE BLOOD, BODY FLUIDS, OR UNFIXED TISSUE AND YOU KNEW THE SOURCE WAS KNOWN TO BE SIV POSITIVE?

1. YES (GO TO B10a.) 2. NO (SKIP TO B11.)

B10a. Approximately how many such injuries have you had? _____ times

PLEASE ANSWER THE FOLLOWING QUESTIONS FOR UP TO THREE OF YOUR MOST SEVERE INJURIES.

.

	Injury #1	Injury #2	Injury #3
B10b. Please indicate the date of each injury. (mm/yy)	___ /___	___ /___	___ /___

B10c. Again, referring to List 1 on the attached Show Card, record the code letter that corresponds to the type of animal _____ _____ _____ involved in each injury.

B10d. Using List 2 on the attached Show Card, record the code number(s) that describe the course of action(s) you took for _____ _____ _____ each injury.

B10e. If you know the virus strain please specify. _____ _____ _____

B11. IN YOUR WORK WITH NONHUMAN PRIMATES, HAVE YOU EVER BEEN BITTEN OR SCRATCHED BY AN ANIMAL THAT WAS KNOWN TO SIV <u>POSITIVE</u>?

1. YES (GO TO B11a.) 2. NO (SKIP TO C1.)

B11a. Approximately how many such injuries have you had? _____ times

PLEASE ANSWER THE FOLLOWING QUESTIONS FOR UP TO THREE OF YOUR MOST SEVERE BITE INJURIES.

	Injury #1	Injury #2	Injury #3
B11b. Please indicate the date of each injury. (mm/yy)	___ /___	___ /___	___ /___

B11c. Again, referring to List 1 on the attached Show Card, record the code letter that corresponds to the type of animal _____ _____ _____ involved in each injury.

B11d. Using List 2 on the attached Show Card, record the code number(s) that describe the course of action(s) you took for _____ _____ _____ each injury.

B11e. If you know the virus strain please specify. _____ _____ _____

C1. Have you ever worked in a laboratory with nonhuman primate blood, body fluids, other fresh tissue or primary monkey cell cultures? (Circle One)

1. YES (GO TO C2.) 2 NO (SKIP TO D1.)

C2. What is the total number of years that you have worked with nonhuman primate blood, body fluids, other fresh tissue or primary monkey cell cultures? (Circle One)

1 One year or less 3 More than 3 years but less than 5 years

2 More than 1 year but less than 3 years 4 More than 5, 10, 15, 20 years (Circle appropriate answer) C3 Which one of the following best describes the most recent time you worked with nonhuman primate blood, body fluids, other fresh tissue or primary monkey cell cultures? (Circle One)

1 Within the last year 3 More than 2 years

2 More than 1 year but less than 2 years

C4. Please refer to the Show Card attached to the back of this questionnaire. Using List 1, record the code letter(s) that correspond to the types of nonhuman primates that were the source you worked with.

____ _____ ____ _____ ____ _____

C5. IN YOUR WORK,HAVE YOU EVER SUSTAINED A NEEDLE STICK OR OTHER SHARP INJURY INVOLVING NONHUMAN PRIMATE BLOOD, BODY FLUIDS, OTHER FRESH TISSUE, OR PRIMARY MONKEY CELL CULTURES? (Circle One) ?

1. YES (GO TO C5a.) 2. NO (SKIP TO C6.)

C5a. Approximately how many such injuries have you had? _____ times

PLEASE ANSWER THE FOLLOWING QUESTIONS FOR UP TO THREE OF YOUR MOST SEVERE INJURIES.

	Injury #1	Injury #2	Injury #3
C5b. Please indicate the date of each injury. (mm/yy)	___ /___	___ /___	___ /___

C5c. Again, referring to List 1 on the attached Show Card, record the code letter that corresponds to the type of animal involved in each _____ _____ _____ injury.

C5d. Using List 2 on the attached Show Card, record the code number(s) that describe the course of action(s) you took for each injury. _____ _____ _____

C6. IN YOUR WORK, HAVE YOU EVER SUSTAINED A SKIN OR MUCOUS MEMBRANE (EYE, NOSE, MOUTH) EXPOSURE INVOLVING NONHUMAN PRIMATE BLOOD, BODY FLUIDS, OTHER FRESH TISSUE OR PRIMARY MONKEY CELL CULTURES? ?

1. YES (GO TO C6a.) 2. NO (SKIP TO D1.)

C6a. Approximately how many such injuries have you had? _____ times

PLEASE ANSWER THE FOLLOWING QUESTIONS FOR UP TO THREE OF YOUR MOST SEVERE SKIN OR MUCOUS MEMBRANE EXPOSURES.

	Injury #1	Injury #2	Injury #3
C6b. Please indicate the date of each injury. (mm/yy)	___ /___	___ /___	___ /___

C6c. Again, referring to List 1 on the attached Show Card, record the

code letter that corresponds to the type of animal involved in each _____ injury._____ _____

C6d. Using List 2 on the attached Show Card, record the code number(s)
_____ that describe the course of action(s) you took for each injury. _____ _____

D1. Have you ever worked in a laboratory with SIV?

1. YES (GO TO D2.) 2 NO (SKIP TO LAST PAGE)

D2. In your work, do you . . .

	YES	NO	DONT KNOW
a. culture/purify SIV?	1	2	3
b. handle cell-free supernatant of SIV infected cultures? .	1	2	3
c. work with purified SIV?	1	2	3
d. concentrate SIV?	1	2	3
e. clean, maintain, decontaminate, and/or service laboratory equipment potentially contaminated with SIV? . . .	1	2	3

D3. What is the total number of years that you have worked with SIV in a laboratory setting? (Circle appropriate answer)

1. One year or less
2. More than 1 year but less than 3 years
3. More than 3 years but less than 5 years
4. More than 5, 10, 15, 20 years

D4. Which one of the following best describes the most recent time you worked with SIV in a laboratory setting? (Circle One)

1. One year or less
2. More than 1 year but less than 3 years
3. More than 3 years but less than 5 years
4. More than 5, 10, 15, 20 years

D5. IN YOUR WORK, HAVE YOU EVER SUSTAINED A NEEDLE STICK OR OTHER SHARP INJURY INVOLVING SIV? (Circle One)

1 YES (GO TO D5a.) 2 NO (SKIP TO D6.)

D5a. Approximately how many times have you sustained such an injury? _____ times

PLEASE ANSWER THE FOLLOWING QUESTIONS FOR UP TO THREE OF YOUR MOST SEVERE INJURIES.

	Injury #1	Injury #2	Injury #3
D5b. Please indicate the date of each injury. (mm/yy)	___ /___	___ /___	___ /___

D5c. Please describe the laboratory equipment and material involved in each injury. _____ _____ _____

D5d. Using List 2 on the attached Show Card, record the code number(s) that describe the course of action(s) you took for each injury. _____ _____ _____

D5e. If you know the virus strain please specify.

_____ _____ _____

D6. IN YOUR WORK, HAVE YOU EVER SUSTAINED A SKIN OR MUCOUS MEMBRANE (EYE, NOSE, MOUTH) EXPOSURE INVOLVING SIV?

1. YES (GO TO D6a.) 2. NO (SKIP TO LAST PAGE)

D6a. Approximately how many times have you sustained a skin or mucous membrane exposure involving SIV? _____ times

PLEASE ANSWER THE FOLLOWING QUESTIONS FOR UP TO THREE OF YOUR MOST SEVERE SKIN OR MUCOUS MEMBRANE EXPOSURES.

.	Injury #1	Injury #2	Injury #3
D6b. Please indicate the date of each injury. (mm/yy)	___ /___	___ /___	___ /___

D6c. Please describe the laboratory equipment and material involved in _____ _____ _____ each injury.

D6d. Using List 2 on the attached Show Card, record the code number(s) that describe the course of action(s) you took for each injury. _____ _____ _____

D6e. If you know the virus strain please specify. _____ _____ _____

IMPORTANT

Please report all suspected injuries and exposures involving retroviruses to the health unit when they occur. Promptly report medical complaints that you suspect may be related to your work with retroviruses. Do not wait to report such accidents or illnesses until your periodic surveillance visit.

THANK YOU FOR PARTICIPATING IN THIS PROGRAM.
PLEASE RETURN THIS FORM TO A PROGRAM REPRESENTATIVE BEFORE YOU LEAVE.

SHOW CARD

LIST 1		LIST 2
A	RHESUS	1 NO ACTION TAKEN
B	CYNOMOLGUS	2 CLEANED WOUND
C	OTHER MACAGUE (e.g., Bonnet,	3 INFORMED SUPERVISOR
D	SPIDER MONKEY	4 REPORTED TO HEALTH UNIT
E	MARMOSET	5 OTHER (Please Specify)
F	AFRICAN GREEN MONKEY	
G	BABOON	H MANGABY I PIGTAIL
J	OTHER (Please Specify)	
K	Don't Know	

Attachment V Procedure for Specimen Collection and Processing

XVI. Specimen Collection

A. Prior to collecting participant's blood the OMS lab technician asks participant if he/she:

12. . is currently taking "blood thinners" such as coumadin, aspirin, or persantine; or has ever fainted while having blood drawn;

3. has an arterial-venous shunt or fistula.

B. The OMS lab technician collects an appropriate amount of blood from an antecubital vein for any of the following, as needed:

1. serum storage and applicable retrovirus antibody testing: one 7.5 ml. SST tube.

If antibody testing for more than one virus is indicated, an additional 7.5 ml.

SST tube is used.

2. hematology studies: one 2.5 ml. EDTA;
3. chemistry studies: one 7.5 ml. SST tube. If a serum lipase level is desired a second 7.5 ml. SST tube is used.

XVII. Specimen Coding and Processing

A. Blood drawn for retrovirus antibody testing.

1. The vacutainer tube label includes the participant's name, social security number, test code letter to identify the type of test requested (H=HIV-1, T=HTLV-I, S=SIV/HIV-2, R=SRV), date, the laboratory identification (LID) number if applicable, and the sample identification number (SID). The label is computer generated.

a. The vacutainer tube is centrifuged for 12 minutes at 2000 revolutions per minute.

b. Within 24 hours, the serum is separated into two samples, one 1 ml and one-1.8 ml.

2. The 1ml serum sample is used for testing.

a. The 1ml serum sample contains the identification of the testing center, the test

code letter, the date, the LID (when applicable), and SID b . The sample is

refrigerated in preparation for shipment to the appropriate testing center.

c. Shipment occurs within a week from the day the sample is obtained.

3. The 1.8ml serum sample is stored at the OMS repository for possible future testing.

   a. The 1.8 serum sample label is titled "storage sample" and contains the participant's name, test code letter, date, and SID.

   b. The information is recorded in the master inventory log.
   c. The sample is stored at -20 C for subsequent shipment to the OMS repository where it will be stored for ten years.

B. Other testing

1. Post Exposure testing - the sample is coded using the last four digits of the individuals social security number. A numerical suffix is added to that number to denote the approximate number of weeks that have elapsed since the date of exposure.
2. Following an indeterminate retrovirus antibody test - the sample is coded using a computer generated SID. A numerical suffix is added to the SID to denote the approximate number of weeks that have elapsed since the indeterminate antibody test date.

Attachment VI

DATE:

TO: Program Participant

FROM: Medical Director Occupational Medical Service, DS

SUBJ:

The blood sample you recently had drawn, as part of your participation in the Retrovirus Exposure Surveillance Program, tested negative for antibodies to _____ .

If you experience a work injury where there is a known or suspected exposure to HIV-1 or other primate retroviruses (e.g., HIV-2, HTLV-1, SIV, SRV-1, SRV-2) you should immediately administer fist aid at the worksite and then report the exposure to the Occupational Medical Service (OMS) clinic. Do not wait until your periodic surveillance visit to report such accidents.

The recommended first aid for skin exposures is vigorous scrubbing and soaking for 15 minutes with Betadine. Contaminated mucous membranes should be irrigated for 15 minutes with normal saline or water. Consideration for systemic chemoprophylaxis, (e.g., zidovudine, lamivudine, and possibly indinavir) will be given on an individual basis for significant exposures.

The OMS is located on the sixth floor of the ACRF and is open from 7:30 am to 7:30 pm Monday through Friday excluding federal holidays. In the event an exposure occurs during non- clinic hours, you should contact the Clinical Center telephone operator (496-4567) who will notify an OMS physician. Provide the operator with your name, work and home phone number(s), and your supervisor's name. An OMS physician will contact you directly.

Thank you for your participation in this surveillance program.

Sincerely,

Attachment VII
Initial Report of an Exposure/Injury Research Lab Worker

Employee

Last Name_____ First_____ MI__

SS# _____ Occupation_____

Bldg/Rm# _____ Phone # _____

History

Date of report _____ Time of report _____

Date of exposure/injury_____ Time of injury_____

Location (Bldg, Floor, Wing)_____

Lab biosafety level (Circle) 1 2 3 4

1. Safety measures employed at time of exposure/injury

_____ gloves, if yes, list number of pairs: _____ _____eye protection _____biological safety cabinet

_____ gown _____ mask _____ mask _____ none
other: (specify) _____

2. Type of exposure/injury

_____ skin contact location_____
integrity _____
_____ mucous membrane _____eye(s) specify: ____ OD ____ OS _____ OU
____ nose ____mouth ____ percutaneous
instrument involved, specify (if needle, give gauge)

_____

_____puncture
_____laceration depth_____ length_____

3a. Type of virus

____HIV-1 ____ SIV ____ HIV-2
____ SRV ____ HTLV-I ____ HTLV-II
Other:
_____
concentration of virus:_____
estimated amount: _____
Inactivation of virus prior to injury:_____
_____
_____ 3b.

Human blood/body fluid exposure

____whole blood ____serum ____ diluted blood/serum
other:_____

4. Activity involved

____ working with purified viral antigen or protein

____ working with cloned or recombinant viral DNA and/or RNA (including mutants)

____ handling potentially infectious material
(such as blood, body tissues/fluids, animal tissues, etc.)
specify: _____
____ handling cell-free supernatant
____ culturing virus
____ purifying virus
____ concentrating virus
____ working with potentially infected animals (transgenic, immunized, etc.)

____ cleaning, maintaining, decontaminating and/or servicing potentially contaminated laboratory equipment.

____ other: _____

5. Biosafety level of procedure involved(circle): 1 2 3 4

6. How injury occurred:

_____

_____

_____

_____

_____

7. Clinician's assessment of the extent of exposure

____ definite, massive ____ definite, non-massive

____ possible ____doubtful

8. First Aid Measures, worksite

____ none ____ wound cleansed/irrigated

time elapsed from injury to first aid at work site_____

agent utilized:_____ duration_____

other, specify:_____

9. First Aid Measures, OMS

____ none indicated, explain:_____

_____ wound cleansed/irrigated time elapsed from injury to first aid at OMS: _____ agent utilized:_____ duration: _____ 10 Enrollment in Retrovirus Exposure Surveillance Program

_____ enrolled today

_____ previously enrolled

_____ occupationally indicated, but refused

_____ not occupationally indicated

11. If working with human blood or body fluids - Hepatitis B Immunization Status

_____ previously infected

_____ previously vaccinated

____ series complete date of last titer_____ result_____

____ series incomplete # of doses received_____ date of last dose_____

_____ previously enrolled; series not initiated

_____ enrolled today

_____ occupationally indicated but refused

_____ not occupationally indicated

12. Employee's Labs

_____ none needed ____HBsAg
_____ anti-HIV-1 _____ anti-HBs ____ anti-HCV ____ ALT/AST
_____ anti-HTLV-I/II
_____ anti-HIV-2/SIV

_____ save serum
_____ other, specify: _____

TREATMENT

13.

_____ decision held pending results of source's and/or employee's lab studies.
_____ none indicated.
_____ treatment indicated as follows:

	Time elapsed from time of injury to 1st dose	Date	Dose	Lot#	Location
HBIG, 1st inj.	_____	_____	_____	_____	_____
HBIG, 2nd inj.	_____	_____	_____	_____	HB vaccine
	_____	_____	_____	_____	Dt _____
_____	_____	_____	zidovudine	_____	_____
_____	_____	_____	lamivudine	_____	_____
_____	_____	_____	indinavir	_____	_____ _____
_____	_____				

14. Follow-Up.

_____ HIV-1 Exposure. Anti-HIV-1 at 6 wks, 3 months, and 6 months..
_____ HTLV-I/II Exposure. Anti-HTLV-I/II at 6 wks, 3 months, and 6 months..
_____ HIV-2/SIV Exposure. Anti-HIV-2/SIV at 6 wks, 3 months, and 6 months..
_____ HBV Exposure. HBsAg, anti-HBs, anti-HBc, ALT/AST in 3 and 6 months..
_____ HCV or NANB Exposure. Anti-HCV, ALT/AST in 3,and 6, months..
_____ other, specify: _____.
_____ No identified risk of infection. No follow-up indicated..

Comments: _____
RN _____
MD_____

Biosafety levels are described as follows:

Biosafety level 1	Work is done with defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans.
Biosafety varying level 2	Work is done with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of severity. Potential for producing aerosols is low.

Biosafety level 3	infection by aerosols is real and the disease may have serious or lethal consequences.
Biosafety level 4	Work is done with dangerous and exotic agents which pose a high individual risk of life-threatening disease. Work is done with indigenous or exotic agents where the potential for

Control Methods
Work Practice Controls-Biosafety Levels 2 and 3

All clinical specimens of blood, human tissue, and body fluids are to be handled utilizing Biosafety Level 2 practices and procedures which equates with the concept of Universal Precautions in the clinical setting. In laboratories working with the human immunodeficiency viruses, other human retroviruses, infected cell lines, and/or simian immunodeficiency virus (SIV) at the research scale, Biosafety Level 3 practices and procedures must be utilized in a certified Biosafety Level 2 facility. Certification of laboratory facilities is performed by the Division of Division of Occupational Health and Safety. Large scale work with HIV or the other human retroviruses must be performed in a Biosafety Level 3 facility using full Biosafety Level 3 practices and procedures. These requirements extend to all bloodborne pathogens.

Certain laboratory procedures or other factors may require that these organisms be handled at a higher biological safety level than described above. DOHS will conduct situational risk assessments on a case-by-case basis in order to determine the appropriate biological safety practices and procedures.

These practices, procedures, and facility requirements are described in the CDC/NIH publication entitled Biosafety in Microbiological and Biomedical Laboratories and are to be adhered to by all NIH employees working with potentially infectious material. A copy of this publication should be in all laboratories and is available to all NIH employees upon request from DOHS (301-496-2960). The document is also available online at: http://bmbl.od.nih.gov

Fire, emergency response, and law enforcement personnel are required to follow procedures specific for their job categories, as outlined in Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public Safety Workers. Copies of this document are available from the NIH Biosafety Officer (301-496-3353).

Control Methods
Engineering Controls

Engineering controls must be used to eliminate or minimize worker exposure to blood or other potentially infectious materials. At the NIH these engineering controls include biological safety cabinets, mechanical pipetting devices, sharps disposal containers, self-sheathing needles, sharps with engineered sharps injury protections, and needleless systems.

Primary Barriers - Class II biological safety cabinets or other physical containment devices are to be used when procedures with a high potential for creating potentially infectious splashes or aerosols are conducted. Such procedures may include centrifuging, grinding, vortexing, blending, sonic disruption, flaming inoculation loops, transferring liquids, homogenizing, withdrawing liquids under pressure, and opening containers of infectious materials having internal pressures different from ambient pressures. Intranasal inoculations or other animal necropsy, may be performed on an open bench if it is determined by the NIH Biosafety Officer (BSO) that conducting the procedure in a biological safety cabinet would place the employee at a significantly increased risk of percutaneous exposure to a blood-borne pathogen. In these cases, strict adherence to mucous

membrane protective practices is required, which includes face masks and goggles or face shields with eye protection, as well as using appropriate gloves and protective garments.

Annual Inspections of Primary Barrier Equipment and Local Exhaust Ventilation - Annual inspection and certification of all biological safety cabinets (BSC), fume hoods and other local exhaust ventilation equipment is performed by the Division of Occupational Health and Safety. Trouble calls or questions should be directed to the Technical Assistance Section and the appropriate Safety Specialist

Mechanical Pipetting Devices - Mechanical pipetting devices are to be used for all pipetting activities. Mouth pipetting is strictly prohibited. Automatic pipetting devices are readily available in the NIH Self Service Stores or through the NIH stock catalog.

Needleless Systems - Needleless systems are devices that do not use needles for:

1. The collection of bodily fluids or withdrawal of body fluids after venous or arterial access is established;
2. The administration of medication or fluids; or
3. Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Sharps Containers - Puncture resistant sharps containers are to be used at all work sites where needles and syringes, pasteur pipettes, scalpel blades, razor blades, and other sharps are used. When appropriately filled, the containers are to be placed in a Medical Pathological Waste (MPW) box for disposal by incineration. Puncture resistant sharps containers are available from the NIH Self Service Stores and through the NIH Stock catalog.

Safety Devices for Centrifuges - For low speed centrifugation of infectious materials, safety centrifuge cups are recommended. If used, the cups are to be loaded and unloaded within a BSC. High-speed centrifugation of infectious materials should be performed using a safety rotor which is loaded and unloaded within a BSC.

Devices with Engineered Sharps Injury Protections - Devices with engineered sharps injury protection may utilize non-needle technology or incorporate built-in safety features or mechanisms that effectively reduces the risk of exposure incidents. These devices may be used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids.

Control Methods
Personal Protective Equipment

A variety of personnel protective equipment in a variety of sizes is available to all NIH employees through the NIH Self Service Stores or through the NIH Stock catalog. The items stocked by the NIH for use by its employees are routinely reviewed by Division of Division of Occupational Health and Safety personnel to ensure that the items stocked meet the needs of the user community. New items are added as specific safety needs are identified. All personnel are encouraged to discuss their needs, with regard to personal protective equipment, with the Occupational Safety and Health Specialist assigned to their IC. The Specialist may be reached by calling 301-496-2960. If equipment is required, which is not currently available through the NIH stores or stock catalog, it is to be ordered from the appropriate source at no cost to the employee. However, personal preference is not justification for special ordering of personal protective equipment.

Gloves - Gloves are to be worn by all employees when directly handling potentially infectious material or when in contact with contaminated surfaces. Vinyl examination gloves, surgical latex, or nitrile gloves may be chosen by the employee based on individual need. Gloves are to be changed routinely and rigorous hand washing policies established in laboratory areas. Employees must inspect gloves routinely and replace them whenever they are visibly soiled, torn, or punctured. All gloves are to be discarded into the medical pathological waste (MPW) stream. Hands are to be washed when gloves are changed or removed on completion of work.

Other Protective Garments - Laboratory coats, gowns, aprons, or suits, whichever is most appropriate for the particular application, are to be worn by all personnel manipulating or otherwise handling infectious or potentially infectious materials. These garments are not to be worn outside of the laboratory area. After disposable protective garments are used, discard them in the MPW stream as described in the NIH Waste Calendar. Cloth laboratory coats are not to be taken home by the employee for laundering. The NIH provides laundry service for laboratory coats, uniforms, and linens. Call 301-494-2417 to obtain information about this service and acquire pick-up and delivery schedules for each building.

Respirators - Respirators must not be used in the laboratory without prior approval of the Division of Occupational Health and Safety . Supervisors are not authorized to select or recommend the use of respiratory protection, regardless of the type. Call your IC Safety and Health Specialist if you feel respiratory protection is required. Surgical face masks, used for mucous membrane protection, are not considered respirators and are not to be used in situations where respiratory protection is required. All respirator users must be enrolled in the NIH Respiratory Protection Program. Each IC will supply and maintain the recommended respiratory protective device.

Hepatitis B Virus and HBV Vaccination

Occupationally acquired HBV - Hepatitis B is the leading occupationally acquired illness among health care workers, affecting approximately 15,000 workers annually. Hepatitis B virus (HBV), formerly known as “serum hepatitis” is one of several viruses which attacks the liver producing swelling, tenderness, and sometimes permanent liver damage. HBV is spread primarily through contact with blood and body fluids that contain blood. The virus may also be transmitted via blood transfusion, sexual contact, ear piercing, tattooing, and acupuncture if appropriate precautions are not taken.

Symptoms of HBV - The most frequent symptoms of HBV infection include fatigue, mild fever, muscle or joint pain, nausea, vomiting, loss of appetite, and abdominal pain. Many symptoms suggest a flu-like illness but tend to last longer and jaundice may occur in up to 25% of cases. However, 50% of infected individuals have no symptoms.

Risk of HBV Infection - The risk of HBV infection for NIH employees is considered to be high if their jobs entail frequent contact with blood and body fluids. NIH employees can protect themselves from occupationally acquired HBV infection by practicing Biosafety Level 2 practices and procedures (Universal Precautions) and by becoming immunized against HBV.

HBV Vaccine - A recombinant HBV vaccine is available, free of charge, to all NIH employees who may come in contact with blood and body fluids during the performance of their duties. To receive the vaccine, call the OMS at 496-4411. It is strongly recommended that eligible employees accept the vaccine.

The recombinant HBV vaccine does not contain any human blood products; it is both safe and effective. Clinical studies have shown that over 90% of healthy adults administered the vaccinedeveloped antibody to the hepatitis B virus. The HBV vaccine may also be used

prophylactically in combination with hepatitis B immune globulin (HBIG) and is 90% effective in preventing hepatitis B following a documented exposure.

Side effects of the vaccine are minimal. The most common complaint (20%) is a sore arm lasting one or two days. A few individuals have reported headache, fatigue, weakness, or rarely, a lowgrade fever. Eligible employees who decline to accept the vaccination must sign the following statement:

> I understand that due to my occupational exposure to blood or other potentially infectious material I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Further information on hepatitis B and the HBV vaccine can be obtained by calling the OMS (301496-4411).

Hepatitis C Virus

Occupationally acquired HCV. HCV is a leading cause of chronic liver disease and is the leading reason for livre transplant in the United States. Although the potential for HCV transmission associated with percutaneous injury is low, varying between 3 and 10% depending on the study, the risk of infection appears to correlate with the severity of the wound. It is estimated that 85% or greater number if people who acquire an HCV infection will become chronically infected and greater than 70% of HCV-infected people will not be detected unless the polymearase chain reaction is used to detect HCV RNA. Cirrhosis and primary heptaocellular carcinoma may result from chronic HCV.

Symptoms of HCV. HCV infection has two phases. The first, experienced by 75% of infected persons, is a flu-like illness which included headache, loss of appetite, nausea and vomiting, and fatigue. Eventually, 20-30% of infected persons will progress to the second phase of HCV infection, which includes the development of overt signs and symptoms such as jaundice, claycolored stools, and dark brown urine.

Risk of HCV Infection. Employees who must routinely handle human blood and body fluids are considered to be at risk for HCV infection. The risk of infection may be reduced through the use of Biosafety Level 2 practices and procedures and appropriate mucous membrane and eye protection in the biomedical research laboratory.

HCV Vaccine. There is currently no vaccine available to protect persons from becoming infected with HCV and immune globulin is not recommended for post-exposure prophylaxis. It is therefore very important to use personal protective equipment, and to be especially careful when handling sharps. It is also very important to report any potential exposures to the Occupational Medical Service (OMS).

Medical Surveillance and Post-Exposure Evaluation and Follow-up

Exposure Reporting Responsibilities – The ultimate responsibility for reporting exposures, spills, and other biological hazards rests with the Principle Investigators, supervisors, and the NIH employees. Such exposures and hazards need to be reported to supervisors, principle

investigators, the Division of Occupational Health and Safety, and Occupational Medical Services. The following areas serve as examples:

- The ultimate responsibility for reporting and exposure to a potentially infectious material rests with the NIH employee who has been exposed.
- Notifying employees of the presence of potentially infectious materials in any workplace is the responsibility of the Principle Investigator or supervisor in charge of the work area.
- Notifying emergency services, DOHS, and OMS of spills is the responsibility of all NIH employees.
- Notification of exposures, spills, and other hazards must be done immediately upon becoming aware of the situation.

Retrovirus Exposure Surveillance Program - The Retrovirus Exposure Surveillance Program (RESP) is a medical surveillance program designed for NIH employees who either work with human retroviruses or have a potential for occupational exposure to human blood and body fluids or other potentially infected materials. The objectives of the RESP are to:

1. perform serologic monitoring of participants for antibodies to the retrovirus (es) to which they may be exposed and for which a licensed test is commercially available;
2. provide examination and periodic follow-up for individuals experiencing an overt (known) or suspected exposure;
3. collect epidemiological information related to daily work practices and overt exposures; and
4. provide updated epidemiological and safety information on avoidance of potential worksite exposures to retroviruses.

Participation in the program is voluntary, however, all eligible employees are encouraged to enroll. More information on the RESP may be obtained by calling OMS (496-4411).

Animal Exposure Surveillance Program - The Animal Exposure Surveillance Program (AESP) is a mandatory program designed to monitor and support the health of personnel who have direct contact with a variety of animals, their viable tissues, body fluids, wastes or living quarters. NIH employees are eligible for AESP if they participate in at least one of the following activities:

1. direct care of animals or housing;
2. direct contact with animals (live or dead), their tissues, body fluids, or wastes; or,
3. work with a zoonotic disease agent.

All employees must report bites and scratches promptly to OMS. Further information on the AESP may be obtained by calling the OMS.

Emergency Steps to Take in the Event of an Exposure - If an employee sustains a potential exposure to HIV or other bloodborne pathogen, immediate first aid should be initiated before leaving the worksite. Contaminated skin should be vigorously scrubbed for fifteen minutes using a povidone iodine solution (such as Betadine) and copious amounts of water. Povidone iodine solution can be obtained from Self Service Stores or the Stock Catalog. Contaminated eyes and mucous membranes should be irrigated for 15 minutes using normal saline or water. Notify your supervisor, if he or she is immediately available. Report to the Occupational Medical Service (OMS), in building 10, room 6C306, within one hour of the exposure. If emergency transport is needed call 911 (on campus). When OMS is closed, contact the Clinical Center Operator (4964567) to notify an OMS physician.

A poster entitled 3 Emergency Steps to Take in the Event of a Potential Bloodborne Pathogen Exposure is to be placed prominently in all work areas where there is a potential for exposure to

human blood, body fluids, human retroviruses, or other potentially infectious material. Copies of this poster may be obtained by contacting your ICD Safety and Health Specialist (496-2346).

Post-Exposure Evaluation and Follow-up - Post exposure evaluation and follow-up are provided by the OMS for NIH employees according to the protocol included in the Exposure Control Program. Employee counseling is provided free of charge by the OMS.

Emergency care will be provided to visitors and contract personnel who sustain a potential exposure. These individuals will be referred to their private or company physicians for follow-up.

Post-Exposure Incident Review - In the event an employee sustains a potential exposure to HIV or other bloodborne pathogen, the incident will be reviewed by the IC Safety and Health Specialist as well as the employee's supervisor. As part of the incident review, an injury log will be maintained for the recording of percutaneous injuries and mucous membrane exposures. The log contains information on the type and brand of device involved in the incident; the IC and work area where the incident occurred; and an explanation of how the incident occurred. The log will be maintained by the Division of Occupational Health and Safety, and used to gather information which may aid in the implementation of safer technologies.

Employee Notification

Employees must be notified of the presence of potentially infectious materials in any workspace. Laboratories and other work areas handling human blood and body fluids and any human pathogens must be posted with an NIH-approved biohazard sign. Work areas are posted by OSHB personnel upon completion of a survey and certification of the area at the appropriate biosafety level. Any special requirements (i.e. immunizations, personnel protective equipment) required for entry to a workspace will be designated on the biohazard placard affixed to the entry door.

All infectious waste transferred to the incinerators will be placed in a "burn box" imprinted with the international biohazard warning symbol.

All containers used to transport infectious materials between laboratories or buildings will be labeled with stickers carrying the international biohazard-warning symbol. These stickers are available in the Self-Service Store.

Transportation of Infectious Materials

All potentially infectious materials which must be transported between NIH main campus, Bethesda and outlying buildings must be packaged and transported according to applicable Federal regulations (42 CFR 72 and 49 CFR 173.386-172.388). Guidance in complying with regulations pertaining to the shipment of biological materials can be obtained by contacting your ICD Safety and Health Specialist) or the Technical Assistance Section, OSHB (496-3353). International shipments of biological materials must be coordinated through the Quarantine Permit Service Office (QPSO) (496-3353) so that the correct import and export licenses can be issued (NIH Manual Issuance 1340-1). Under no circumstances shall personal vehicles be used to transport infectious materials to or from the Bethesda Campus. Public transportation may not be used. Materials shall be transported by government vehicle or commercial carrier only.

Decontamination and Spill Clean up

All work surfaces where blood, body fluids, any infectious agents or materials are handled must be disinfected daily with an appropriate disinfectant. Additionally, work surfaces must be disinfected after any overt spill. Work surfaces should be covered with plastic-backed absorbent toweling to facilitate clean up and reduce production of aerosols that may result from a spill. Spills within work areas are to be cleaned up by laboratory or research personnel. Housekeeping staff

is not authorized to clean up spills of potentially infectious material. Spills of potentially infectious material are to be cleaned up using the following method:

- Notify persons in the immediate area that a spill has occurred.
- Wearing the appropriate protective equipment (gloves, lab coat, etc.) cover the spill with absorbent toweling or other material.
- Carefully, pour a freshly prepared 1 in 10 dilution of household bleach (or other suitable disinfectant prepared to manufacturer's specifications) around the edges of the spill working toward the center. Allow a twenty-minute contact time.
- Using paper toweling, wipe up the spill working from the outside edges toward the center.
- Be careful to avoid cuts with broken glass. To eliminate the potential for cuts use tongs, dust pan, or some other device for pickup and carefully discard into an approved sharps container.
- Clean the spill area again with fresh disinfectant.
- Place all used materials into an MPW box for disposal.

In the event of an unusual or particularly large spill contact the Fire Department (911) for clean up.

In the event of a spill of infectious material in a public access area (hallway, elevator, etc.) keep all persons away from the spill area and call 911 for clean up.

Infectious Waste Disposal

All employees shall comply with the guidance given in the NIH Waste Calendar. Additional copies of this document are available from your IC Safety and Health Specialist.

Equipment Repair and Transfer

All equipment which may have been exposed to hazardous materials (i.e., known hazardous chemical, radiological, or biological substances) must be appropriately decontaminated and certified as being clear of hazards, using NIH Form 2683 to transfer, service, or repair. Included are all scientific/medical equipment and any office furniture/equipment or supplies that have been used in clinical areas, laboratories, or other potentially hazardous locations. Guidance for the decontamination of such equipment is provided by Instruction and Information (I&I) Memorandum DL 91-3.

Training and Education

Training for employees, in compliance with the OSHA Bloodborne Pathogen Standard, is provided on a monthly basis for all laboratory employees. Principal Investigators and Supervisors are responsible for assuring that all employees, under their direction who may be potentially exposed to a bloodborne pathogen, attend one of these sessions prior to handling infectious materials and that they receive refresher training on an annual basis. Consult the Division of Occupational Health and Safety website http://www.nih.gov/od/ors/ds/train.html or call the DOHS office (301-496-2960) for current course schedules. Principal Investigators and Supervisors are responsible for job-specific safety training and must document that employees selected for jobs, involving manipulation of infectious materials, have been adequately trained to perform these tasks.

Fire, emergency response personnel, and NIH law enforcement officers receive training consistent with the information provided in the HHS publication entitled Guidelines for Prevention of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety

Workers. These guidelines were developed in response to P.L. 1000-607 The Health Omnibus Programs Extension Act of 1988 portions of which are specific for personnel working in the emergency response or law enforcement arenas. Training is provided upon employment and annually.

Bloodborne Pathogen Training Courses Available: For details contact the Division of Occupational Health and Safety.

Working Safely with HIV and Other Bloodborne Pathogens

Laboratory Safety at the National Institutes of Health

Bloodborne Pathogen Training for NIH Fire and Emergency Response Personnel

Bloodborne Pathogen Training for NIH Law Enforcement Officers

NIH Exposure Control Program for Non-Hospital Personnel Introduction

NIH employees are at risk of infection and subsequent illness as a consequence of exposure to human blood or other potentially infectious body fluids. Therefore, this Exposure Control Program (ECP) has been developed to minimize employee exposure to bloodborne pathogens, such as HBV and HIV. The ECP establishes the policy for the implementation of procedures which relate to the control of infectious diseases which may be contracted by the bloodborne route. The ECP is in compliance with the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard (29 CPR 1910.1030), and serves as both the written program, for compliance purposes, and as a training document. The ECP will be reviewed annually by the NIH Institutional Biosafety Committee. A copy of the exposure control plan is made available to all NIH employees, upon request, by contacting the Institute, Center, or Division (ICD) Safety and Health Specialist (301-496-2960).

Exposure Determination

At the NIH, the principal method by which exposure determination information, for laboratory personnel, is gathered is with the Registration of Materials (Potentially) Infectious for Humans form. All Principal Investigators (PIs) working with human pathogens, human blood, body fluids, or tissues, and/or toxins must submit a properly completed registration form to the NIH Biosafety Officer for subsequent review by the NIH Biosafety Committee. If animals are to be used in the research protocol, a copy of the animal care and use protocol must also be attached. After initial review, a copy of the registration document is forwarded to the Occupational Medical Service (OMS) for review and enrollment of participants in the appropriate medical surveillance program. Upon receipt of the registration document, the OMS will offer employees immunizations appropriate for the work being performed.

Information collected on the registration document is annually updated by the Principal Investigator or Supervisor and reviewed by Division of Occupational Health and Safety (DOHS) staff to ensure that exposure determinations are adequately performed and correct. Laboratory surveys and routine walk-through visits of areas are made to ensure that appropriate equipment is being used and procedures are being followed.

Law enforcement officers may face the risk of exposure to blood during the conduct of their duties. For example, at the crime scene or during the processing of suspects, NIH law enforcement officers may encounter blood-contaminated hypodermic needles or weapons, or be called upon to render emergency aid. Therefore, NIH law enforcement personnel are covered

under the ECP for bloodborne pathogens and are offered hepatitis B immunization and will receive appropriate training.

Fire and emergency response personnel often provide emergency medical services and, therefore, encounter exposures common to those experienced by paramedics and emergency medical technicians. Job duties may be performed hurriedly in the pre-hospital setting under uncontrolled conditions. Fire and emergency response personnel are, therefore, covered under the ECP for bloodborne pathogens and are offered hepatitis B immunization and will receive appropriate training.

The document entitled Waste Disposal at NIH, also referred to as the NIH Waste Calendar describes waste handling procedures at the NIH. The implementation of these procedures allows a negative exposure determination to be made for housekeeping, maintenance, and other support personnel. However, in an effort to reduce the chance of illness from an accidental hepatitis B virus exposure, these NIH employees are offered hepatitis B vaccine through the Occupational Medical Service.
Bloodborne Pathogen Refresher Training for Laboratory Personnel

NIH POLICY MANUAL

3035 - WORKING SAFELY WITH HAZARDOUS BIOLOGICAL MATERIALS

Issuing Office: ORS/DS 496-2960 Release
Date: 05/06/98

1. **Explanation of Material Transmitted:** This chapter establishes the NIH policy on working with hazardous biological materials in the NIH research environment and instructions for transferring Select Agents as defined in 42 CFR 72.6, Additional Requirements for Facilities Transferring or Receiving Select Agents.

2. **Filing Instructions:**

   Remove: NONE
   Insert: NIH Manual Chapter 3035 dated: 05/06/98

3. **Distribution:** NIH Manual Mailing Keys F-401 and F-405 **PLEASE NOTE:**

   For information on:

- Content of this chapter, contact the issuing office listed above.
- On-line information, enter this URL: http://www3.od.nih.gov/oma/manualchapters/
- To sign up for e-mail notification of future changes, please go to the NIH Manual Chapters LISTSERV Web page.

A. Purpose:

Established under this chapter is the National Institutes of Health (NIH) policy governing the conduct of work with hazardous biological materials in the research environment, including recombinant DNA materials, toxins and human pathogens classified at Biosafety Level 2 (BL-2) and higher and Select Agents as defined in 42 CFR 72.6, Additional Requirements for Facilities Transferring or Receiving Select Agents.

B. Background:

The safe handling of hazardous biological materials in the biomedical research setting has been and will continue to be a concern. The emergence of the human immunodeficiency virus (HIV) prompted public awareness and enhanced the need for guidelines relative to the handling of potentially infectious materials. The CDC/NIH publication, Biosafety in Microbiological and Biomedical Laboratories, serves as the primary resource guide on biological safety issues. The guide provides both laboratory

and animal biosafety level criteria, recommended biosafety levels for infectious agents and infected animals, risk assessment criteria and biological agent summary statements.

The Occupational Safety and Health Administration (OSHA) has promulgated a standard on working safely with human blood and body fluids (29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens). This standard applies to research laboratories and outlines the requirements for working with human body fluids, tissues and potential bloodborne pathogens. The standard provides information concerning facility requirements, safe work practices, medical surveillance, personal protection, first aid procedures and worker training.

Concerns about the potential use of certain biological agents for terrorist purposes caused the U.S. Congress to enact Public Law 104-132, The Antiterrorism and Effective Death Penalty Act of 1996. Section 511 of the Act required the Secretary of Health and Human Services to regulate the transfer of Select Agents. The Centers for Disease Control and Prevention implemented regulations that govern the transfer of certain biological agents and toxins, defined as Select Agents (42 CFR 72.6). Facilities that apply to transfer or receive these agents must be equipped and capable of handling the agents at the appropriate biosafety level and meet all record keeping requirements. The NIH Biosafety Officer is the Responsible Facility Official for the implementation of Part 72.6. A list of the regulated agents can be found in Appendix 1, Appendix A to Part 72, CFR 42 Select Agents. The Centers for Disease Control and Prevention (CDC) provides an updated list of Select Agents on the CDC webpage (http://www.cdc.gov/od/sap/appinfo.htm).

C. Policy:

The policy of the NIH is to ensure that all biomedical research involving hazardous biological materials, including recombinant DNA molecules and human pathogens classified at BL-2 and higher, is conducted in a manner which protects research personnel, support staff and the environment. All work with hazardous biological materials will be conducted in compliance with the publication, Biosafety in Microbiological and Biomedical Laboratories. The policy for working with bloodborne pathogens is set forth in the NIH Bloodborne Pathogen Exposure Control Plan for Non-Hospital Personnel. Copies of these documents may be obtained from the Occupational Safety and Health Branch, Division of Safety (OSHB, DS) 496-2960 or on the DS webpage (http://www.nih.gov/od/ors/ds).

Employee training is an important component in the safe conduct of work with biological materials. Providing the initial training and annual retraining of personnel, as required under 29 CFR 1910.1030 and subsequent health standards, is the responsibility of the immediate supervisor. Supervisors are also accountable for ensuring that their employees are advised of the potential hazards associated with infectious agents and the proper use of laboratory equipment, including containment devices. The Occupational Safety and Health Branch provides training support to help supervisors fulfill the training requirements stated in the OSHA Standard. Training

classes which address the recognition and control of common biological, chemical and physical hazards found in NIH laboratories, as well as safe work practices with human and nonhuman primate retroviruses and other bloodborne pathogens are routinely presented.

The OSHB is responsible for managing biological safety at the NIH and provides a broad range of support services, consultation and assistance. The NIH Institutional Biosafety Committee (IBC), whose functions are defined under the NIH Guidelines for Research Involving Recombinant DNA Molecules (Guidelines), reviews and approves research protocols involving the use of potentially infectious materials.

Principal Investigators working with recombinant DNA shall complete and submit to the IBC, NIH form 2690 Registration Document for Recombinant DNA Experiments, prior to the initiation of any experiment which requires approval under the Guidelines. The PI is responsible for compliance with the Guidelines in the conduct of recombinant DNA research and ensuring that appropriate reviews and approvals are obtained prior to initiation of experiments.

Principal Investigators (PIs) are responsible for submitting the form, Registration of Materials (Potentially) Infectious for Humans (OSHB 1/97), for all work involving human pathogens or human blood, tissues and body fluids including primary human cell cultures.

Principal Investigators who wish to transfer or receive a Select Agent (virus, bacterium, fungus, rickettsia or toxin) or
associated genetic elements (shown to produce or encode for a factor associated with disease) as listed in Appendix A, 42 CFR Part 72.6 must contact the NIH Biosafety Officer (OSHB, DS) for assistance and approval.

Laboratories where work at BL-2 and higher is conducted, shall be posted with signage indicating the assigned biosafety level, biological material(s) in use, special procedures or precautions for entry, name of the Principal Investigator with work and emergency phone numbers. These laboratories will be inspected by OSHB staff to ensure that the facility is operating properly for the biosafety level and that appropriate practices and procedures are observed. Follow-up inspections shall be conducted.

Principal Investigators operating or working in a BL-3 laboratory must secure all potentially infectious materials prior to allowing entry of support personnel such as maintenance employees. All laboratory components (sinks, countertops, etc.) and equipment scheduled for repair or servicing will be thoroughly decontaminated by research personnel prior to initiation of the work. A staff member familiar with the operation of the laboratory shall be present during normal working hours whenever maintenance/repair work is being conducted.

In the event of an after hours emergency in a BL-3 laboratory, the PI will be contacted at home prior to maintenance personnel entering the area. The information posted on

the laboratory door sign must be kept current to facilitate this response. **D. References:**

1. References and copies of registration forms are available from the Occupational Safety and Health Branch, Building 13 Room 3K04, 496-2960. OSHA references are also available on the OSHA webpage (http//www.osha.gov).

2. Additional Requirements for Facilities Transferring or Receiving Select Agents. Centers for Disease Control and Prevention 42 CFR 72.6, Federal Register, June 10, 1996, (61 FR 29327).

3. Biosafety in Microbiological and Biomedical Laboratories. Centers for Disease Control and Prevention/National Institutes of Health, (current edition).

4. NIH Bloodborne Pathogen Exposure Control Plan for Non-Hospital Personnel. Prepared in compliance with 29 CFR 1910.1030, December 4, 1992.

5. NIH Guidelines for Research Involving Recombinant DNA Molecules (Guidelines). Federal Register, July 5, 1994 (59 FR 34496). Amendment Federal Register, March 12, 1996, (61FR10004).

6. Occupational Exposure to Bloodborne Pathogens. Occupational Safety and Health Administration Standard 29 CFR 1910.1030, Federal Register, December 6, 1991.

E. Records Retention and Disposal:

All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743, "Keeping and Destroying Records, Appendix 1, NIH Records Control Schedule, " Item 7000.

NIH e-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

F. Management Controls:

The purpose of this manual issuance is to establish the NIH policy on working with hazardous biological materials in the research environment including recombinant DNA materials, toxins and human pathogens classified at Biosafety Level 2 and higher and Select Agents as defined in 42 CFR 72.6, Additional Requirements for Facilities Transferring or Receiving Select Agents.

1. Office Responsible for Reviewing Management Controls Relative to this Chapter (Issuing Office):

Through this manual issuance, the Division of Safety (DS), Occupational Safety and Health Branch (OSHB) is accountable for the method used to ensure that management controls are implemented and working.

2. Frequency of Review (in years):

Annual.

3. Method of Review:

Other Review (describe): The OSHB will maintain oversight and ensure effective implementation and compliance with this policy through review of Science Citation Index Expanded, a multidisciplinary library database covering the journal literature of the sciences. Literature reviews of a sampling of NIH PIs, working with hazardous biological materials, will be conducted and the PIs' names cross-referenced with OSHB records. The OSHB maintains information from NIH form 2690 Registration Document for Recombinant DNA Experiments, Registration of Materials (Potentially) Infectious for Humans (OSHB 1/97) and Select Agent transfer documentation. Any discrepancies will be noted and the PI will be provided with the correct documentation. Information on missing or inadequate documentation for laboratories using hazardous biological materials will be reviewed by the NIH Biosafety Committee and an Executive Summary will be forwarded to the Deputy Director for Intramural Research (DDIR).

4. Review Reports are sent to:

DDIR (Executive Summary)

Appendix 1:

Appendix A to Part 72, CFR 42 Select Agents, Department of Health and Human Services

Viruses

1. Crimean-Congo haemorrhagic fever virus
2. Eastern Equine Encephalitis virus
3. Ebola viruses

4. Equine Morbillivirus
5. Lassa fever virus
6. Marburg virus
7. Rift Valley fever virus
8. South American Haemorrhagic fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)
9. Tick-borne encephalitis complex viruses
10. Variola major virus (Smallpox virus)
11. Venezuelan Equine Encephalitis virus
12. Viruses causing hantavirus pulmonary syndrome
13. Yellow fever virus

Exemptions: Vaccine strains of viral agents (Junin Virus strain candid # 1, Rift Valley fever virus strain MP-12, Venezuelan Equine encephalitis virus strain TC-83, Yellow fever virus strain 17-D) are exempt.

Bacteria

1. Bacillus anthracis
2. Brucella abortus, B. melitensis, B. suis
3. Burkholderia (Pseudomonas) mallei
4. Burkholderia (Pseudomonas) pseudomallei
5. Clostridium botulinum
6. Francisella tularensis
7. Yersinia pestis

Exemptions: vaccine strains as described in Title 9 CFR, Part 78.1 are exempt.

Rickettsiae

1. Coxiella burnetii
2. Rickettsia prowazekii
3. Rickettsia rickettsii

Fungi

1. Coccidioides immitis

Toxins

1. Abrin

2. Aflatoxins
3. Botulinum toxins
4. Clostridium perfringens epsilon toxin
5. Conotoxins
6. Diacetoxyscirpenol
7. Ricin

8. Saxitoxin
9. Shigatoxin
10. Staphylococcal enterotoxins
11. Tetrodotoxin
12. T-2 toxin

Exemptions: Toxins for medical use, inactivated for use as vaccines, or toxin preparations for biomedical research use at an LD50 for vertebrates of more than 100 nanograms per kilogram body weight are exempt. National standard toxins required for biologic potency testing as described in 9 CFR Part 113 are exempt.

Recombinant organisms/molecules

1 . Genetically modified microorganisms or genetic elements from organisms on Appendix A, shown to produce or encode for a factor associated with a disease.
2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed in this Appendix, or their toxic subunits.

Other restrictions

The deliberate transfer of a drug resistance trait to microorganisms listed in this Appendix that are not known to acquire the trait naturally is prohibited by NIH "Guidelines for Research Involving Recombinant DNA Molecules," if such acquisition could compromise the use of the drug to control these disease agents in humans or veterinary medicine.

Additional Exemptions

1. Products subject to regulation under the Federal Insecticide Fungicide and Rodenticide Act (7 U.S.C. Section 136 et seq.) and the Toxic Substances Control Act (15 U.S.C. Section 2601 et seq.) are exempt.

2. Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents in this Appendix. Individuals seeking an exemption should submit a request to CDC that specifies the agent or strain to be exempted and explains why such an exemption should be granted. Future exemptions will be published in the Federal Register for review and comment prior to inclusion in this Appendix.

IC OCCUPATIONAL SAFETY AND HEALTH COMMITTEE WORKSITE SURVEYS STANDARDIZED REPORTING FORMAT

1. Imminent Hazards
2. Compliance with Prudent Practices

A. Biologicals

- Laboratories are posted with a sign listing the agent(s) in use, the appropriate biosafety level and the name and phone number of the Principal Investigator (PI).
- Sinks are available for hand washing.
- Biological Safety Cabinets and all HEPA filtered devices are certified.
- Directional airflow from the corridor to the laboratory is evident. Appropriate disinfectants are available and proper waste management procedures are being followed (needle disposal containers, autoclaves and /or MPW boxes are in use, etc.).
- The poster listing the **3 Emergency Steps to Take in the Event of a Potential Bloodborne Pathogen Exposure** (NIH DS, 3/97) is placed prominently in laboratories where HIV, other related retroviruses or human blood, body fluids and tissues are in use.

B. Chemicals

- Flammable storage cabinets are present and utilized; chemicals are properly segregated, stored on shelves (below eye level) and not on the floor.
- Proper waste management procedures are being followed (Chemical Waste Tags are completed and affixed to waste chemicals, safety cans for solvents are being used and waste minimization techniques are being followed).
- Chemical Fume Hoods and all local exhaust devices are certified.

C. Corridors

- No hazardous materials (chemicals, gas cylinders, etc) or equipment are present.
- The appropriate corridor width is maintained free and clear of storage and obstructions and no storage is present in horizontal exits, stairwells, areas of refuge and elevator lobbies.
- Combustible materials are stored within suitable metal cabinets with metal doors.
- All emergency equipment including safety showers, eyewashes, sprinklers, fire extinguishers and fire alarm pull stations are maintained with full and unobstructed access.
- Exit signs are in place and easily visible.
- No radioactive materials are stored in corridors, except for autoradiographic film cassettes in locked refrigerators or freezers.

D. Physical

- Eye washes and safety showers are available.
- Utility panels, closets and electrical boxes are accessible.
- Extension cords are not in use. Electrical outlets within two feet of a water source are equipped with ground fault circuit interrupters (GFCIs).
- All telephones have a red sticker listing the NIH emergency telephone numbers.

E. Radiation

- Each lab which has radioactive waste containers or other items labeled "Caution

Radioactive Material" in it has a "Caution Radioactive Material" sign at the

entrance. The name and phone number of a researcher to contact in case of emergency is noted on this sign.

- Source vials of radioactive material are secured when unattended.
- Lab coats, gloves, and absorbent paper are available and are used when working with radioactive materials.

F. Physical environment of the lab, office, loading docks.

- Electrical cords are secure and not on the floor or draped across or under other
- pieces of equipment. Combustible materials are kept to a minimum and stored in metal cabinets with metal doors.
- The environment is clear and free of debris.

3. Safety and Health Committee Accomplishments

initiatives within the IC, special projects or training. Discuss any other accomplishments

such as development of a website, communication