OFFICE OF RESEARCH AND GRADUATE STUDIES
AND
DEPARTMENT OF ENVIRONMENTAL HEALTH AND SAFETY

DREXEL UNIVERSITY
AND
DREXEL UNIVERSITY COLLEGE OF MEDICINE

LABORATORY
SAFETY MANUAL

May 2011

"Safety is a Personal Decision that Impacts others on a Daily Basis"

DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

LABORATORY SAFETY MANUAL

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FROM THE SENIOR VICE PRESIDENT FOR RESEARCH

Our faculty, staff and students bring a wealth of expertise to our institutions. They are vital to our mission of research, teaching and service to everyone within and outside of our universities' community. This expertise requires our institutions to demonstrate its leadership in providing health protection and apply safety standards beyond the laws and regulations relating to environment, health and safety.

Our mission is to prevent or minimize injuries and illnesses and control potential hazards from our activities. Our intentions are to continually consult with each of the departments for complete compliance with laws and regulations regarding occupational health and safety and environmental protection. This Laboratory Safety Manual is intended to inform you the policies and procedures of our universities, directions and describe procedures of technical assistance for your protection, protection of our research subjects and for the protection of our community. It describes how our offices have carefully developed compliance strategies, which include training, periodic inspections, consultations and emergency response services. This manual also describes in detail biosafety, sanitation, radiation protection, hazardous materials handling, hazardous waste management, general safety, occupational health, disaster preparation and reporting of unauthorized potentially hazardous activities.

We must all remember that good environmental health and safety practices are a responsibility of each faculty member, staff member, students and visitors. Our participation and adherence to regulatory compliance is essential to a smooth and effective operation of a safety program. Achievement of these goals is critical for the growth of our research enterprise.

The Office of Research Compliance and the Department of Environemental Health and Safety (EH&S) welcome your suggestions and cooperation in making our universities the safest place to work.

Drexel University and Drexel University College of Medicine
Important Contact Numbers

Department	Center City Campus	Queen Lane Campus	University City Campus	Doylestown Campus
Emergency Telephone Operator	80	215-895-2222	215-895-2222	215-895-2222
Environmental Health and Safety	215-895-55919	215-895-5919	215-895-5919	215-895-5919
Hospital Safety Office	215-762-8617	N/A	N/A	N/A
Office of Research	215-255-7857	215-255-7857	215-895-2499	215-895-2499
Service Center; Environmental Services Maintenance/ Materials Management	 215-762-4700 215-762-6500	 215-991-8484 215-991-8484	 215-895-2808	 215-489-4904 215-489-4904
Employee Health	215-762-8590	215-762-8590	215-467-5800	215-762-8590
Student Health	215-762-8590	215-762-8590	215-895-5800	215-762-8590
Radiation Safety	215-762-4050	215-762-4050	215-762-4050	215-762-4050
Glass Wash Facility	N/A	215-991-8448	N/A	N/A
Animal Facilities	215-762-7968	215-991-8167	215-895-1348	N/A
University Biosafety Committee	215-255-7857	215-255-7857	215-255-7857	215-255-7857
University Biosafety Officer	215-895-5891	215-895-5891	215-895-5891	215-895-5891
Recombinant DNA Officer	215-762-7398	215-762-7398	215-762-7398	215-762-7398
Security	215-762-7110	215-991-8102	215-895-2822	215-895-2822

DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

I. INTRODUCTION

The purpose of this laboratory safety manual is to provide information concerning safety policy and procedures in effect at Drexel University and Drexel University College of Medicine, and thereby promote a safe working environment. Although the manual is primarily designed for compliance by the institutional scientific, technical and supportive staffs, all other employees must be knowledgeable about these safety policies and the procedures for implementation.

In 1983, the federal occupational safety and health administration (OSHA) set forth the occupational safety and health standard entitled "Hazard Communication Standard" (29 CFR 1910.1200) and “laboratory standard” (29 CFR 1910.1450). These standards and similar existing state and local governmental ordinances have been commonly called the "worker's and community right to know" laws which provide minimum standards that employers must adhere to for informing employees about occupational-related hazards in the work place.

On august 28, 1987, OSHA published a final rule (standard), which supersedes all state and local regulations regarding the use of toxic substances in laboratories. All employers in the non-manufacturing sector had until May 23, 1988 to be in compliance with all provisions of the standard.

The policies, regulations and procedures defined in this manual are one means of compliance with the right to know laws. However, this manual has a much broader scope than occupational-related hazards. It is not just a means for Drexel University and Drexel University College of Medicine to resolve its obligation to inform its employees, but a guide to follow in making this a safer workplace. Accordingly, this manual covers a wide spectrum of safety precautions, ranging from daily housekeeping chores to procedures to follow in emergencies. It addresses the following five specific issues:

1. General Laboratory Safety
2. Biological Safety
3. Chemical Safety
4. Radiation Safety
5. Emergency Procedures

As a Drexel and/or Drexel University College of Medicine employee, it is your right and responsibility to follow the rules of laboratory safety. It is your responsibility to read and understand the information contained in the manual and to keep the manual readily accessible for review and emergency use. It will be updated as new safety information or governmental regulations are obtained. This manual is to be used as an informational resource. The handbook is not a contract, nor a legal document. Drexel University and Drexel University College of Medicine reserve the right to delete, add or amend the contents of this manual. Occupational hazards and regulatory rules will undoubtedly continue to be changed. Accordingly, no representation can be made or responsibility undertaken by Drexel and/or Drexel University

College of Medicine regarding the completeness, accuracy or continuing validity of the contents of this manual.

In the final analysis, each employee must assume his or her responsibility to work in a safe manner hereby avoiding personal harm or endangering others.

II. DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

Drexel University and Philadelphia Health Education Corporation dba Drexel University College of Medicine are two separate corporations each having their own board of trustees. Drexel University College of Medicine is a subsidiary of Drexel University. The two entities have established a common Biosafety and Recombinant DNA Compliance program lead by the Institution's Provost, Vice Provost for Research and Graduate Policies (VPRGP) and the Dean of the College of Medicine. All of the executives mentioned above have sufficient standing, authority and independence to ensure implementation and maintenance of the program.

Right to Know Guidelines

Biological and Chemical research often requires the use of hazardous materials including radioisotopes, infectious agents, and hazardous chemicals. While working at Drexel and/or Drexel University College of Medicine, it is likely that you will be required to handle such materials. In this regard it will be your specific right and obligation to know, before using a hazardous material in an experiment, what is the nature of the material, its specific hazard and the proper procedures for its use.

Radioactive material use will continue to be monitored by and under the control of the Drexel University and Drexel University College of Medicine' Radiation Safety Office.

With your right to know emerge specific responsibilities for your protection and the protection of others. Adherence to all Government and Drexel and/or Drexel University College of Medicine guidelines and regulations for the use and disposal of any hazardous materials is mandatory. In addition, all reasonable precautions to assure the safety of yourself and others must be taken. This may include vaccination and/or medical monitoring.

If you are ever in doubt or have a problem with the use of any materials or have a complaint about experiments done by others, the following procedures are to be followed:

1. Discuss the problem with your immediate supervisor.
2. If you are not satisfied, discuss with the Department Chair.
3. If you are not satisfied, then discuss the problem with the Drexel University and Drexel University College of Medicine' Safety Office.
4. If still unsatisfied, discuss the problem with the University Biosafety Officer.
5. If still unsatisfied, contact the University Biosafety Committee Chair.
6. If still not satisfied, request a meeting with the Vice Provost for Research Compliance.
7. If still not satisfied, request a meeting with the Vice Provost for Research and Graduate Policies.

Please note that Exhibit II - provides a copy of a Right-to-Know guideline form. This form must be completed by all laboratory personnel.

III. LABORATORY SAFETY TRAINING

A. Policy

As an integral part of Drexel University and Drexel University College of Medicine' Safety Management Program, all new Scientific, Technical and Research Support Personnel must complete the online mandatory safety training concerning Drexel University and Drexel University College of Medicine' Safety Policies and Procedures. This includes all fulltime, part time and temporary employees. Initial training will be provided to all newly hired employees. Additional training will be conducted on an annual basis.

It is the responsibility of the Principal Investigator (PI) to schedule laboratory safety training for all affected employees. It is your individual responsibility to attend in accordance with this University's Policies and Procedures. Laboratory safety training is available online at www.drexelehstraining.com/. Additional classroom training can be scheduled by contacting the Department of Environmental Health and Safety at 215-895-5919.

The PI in each laboratory is responsible for ensuring that all activities under his / her control are conducted in a manner that represents the least possible risk to human health and the environment. If the activity involves the use of extremely hazardous chemicals or recombinant DNA/RNA material, the use of such material must be approved by the biosafety committee before a procedure to use such material is implemented. The PI must ensure that all safety policies and regulations are enforced and that necessary safety equipment is available in the laboratory. **The PI has the primary responsibility for the health and safety of all personnel under his / her jurisdiction including employees, students, guest scientist and visitors**.

Principal Investigator Responsibilities are to:

a. Identify hazards and assess the risks associated with operations;
b. Ensure that program personnel are aware of hazards and of the precautions they should take in carrying out their assigned tasks;
c. Select proper laboratory safety practices and engineering controls necessary to minimize personal injury or property damage;
d. Select appropriate preventative medical practices, serological monitoring, and immunization protocols, and inform program personnel of the rationale for their selection In conjunction with Human Resources, Biosafety Committee, Safety Office and Office of Research;
e. Provide instruction and training programs for personnel in the practices and techniques required for their assigned tasks and laboratory operations;

f. Maintain a laboratory procedure notebook;
g. Ensure that necessary safety equipment is available in the laboratory; it is used when required, and is adequately maintained;
h. Periodic review of emergency procedures for accidental spills and any overt exposure to hazardous substances. This should be done in conjunction with the Biosafety Committee and Safety Office;
i. Arrange for immediate medical attention for injured personnel and reporting of incidents as required;
j. Comply and assure that you and other support personnel adhere to policies and procedures as outlined in this manual and
k. Keep each appropriate office informed regarding new personnel or procedures used in the laboratory

Employee and Student Responsibilities are to:

a. Comply with all University safety policies and procedures;
b. Maintain awareness of the risks associated with assigned duties;
c. Take all necessary and appropriate safety precautions relevant to performance of duties;
d. Become familiar with emergency procedures prior to accidental spills, overt personal exposures, fire, etc.;
e. Report unsafe conditions or practices to the PI, Safety Office, Office of Research or the Biosafety Committee Chair and
f. Report all incidents resulting in injury or exposure to hazardous agents to the PI, Safety Office, Office of Research, or Biosafety Committee Chair.

Health and safety awareness will be promoted among PI's, managers, supervisors, employees, students and others (visitors, contractors, community members) through orientation programs and regularly scheduled education sessions and online training, as appropriate. If you are interested in scheduling classroom training services, please contact the Department of Environmental Health and Safety at (215) 895-5919.

B. Laboratory Safety Training Curriculum

The Laboratory Safety Training curriculum shall include, but not be limited to the following list of subject matter:

1. GENERAL LAB SAFETY

- Hazard Communication
- Emergency Spill Response
- Chemical Fume Hoods
- Biological Safety Cabinets
- Centrifuge Use
- Compressed Gas Cylinders
- Laser Safety

- Hazardous Waste Management
- Personal Protective Equipment
- Respiratory Protection
- Fire and Life Safety

2. CHEMICAL HYGIENE

- Laboratory Signage
- Labeling and Storage of Chemicals
- Material Safety Data Sheets
- Engineering Controls
- Routes of Exposure
- Toxic, Flammable and Reactive Substances
- Emergency Spill Response
- Decontamination
- Eye Wash Stations and Safety Showers
- Medical Surveillance

3. BIOLOGICAL SAFETY

- Bloodborne Pathogens
- Other Biological Hazards
- Standard / Universal Precautions
- Sharps
- Primary Barriers and Containment
- Personal Protective Equipment
- Vaccination and Surveillance
- Spill Response
- Shipping Biological Materials

4. RADIATION SAFETY

- Radiation Safety Office – Licensing and Monitoring
- Common sources of Radiation at Drexel University and Drexel University College of Medicine' Facilities
- UV Microscopes and Lamps
- Exposure – Time, Distance, Shielding
- Decontamination

5. WASTE MANAGEMENT

- Infectious / Biohazardous Waste / Sharps
- Radioactive Waste
- Hazardous Waste

As stated above all newly hired personnel will receive basic safety training at their orientation. Additionally, these individuals must receive site-specific laboratory safety training from their perspective PI's. This training must be documented. Copies of syllabus and completed sign-in sheets must be forwarded to the Department of Environmental Health and Safety located at:

400 N. 31st Street
Philadelphia, PA 19104
Fax – 215-895-5926

C. SPECIAL ORIENTATION FOR BIOSAFETY LEVEL 3 (BL-3) LABORATORY

Specific orientation sessions will be held for all laboratory personnel whose work assignments require the use of the University's BL-3 facility. A biosafety level 3 or BL-3 laboratory is equipped to work with small quantities of infectious agents for which a vaccine may not be available. The facility is prefaced by an anteroom, is equipped with a pass through autoclave, has a collection basin for all drains and has specially designed ventilation and filtration systems. The orientation session must be held and approval obtained prior to allowing the applicant admission to the BL-3 facility. Whenever possible, the orientation will be held on an individual basis and shall consist of the following steps:

1. Personal interview with the applicant by the Biosafety Officer for determining the applicants' knowledge and experience with indigenous or exotic agents.
2. Applicant will be given a copy of the Standard Operation Procedures.
3. Applicant will be required to sign an acknowledgment form.
4. Applicant will have their ID cards activated for entrance and egress to and from the BL-3 laboratory, respectively.
5. Facility users are encouraged to participate in a voluntary surveillance program to monitor occupational exposure to infectious agents.

IV. GENERAL LABORATORY SAFETY

A. HOUSEKEEPING

Many safety and health problems can be avoided through observance of good housekeeping procedures. Take time, at least once a week or as needed, to clean and straighten up your laboratory. Absorbent pads should be discarded and counter tops wiped down at least once a day. Clear bench tops of all unnecessary glassware and materials. Keep floors free of boxes, instruments, and supplies by storing them properly. Your lab will be inspected by the Department of Environmental Health and Safety office on a regular basis.

B. PERSONAL PROTECTIVE EQUIPMENT

A lab coat, safety glasses and gloves must be worn when in a laboratory. Lab coats are worn to protect street clothes from hazardous materials and should be removed prior to whenever leaving the laboratory environment. Open-toed footwear is not to be worn in Drexel University's laboratories or clinical area. As a precautionary measure, disposable gloves, chemical aprons, respirators, splash goggles or face shields must be used when appropriate. Furthermore, disposable gloves are not to be worn outside of the laboratories, I.E., gloves must never be worn in hallways, elevators, or public areas of the institution. Wash hands after removing gloves and prior to leaving the lab. When transporting radioactive or hazardous materials one hand should be gloved for protection, leaving the other hand ungloved to facilitate opening doors, pressing elevator buttons, etc.

C. EATING, DRINKING AND COSTMETICS

Eating, drinking, the preparation of food, and the application of cosmetics in the laboratory are forbidden. Food and drink must not be stored in laboratory refrigerators. All refrigerators used to house biological, chemical or radioactive substances must be labeled accordingly and must have a sign, "no food or drink to be stored in this refrigerator."

D. PIPETTING

Pipetting by mouth is forbidden. This regulation is very important. There are many alternatives to mouth pipetting. With a little practice, it is possible to work safely, quickly and accurately with mechanical devices."

E. SYRINGES AND PASTEUR PIPETTES

Bending, recapping or cutting of syringes is forbidden. Do not attempt to re-sheath needles or remove them from the syringe, as these manipulations can easily result in accidents. Instead, exposed needles must be carefully placed in the special sharps containers (call the Drexel University's Department of Environmental Health and Safety at 215-895-5919 for containers) for disposal.

F. BROKEN GLASSWARE

Use tongs, dustpan and broom or heavy gloves when disposing of broken glassware. Please place all broken glassware in the sharps containers located within the lab.

G. GAS CYLINDERS – (Please refer to "Safe work practices for compressed gas cylinders")

All cylinders, including empty cylinders, must be firmly secured to the wall or bench at all times. Please call the facilities managementdepartment at your facility for securing cylinders. Proper regulators must be used. Do not lubricate, modify or tamper with a cylinder or regulator valve.

H. HAZARD WARNINGS

As a precautionary measure, all equipment, reagents and laboratory containers (i.e. beakers, flasks, bottles and test tubes) used for chemical, radioactivity, and biological purposes must be clearly identified with appropriate labels, signs, decals or other conspicuous identification. Labels must be present on doors, storage cabinets, refrigerators, cold rooms, incubators, etc. The exterior surface of laboratory doors should be reserved for hazard communication and appropriate information purposes only. All other items i.e. pictures, cartoons, etc. must be removed. If you have questions regarding which type of labels may be required in your lab please contact the Department of Environmental Health and Safety at (215) 895-5919.

Removal of Warnings: Radioactive and Biohazard Warning Labels can only be removed after appropriate decontamination or sterilization procedures have rendered them safe for further usage. Warning labels must be removed and/or changed after proper decontamination if future use is inconsistent with current labeling. For assistance on decontamination and sterilization procedures, please call the Department of Environmental Health and Safety at (215) 895-5919.

Multipurpose Warnings: PI's must provide multipurpose warning signals to notify occupants and standardize information concerning laboratory procedures currently conducted, or to be conducted in a given laboratory. These signs must be placed on all entrances to a respective laboratory with the appropriate hazard warning decal(s).

(Please refer to the Drexel University chemical hygiene plan for details pertaining to labeling & storage of chemicals.)

I. ELECTRICAL EQUIPMENT

High voltage electrical equipment must be labeled accordingly.

Inspect electrical equipment periodically for frayed cords and faulty control switches and thermostats. Do not try to repair equipment yourself. The Maintenance Department should be contacted for all repairs and maintenance. Never try to by-pass the ground or safety devices on a piece of electrical equipment.

J. FIRE SAFETY-*(Please refer to the Seasonal Decoration Policy.)*

Fire safety is a precautionary practice applicable to all personnel. At Drexel University, there are three basic elements to the fire safety program.

1. **Prevention: -** The ability to identify potential fire risks and eliminates them. Some of the ways you can eliminate risk of fire is:

   Practice good housekeeping:

   a. Do not allow trash to accumulate.

   b. Use the proper trash receptacles.

   c. Keep combustibles to a minimum in your work area.

   d. Keep flammable liquids properly stored.

   e. Keep corridors, aisles and doors free of clutter to assure safe passage in the event of an emergency.

   f. Smoking is **PROHIBITED** inside all of our buildings. Please remember, careless smoking accounts for 80% of all health care fires.

   g. **Practice electrical safety:**

      i) Do not overload outlets.

      ii) Do not use extension cords in place of permanent wiring.

      iii) Do not use ungrounded or damaged equipment.

      iv) Do not store combustible or flammable material near electrical appliances that produce heat.

2. **Detection**: even with a good program of prevention in place the possibility of a fire occurring still exists. In the event of a fire, remember **R.A.C.E**.

R-rescue people in immediate danger.
A-alarm - activate a fire alarm pull station and call security if in Center City at (215)-762-7110 or Public Safety if in University City or Queen Lane at 215-895-2222 or the Fire Department if on Doylestown Campus at 911, state your name, location and describe the emergency.
C-close (but do not lock) all windows and doors as you leave the area.
E-evacuate visitors, students, and employees to safe areas according to your building specific fire evacuation plan and/or the direction provided by the fire department.

3. **Extinguishment:** this element of the fire safety program requires that each employee become familiar with the types of fires that could occur on campus, the correct fire extinguisher to use to fight the fire, how to use the extinguisher, and where they are located.

TYPES OF FIRES AND EXTINGUISHERS		
CLASS	**MATERIAL**	**EXTINGUISHER**
CLASS A	COMBUSTIBLES (WOOD, PAPER)	WATER OR DRY CHEMICAL
CLASS B	SOLVENTS, GASOLINE, OILS	CO2 OR DRY CHEMICAL
CLASS C	ELECTRICAL	CO2 OR DRY CHEMICAL
CLASS ABC	ALL OF THE ABOVE	ALL OF THE ABOVE

4. **When using the extinguisher**

Unless you have been trained in fire fighting techniques, do not attempt to fight a fire. Each facility has individuals trained in the use of fire extinguishers. Remember R.A.C.E. only use an extinguisher if a fire has come between you and the exit, or on extremely small, contained fires. Exercise good judgment when deciding to extinguish a fire! If you do need to operate an extinguisher in an emergency remember **P.A.S.S**.

P-pull the pin.
A-aim the extinguisher at the base of the fire (the burning material).
S-squeeze the handle while holding the extinguisher upright.
S-sweep the nozzle from left to right to extinguish the fire.

REMEMBER: DON'T LET THE FIRE GET BETWEEN YOU AND THE EXIT!

Accordingly, all personnel, upon employment, should know where the nearest:

- Location of the fire alarm is and how to use it (usually located near fire exits).

- Fire extinguisher is and how to use it (check if it is a Class ABC Extinguisher).
- Eye wash station and how to use it.
- Safety shower and how to use it.
- Exit (and alternative exit) .

5. IF THE FIRE ALARM SOUNDS:

University Space

Leave building by the nearest (or designated) fire exit or smoke compartment. Close all doors behind you. Use stairways. Do not use elevators. At Drexel university facilities and hospitals condition "red" means fire. Condition "green" means its safe to reoccupy the building. Building specific fire evacuation plans for university space are located at each elevator lobby.

Hospital space

Hospitals are constructed to keep people safe in the event of a fire having "smoke compartments" constructed within the building. Evacuation in a typical hospital may mean moving across a floor to another wing rather than out of the building. It is important that you observe the fire evacuation plans specific to the hospital in which you are located, as these plans often change from building to building. Remember, not knowing what to do can endanger the lives of coworkers, patients and students.

(Additional Fire Safety information is available at www.drexel.edu/publicsafety/fire or by contacting Fire, Life and Safety at (215) 895-5908.

K. VISITORS (UNAUTHORIZED PERSONNEL)

Drexel University's policy prohibits the admittance of minors (under 18 years of age) into the laboratory unless he/she is participating in an organized educational program sponsored by his/her school and approved by the Vice Provost of Research Compliance, the Department of Environmental Health and Safety , and the Chair of the Department where the program will take place.

Pregnant visitors may only be permitted in a laboratory area upon prior approval of the principal investigator.

All visitors and volunteers must complete the appropriate online training modules provided through the Department of Environmental Health and Safety's website. These individuals must also read and comply with the University's Laboratory Safety Manual and Chemical

Hygiene Plan. The Principal Investigator or the visitor's/volunteer's sponsor will be required to provide task-specific training in handling hazardous materials. The sponsor is responsible for assessing the individual's level of competence and providing further training as necessary.

There are several restrictions and approvals necessary for visitors and volunteers performing various types of work. The following restrictions and approvals are required where applicable:

- May not work with human subjects without the prior approval of the University's Institutional Review Board (IRB);
- May not work with patient records or protected health information without completing HIPAA training
- May not work with research animals without the prior approval of the University's Institutional Animal Care and Use Committee (IACUC);
- May not work with recombinant DNA or infectious agents without prior approval from the University Biosafety Committee – the individual should be listed as a visitor or volunteer on the protocol submitted by the sponsoring Principal Investigator

It is the responsibility of any person sponsoring a visitor or volunteer to ensure the individual understands and is compliant with the requirements contained in this guideline. It is also the sponsor's responsibility to ensure the laboratory/facility is in full compliance with all applicable university safety policies and procedures. In the event that the visitor/volunteer or the laboratory is not compliant with the requirements in this guideline, the visitor/volunteer may be removed from the laboratory and no longer granted permission to perform research activities in a Drexel lab. You may contact the Office of Research Compliance with any questions or concerns regarding the content of this guideline.

The Visitor/Volunteer Authorization Form must be completed, signed, and submitted to the Department of Environmental Health and Safety prior to any visitor or volunteer performing research activities in a Drexel Universtiy or Drexel University College of Medicine laboratory.

Additonal information regarding minors and visitors in Drexel University and Drexel University College of Medicine can be obtained by contacting the Department of Environmental Health and Safety.

L. HAZARDOUS WASTE DISPOSAL

1. Hazardous Waste

Hazardous waste includes substances that are solids, liquids and gases. The EPA definition of hazardous waste includes substances that possess a hazardous characteristic (e.g. toxic, ignitable, corrosive or reactive with other substances), or substances that are listed as hazardous waste by the EPA on the basis of their usage or chemical constituents.

Hazardous Waste Identification

The Department of Environmental Health and Safety will perform identification of hazardous wastes. Since the majority of chemicals used in our facility are reagent grade the identification will be performed using Material Safety Data Sheets, bottle labels, and 40 CFR Part 261 Subpart B, C, and D. A third party contractor will test for the ignitability, corrosivity, reactivity, and toxicity of unknown hazardous wastes.

Mixed Chemical Waste

The Department of Environmental Health and Safety shall require that only compatible chemical waste be combined into one waste container. Refer to the Laboratory Safety Manual and MSDS for chemical compatibilities.

Multi-Hazardous Waste

Multi-Hazardous waste is waste that contains any combination of chemical, radioactive, or biological hazards. Any waste stream that presents more than one type of hazard will require special management consideration because the selected treatment technology appropriate for one type of waste may not be appropriate for the other types. Multi-hazardous waste will be evaluated on an individual basis and the constituent that poses the greatest hazard will be given priority. Please contact the Department of Environmental Health and Safety at 215-895-5919 for further instructions.

Drain Disposal

The Department of Environmental Health and Safety will permit drain disposal of elementary neutralized (pH adjustment of waste that are hazardous only because they exhibit the corrosivity characteristic) acidic aqueous solutions. The elementary neutralized aqueous solution must have a final pH value between 6 and 8. **The limit of material that may be neutralized is 1 liter**.

The Department of Environmental Health and Safety will also permit drain disposal of common salts, sugars and agars in both liquid and solid forms. For solids, the material must be dissolved in tap water. The limit of material that may be disposed is 1kg of solid or 1 liter of liquid.

The Department of Environmental Health and Safety shall prohibit the drain disposal of the following:

- Flammable or explosive pollutants
- Pollutants that will cause corrosive structural damage to the Publicly Owned Treatment Works (POTW), but in no case discharges with pH lower than 5.0.
- Solid or viscous pollutants that may cause an obstruction of flow in the POTW
- Pollutants capable of releasing fumes or vapors
- Pollutants, including oxygen-demanding pollutants (high biological oxygen demand), which may cause interference with the POTW

- Wastewater with sufficient heat to inhibit biological activity in the POTW (must not exceed 104 F at the POTW)
- Petroleum, oil, non-biodegradable cutting oil or products of mineral oil origin in amounts that will cause interference or pass through
- Organic chemicals
- Heavy metal solutions
- Nitric, Hydrofluoric, Perchloric, and Chromic acid
- Toxic/Poisonous solids and liquids

Satellite Accumulation Areas

A satellite accumulation area is an area at or near a process that generates chemical wastes. The area must be under the control of the operator of that process.

The Drexel University Department of Environmental Health and Safety designates each laboratory as a satellite accumulation area. The laboratory Principal Investigator, Moderator, Chemical Hygiene Officer, is responsible for following the policies of the safety and health department regarding satellite accumulation areas.

1) Allowable Amount Accumulated

- Laboratories may accumulate as much as 5 gallons of hazardous waste or one quart of acutely hazardous waste (immediately hazardous to life and health) in compatible containers at or near any point of generation.

2) Labeling

- All containers must be labeled with the complete chemical name of each primary component. Formulas, acronyms and abbreviations are not acceptable.
- If possible, the label should include the approximate percentage of each chemical.
- Do not place the date or the words “Hazardous Waste” on the container. The Drexel University Department of Environmental Health and Safety will re-label the container during pick-up as either a recyclable/re-distributable material or as hazardous waste at which time the container will be dated and moved to the temporary storage vault.

3) Container Types

- All containers must be kept closed except when it is necessary to add or remove material. Evaporation of waste in fume hoods is STRICTLY PROHIBITED.
- All containers must be maintained in good condition (i.e. no rust, dents, or leaks, etc.)
- All containers must be compatible with the hazardous wastes they contain. Refer to Material Safety Data Sheets for container compatibility. If the

MSDS is not available contact the Drexel University Department Safety and Health at 215-895-5919.

4) Accumulation Time

- There will be no limit on accumulation time; however, once a container is full or more than 5 gallons of hazardous waste or 1 quart of acutely hazardous waste is accumulated, the full container or excess waste must be moved to the accumulation area within 72 hours.

5) Inspection

- Inspection of each satellite accumulation area shall be the responsibility of the principle investigator.

2. Chemical Pick-up Request

The Department of Environmental Health and Safety shall provide access to an online chemical pick-up request form. This form should be immediately filled out when:

1) Unwanted and old chemical reagents need to be removed
2) The satellite accumulation waste container is full
3) There is more than 5 gallons of hazardous waste or one quart of acutely hazardous waste accumulated.

Laboratory personnel can submit chemical pick-up requests by visiting the University Department of Environmental Health and Safety's website at www.drexel.edu/facilities/healthSafety/ and select the Service Request Forms link on the navigation bar. Once the request is submitted a return email is sent to confirm the request. Personnel from the Department of Evnironmental Health and Safety shall respond to chemical pick-up request within 72 hours of receipt of request.

Training

The Department of Environmental Health and Safety will provide training to all university employees/students who handle hazardous waste in laboratories. Each employee/student shall receive training on proper handling of chemicals and emergency response procedures. Initial training must be completed during the first month of employment (refresher training is provided annually thereafter). Hazardous waste training shall be provided online under the Training link at www.drexel.edu/facilities/healthSafety/. Additional training sessions can be arranged by calling the Department of Environmental Health and Safety at 215-895-5919.

The Department of Environmental Health and Safety shall document all hazardous waste training. Training records will be kept for at least three years from the date the employee last worked at the university.

3. **Radioactive waste**

Radioactive waste shall be collected and disposed of in accordance with the radiation safety manual. Please refer to Section VII of this manual for detailed instructions on the proper handling of infectious waste.

4. Infectious, biohazardous or regulated medical waste

Infectious Waste shall be disposed in accordance with the requirements setforth by the University's Hazardous Waste Management Plan. Please refer to Section V and Exhibit IV-b of this manual for detaied instructions on the proper handling of infectious waste.

5. Pharmaceutical Compounds

Scheduled pharmaceutical compounds must be disposed of in accordance with DEA policies and procedures for the destruction and disposal of scheduled substances. Individuals using such materials for research or clinical activities must be licensed to purchase, use and possess these items. The DEA must be notified of quantities that are disposed so that they can remove these items from an individual's license.

All non-regulated or scheduled pharmaceutical compounds can be disposed by contacting the Department of Safety and Health. **These compounds cannot be disposed in the infectious waste stream. This is strictly prohibited.** Disposal services are offered free of charge and will be provided in a timely manner.

6. Compressed Gas Cylinders

Compressed gas cylinders empty or full must be returned to the gas supply distributor. If a gas cylinder is not returnable please contact the Department of Environmental Health and Safety at 215-895-5919.

(Please refer to the Drexel University Hazardous Waste Management Plan.)

M. GENERAL PERSONAL PROTECTIVE EQUIPMENT (PPE)

- Hallways and laboratory exits must never be blocked with equipment, file cabinets and other laboratory paraphernalia.
- Safety showers and eye wash stations are located in designated areas of the facility; find the one nearest your lab. Safety showers and eye wash stations should be free from obstructions and should be tested on a weekly basis by the laboratory occupants and certified annually by the Department of Environmental Health and Safety.
- Volatile substances should only be used in chemical fume hoods and stored in explosion proof flammable storage cabinets. Keep all flames well away from volatile solvents.

- Safety glasses, lab coats and gloves should be a part of your lab equipment and should be required at all times while in the laboratory.

- Ear protection should be used when working with high frequency sonic cell disrupters. Sonicators should be operated in an enclosed cabinet.

- Safety-approved bottle carriers should be used instead of glass jugs for transporting liquids. When glass jugs are used, the jug should not be carried by the handle. Use both hands with one hand clasping or supporting the base of the jug. The purpose of the handle is to facilitate pouring.

- Running in halls is not permitted.

N. PREGNANCY PROTECTION

The pregnant woman and her fetus are uniquely susceptible to the effects of ionizing radiation, toxic chemicals and infectious organisms, which may be present within the laboratory. The period of greatest susceptibility is the first 8 - 12 weeks of pregnancy, which includes a period when a woman may not know she is pregnant. The following precautions should be taken:

1. Pregnant women have the right to declare their pregnancy. If the pregnant woman chooses to declare her pregnancy, the Drexel University's Radiation safety office should be notified as soon as possible. Radiation exposure limits for women whom declared their pregnancy are 1/10th those allowed for the average laboratory worker. See the Drexel university's radiation safety guide for specific procedures.

2. Women of childbearing age who are considering becoming pregnant or who may be pregnant should, if at all possible, avoid exposure to known teratogens (embryo toxins), mutagens, carcinogens and infectious agents. Commonly used laboratory teratogens include formamide, organomercurials, lead compounds and anesthetic agents (additional reproductive hazards are listed in the chemical safety portion of this manual). Exposure reduction / elimination can be achieved through reassignment, engineering controls, administrative requirements and as a last resort, the use of additional personal protective equipment.

3. If you are pregnant or planning a pregnancy, you should discuss your work with your physician to determine any additional precautions that should be observed. If your duties require you to work with infectious agents, you must consider all possible consequences to yourself and your child. Special note: NIH Publication 73-439 recommends that pregnant women are not to be employed in a laboratory, which conducts studies on infectious viruses.

4. Pregnant women may consider the following protocol in an effort to reduce the potential risks:

   a. Declare your pregnancy through the Department of Environmental Health and Safety and the Radiation Safety Office

   b. Request a meeting with a university's safety representative, your PI and radiation safety officer to discuss all possible options

   c. Review all options with you doctor

   d. Notify your PI, EH&S, and radiation safety of your decision as soon as possible so that proper procedures are implemented in an expeditious manner.

O. EMERGENCIES/FIRST AID

Each department should maintain a first aid kit in an area freely accessible to all personnel. These kits should be utilized for minor injuries only. Only personnel certified in first aid are to administer first aid to those in need.

In the case of a serious or life threatening injury or illness call 911 immediately and then contact the Tenet Security if on Center City Campus at 215-762-7110 or Drexel Public Safety if on University City, Queen Lane or Doylestown campuses at 215-895-2222. The operator will notify security and the emergency response team who will perform rescue procedures and/or transfer the victim to the nearest emergency room (HUH or HUP). When speaking to the emergency operator state your name, location and the nature of the incident.

For all non life threatening injuries or illnesses contact Tenet Security if on the Center City Campus at 215-762-7110 or Drexel Public Safety if on the University City, Queen Lane or Doylestown campusesa t 215-895-2222. .

P. EXPLOSION PROOF REFRIGERATORS & FREEZERS

Special explosion proof freezers are required for the storage of unstable and/or flammable materials. Do not, under any circumstance, place these items in normal (non-explosion proof) refrigerators or freezers.

Q. ABSORBENT PAPER

Plastic-backed absorbent paper on laboratory bench tops will help control spills only if it is placed plastic side down. This paper should not be secured with tape and should be removed at the end of each work shift or immediately following any incidental spills.

R. DISINFECTANTS

Several studies have shown that disinfectants containing sodium hypochlorite (Clorox and alcide) are at least four times more effective than solutions of 70% alcohol, iodine compounds, phenolics and ammonium compounds.

S. AUTOCLAVE OPERATION

Exhibit IV-C sets forth guidelines to follow when operating an autoclave. Careful adherence to these precautionary measures will increase operational efficiency and help prevent accidents. Please make a photocopy of this Exhibit IV -C and post it next to the autoclave.

T. HBV VACCINATION *(Please refer to the Drexel University BBP Exposure Control Plan for additional information)*

Drexel University and Drexel University College of Medicine, in keeping with OSHA 29CFR1910.1030, will offer Hepatitis B vaccine at no cost to all employees at risk for HBV infection. The program can be scheduled through the Department of Environmental Health and Safety in conjunction with the immunization service of Tenet Hospitals. Principal Investigators should inspect their labs to determine the need for universal blood and body fluid precautionary measures. The Principal Investigator should set up the vaccination series for all employees who meet the established criteria. For further information, please see Exhibit IV-d, Drexel University's Exposure Control Plan in this manual. The university will also offer all employees who may be at risk for other infectious agents for which a vaccine exists a complete vaccination series free of charge. The need for these specific vaccinations is determined by the employee's supervisor and reviewed by the Biosafety Committee and/or IACUC in consultation with the physician responsible for Occupational Health and Safety. These medical services are scheduled as needed.

Individuals requiring immunization for any of the infectious agents noted above must sign a release form indicating their comprehension of the need for immunization and their agreement to be immunized. Individuals requiring immunization who refuse to be immunized must sign an immunization declination form.

U. ETHYLENE OXIDE STERILIZERS

The *Drexel University Ethylene Oxide Exposure Through the Use of Sterilizers Protection Program* is designed to protect employees whose duties require them to work in areas where the potential for ethylene oxide (EtO) exposure exists. The purpose of this program is to

reduce and limit exposure to EtO through the use of engineering and work practice controls. Due to the determination that Ethylene Oxide presents a carcinogenic, mutagenic, genotoxic, reproductive, neurologic, and sensitization hazard to exposed workers, the Occupational Safety and Health Administration created the Ethylene Oxide Standard, 29 CFR 1910.1047. The *Drexel University Ethylene Oxide Exposure Through the Use of Sterilizers Protection Program* complies with this standard. Please contact the Department of Environmental Health and Safety at 215-895-5919 for further details regarding this program.

V. LABORATORY AUDITS

The Department of Environmental Health and Safety conducts semi-annual laboratory safety audits. These audits assess chemical, biological and physical hazards. The audit process is performed utilizing an online checklist system that generates reports automatically. These reports are sent electronically to each responsible party immediately upon completion of the audit. The report summarizes the unacceptable issues identified during the audit. Corrective actions and importance levels are included in the report to assist each responsible party in addressing the issue. The importance levels are listed from one (1) to five (5) with five (5) being the highest priority item. The corrective actions for priority five (5) items must be completed within thirty (30) days. All other importance levels must be completed within ninety (90) days.

Audit Corrective Action Follow Up

The automated system will send an electronic follow up email for all unacceptable issues to each responsible party. All responsible parties with priority five (5) issues will receive a follow up message thirty (30) days from the initial audit date. All responsible parties with priory less than five (5) will receive a follow up message ninety (90) days from the initial audit date.

Repeat Issues

The automated system tracks repeat issues in each audit. The Department of Environmental Health and Safety will contact the responsible party if repeat issues are identified in the laboratory. A request for a meeting will be sent to discuss corrective actions and training. The Department of Environmental Health and Safety shall perform the following response action for repeat issues:

Number of Repeats per Issue	Response Action
1	Meeting request with laboratory PI
2	Meeting request with Department Chair or Head
3	Meeting request with Dean

V. BIOLOGICAL SAFETY

A. Introduction

Almost all forms of biological research involve the use of some potentially hazardous biological materials ("biohazards"). Biohazards include certain types of recombinant DNA molecules, bacterial or viral infectious agents, biologically derived infectious materials, or chemical agents (e.g., carcinogens or cytotoxic compounds) that are potentially hazardous presenting significant health risk for humans or animals.

A successful program to ensure biological safety and environmental control in the laboratory depends on careful observance of regulations and standards. In addition, careful and meticulous attention to safe laboratory practices for "containment". The purpose of containment is to reduce or eliminate exposure to potentially hazardous agents. Emphasis should be placed on the use of containment equipment to protect the experiment and laboratory personnel. In this regard, having each laboratory worker trained to maintain good safety practices is the most important element in a safety program.

All NIH-funded and non-NIH funded projects involving recombinant DNA techniques conducted at or sponsored by an institution that receives NIH funds for projects involving such techniques must comply with the NIH Guidelines. The current NIH Guidelines may be viewed or downloaded from:

http://www4.od.nih.gov/oba/rac/guidelines/guidejan01.htm

The NIH Guidelines mandate that "The institution shall establish an Institutional Biosafety Committee whose responsibilities need not be restricted to recombinant DNA." Furthermore, "On behalf of the institution, the Institutional Biosafety Committee is responsible for:

1) reviewing recombinant DNA research conducted at or sponsored by the institution for compliance with the NIH Guidelines;
2) setting containment levels;
3) Periodically reviewing recombinant DNA research conducted at the institution to ensure compliance with the NIH Guidelines; and
4) Adopting emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research." While the NIH Guidelines referred to above deal exclusively with recombinant DNA, the Institutional Biosafety Committee is charged in the University Bylaws with assuring that personnel in research laboratories or potentially impacted by laboratory research (including research-type activities performed in teaching laboratories) are not placed at avoidable risk from biohazards, as defined above.

B. Examples of Biohazardous Agents; Risk Categories

Biohazardous agents may or may not conform to easily assignable risk categories. Biohazards of the lowest risk category typically do not require review or approval from the Biosafety Committee.

Carcinogenic or cytotoxic compounds are regarded as high risk, except in those cases where "safe" lower limits of exposure have been identified. The list of known or suspected carcinogens is subject to revision, but a current list can be viewed in Exhibit VI-A.1.

Human tissues, including cells and blood products, are similarly assumed to be of high risk and require the standard Universal Precautions associated with blood-borne pathogens.

Infections agents (bacterial, viral, fungal, or parasitic) can be classified into four groups of increasing risk, according to their relative pathogenicity for healthy adult humans, by the following criteria:

i Risk Group 1 (RG1) agents are not associated with disease in healthy adult humans.

ii Risk Group 2 (RG2) agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

iii Risk Group 3 (RG3) agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.

iv Risk Group 4 (RG4) agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

A list of specific infectious agents is found in Exhibit V-a: Classification of Human Etiologic Agents on the Basis of Hazard In general, these Risk Groups correspond to Biosafety levels 1-4 with respect to the containment procedures needed for their use.

Recombinant DNA experiments may involve any of the biohazards listed above plus the risks associated with the modified genes themselves. The NIH Guidelines define several levels of risk associated with recombinant DNA experiments:

i. Certain types of experiments are of no risk and are exempted from review.
ii Other experiments, typically carried out under Biosafety Level 1 containment, may receive expedited review and be initiated concurrent with filing appropriate documents with the Biosafety Committee; review and approval is required but may occur later.
iii Non-expeditable experiments require full review by the Committee prior to the initiation of experiments.
iv Some experiments, typically involving the introduction of recombinant DNA into humans, require approval both from the Biosafety Committee and the Recombinant DNA Advisory Committee (RAC) of the NIH. The Institutional Biosafety Committee is not currently constituted to review such protocols in a lawful way.

A description of which experiments fall into these various approval categories can be found in the NIH Guide http://www4.od.nih.gov/oba/IBC/ibcnihguidelines.htm.

C. Select Biological Agents

The U.S. Departments of Health and Human Services (DHHS) under the control of the Centers for Disease Control (CDC) and the Animal and Plant Health Inspection Service (APHIS) / U.S. Department of Agriculture (USDA) have established new safeguards for the possession, use and transfer of select biological agents and toxins (select agents) that could pose a threat to human health or the environment. This new rule will continue to strengthen aimed at protecting the American people from acts of terrorism and these safeguards will help protect the food supply without sacrificing valuable research being done on these agents. The rule updates the previous select agent rule by requiring facilities to register with the CDC if they possess a select agent or agents that pose a potential threat to human health. The new rule became effective February 7, 2003.

In an effort to comply with the new regulations, Drexel University and Drexel University College of Medicine's Office of Research Compliance has developed very stringent compliance plans to be followed by any DU / DUCOM engaging in such activities.

(Please refer to the "Drexel University Policies for the Possession, Use, Transfer and Receiving Select Biological Agents" for additional information.)

D. Biosafety Levels

The essential elements of the four biosafety levels for activities involving infectious microorganisms and laboratory animals are summarized in the table below. The levels are designated in ascending order, by degree of protection provided to personnel, the environment, and the community.

Biosafety Level I
Suitable for work involving well characterized agents not known to cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment. The laboratory is not necessarily separated from the general traffic patterns in the building. Work is generally conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required nor generally used. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training, in microbiology or a related science.

Biosafety Level 2
Similar to Level I and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs from level I in that (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists, (2) Access to the laboratory is limited when work is being conducted, (3)

Extreme precautions are taken with contaminated sharp items, and (4) certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

Biosafety Level 3
Applicable to clinical, diagnostic, teaching, research or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents, and are supervised by competent scientists who are experienced in working with these agents.

Procedures involving the manipulation of infectious materials must be conducted within biological safety cabinets or other physical containment devices, or by personnel wearing appropriate personal protective clothing and equipment. The laboratory has special engineering and design features.

It is recognized, however, that many existing facilities may not have all the facility safeguards recommended for BL3 (e.g. Access zone, sealed penetrations and directional airflow, etc.). In these circumstances, acceptable safety may be achieved for routine or repetitive operations (e.g. Diagnostic procedures involving the propagation of an agent for identification, typing, and susceptibility testing) in BL2 facilities. However, the recommended Standard Microbiological Practices, Special Practices, and Safety Equipment for BL3 must be rigorously followed. The decision to implement this modification of BL3 recommendations should be made only by the laboratory director in consultation with the Department of Environmental Health and Safety.

Biosafety Level 4
Required for work with dangerous and exotic agents, which pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease. Agents with a close or identical antigenic relationship to Biosafety Level 4 agents are handled at this level until sufficient data are obtained either to confirm continued work at this level, or to work with them at a lower level. Members of the laboratory staff have specific and thorough training in handling extremely hazardous infectious agents; and they understand the primary and secondary containment functions of the standard and special practices, the containment equipment, and the laboratory design characteristics. They are supervised by competent scientists who are trained and experienced in working with these agents. Access to the laboratory is strictly controlled by the laboratory director or in case of emergency the director of safety and health. The facility is either in a separate building or in a controlled area within a building, which is completely isolated from all other areas of the building. The director of this laboratory in consultation with the Department of Environmental Health and Safety must prepare a specific facility operations manual and procedures set forth in the manual must be observed.

Within work areas of the facility, all activities are confined to Class III biological safety cabinets, or Class II biological safety cabinets used with one-piece positive pressure personnel suits ventilated by a life support system. The Biosafety Level 4 laboratory has

special engineering and design features to prevent microorganisms from being disseminated into the environment.

Table V-1 Summary of Recommended Biosafety Levels for Infectious Agents

Biosafety Level/Risk Group Level	Agents	Practice	Safety Equipment	Facilities
1	Not known to cause disease in healthy adults	Standard Microbiological Practices	None Required	Open bench top, sink required
2	Associated with human disease, hazard = auto-inoculation, ingestion, mucous membrane exposure	BL1 practice plus: Limited access Biohazard warning signs Sharps precautions Biosafety manual defining any needed waste decontamination or medical surveillance policies	**Primary Barriers:** Class I or II BSC's or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPE: Lab coats, face protection as needed	**BL1 plus:** Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmission; Disease may have serious lethal consequences	BL2 Practice plus: Controlled Access Decontamination of all waste Decontamination of all lab clothing befo Baseline serum	**Primary Barriers:** Class I or II BSC's or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials; PPE: Lab coats, respiratory protection as needed	**BL2 plus:** Physical separation Self closing double Exhausted air, not re-circulated Negative airflow into the laboratory
4	Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections; or related agents with unknown risk of transmission	BL3 practices plus: Clothing change before entering Shower on exit All material decontaminated on exit from facility	**Primary Barriers:** All procedures conducted in Class III BSC's or Class I or II BSC's with full body, air supplied, positive pressure personnel suit	**BL3 Plus:** Separate building or isolated zone Dedicated supply / exhaust vacuum, and decon systems Other requirements outlined in text

E. Safety Equipment

Safety equipments serve as primary barriers. These include biological safety cabinets, enclosed containers, and other engineering controls designed to remove or to minimize exposures to hazardous biological materials.

1. Biological Safety Cabinets

(Refer to the Drexel University Management Plan for Biological Safety Cabinets and Chemical Fume Hoods for additional information www.drexel.edu/facilities/healthSafety/labSafety/).

Biological safety cabinets are designed to:

a) Protect personnel from harmful agents inside the cabinet (Personnel Protection). All three classes of biologic safety cabinets are effective in protecting personnel from harmful agents. Laminar flow hoods are not considered biological safety cabinets and are not always designed to protect laboratory personnel.
b) Protect the work, product, experiment, or procedure performed in the cabinet from contaminants in the laboratory environment or from cross contamination inside the cabinet (Product Protection). Only Class II and III are effective.
c) Protect the environment from contaminants in the cabinet (Environmental Protection). All three classes are effective.

Biological Safety Cabinets are the principal equipment used to provide physical containment. They are used as primary barriers to prevent the escape of aerosols into the laboratory environment. This is an important function, because most laboratory techniques are known to produce inadvertent aerosols that can be readily inhaled by the laboratory worker. Certain cabinets can also protect the experiment from airborne contamination.

The selection of a Biological Safety Cabinet is based on the potential hazard of the agent used in the experiment, the potential of the laboratory technique to produce aerosols, and the need to protect the experiment from airborne contamination.

Three types of Biological Safety Cabinets are used in the microbiological laboratory: they are classified as Class I, Class II and Class III Biological Safety Cabinets. The NIH Guidelines for Recombinant DNA Research require that either the Class I or Class II cabinet be used as the primary containment equipment when the BL-2 or BL-3 level of physical containment is specified. The Class III cabinet is required at the BL-4 level of physical containment. The description, capabilities, and limitations of these cabinets are described below.

Table V-2 Comparison of Biological Safety Cabinets

Type	Face Velocity (LFPM)	Airflow Pattern	Radionuclides/Toxic Chemicals	Biosafety Level (s)	Product Protection
Class I*, open front	75	In at front; out rear and top through HEPA filter	No	2,3	No
Class II: Type A	75	70% recirculated through HEPA; exhaust through HEPA	No	2,3	Yes
Type B1	100	30% recirculated through HEPA; exhaust via HEPA and hard ducted	Yes (low levels / volatility)	2,3	Yes
Type B2	100	No recirculation; total exhaust via HEPA and hard ducted	Yes	2,3	Yes
Type B3	100	Same as IIA, but place under negative pressure to room and exhaust air is ducted	Yes	2,3	Yes
Type III	N/A	Supply air inlets and exhaust through 2 HEPA filters	Yes	3,4	Yes

* Glove panels may be added and that will increase face velocity to 150 lfpm. Gloves may be added with an inlet air pressure release that will allow work with chemicals / radionuclides

Class I Biological Safety Cabinet

The Class I cabinet is a ventilated cabinet that may be used in three operational modes: with a full width open front, with an installed front closure panel without gloves, and with an installed front closure panel equipped with arm length rubber gloves. Materials may be introduced and removed through the panel opening and, if provided, through the hinged front view panel or a side W air lock. Lights, vacuum, water, and drain can be provided. To restrict ignition sources and avoid the risk of explosion from gas piped to a sealed cabinet, an electric incinerating device can be provided for sterilizing bacteriological loops and needles. If a flame is needed, an alcohol lamp can be utilized. The materials of construction should be selected to withstand wear, corrosive action of gases and liquids, and decontaminants. Room air flowing into the cabinet prevents the escape of airborne contaminants from the cabinetwork area. It flows across the workspace, over and under a back wall baffle; out through a HEPA filter and blower in an overhead duct to the building air exhaust system or outdoors. When operated with a full-width open front, a minimum inward face velocity normal to the work opening of at least 75 feet per minute is required.

Protection is provided to the user and the environment, but not to the product (experiment). A wide range of activities is accommodated using equipment as varied as pipetting aids, burettes, ph meters, sonicators, shielded centrifuges, blenders, and lyophilizers. Chemical carcinogens, low levels of radioactive materials and volatile solvents can be used in Class I cabinets equipped with ducted exhaust and a minimum face velocity of 100 ft/min. When these materials are used in the Class I cabinet, a careful evaluation must be made to determine that concentrations do not reach dangerous levels or cause problems of decontamination of the cabinet.

The cabinet is a partial containment unit. Its primary barrier function can be compromised by the pumping action of sudden withdrawal of the hands, the opening and closing of the room door, or

rapid movements past the front of the cabinet. Aerosols created in large quantities, and forcefully, may overcome even higher face velocities. Also, the cabinet does not protect the experimenter's hands and arms from contact with hazardous materials. Such protection is dependent on technique, the use of gloves and other personal protective equipment.

Class II Biological Safety Cabinet

The Class II cabinet is commonly known as a laminar airflow Biological Safety Cabinet. Class II cabinets have a front opening for access to the workspace and for introduction and removal of materials. Airborne contaminants in the cabinet are prevented from escaping across this opening by a curtain of air formed by (i) unfiltered air flowing from the room into the cabinet and (ii) HEPA filtered air supplied from an overhead grille in the cabinet. This curtain of air also prevents airborne contaminants in the room air from entering the workspace of the cabinet across the front opening. The curtain of air is drawn through a grille at the forward edge of the work surface into a plenum below. Air from this plenum is HEPA filtered and re-circulated through the overhead grille down into the cabinet. A portion of this filtered air is used to maintain the air curtain and the remainder passes down onto the work surface and is drawn out through grilles at the back edge of the work surface. The HEPA filtered air from the overhead grille flows in a uniform downward movement to minimize air turbulence. It is this air that provides and maintains a clean-air work environment. A percentage of air drawn through the front and back grilles of the work surface, which is equal to the flow of room air into the cabinet, is also filtered by HEPA filters and exhausted from the cabinet. The selection of utility services and materials of construction are similar to those for Class I cabinets. There are two types of Class II cabinets, A and B. These differ principally as to: vertical dimension of the front opening e proportion of air re-circulated o velocity of airflow to work surface manner of discharge of exhaust air whether contaminated air plenums are under positive pressure. The type A cabinet has a fixed front access opening. The inward face velocity through the front opening is at least 75ft/min.

Contaminated air plenums are normally operated at positive pressure. The cabinet operates with a high percentage (approximately 70%) of re-circulated air. The type A cabinets can be operated with re-circulation of the filtered exhaust air to the room in which they are located. This minimizes extra demand on supply and exhaust air systems unless the build up of heat and odor from the re-circulated exhaust air requires otherwise.

Type B cabinets do not re-circulate their exhaust air to the room. They have a vertical sliding sash rather than the fixed opening of the type A. Inward air velocity of 100 ft/min is attained at an 8-inch sash opening. The cabinet operates with a low percentage (approximately 30%) of re-circulated air.

Type A and B cabinets are partial containment units with the same limitations as Class I cabinets. These cabinets provide protection to the user, environment, and product (experiment). Activities are accommodated that use pipetting aids, burettes, ph meters, sonicators, blenders, lyophilizers, and shielded centrifuges. The type B cabinets with ducted exhaust can be used with dilute preparations of chemical carcinogens, of low-level radioactive materials, and of volatile solvents when the face velocity of 100 ft/min is maintained. When these materials are used, however, a careful evaluation must be made to determine that concentrations do not reach

dangerous levels or cause problems of decontamination of the cabinets. The type A cabinets cannot be used with toxic, explosive, flammable, or radioactive substances because of the high percentage of re-circulated air.

Class III Biological Safety Cabinet

The Class III cabinet is a totally enclosed ventilated cabinet of gas-tight construction. Operations within the Class III cabinet are conducted through attached rubber gloves. Supply air is HEPA-filtered, and the cabinet exhaust air is filtered by two HEPA filters in series, or HEPA filtration followed by incineration, before discharge outside of the facility. The exhaust fan for the Class III cabinet is generally separate from the exhaust fans of the facility ventilation system.

Materials are introduced and removed through attached double-door sterilizers and dunk baths with liquid disinfectants. The usual utility services can be provided, but not gas. Liquid wastes go to a holding tank for appropriate decontamination before release into "common" sewage lines. Stainless steel is the usual construction material. Modular designs provide for inclusion of refrigerator, incubator, deep freeze, centrifuge, animal holding, and other special cabinet units.

The Class III cabinet provides the highest level of personnel and environmental protection. Protection is also provided to the product (experiment). Most laboratory activities can be accommodated: the usual cultivation of microorganisms, fertile eggs, tissue cells; microscopy, serology; animal dissections and injections; experimental aerosol exposures; various physical measurements; and many others, on small- to large-scale. Selected gaseous atmospheres can be maintained at desired humidity and temperature conditions.

The Class III cabinet protection can be compromised by puncture of the gloves or accidents creating positive pressure in the cabinet. Flammable solvents should not be used in these cabinets unless a careful evaluation has been made to determine that concentrations do not reach dangerous levels. When required and determined safe, these materials should only be introduced into the system in closed, non-breakable containers. These materials should not be stored in the cabinet. Electric heaters are preferred over portable, canned-gas heaters. Flammable gas should not be piped to the units.

The following are recommended procedures to follow when using a biosafety cabinet:

a) Wipe down the work surface of the hood with disinfectant (CLOROX or ALCIDE) before beginning work. If the hood was turned off overnight, allow 5 minutes of running time before starting your work.

b) Assemble your materials and equipment BEFORE going into the hood. Minimize the number of times objects, stands and arms included, pass through the air barrier at the front of the hood

c) Minimize room activity especially near the hood--never walk behind someone working at a hood.

d) Employ aseptic technique as you would on the bench top; avoid the movement of contaminated items over clean ones; keep clean items out of your work area

e) Clean up promptly and thoroughly when you are finished; wipe down the work surface with disinfectant

f) Decontaminate any objects that were used inside the hood.

NOTE: Detailed information about laminar flow hoods is available through the Drexel University Department of Environmental Health and Safety. The Department of Environmental Health and Safety is also responsible for ensuring that testing and certification of hoods is performed. Hoods must be tested whenever they are installed, moved or whenever maintenance is performed, otherwise, they are tested once a year. Hoods cannot be serviced or moved without approval from the Principal Investigator or the Biosafety Officer when necessary. Further, for their own protection, mechanics must have a written order to work on any hood.

2. Ultraviolet Lighting

Ultraviolet is not recommended for use in Class II (laminar flow) Biohazards cabinetry. The effectiveness of the Ultraviolet lighting is dependent on thorough maintenance, unshielded microorganisms (i.e., unshielded by dirt, protein, etc.), and exposure time. Ultraviolet lighting is not penetrating, has limited effectiveness in a dynamic air stream, and may produce ozone levels sufficient to affect rubber material. Ultraviolet irradiation can cause erythema of skin and eye damage. (NSF #49)

3. Centrifuges - *(Please contact the Department of Environmental Health and Safety for a copy of Appendix I "Safe Operating Procedures for Centrifuges")*

Centrifuges may be a source of bioaerosols in the laboratory. In an effort to reduce the risk of aerosols containing potentially pathogenic agents, a safety centrifuge cabinet or safety centrifuge enclosed carriers may be used to house or safeguard centrifuging of infectious substances. Before centrifuging, inspect tubes for cracks, inspect the inside of the trunnion cup for rough walls caused by erosion or adhering matter, and carefully remove bits of glass from the rubber cushion. A germicidal solution added between the tube and trunnion cup not only disinfects the outer surface of both of these, but also provides an excellent cushion against shocks that might otherwise break the tube

4. Vacuum Lines, Filters, and Traps

When the building vacuum line or when portable vacuum pumps are used, suitable traps and filters (such as Millipore or Gelman Vacushield filters) should be interposed to insure that pathogens do not enter the fixed system. Vacuum flasks should contain disinfectants such as Alcide or Clorox. Please refer to Exhibit V-f for the proper techniques for protecting vacuum systems from contamination.

5. Freezers and Refrigerators

Freezers and refrigerators should be periodically cleaned out. All infectious or toxic material stored in refrigerators or freezers should be properly labeled. Do not place flammable solvents (i.e., ether) in normal refrigerators--use explosion proof refrigerators and freezers.

F. Safe Laboratory Practices

1. Personal Habits

Develop the habit of keeping your hands away from your mouth, nose, eyes, and face. This habit may prevent self-inoculation. Never eat, drink, smoke, or apply cosmetics in a laboratory. Always remember to remove gloves before answering telephones and remove both gloves and lab coats prior to exiting the lab. If you need to transport research materials from one lab to another remove one glove – use the gloved hand to handle research materials and bare hand to open doors push buttons, light switches, etc.

2. Pipetting

Mouth Pipetting is Strictly Forbidden!!!

3. Counter-tops and Non-Autoclaveable Equipment

All non-autoclavable equipment should be treated with a disinfectant immediately after use. Disinfectants do not work instantaneously but must be given several minutes to "work" before rinsing off the following are effective: Clorox or Alcide. Alternatively, equipment may be sterilized using ethylene oxide.

4. Aerosol

Care should be taken to avoid "blowing out" the last few droplets in a pipette since this can cause aerosols. Sonification blending, or any procedure that produces an infectious aerosol should be avoided. If it is necessary to perform these procedures, they must be carried out in a Biological Safety Cabinet. Special precautions such as protective clothing and breathing devices should be used. Glass containers should not be used because of potential breakage. All equipment must be sterilized or disinfected after use.

5. Infectious Material Incubation and Transport

Ensure that all virulent fluid cultures or viable powdered infectious materials in glass vessels are transported, incubated, and stored in easily handled, non-breakable, sealed leak proof containers that are large enough to contain all the fluid or powder in case of leakage or breakage of the glass vessel. Water baths used to evaporate or incubate infectious materials should contain a disinfectant.

6. Human Material with reference to AIDS/HIV

Many Principal investigators take blood and other tissues from patients and volunteers to use in their experimental work. All such material should be treated as potentially infectious and handled as biohazardous using Standard (Universal) Precautions. It should be remembered that AIDS and/or HIV patients in the early stages of the disease may test negative yet have the agent in their blood

Blood donors at Hahnemann are prescreened for pathogens such as hepatitis virus and AIDS (HIV) virus. However, such prescreening may not take place with materials obtained from patients. You must observe standard precautions at all times.

Again, all potentially infectious material should be handled with a professional attitude and every reasonable precaution should be taken.

Copies of the publication "Guidelines for Handling Human Tissue and Body Fluids used in Research" are available to all personnel using human material. Copies are available through the Drexel University and Drexel University College of Medicine' Office of Research (215-255-7857).

G. Infectious Waste Disposal

An infectious was is any waste with the presence or the reasonable anticipated presence of blood or other potentially infectious materials on an item or surface. The following are typical materials considered infectious wastes (this is not an all inclusive list):

- Human body fluids like semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult to differentiate between body fluids;
- Any unfixed human tissue or organ (other than intact skin);
- HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture medium or other solutions;
- Microbiological cultures and stocks of infectious agents, including the following: cultures and stocks of infectious agents, wastes from the production of biologicals, and culture dishes, assemblies and devices used to transfer, inoculate and mix cultures;
- Contaminated animal carcasses, body parts, blood, blood products, secretions, excretions and bedding of animals that were know to have been exposed to zoonotic infectious agents ro non-zoonotic human pathogens.

Pharmaceutical drugs and chemicals that are not infectious must not be disposed in the infectious waste streams.

Infectious waste shall be sorted at the point of generation into the following three (3) classess, and each class shall be placed in a separate container:

- Infectious Sharps Waste
- Infectious Non-Sharps Waste
- Infectious Contaminated Glassware and Equipment

1. Infectious Sharps Waste

   Any item contaminated with potentially hazardous biological materials that, when broken or intact, may pierce or scratch the skin is considered a “sharp” and should only be disposed of in an approved sharps container. This includes but is not limited to syringes, needles, blades, glassware, sharp metal objects and hard plastic items like pipettes, pipette tips, petri dishes, etc.

   Sharps containers should be puncture resistant, leak proof and labeled. Cardboard sharps containers are not acceptable for use at Drexel University and Drexel University College of Medicine .

   Infectious sharps contaminated with radioactive agents must be placed in a separate approved sharps container labeled as radioactive and infectious. This waste must not be mixed with non-radioactive infectious sharps waste. Please contact the Radiation Safety Office at 215-762-4050 for additional information.

   Sharps removal service is available via an outside contractor for all campus locations. This service is offered free of charge to research personnel.

   If you are in need of sharps containers or if your containers need to be serviced, please contact the Department of Environmental Health and Safety.

2. Non-sharp Infectious Waste

   All waste paper and soft plastic materials contaminated with potentially hazardous biological materials must be placed in RED Biohazard / Infectious Waste bags. These bags must be located within each laboratory performing functions that would generate such waste. The containers used to hold these bags should be labeled with Biohazard or Infectious Waste stickers. These containers should be decontaminated periodically by laboratory personal using a diluted (10%) bleach solution.

   High-risk material should be autoclaved by the respective laboratory personnel using the Common Use autoclaves. Red bags should be sealed with tape and identified with a note attached indicating, "AUTOCLAVE AND DISCARD". All material should then be placed in the metal autoclaved cans for disposal.

Removal of infectious non-sharp waste bags is performed in the following manner:

Campus	Removal Service	Contact Number	Schedule
University City	Contractor	215-895-5919	Weekly
Center City	Housekeeping	215-762-6500	As Needed
Queen Lane	Housekeeping	215-991-8500	Weekly
Doylestown	In-house	215-489-4947	As Needed

If you have red bags that have not been emptied or are in need of service please contact the Department of Environmental Health and Safety at 215-895-5919.

Non-sharp infectious waste can be further divided into five (5) sub categories. The categories are as follows:

- Infectious Animal Waste
- Non-Infectious Animal Waste
- Pathological/Chemotheraputic Infectious Waste
- Infectious Liquid Waste
- Infectious Mixed Waste

a. Infectious Animal Waste

Infectious animal waste is any animal carcasses and body parts that have been exposed to zoonotic infectious agenst or non-zoonotic human pathogens during research. The infectious waste must be placed in RED Biohazard Infectious waste bags and sent to the animal facility for disposal.

b. Non-infectious Animal Waste

Non-infectious animal waste is any animal carcasses and body parts from animals that have not bee exposed to zoonotic infectious agents or human pathogens during research. This waste must be placed in RED Biohazardous Infectious waste bags and sent to the animal facility for disposal.

c. Pathological/Chemotheraputic Infectious Waste

Chemotherapeutic and pathological waste containing potentially infectious materials must be disposed of in red Biohazard / Infectious Waste bags and labeled as pathological or chemotheraputic waste. Removal of these containers from the laboratories is performed in the same manner as the non-sharp infectious waste. However, these wastes must be incinerated. Drugs and chemical agents that are used in conjunction with biological materials or animals are not effectively destroyed through the autoclave process and hence must be sent out for destruction via incineration.

If you have materials or wastes that are pathological or chemotherapeutic or if you need further clarification please contact the Department of Environmental Health and Safety.

d. Infectious Liquid Waste

Infectious liquid waste can be disposed in the following manners:

- Dispose in sanitary sewer after chemical decontamination with a fresh solution of 10% bleach. Wait 10 to 15 minutes prior to discharging down the drain.
- Dispose in RED Biohazardous Infectious waste bags provided there is an adequate amount of absorbing material present
- Dispose in a RED Biohazarous Infectious waste bag in a leak proof container labeled as infectious waste.

e. Infectious Mixed Waste

Infectious mixed waste is any infectious waste that is mixed chemical or radioactive agent. This waste must be handled in a special manner. Please contact the Department of Environmental Health and Safety at 215-895-5919.

3. Infectious Contaminated Glassware and Equipment

Please comply with the following procedures regarding the transfer of contaminated glassware and plastic ware to the glasswash service.

A. <u>Things to be returned to glassware washing facility</u>

- All Laboratory Glassware
- All Bottles Except those used to Contain Chemicals
- Caps, Stoppers, etc.
- Pipette Cams
- Culture Tube Racks
- Petri Dish Cans

B. <u>Things not to be returned glassware washing facility</u>

- Chemicals
- Radioactive Materials
- Animals or Animal Parts, including eggs
- Plastic Disposables

C. <u>Methods to be followed</u>

i Dirty Glassware should be placed in plastic trays only after the trays have been lined with an autoclavable bag. Do not put dirty glassware in an unlined tray.

ii Potentially dangerous items such as Pasteur pipettes, hypodermic needles, syringes, etc. Are not to be returned for glassware washing

Further guidance on the proper disposal of infectious waste please refer to Exhibit IV-b.

I. Spill of Potential Biohazardous Materials

If an accident occurs involving the possible spread of potentially dangerous biologicals (virus, etc), immediate steps must be taken to decontaminate the area the amounts of material and hazards involved will determine the appropriate action. *(Additional information is available in the Drexel University "Hazardous Material Emergency Response Plan")*

1. Small Spills

If only a small amount of material (up to a few ml and/or little or no virulence), simply use a towel to absorb the spill, apply disinfectant to the area let stand for several minutes and wipe up. Rather than pour the disinfectant directly to the spill area and risk splashing, it is better to allow the disinfectant to flow onto the spill. Be sure to:

a. Use universal precautions when handling potentially biologically hazardous materials (i.e. Personal protective equipment).
b. Place absorbed material into a biohazards bag.
c. Do not let the spill dry because this will allow contaminated dust to form and spread

2. Large Spills

If a spill of larger volume or of highly virulent material occurs, warn others, hold your breath and leave the room. Warn others not to enter the room. Contact Tenet Security if on the Center City Campus at 215-762-7110 or Drexel Public Safety if on the University City, Queen Lane or Doylestown campusesa at 215-895-2222.. Provide the operator with the specific room number, and nature of spill.

(Please refer to Drexel Universities "Hazardous Material Emergency Spill Response Plan" and Drexel's site specific response plans for spills involving CDC regulated select agents and / or BSL 3 pathogens for additional information.)

3. Laboratory Spills

A problem that may occur in the laboratory is an overt biological spill. A spill that occurs m the open laboratory may create a serious problem. Every effort should be taken to avoid such occurrences. A spill poses less of a problem if it occurs in a Biological Safety Cabinet provided splattering to the outside of the cabinet does not occur. Direct application of concentrated liquid disinfectant and a thorough wipe down of the internal surfaces of such cabinetry will usually be effective for decontaminating the work zone, but gaseous sterilants will be required to disinfect the interior sections of the cabinet. Each researcher must realize that in the event of an overt accident, research materials such as tissue cultures, media, and animals within such cabinets may well be lost to the experiment.

4. Spill in a Biological Safety Cabinet

A spill that is confined to the interior of the Biological Safety Cabinet should present little or no hazard to personnel in the area. However, chemical disinfection procedures should be initiated at once while the cabinet ventilation system continues to operate to prevent escape of contaminants from the cabinet. Spray or wipe walls, work surfaces, and equipment with a disinfectant. A disinfectant with a detergent has the advantage of detergent activity, which will help clean the surfaces by removing both dirt and microorganisms. A suitable disinfectant is a 3% solution of an iodophor such as Wescodyne or a 1 to 100 dilution of a household bleach (e.g. Clorox) with 0.7% nonionic detergent. The operator should wear gloves during this procedure. Use sufficient disinfectant solution to ensure that the drain pans and catch basins below the work surface contain the disinfectant. Lift the front exhaust grill and tray and wipe all surfaces. Wipe the catch basin and drain the disinfectant into a container. The disinfectant, gloves, wiping cloth and sponges should be discarded into an autoclave pan and autoclaved. This procedure will not disinfect the filters, blower, air ducts or other interior parts of the cabinet. If the entire interior of the cabinet is to be sterilized contact the Department of Environmental Health and Safety at 215-895-5919.

5. Spill in the Open Laboratory

If potentially hazardous biological material is spilled in the laboratory, the first essential is to avoid inhaling any airborne material by holding the breath and leaving the laboratory. Warn others in the area and go directly to a wash or change room area. If clothing is known or suspected to be contaminated, remove the clothing with care, folding the contaminated area inward. Discard the clothing into a bag or place the clothing directly in an autoclave. Wash all potentially contaminated areas. Contact Tenet Security if on the Center City Campus at 215-762-7110 or Drexel Public Safety if on the University City, Queen Lane or Doylestown campusesa t 215-895-2222.

J. Shipping, Receiving, or Transferring Etiologic Agents

For information on shipping or transferring etiologic agent, refer to the following exhibits:

Exhibit V-c: Biological Materials Shipping Guide
Exhibit V-b: Importation Permits for Etiologic Agents
Exhibit V-d: Final Rule: Additional Requirements for Facilities Transferring or Receiving Select Agents

K. Care and Use of Laboratory Animals

Special attention must be given to the humane treatment of all laboratory animals in accordance with the Animal Welfare Act of 1996 as amended, the Public Health Service Policy on the Humane Care and Use of Laboratory Animals and the policies of the University.

The University Laboratory Animal Resources (ULAR) has established procedures to ensure the use of animals that are free of disease prejudicial to the proposed experiments and free from carriers of disease or vectors, such as ectoparasites, which endanger other experimental animals or personnel. In addition to obtaining animals from strains known to be disease free, quarantine and testing measures are implemented on higher risk species such as certain non-human primates.

Drexel University and Drexel University College of Medicine has developed a written program entitled "Occupational Safety and Health Program for All Personnel Handling or Working Near Laboratory Animals" (see Exhibit V-g). This program is protocol driven and plays an integral part in protecting the health of individuals working with research animals.

This program outlines medical services that are required for those working with animals. The medical services required are based on the species type, the nature of the research activities as per the IACUC and Biosafety Protocol's, and the recommendations of the Occupational Health Physicians.

All individuals included in this program are required to have specific training on the hazards associated with laboratory animals. This training covers the written occupational health program, medical consultations and surveillance, the University Committee's involvement and 16 different topics specific to hazards associated with laboratory animals.

1. Care and Handling of Infected Animals

Comprehensive reviews indicate that animals infected with a wide range of etiological agents are capable of shedding infectious microorganisms in the saliva, urine, or feces. In the absence of specific information to the contrary, all infected animals should be regarded as potential shedders.

Procedures appropriate for the handling of infected animals are given below:

a) Careful handling procedures should be employed to minimize the dissemination of dust from animal and cage refuse.

b) Cages must be sterilized by autoclaving. Refuse, bowls, and watering devices should remain in the cage during sterilization.

c) All watering devices should be of the "non-drip" type

d) Cages should be examined each morning and at each feeding time so that dead animals can be removed. Dead animals should be placed in leak-proof containers (red plastic bags) that are appropriately marked with respect to date, experiment, "Biohazardous" or "Infectious," and stored in designated refrigerators or cold rooms prior to necropsy.

e) Heavy gloves should be worn when feeding, watering, handling, or removing infected animals. Bare hands must NEVER be placed in the cage to move any object therein.

f) Animals exposed to biohazardous aerosols should be housed in special ventilated cages, in gas tight cabinet systems, or in rooms designed for protection of personnel by use of ventilated suits.

g) Animals inoculated by means other than by aerosols should be housed in equipment suitable for the level of risk involved.

h) Infected animals transferred between buildings must be placed in cages approved by the IACUC.

i) The oversize canine teeth of large monkeys present a particular biting hazard, these are important in the potential transmission of naturally occurring, and very dangerous, monkey virus (Herpes B) infections. Personnel should handle these animals with extreme caution. Personnel should handle these animals with extreme caution and must carry wallet size cards outlining the appropriate treatment to be provided by medical staff when seeking care. Bites and/or scratches should be reported immediately and taken extremely seriously.

j) Presently available epidemiological data indicate that many zoonotic diseases, including infectious hepatitis and tuberculosis, can be

transmitted from some non-human primates to humans. Newly imported animals may be naturally infected with these or other infectious diseases, and persons in close contact with such animals may become infected. The inadvertent transmission of zoonotic diseases from the experimental animal to the humans should be protected against by the use of personal protective equipment or cage systems designed to contain infectious material at its post or origin. Information concerning the level of hazard associated with work with a wide range of etiological agents and the selection of personal protective equipment and ventilated cage systems can be found in numerous publications

2. <u>Guidelines that Apply to Animal Room Maintenance</u>

a) Doors to animal rooms should be kept closed at all times, except for necessary entrance and exit.

b) Unauthorized persons should not be permitted to enter animal rooms.

c) A container of disinfectant is kept in each animal room for disinfecting gloves and hands and for general decontamination even though no infectious animals are present. Hands, floors, walls, and cage racks are washed with an approved disinfectant at the recommended strength as frequently as the supervisor directs.

d) Floor drains in animal rooms, as well as floor drains throughout the building, should be flooded with water or disinfectant periodically to prevent backup of sewer gases. Some floor drains are intentionally capped in the Animal Facility.

e) Shavings and other refuse on floors should not be washed down the floor drain because such refuse clogs the sewer lines.

f) An insect and rodent control program should be maintained in all animal rooms and in animal food storage areas.

g) Special care should be taken to prevent live animals, especially mice, from finding their way into disposable trash.

h) Specific instructions involving the housing, care, and maintenance of laboratory animals are available from the following sources (see (I) Laboratory Safety Monograph, A Supplement to the NIH Guidelines for recombinant DNA Research, January 1979., (II) Standard Operating Procedures for Animal Use and Care, AUHS, February 1997 ., (III) Occupational Health and Safety in the Care and Use of Research Animals, 1997.)

3. Necropsy Rules for Infected Animals

a) Necropsy of infected animals must be carried out by trained personnel in certified Biological Safety Cabinets.

b) Disposable protective outerwear should be worn over laboratory clothing during necropsies.

c) Rubber gloves should be worn when performing necropsies. When necropsying non-human primates double-gloving is required.

d) The fur of the animal should be wetted with a suitable disinfectant.

e) Small animals should be pinned down or fastened on an autoclavable or disposable surface.

f) Upon completion of necropsy, all potentially biohazardous material should be placed in suitable containers and sterilized immediately.

g) Contaminated instruments must be carefully rinsed according to procedures approved by the University Biosafety Committee and then autoclaved or properly disposed of.

h) The inside of the Biological Safety Cabinets and other potentially contaminated surfaces should be disinfected with a suitable germicide.

i) Grossly contaminated rubber gloves should be cleaned with disinfectant before removal from the hands, preparatory to sterilization.

j) Dead animals should be placed in proper leak proof containers autoclaved if necessary, and properly tagged before being placed outside for removal.

L. Visitors (Unauthorized Personnel)

Unauthorized visitors are prohibited from entering the laboratories and the animal facilities. Individuals under 18 years of age, immunosuppressed persons, and pregnant visitors are forbidden to enter the laboratories of Drexel University and Drexel University College of Medicine unless in compliance with the Minor and Visitor Procedure. An exception to this policy is if an individual under 18 years of age is participating in a research experiment approved by the principal investigator or mentoring program sponsored by the University and/or outside agency. Contact the Office of Research if there are any questions about provisions for high school students. As is the case for all personnel and visitors in a research laboratory, the Principal Investigator is responsible for training, assigning appropriate tasks and monitoring for safety practices.

M. Bloodborne Pathogen Training

Each employer having an employee(s) with occupational exposure as defined by: reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure and shall be trained in accordance with this plan and the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030

Training will cover the following topics

- An explanation of the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030
- The DU / DUCOM Exposure Control Plan
- Standard (formerly Universal) Precautions
- Work Practice Methods
- Engineering Controls
- Management of regulated waste such as sharps and infectious waste
- Epidemiology and Symptomology of Hepatitis B, C and HIV
- Modes of transmission of HBV, HCV and HIV
- Review of procedures which may result in exposure to potentially infectious materials
- Use of Personal Protective Equipment
- An explanation of labels and signs used
- Hepatitis B Vaccine Program
- Post-exposure evaluation and follow-up procedures

Frequency of Training

New Hire – All new employees will be trained on the contents of the bloodborne pathogen Standard 29CFR1910.1030 and information specific to their individuals work areas. Training will be scheduled through the Department of Environmental Health and Safety on an as needed basis. Please contact the department at 215-895-5919.

Annual – Refresher training will be provided to all employees through the in-service training program. This training session will review items covered in the initial new hire training but will also include changes in regulations and any new policies adapted by the University. Please contact the Department of Environmental Health and Safety at 215-895-5919 to schedule training sessions.

N. Insect and Rodent Control

It is the policy of Drexel University and Drexel University College of Medicine that all Microbiological and Biomedical laboratories engage a proactive insect and rodent control

program. The current program employed at Drexel University and Drexel University College of Medicine utilizes our in-house Facilities Management Department and a licensed contractor. The Facilities Management Department records any noted problems on a written log. The contractor visits the buildings that house BSL3 Labs one time per week to review the log, inspect the facility and treat as required.

VI. CHEMICAL SAFETY –

The Occupational Safety and Health Administration (OSHA) promulgated a final rule on January 31, 1990 for occupational exposure to hazardous chemicals in laboratories (The Lab Standard – 29CFR1910.1450). The basis for this standard is that laboratories typically differ from industrial operations in their use and handling of hazardous chemicals and that a different approach from the Hazard Communication Standard of 1987 is warranted.

The final OSHA standard, commonly known as the "Chemical Hygiene Plan for Laboratories," applies to all laboratories that use hazardous chemicals in accordance with the definition of laboratory use and laboratory scale as provided in the OSHA standard.

The effective date of the OSHA Standard is May 1, 1990 and all Chemical Hygiene Plans (CHP) are required to be in place by January 31, 1991 in accordance with 29 CFR Part 1910.1450 of the Federal Register.

In compliance therewith, DU / DUCOM has developed a Chemical Hygiene Plan (CHP), as described herein, and made effective this date.

DU / DUCOM reserves the right to change, amend, add or delete any part or the whole of this plan at any time. Although the information in this plan is compiled from sources believed to be reliable, its accuracy is not guaranteed, nor is any responsibility assumed or implied for any damage or loss resulting from inaccuracies or omissions.

A. FORMAL POLICY STATEMENT

Drexel University and Drexel University College of Medicine is committed to providing a safe working environment and believes employees have a right to know about health hazards associated with their work. This Chemical Hygiene Plan (CHP) introduces policies, procedures and responsibilities designed to develop in employees an awareness of potentially hazardous chemicals in the work place as well as the need to maintain appropriate and safe working areas and conditions. It is designed to assist employees in making knowledgeable decisions about any personal risks associated with employment at this institution.

A copy of the CHP must be located in a visible area of each laboratory and be familiarized by all lab personnel. Copies are available thru the Department of Environmental Health and Safety or on their webpage www.drexel.edu/facilities/healthSafety/. This web page also has additional information on other important subjects, such as the Hazardous Waste Management Plan, Emergency Spill Response Plan, Lab Safety Manual, Blood born Pathogen Policy, and Chemical Fume Hood/Biological Safety Cabinet plans.

Every Drexel University and Drexel University College of Medicine student and employee is responsible for following the safety rules of Drexel University and Drexel University College of Medicine by reading and understanding the regulations and procedures contained within this document. All students and employees will have access to pertinent safety information through their supervisor who is the first individual to contact for information or problems. In this regard, the following procedure must be followed:

Teaching Laboratories

1. Discuss the problem with your Teaching Assistant.

2. If not satisfied, discuss the problem with the Faculty member in charge of the laboratory.

3. If still not satisfied and the problem is that of …

    a. A chemical or physical hazard (other than radiation or laser) discuss the problem with the University Chemical Hygiene Officer.
    b. A radiation or laser hazard discuss the problem with the Radiation Safety Officer.
    c. A biological hazard discuss the problem with the University Biosafety Officer.

4. If still unsatisfied, request a meeting with the appropriate Safety Officer, the Faculty Member/Laboratory Supervisor and your Department Head.

5. If still not satisfied, request for a meeting with the Dean of the College.

6. If still not satisfied, request for a meeting with the University Provost.

Research Laboratories

1. Discuss the problem with your immediate supervisor.

2. If you are not satisfied, then discuss the problem with the Principal Investigator

3. If still not satisfied and the problem is that of…

    a. A chemical or physical hazard (other than radiation or laser) discuss the problem with the University Chemical Hygiene Officer.
    b. A radiation or laser hazard discuss the problem with the Radiation Safety Officer.
    c. A biological hazard discuss the problem with the University Biosafety Officer.

6. If still unsatisfied, request a meeting with the appropriate Safety Officer, the Principal Investigator and your Department Chair.

7. If still not satisfied, request for a meeting with the Associate Vice President for Research Compliance

The Department of Environmental Health and Safety provides online training for all employees whether part time or temporary about the hazards of the work place and procedures to follow to

avoid accidents. The training can be accessessed at www.drexel.edu/facilities/healthSafety/. Additional site-specific training is available and may be necessary to fully educate employees on the hazards associated with different work practices, protocols and procedures. These training events may be presented by any of the appropriate University Safety Officers, the PI or the Department Head. In any event, however, training activities must be properly documented and copies of all syllabi and sign-in sheets must be sent to the Department of Environmental Health and Safety by faxing the information to 215-895-5926.

For the purposes of this CHP, the term "supervisor" applies to that individual with the authority to assign, direct and review the work of one or more subordinates. This definition applies to laboratory, office or department heads and may, in some instances, apply to certain individuals who have supervisory functions under a laboratory, office or department head.

B. RESPONSIBILITIES AND FUNCTIONS

1. University Chemical Hygiene Officer (CHO)

The University Chemical Hygiene Officer (CHO) is charged with the responsibility of implementing and monitoring the chemical hygiene plan. The Chemical Hygiene Officer at Drexel University is Martin W. Bell. The Drexel University CHO can be reached at (215) 895-5892.

The CHO's functions include, but are not limited to the following responsibilities:

- The development of chemical hygiene policies and procedures.
- Conduct safety audits of all the University's laboratory spaces.
- Assist PI's in complying with local, state, and federal regulatory agencies and developing a healthy workplace environment.
- Conduct implementation and monitoring procedures in accordance with approved policies and procedures.
- Certify the performance of protective equipment.
- Monitor procurement, use, and disposal of hazardous materials used in the lab
- See that appropriate audits are maintained.
- Help supervisors develop precautions and adequate facilities.
- Know the current legal requirements concerning regulated substances.

2. Principal investigator/Faculty Member/Laboratory Supervisor

The principal investigator/laboratory supervisor/faculty member has overall responsibility to:

- Ensure that workers know and follow the chemical hygiene rules that protective equipment is available and in working order, and that appropriate training has been provided.
- Provide regular, formal, chemical hygiene and housekeeping audits including routine inspections of emergency equipment.
- Know the current legal requirements concerning regulated substances.

- Determine the required levels of protective apparel and equipment. Ensure that facilities and the training for use of any material being ordered are adequate.

3. Laboratory employee/Student

The laboratory employee is responsible for:

- Planning and conducting each operation in accordance with Drexel University's chemical hygiene procedures.
- Developing good personal chemical hygiene habits

C. STANDARD OPERATING PROCEDURES

Four fundamental principals define all work area and procedural precautions set forth in this Chemical Hygiene Plan:

- **Plan Ahead!**
- **Minimize Exposure to Hazards**
- **Do Not Under Estimate Risks!**
- **Be Prepared for Accidents**

Because few laboratory chemicals are without hazards, and based on the premise that many mixtures of hazardous chemicals are more toxic than the most toxic component, the following procedures must be observed when working with most chemicals:

1. Chemical Exposure:

- **Eye Contact**: Promptly flush eyes with water for a prolonged period (15 minutes), obtain information from MSDS. Contact 911 if life threatening injury. If non-life threatening contact Tenet Security at 215-762-7110 if on Center City Campus or contact Drexel Public Safety at 215-895-2222 if on University City, Queen Lane or Doylestown campuses. If necessary report to Employee/Student Health or nearest emergency room for evaluation.
- **Ingestion**: Call 911 or Poison Control Center at 1-800-222-1222. Do not induce vomiting or drink large quantities of water unless directed to do so by a medical professional.
- **Skin Contact**: Promptly flush the affected area with water for 15 minutes. Remove all contaminated clothing. Use a safety shower when contact is extensive.

Note: In any of the above events, seek medical advice immediately. Phone or contact Drexel Public Safety 24-Hour Call Center (215) 895-2222 and the Department of Environmental Health and Safety at (215)-895-5919

2. Chemical Spills

Please refer to the Section IX for detailed procedures regarding hazardous materials spills.

3. Work Area Precautions

- Keep all work areas clean and free of clutter. Clean up the work area on completion of an operation or at the end of each work shift or class.

- Keep chemicals and equipment properly labeled and stored appropriately. Segregate chemicals as noted in Part 8 of this section.

- Do not store, handle or consume food or beverages in laboratory areas, refrigerators, or with glassware or utensils that are also used for laboratory operation.

- Seek information and advice about hazards, review MSDS (www.hazard.com) plan appropriate protective procedures, and plan positioning of equipment before beginning new operation.

- Leave lights on during work hours.

- Provide for containment of toxic substances in the event of failure of a utility service in an unattended operation.

- Beware of any unsafe conditions and see that they are corrected when detected.

- Chemical Fume Hoods

- Use a hood for operations that might result in release of chemical vapors or fine powders and dust. Respirators may be necessary for work with some substances. If a substance's OSHA permissible exposure limit (PEL) can be predicted to be exceeded than a respirator will be necessary for work with that substance. Laboratory personnel and/or students must fulfill all the requirements set forth by the University's Respirator Protection program prior to working with respirators. For further details please contact the Department of Environmental Health and Safety at 215-895-5919.

- As a rule of thumb, use a hood or other local ventilation device when working with any appreciably volatile substance having a threshold limit value (TLV) of less than 500 ppm. Contact the Department of Environmental Health and Safety for the TLV information.

- Confirm adequate hood performance before use (i.e. kimwipe test). Keep hood closed at all times except when adjustments within the hood are being made. Do not store chemicals in hoods for extended periods of time, and do not allow materials to block vents or airflow. Refer to the University's Chemical Fume Hood Plan (available at www.drexelsafetyadnhealth.com) for more details concerning chemical fume hoods.

- Leave the hood "on" when it is not in active use, if toxic substances are stored in it; or if it is uncertain whether adequate general laboratory ventilation will be maintained when it is "off."

- Be aware of any unsafe conditions and see that they are corrected when detected. Contact the Department of Environmental Health and Safety for advice.

4. <u>Procedural Precautions</u>

- Mouth suction for pipetting or starting a siphon is strictly forbidden.

- Do not smell or taste chemicals.

- Apparatus that can discharge toxic chemicals (vacuum pumps, distillation columns, etc.) must be vented into local exhaust devices or Chemical Fume Hoods.

- Handle and store laboratory glassware with care to avoid damage. Do not use damaged glassware.

- Use extra care with Dewar flasks and other evacuated glass apparatus; shield or wrap them to contain chemicals and fragments in the event that implosion might occur.

- Use equipment only for its designed purpose.

- **Highly Toxic and Reactive material precautions are as follows:**

  - Review the Material Safety Data Sheets prior to working with any toxic or reactive chemicals.

  - Preparations for handling highly toxic and/or reactive substances must include sound and thorough planning of the experiment, understanding the intrinsic hazards of the substances and the risks of exposure inherent in the planned process, selecting additional precautions that may be necessary to minimize or eliminate these risks, and reviewing all emergency procedures to ensure appropriate response to unexpected spills or accidents.

  - Do not allow release of toxic substances in cold rooms or warm rooms, since these areas have contained re-circulated atmospheres.

  - Do not use any chemicals that require ventilation in excess of your lab's capabilities. Most labs have between 6 and 12 air changes per hour. Chemicals requiring additional ventilation must be used only in hoods and glove boxes.

  - Procedures involving highly toxic chemicals that can generate dust, vapors, or aerosols must be conducted in a hood, glove box, or other suitable containment device.

  - When working with toxic liquids or solids, it is critical that gloves be worn to protect the hands and forearms. These gloves must be carefully selected to ensure that they are impervious to the chemicals being used and are of appropriate thickness to allow reasonable dexterity while also ensuring adequate barrier protection. Contact the Department of Environmental Health and Safety for assistance or glove selection.

  - Always inspect all personal protective equipment prior to starting any experiment and never work alone.

- When using toxic substances that could generate vapors, aerosols, or dusts, additional levels of protection, including full-face shields and respirators, are appropriate, depending on the degree of the hazard represented.

- Equipment used for the handling of high toxic chemicals must be isolated from the general laboratory environment.

- After using toxic materials laboratory personnel shall wash his or her face, hands, neck and arms prior to leaving the laboratory.

- Laboratory personnel must be specifically trained on the use of certain highly toxic and/or reactive materials. The Department of Environmental Health and Safety provides additional training to anyone working with any of the Highly toxic or reactive materials or any on the OSHA regulated materials (for example: Hydrofluoric Acid, Formaldehyde, Chlorine Gas, and Ammonia Gas).

- **Perchloric Acid precautions are as follows:**

  - Perchloric acid is a very dangerous corrosive and oxidizing agent at high concentrations and elevated temperatures. Room temperature concentrations of 70% or less are not significant oxidizers, but are still highly corrosive.

  - Always review the Material Safety Data Sheet before using perchloric acid.

  - Always wear appropriate personal protective equipment when using perchloric acid.

  - Do not store perchloric acid with organic materials. Upon contact with perchloric acid, organic materials such as wood or cloth may ignite. Perchloric acid also must not be stored with bases, organic acids, or flammables.

  - Perchloric acid spills must not be allowed to dry as they become more unstable as the acid is concentrated. Also, do not leave containers uncovered. Neutralize any spill with soda ash or similar and use an inorganic absorbent to clean up the material. Do not use rags or paper towels unless wetted. Seal any cleaning materials to be discarded in a plastic bag and contact the Department of Environmental Health and Safety for disposal

  - Salts of perchloric acid are also oxidizers and may be explosive.

  - Any experiment involving the heating of perchloric acid MUST be done in a chemical fume hood specially designed as a perchloric acid hood. Do not use direct flame heating or oil baths. Perchloric Acid Hoods are made of stainless steel and have wash-down water spray systems.

  - The Department of Environmental Health and Safety requires any lab using perchloric acid to write the receive and open dates on the container's label.

- **Hydrofluoric Acid (HF) precautions are as follows:**

- Hydrofluoric acid is an extremely dangerous material and all forms, including vapors and solutions, can cause severe, slow-healing burns to tissue. At concentrations of less than 50%, the burns may not be felt immediately and at 20% the effects may not be noticed for several hours. At higher concentrations, the burning sensations will become noticeable much more quickly, in a matter of minutes or less. HF burns pose unique dangers distinct from other acids, it readily penetrates skin, damaging underlying tissue. The fluoride ion can then cause destruction of soft tissues and decalcification of the bones. HF can cause severe burns to the eyes, which may lead to permanent damage and blindness. The Hydrofluoric Acid Standard Operating Procedure, which is available from the Department of Environmental Health and Safety, and its MSDS must be posted prominently.

- Review the MSDS before working with this material.

- Do not work alone when using hydrofluoric acid.

- For skin contact, a 2.5% calcium gluconate gel is recommended. For eye contact, a sterile solution of 1% calcium gluconate or dropper bottle of 0.5 % pontocaine hydrochloride is required to be made available. The Department of Environmental Health and Safety can supply any lab using HF the calcium gluconate gel.

- **Flammable material precautions are as follows:**

  - Handle flammable substances only in areas free of ignition sources. Besides open flames, ignition sources include electrical equipment (especially motors), static electricity, and, for some materials (e.g., carbon disulfide), even hot surfaces.

  - Check the work area for flames or ignition sources prior to using a flammable substance.

  - Never heat a flammable substance with an open flame. Preferred heat sources include steam baths, water baths, oil and wax baths, salt and sand baths, heating mantles, and hot air.

  - Keep containers of flammable substances tightly closed at all times when not in use.

  - Use only refrigeration equipment certified or listed as explosion proof for storage of flammable materials.

- **Pyrophoric Organometallic material precautions are as follows**:

  - Always read the relevant Material Safety Data Sheet before using these materials.

  - Pyrophorics users must be thoroughly trained in the proper lab techniques.

  - Never work alone when using these materials.

- Set up work in a laboratory fume hood or glove box and ALWAYS wear the appropriate personal protective equipment. Portable shields might be acceptable. Glove boxes are recommended when an inert or dry atmosphere are required.

- A face shield is required at any time there is a risk of explosion, large splash hazard or a highly exothermic reaction.

- Lab coats or aprons, not made of easily ignited materials such as nylon or polyester, must be worn. Fire-resistant lab coats made from materials such as Nomex are required.

- Minimize the quantity of pyrophoric reagents used or stored.

- Pyrophoric chemicals must be stored under an atmosphere of inert gases or under kerosene, as appropriate.

- Avoid working or storing these materials in areas near heat/flames sources, oxidizers, and water sources.

- A container with any pyrophoric residue must never be left open to the air.

- The use of smaller syringes is encouraged. If handling more than 20 ml of sample, one should use a cannula for transfer or use a 20 ml syringe repeatedly.

- The Aldrich Sure/Seal Packaging system provides a convenient method for storing and dispensing air sensitive reagents. Replace the plastic cap after each use, particularly for long term storage. The Sure/Seal septum-inlet transfer adapter must be used when repeated dispensing is necessary.

- **Compressed Gas Cylinders precautions are as follows:**

  - Compressed gas is any gas or mixture of gases exerting in a container a pressure exceeding 40.6 psia at 68 degrees Fahrenheit. Also any flammable liquid having an absolute vapor pressure exceeding 40.6 psia at 100 degrees Fahrenheit.

  - All compressed gases are considered hazardous and contain a certain volume of gas even if the gauge reads empty or zero.

  - Gases MUST be stored in separate hazard classes: Flammable, Asphyxiant, Oxidizing, Corrosive, Toxic, Cryogenic, High Pressure, and Pyrophoric. Some gases combine hazard classes, such as Hydrogen has both high pressure and flammable hazards.

  - Gas cylinders of all sizes, whether empty or full, must be secured in an upright position at all times. The uses of straps, chains, or a suitable stand to prevent them from falling are all acceptable practices. Contact the Department of Environmental Safety and Health or Facilities Management for options.

- Cylinders not in use must be capped at all times to protect the valve stems.

- Do not expose cylinders to temperatures higher than about 50 degrees Celsius. This might result in excessive cylinder pressure. Some rupture devices on cylinders will release at about 65 degrees Celsius. Small cylinders, such as lecture bottles are not fitted with rupture devices and may explode if exposed to high temperatures.

- Old/Empty gas cylinders must be returned to the supplier in a timely fashion.

- Disposal of used lecture bottles can cost anywhere from $100 to $1000 each, depending on their contents. Use only if there is no other alternative.

5. Protective Clothing And Other Precautions

- Remove laboratory coats immediately upon significant contamination.

- When in the laboratory, appropriate footwear that completely covers the foot must be worn. Sandals, flip-flops, perforated shoes, any shoes made out of canvas, or any other open-toed or open-top shoes in the lab are prohibited.

- When in the lab, pants and dresses must come down to the ankle. Shorts, short skirts, and other clothing that leaves sufficient skin exposed are prohibited in the lab. Shorts and short skirts may only be worn in the lab when wearing an ankle-length lab coat that covers all the exposed legs.

- Do not wear contact lenses in the laboratory. Contact lenses can react with some chemicals, potentially damaging the eyes. They may also interfere with washing out any foreign material in the eyes. Regular prescription eyeglasses are not considered protective eyewear.

- Disposable or special gloves, chemical aprons, goggles or eye shields must be used whenever appropriate.

- Disposable gloves must never be worn in hallways, elevators, or public areas of the University. If hazardous materials must be transported from one area to another, glove one hand to hold the product / apparatus or push cart and use a clean ungloved hand to open doors, press buttons, etc.

- Inspect all gloves before each use. Wash them before removal. Dispose of them appropriately.

- Reusable gloves should be washed and inspected before and after each use. Gloves that might be contaminated with chemicals must not be removed from the immediate area in which the chemicals are located.

- Eating, drinking, smoking, chewing gum or applying cosmetics in the laboratory is strictly forbidden. Lunches are not to be stored in standard laboratory refrigerators, but may be kept in the designated refrigerators.

- Wash areas of exposed skin thoroughly before leaving the laboratory.
- Confine long hair and loose clothing.
- Avoid practical jokes or other behavior that might confuse, startle or distract another worker.
- Refer to Section H of this plan for information concerning Personal Protective Equipment.

Note: Please contact the Department of Environmental Health and Safety for additional information on precautionary measures, i.e., housekeeping, gas cylinders, hazard warnings, etc.

6. Chemical Inventory

An inventory of all hazardous chemicals and non-hazardous chemicals must be prepared for each laboratory. The inventory will be kept in a visible location within each lab. One copy of this inventory will be maintained by the P.I./Faculty Member, a second copy will be maintained in each lab as the first page of the MSDS book and a third electronic copy will be sent to the Department of Environmental Health and Safety. This can be done through the department's website at http://www.drexel.edu/facilities/healthSafety in the "service request forms" section. A separate inventory list of carcinogens, mutagens and teratogens is to be forwarded to the Department of Environmental Health and Safety in accordance with Federal and State Regulations.

Additional inventories must be prepared annually. As new chemicals are obtained, chemical inventory sheets must be updated accordingly.

The PI/Laboratory Supervisor/Faculty Member takes complete responsibility for compliance.

7. Material Safety Data Sheets (MSDS)

MSDS must be kept in each laboratory in a labeled binder. The MSDS must be filed in alphabetical order along with the chemical inventory for that particular laboratory.

If MSDS are missing from a particular chemical inventory, request letters should be sent to the applicable manufacturer or vendor. Vendors and manufacturers are required by federal law to provide MSDS upon request, free of charge, within a reasonable time frame. Additional sources for obtaining MSDS include the internet at:

www.msds.com
www.msdssearch.com
www.ilpi.com/msds
www.hazard.com
http://www.pp.okstate.edu/ehs/links/msds.htm

Many venders post their MSDS's on their webpages.

The PI/Laboratory Supervisor/Faculty Member is responsible for reviewing the MSDS and recording which materials are carcinogenic, mutagenic or teratogenic. This information must be conveyed to all students and/or employees engaged in research in his/her laboratories, including locations used and stored within the lab. This information must be posted at the entrance to each lab in an effort to inform any individual who may need to enter that space. A copy of this information must be sent to the Department of Environmental Health and Safety.

8. Chemical Storage

All hazardous chemicals must be stored in clearly defined designated areas in accordance with this manual and OSHA Regulation 29 CFR 1910.1450 also known as the "Laboratory Standard". These storage guidelines must be followed when storing hazardous chemicals:

- The chemical inventory must be kept as small as possible. Any old, expired, or unused chemicals should be properly disposed.
- Do not store chemicals on top of high cabinets or shelves. Liquids, in particular corrosives or other hazardous liquids, should not be stored over 5 feet in height. The only exception is that non-hazardous liquids may be stored above 5 feet if there are space limitations.
- Keep exits, passageways, areas under tables, and emergency equipment areas free of stored chemicals.
- Provide a definite storage place for each chemical and return the chemical to that location after each use.
- Do not store chemicals on bench tops and in fume hoods, except for those chemicals being used currently.
- Do not store chemicals on the floor.
- Store chemicals in a cool dry place avoiding direct sunlight.
- Ventilated storage cabinets shall be used to store extremely hazardous chemicals. The vents must be directed outside the building.
- Use chemical storage refrigerators and freezers only for chemical storage. Label these refrigerators with the following signage: "No Food or Drink – Chemical Storage Only"
- Safety containers must be used when transporting chemicals (i.e. carts, rubber totes, secondary containers etc), especially outside of the lab area.
- Observe all precautions regarding the storage of incompatible chemicals.
- Dry chemicals (solid materials) shall not be stored with liquid chemicals. If stored in the same cabinet, liquids are always stored under solid chemicals.

- Separate chemicals into the following hazard classes:

    1. Flammables
    2. Acids
        a. Organic Acids
        b. Inorganic Acids
    3. Bases
        a. Organic Bases
        b. Inorganic Bases
    4. Oxidizers
    5. Reactives
    6. Poisons (Toxic)
    7. Non-hazardous or non-regulated chemicals.

- Chemicals classified as Irritants may be stored separately or with Non-Hazardous Chemicals.

- Weak acids or bases, in their dry form, often can either be stored as Non-Hazardous or separated out as acids or bases, unless the label specifically classifies it as "Corrosive". Any chemical specifically labeled as "Corrosive" must be separated out as an acid or a base.

- The above hazard classes must be separated from each other. This can be accomplished by 1) placing them in different cabinets, 2) placing them on different shelves, or 3) separating them by placing the different hazard classes into separate trays called secondary containment devices. The trays must be able to contain the entire volume of the materials stored in the event of a spill. The tray must be compatible with the stored materials. Cardboard and styrofoam is insufficient.

- Store all flammable liquids in a grounded, flammable storage cabinet with self-closing doors.

- Do not store flammable liquids in a refrigerator unless it is an approved explosion-proof refrigerator.

- Organic Acids can be stored in the flammable storage cabinet; however, overspill containers must be used to contain any spills and to act as a means of separation.

- Acids must be stored separate from bases. Storage in the same cabinet is possible only if overspill containers are used to contain any spills.

- Separate inorganic and organic bases. These can be stored in the same cabinet. Shelves or overspill containers can be used as a means of separation.

- Separate inorganic and organic acids. These can be stored in the same cabinet. Shelves or overspill containers can be used as a means of separation. In particular, nitric acid and acetic acid must not be stored together.

- Store nitric acid, perchloric acid, and hydrofluoric acid separately from all other chemicals if possible (including from each other). Otherwise store them with other inorganic acids.

- Peroxide-forming chemicals may become unstable and potentially explosive when exposed to air. As such, all peroxide-forming chemicals must have a receive date and an open date written on their labels. Examples of commonly used peroxide-forming chemicals include: Tetrahydrofuran, Ethyl Ether, Dioxanes, Isopropyl Ether, Styrene, Vinyl Pyridine, and 2-Propanol. Most peroxide-forming chemicals must be disposed of after 12 months, although some uninhibited peroxide-formers may only be used up to 24 hours after opening. Perchloric Acid is another potentially explosive chemical which should be disposed of after 12 months. While not as potentially hazardous as other peroxide-formers, older containers of 2-Propanol should be handled with care.

- DO NOT handle any peroxide forming chemical if there are signs of crystal growth or precipitation. Contact the Department of Environmental Health and Safety at (215-895-5919) IMMEDIATELY if this occurs and leave the area.

- Oxidizers must be stored in a cabinet separate from all other chemicals.

- Reactive chemicals must be segregated and stored appropriately i.e. flammable cabinet, explosion proof refrigerator, dedicated container etc.

- Toxic chemicals, including carcinogens, must be properly labeled; small containers should be stored together in unbreakable chemical-resistant secondary containers. These containers must be labeled either "Caution: High Chronic Toxicity," or "Cancer Suspect Agent."

- As stated above, a separate inventory list of carcinogens, mutagens and teratogens is to be forwarded to the Department of Environmental Health and Safety in accordance with Federal and State Regulations.

- Alphabetical storage of all dry chemicals is not allowed. This may result in incompatibles appearing together on a shelf. Dry chemicals should first be segregated appropriately then stored alphabetically within each hazard class.

- Cylinders of compressed gases, empty or full, must be labeled, strapped or chained at all times to a wall or bench top, and must be capped when not in use.

- Oxygen and other oxidizing gases must not be stored adjacent to flammable gases (except when in use).

- Do not store flammable gases near sources of heat or ignition.

- If unable to determine the best possible storage options consult the MSDS for the chemical. If further assistance is need contact the Department of Environmental Health and Safety at 215-895-5919.

9. Labeling

- **Chemical Container Labels Requirements**:

OSHA requirements for labeling under the Chemical Hygiene Plan will be the same as those defined in the hazard communication standard 1910.1200. Therefore, all containers in the workplace (including secondary containers (beakers, Erlenmeyer flasks, cap bottles, etc.) must contain the following information:

1. Identity of the substance (complete chemical name; abbreviations and/or symbols are not acceptable).
2. Appropriate hazard warnings (Irritant, Flammable, Corrosive, etc.; completed NFPA diamond is acceptable).

All labels must be prominently displayed and legibly written (printed) in English and other language as appropriate for employees. It is the responsibility of the principal investigator to inspect all incoming shipments of containers of hazardous chemicals to ensure that they bear labels with the appropriate information.

The names of buffers (PBS, TBS, HEPES, Tris, etc.) may be abbreviated, as long as a Key stating the full name is placed in a clearly visible location in the laboratory.

It is recommended that the date be placed on all chemical containers when they are received and opened. This is required for any peroxide-forming chemicals. For any solutions prepared by the laboratory personnel (i.e. buffers, media, and dilutions), it is also recommended to add the date it was made to the container's label.

If a container is improperly labeled, the PI/Laboratory Supervisor/Faculty Member or the PI's Laboratory Supervisor's/Faculty Member's designee must contact the Department of Environmental Health and Safety (215-895-5919), who will notify the vendor for correction, and the receiving department for informational purposes.

Portable or secondary containers used for purposes of transferring hazardous material from a labeled container for immediate and complete use by an investigator or his /her technicians or research staff or student do not require labeling . However, if the transferred hazardous material is to be used by other research personnel/student, or is not immediately used, it is the responsibility of the investigator/lab supervisor/faculty member/student/lab technician for whom the chemical material was first intended, to properly label the portable container.

- **<u>Laboratory Labels Requirements:</u>**

  - All laboratory entrance doors shall be labeled as follows:

    1. NFPA diamond. Laboratory personnel shall fill in the diamond with the highest hazard number pertaining to their laboratory.
    2. Biohazard label and appropriate Biosafety Level (if applicable).
    3. UV Light label (if applicable).
    4. Radiation Hazard Label (if applicable).
    5. Emergency contact information. The information must include a name and number to contact in the event of an emergency. It must be clearly visible and placed on each outer laboratory door

6. Additional warning labels as applicable, i.e. “carcinogen in use”, “water reactive materials”, “inhalation hazard, respiratory protection required in this area”, “high noise, hearing protection required in this area”, etc.

- **Chemical Storage Labeling Requirements:**

All cabinets, shelves and refrigerators containing chemical storage (including the cleaning supplies) must be labeled with the appropriate warning label (Flammable, Acids, Bases, Oxidizers, Reactives, Poisons (Toxic), Non-Hazardous, and/or NFPA Diamond). Refrigerators and freezers used for chemical storage must be labeled with appropriate hazard warnings and with the signage: “NO Food or Drink – Chemicals Storage Only.” Any refrigerator used for food or drink storage must be label as such (these must be kept out of the lab areas). Biohazard labels must be applied to all appropriate areas, such as Biological Safety Cabinets and refrigerators. Radiation hazard tape or labels must be applied to all applicable work and storage areas. UV Light warning labels must be placed on any device that can generate ultra-violet light, such as Biological Safety Cabinets.

Old and obsolete labels in the lab must be removed or defaced.

D. ENGINEERING CONTROLS

1. Chemical Fume Hoods, Biological Safety Cabinets and Ventilation

All chemical fume hoods, biological safety cabinets, and laminar flow hoods must be inspected and certified annually.

Any hood not providing 80 to 120 linear feet per minute of airflow or manufactures recommended value must not be used. Inspections of chemical fume hoods are routinely conducted by the Department of Environmental Health and Safety. If chemical fume hoods do not meet specifications, they will be taken out of service immediately and are not to be used until the hood has met the criteria for certification. Refer to the University’s Chemical Fume Hood Policy for more information (Available at http://www.drexel.edu/facilities/healthSafety/).

The annual inspection and certification of laminar flow hoods and biosafety cabinets is scheduled through the Department of Environmental Health and Safety, the costs associated with these certifications are the investigator’s/faculty member’s responsibility. It is the responsibility of the principal investigator/faculty member/laboratory supervisor to certify, repair or replace such unit(s) in a timely fashion so as not to endanger the health and well-being of employees/students or place them at risk. Refer to the University’s Biological Safety Cabinet Policy (Available at http://www.drexel.edu/facilities/healthSafety/) for more information.

Work involving chemicals with high vapor pressures or low threshold limit values (TLVS) must always be done within a fume hood. Contact the Department of Environmental Health and Safety (215-895-5907) for TLVs for a specific chemical.

Airflow through each laboratory should normally be not less than 20 cubic feet per minute, and exhausted to the exterior of the building. Quality and quantity of ventilation are monitored and

records are maintained by Drexel University Facilities Management. If you need information on this, please contact the Facilities Management Department.

2. Eyewash Fountains and Safety Showers

Eyewash and safety showers are essential in every laboratory. These stations must be within 25 feet and/or 10 seconds of unobstructed path of the laboratory operation. Eyewash stations and showers should be located within the laboratory, especially if corrosive or injurious chemicals, strong irritants, or toxins that can be absorbed through the skin are present, or if the lab is subject to BSL-2 (or higher) regulations. Regulatory standards insist that the eyewash station be hands-free or automatically operated. Drench hoses, sink faucets or showers are not acceptable eyewash substitutes. Facility limitations may affect these requirements. Locations of emergency eyewash stations and safety showers shall be identified with a highly visible sign.

Eyewash fountains must be inspected once a week by the PI/Faculty Member/Laboratory Supervisor. Records are maintained by the Principal Investigator/Faculty Member/Laboratory Supervisor are recommended to be kept near the eyewash station. Inspection forms are available online at http://www.drexel.edu/facilities/healthSafety/. These weekly inspections are not necessary if the eyewash does not have access to a drain.

The Department of Environmental Health and Safety certifies eyewash stations annually. All records will be maintained by the Department of Environmental Health and Safety.

Safety showers are inspected, tested, and flushed annually and records are maintained by the Department of Environmental Health and Safety

3. Fire Safety

Each laboratory should be equipped with the fire extinguisher appropriate for the work that goes on in the lab, or have one located nearby in the hallway. Classes of fire include:

- For fires involving combustibles like wood or paper
- For flammable or combustible liquids and gases
- For fires where electricity may be present
- For combustible materials like magnesium

Only trained employees should use fire extinguishers. If a fire occurs, remember P.A.S.S. when operating a fire extinguisher:

P – Pull the pin
A – Aim the hose at the base of the firs
S – Squeeze the trigger
S – Sweep

All laboratory personnel and/or students shall know the locations of the locations of all the fire extinguishers, fire blankets (if present) and the fire alarms. No smoking is allowed in any University building.

The Principle Investigator/Laboratory Supervisor/Faculty Member shall post laboratory evacuation procedures. During an evacuation, remember R.A.C.E.:

R – Remove everyone from the immediate area
A – Alert others by sounding alarm
C – Confine the fire by closing the door
E – Evacuate the building and report to a pre-arranged meeting place.

All laboratory personnel and students shall be familiar with these evacuation procedures. It is the responsibility of the Principle Investigator, Laboratory Supervisor, or Faculty Member to ensure that the students know these procedures, as well as to eliminate any potential fire hazard.

Fire extinguishers are inspected annually and recharged and/or replaced accordingly by the Facilities Department:

Center City Campus:	215-762-6500
Queen Lane Campus:	215-991-8484
University City Campus:	215-895-2808
PA Biotechnology Center	215-489-4904

Long-term storage of chemicals should be in a well ventilated, secure chemical storage area in accordance with current fire and building codes.

All cold rooms and warm rooms have provisions for rapid escape in the event of electrical failure. Escape instructions should be posted on the inside of the entrance door of each cold or warm room. Please refer to the Fire Safety manual at http://www.drexel.edu/publicsafety/fire.

E. PERSONAL EXPOSURE MONITORING

Upon request of the PI/Faculty Member/Laboratory Supervisor/Student/Laboratory personnel, the University CHO will review laboratory work practices and normal operations in an effort to determine if University employees are at risk of exposure to regulated substances in accordance with the OSHA permissible exposure limits and action levels as outlined in 29 CFR 1910.

Initial and annual surveillance monitoring (environmental and personal) will be conducted whenever exposures to hazardous agents are anticipated to exceed the action level, the American Conference of Governmental Industrial Hygienists (ACGIH) threshold limit values (TLV) or OSHA'S PEL. Additionally, monitoring will be conducted when:

- Past monitoring has indicated elevated exposures,
- When requested by an employee or student,
- When an employee or student experiences signs or symptoms of overexposure, or
- When laboratory operations change such that an area previously identified as not expected to have significant exposure would now be expected to have elevated concentrations of hazardous agents

All personal exposure monitoring activities (including sampling, analysis and record keeping) will be performed in accordance with OSHA requirements and/or NIOSH recommended practices.

F. PERSONAL PROTECTIVE EQUIPMENT (PPE)

The Department of Environmental Health and Safety requires that appropriate eye protection is worn by all persons in laboratories and areas where chemicals are used or stored.

Eye protection consists of safety glasses with side shields, goggles or face shield, or full-face respirator. Chin length face shields are to be worn to prevent splashes or sprays of blood, infectious materials, or hazardous chemicals when there is a potential for eye, nose, or mouth contamination. Eye protection is required whether or not one is actually performing experimental operations and must be worn by all lab personnel and visitors. Prescription eyeglasses and contact lenses are not appropriate protection. In fact, wearing contact lenses in the lab is prohibited as they can cause serious complications when exposed to certain chemicals.

Employees/students are required to wear appropriate gloves when an employee has the potential for direct contact with blood, hazardous chemicals, infectious agents, or other hazardous materials.

Select gloves appropriate for the task. Gloves protect differently for each chemical. Wearing the wrong type of glove can be more hazardous than wearing no gloves at all. If the chemical seeps through, the glove can hold it in prolonged contact with the wearer's hand. For more information concerning glove selection contact Department of Environmental Health and Safety. A link to a website to determine the appropriate glove for the chemical can be found at http://www.drexel.edu/facilities/healthSafety/.

Lab coats and gloves must be worn only in the laboratory area and are to be removed upon exiting the laboratory. Lab coats are worn to protect street clothes from hazardous materials. For safety concerns, short pants, open-toed shoes, and loose clothing must not be worn in the lab and is prohibited. In addition, gloves and lab coats must only be worn in the lab and taken off before leaving, especially when handling infectious material. Gloves are only worn in the laboratory and must be removed before leaving. If transporting hazardous materials from one are to another, glove one hand to hold the product/apparatus or push the cart and use a clean, ungloved hand to open doors, press buttons, etc. Hands must be washed with soap and water immediately after removing the gloves.

Chemical Fume Hoods, Glove Boxes, and Biological Safety Cabinets are not be used as alternatives to PPE. They are used only to augment PPE. Proper PPE must be worn when using these devises.

When the use of respirators, in research laboratories, is necessary to maintain exposure below the permissible exposure limit (PEL), the respirator will be provided by the PI at no cost to the employee or student.

The proper respiratory equipment can be obtained from the Department of Environmental Health and Safety (215) 895-5919. The respirators shall be selected and used in accordance with the requirement of 29 CFR 1910.134 and ANSI Z88.2-1969. Training, an annual physical and pulmonary function test will be required for all individuals requiring the use of respirators in accordance with OSHA's standards on respiratory protection 29 CFR 1910.134.

Use appropriate respiratory equipment when air contaminant concentrations are not sufficiently restricted by engineering controls. The odor threshold for many chemicals is much lower than the permissible exposure limit, and in many circumstances is a great indicator of exposure.

The requirements set forth in the University's Respirator Protection Policy must be fulfilled prior to performing work with a respirator. Contact the Department of Environmental Health and Safety to enroll in the program.

Use any other protective apparel and equipment as appropriate. Know the locations of PPE and how to obtain additional materials when necessary. If appropriate PPE is not readily available do not initiate experiments involving hazardous chemicals.

The Principle Investigator shall provide proper personal protection equipment for all personal in the research laboratory and instruct them of the PPE's locations.

Faculty Members/Laboratory Supervisors shall require students to obtain the appropriate PPE prior to commencing any laboratory activities. If proper PPE is not available, no lab activity can proceed. For proper PPE selection contact the Department of Environmental Health and Safety.

(The Drexel University and Drexel University College of Medicine Chemical Hygiene Plan is available online at http://www.drexel.edu/facilities/healthSafety/labSafety/.

VII. RADIATION SAFETY

A. Introduction

The Radiation Safety Program at Drexel University College of Medicine is administered by the Radiation Safety Office (RSO) at the direction of the Radiation Safety Committee at each of the universities. The policies and procedures, which make up the radiation safety program are contained in the individual Drexel and Drexel University College of Medicine Radiation Safety Manuals. Please refer to these manuals for the current policies and procedures.

The use of radioactive materials is regulated by various agencies including the U.S. Nuclear Regulatory Commission and the Pennsylvania Department of Environmental Protection. Both of these agencies issue licenses, which specifically authorize the use of various radionuclides. The licenses also have conditions and limitations to which Drexel University and Drexel University College of Medicine must adhere, as well as published regulations.

Investigators who desire to use radioactive materials in their laboratory(ies) need to apply for authorization from the Radiation Safety Committee. The Committee reviews the training and experience of the investigator with regard to the use of radioactive materials, the proposed use of radioactive material to determine that the work is within the conditions and limitation of the federal and state licenses, that the facilities and equipment are adequate to perform the work safely, and that the procedures are conducted to minimize the risk of exposure and contamination. Applications are available and should be submitted to the RSO. Investigators that have been approved to use radioactive materials in their laboratory have the responsibility for adhering to any conditions of approval and for complying with the radiation safety program.

The RSO provides a variety of services, including:

- Monitoring radiation exposures, including surveys, personal monitoring, and bioassays.
- Investigating spills, incidents, and other unusual events involving radioactive material
- Investigating overexposures.
- Conducting an ALARA program to assure that radiation exposures are kept as low as reasonably achievable.
- Maintaining an inventory of all radioactive material at Drexel University and Drexel University College of Medicine
- Disposing of radioactive waste
- Surveying packages of radioactive material upon receipt
- Transporting radioactive material in compliance with U.S. Department of Transportation requirements.
- Auditing/inspecting laboratories for compliance with the radiation safety program
- Conducting independent surveys of laboratories.
- Training radiation workers through short courses, in-services, and meetings.
- Approving users and uses of radioactive materials.
- Maintaining requisite records

Contact the RSO (215-762-4050) to request personal monitoring (film badges and ring TL dosimeters); to report accidents, incidents, or spills; to request services; or if there is any question as to proper procedure.

For emergencies after normal business hours, contact the emergency operator who will contact the radiation safety personnel on call.

B. Radioisotope Licensing

The Radiation Safety Office of Drexel University and Drexel University College of Medicine is responsible for issuing licenses to investigators, monitoring the procedures for safety and health involving all individual users, monitoring isotope records, and disposal of all radioactive material. Please consult the Drexel University and Drexel

University College of Medicine' Radiation Safety Manual for information concerning issuance of new, modification or transfer of licenses. Blank license forms for applications, modification, or transfer memos are available from the Radiation Safety Office.

C. Radiation Warning Signs

Radiation warning signs must be placed on the doors of laboratories using radioactive materials. (See Section IV/E, page 5 for further details.) Further, all laboratory equipment such as refrigerators, sinks, centrifuges, etc. And containers used for laboratory procedures involving radioactive material should be plainly marked with radiation hazard warning labels.

D. Radiation Work Areas

Work areas specifically for radioactive materials, must be established in the laboratory. Absorbent paper with a non-porous backing and spill trays should cover the work surfaces to contain spills.

E. General Radiation Safety Procedures

The General Radiation Safety in Laboratory instruction sheet should be posted in each laboratory. (See Exhibit VII-a) The most current version of this instruction sheet is available from the Radiation Safety Office. In case of pregnancy, please refer to Exhibit VII-b.

F. Emergency Instructions

Specific instructions for handling emergencies should be posted in each laboratory. (See Exhibit VII-c.) The most current version of the emergency procedures can be obtained from the Radiation Safety Office.

G. Package Receipt

Most packages containing radioactive material must be surveyed for contamination upon receipt. NRC regulations require formal procedures for safely opening packages containing radionuclides. The initial package check-in is performed by the Radiation Safety Office. Refer to the Radiation Safety Manual for details or call 215-762-4050 for assistance.

H. Radioactive Waste Disposal

Refer to the Drexel University and Drexel University College of Medicine Radiation Safety Manual for radioactive waste disposal procedures.

I. Records of Radioactive Materials Usage

All licensees of radioactive material are required to submit quarterly reports of receipt and disposition of radionuclides in accordance with the instructions contained in the Drexel University and Drexel University College of Medicine Radiation Safety Manual.

VIII. DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

Biosafety Office Responsibilities and Services

A. Introduction

The Drexel University and Drexel University College of Medicine's Safety Offices and the University Biosafety Committee, specifically the University Biosafety Officer are charged with the responsibility to enforce the Laboratory Safety Policies and Procedures as defined in this Safety manual, or as may be added, deleted or amended by the University Biosafety Committee.

B. The University Biosafety Committee (UBSC)

It is the responsibility of the USBC to:

1) Help ensure that all research facilities provide a safe working environment via annual inspections regarding general laboratory safety as well as the acquisition, use, handling and disposal of pathogenic microbial organisms, altered genomic elements (recombinant DNA) and hazardous chemicals;

2) Review and if necessary, require the modification of and secure approval of research protocols for all grants and proposals with respect to biosafety issues; such issues include the use and safe handling of pathogenic microbial organisms, altered genomic elements (recombinant DNA) and hazardous chemicals;

3) Will help assure compliance with the requirements of regulatory agencies governing the institution (e.g., OSHA, PADEP, EPA and the City of Philadelphia)

4) Will promote laboratory safety and educational training related to general laboratory safety and the use of pathogenic microbial organisms, altered genomic elements (recombinant DNA) and hazardous chemicals;

C. The University Biosafety Officer and Recombinant DNA Officer (UBSO and URDO)

The "NIH Guidelines for Recombinant DNA Research" require that institutions engaged in recombinant DNA research at the physical containment levels appoint a person who

will serve as a biological safety officer. Drexel University and Drexel University College of Medicine has appointed a Biosafety Officer to address issues related to safety in microbiological laboratories and a Recombinant DNA Officer to address issues specific to work involving the use of recombinant DNA molecules. Information to contact these officers is provided in Section D below.

The following duties will be among those to be performed by either the University Biosafety or Recombinant DNA Officer:

- Provide technical advice to the principal investigator and UBSC on research safety procedures.
- Provide advice on laboratory security.
- Develop emergency plans for dealing with accidental spills and personnel contamination; and investigate recombinant DNA research laboratory accidents.
- Ensure through periodic inspections that laboratory standards are rigorously followed.
- Serve as a member of the UBSC.

The principal function of the Recombinant DNA Officer should be to advise the principal investigator, the UBSC, the Safety Officer and the laboratory worker concerning the most appropriate safety practice that will assure the safe conduct of recombinant DNA research.

Additional duties and responsibilities may be assigned to the University Biosafety Officer. These will depend on the magnitude and complexity of the institution's recombinant DNA program, whether the position is full or part time, the relationship of the position to the institution's environmental health and safety program, and the qualifications of the individual. The following are examples of additional duties and responsibilities:

1. Provide special laboratory safety training.
2. Serve as a liaison with NIH and other research organizations on matters pertaining to laboratory safety.
3. Conduct or supervise all testing programs designed to demonstrate the integrity of containment equipment and facility safeguards.
   Supervise emergency decontamination measures.
4. Compilation of a safety library of reference publications and training materials.
5. Approved guidance and assistance concerning the packaging and shipping of recombinant DNA materials.

These activities may be distributed among the staff of the institution's environmental health and safety program. In such a case, the University Biosafety Officer should be responsible for the management, supervision or coordination of these activities.

D. Personnel

University Biosafety Committee

Arthur Frank, Co-Chair	(215) 762-3930
Fred Krebs, Co-Chair	(215) 762-5133

Recombinant DNA Officer

Fred Krebs	(215) 762-7398

Drexel University & Drexel University College of Medicine

Biosafety Officer-Jonathan Chase	(215) 895-5891

Drexel University & Drexel University College of Medicine

Chemical Hygiene Officer – Martin Bell	(215) 895-5892

University Biosafety Committee, Coordinator (215) 255-7857

E. Offices

1.	Office of Research	1601 Cherry Street 11th floor	(215) 255-7857
2.	University Safety & Health	400 N. 31st Street	(215) 895-55919
3.	Hospital Safety: HUH	Bobst Building Room B-25	(215) 762-6133
4.	Human Resources DUCOM Drexel University	3201 Arch Street Suite 450	(215) 895-1679
5.	Radiation Safety Office DUCOM & Drexel University	New College Bldg. 3rd Floor 245 N 15th Street	(215) 762-4050
6.	Laboratory Animal Facilities DUCOM	New College Building 245 N. 15th St., 15th Floor	(215) 762-7969
	Queen Lane	2900 Queen Lane Basement, E-Wing	(215) 762-7969
	Drexel University	Lebow Building 31st & Market St., Basement	(215) 895-1348

F. Resource Documents

The following publications constitute the resource documents for the Biosafety Program of Drexel University and Drexel University College of Medicine and as such provide the basis for much of the information contained in this Safety Manual.

1. NIH Guidelines for Research Involving Recombinant DNA Molecules. Federal Register, 1997

2. "Hazard Communication Standard" (29 CFR l9l0 l200) Published by theFederal Occupational Safety and Health Administration (OSHA) as an Occupational Safety and Health Standard.

3. "Worker's Right to Know Laws " A formerly used term to describe the above OSHA laws and applicable state and local government laws concerning occupational safety and health standards and the employer's responsibility to inform. As of August 28, 1987,

state and local laws were superseded by OSHA "Hazard Communications; Final Rule (29 CFR Parts 1910, 1915, 1917, 1918, 1926, and 1928)" regarding the use of toxic substances in laboratories.

IX. HAZARDOUS MATERIAL RESPONSE

The University Department of Environmental Health and Safety separates hazardous material spills into two main categories:

A. Major Spill Identification

- **Chemical Spills Greater than 500ml/gm –**

  The University Department of Environmental Health and Safety defines major spill as a large spill that is greater than 500 gm or 500 ml or any amount of an acutely hazardous material. An acutely hazardous material is any material that is imminently dangerous to life and health.

- **Select Agent Release**

  The University Department of Environmental Health and Safety defines select agent releases as any amount of regulated select agent released into the environment that could threaten the safety and health of the building occupants. Select agent releases are considered major spill events. Upon identifying a release laboratory occupants must immediately implement the major spill procedures.

- **Hazardous Gas Release**

  The University Department of Environmental Health and Safety defines hazardous gas releases as any amount of hazardous gas released into the environment that could threaten the safety and health of the building occupants. Hazardous gas releases are considered major spill events. Upon identifying a release laboratory occupants must immediately implement the major spill procedures.

- **Mercury Releases**

  The University Department of Environmental Health and Safety considers mercury an extremely toxic and dangerous material. In effort to reduce possible exposure risks to personnel and students all mercury spills are regarded as major spills. Upon identifying a release immediately implement the major spill procedures.

B. Minor Spill Identification

- The University Department of Environmental Health and Safety defines minor spill as a small spill that is less than 500 gm or 500 ml of non-acutely hazardous materials.

C. Major Spill Response Procedures

The following procedure applies to:

- Laboratory personnel
- Education personnel
- Maintenance personnel
- Outside Contractor Personnel
- Environmental Services personnel
- Administrative personnel

In the event of a major spill in a university area, all laboratory, education, maintenance, outside contractor, administrative, and/or environmental services personnel will implement the following plan:

1. Notify persons in the immediate area that a spill has occurred.
2. Avoid breathing vapors, mists or dust of the spilled material.
3. Turn off all ignition sources if reasonably accessible.
4. If injured or contaminated with hazardous chemicals immediately proceed with personal decontamination procedures.
5. Evacuate room and close the door.
6. From a safe area, contact the following using any in house telephone:

Campus	**Public Safety Dispatcher**	**Emergency Operator**
Center City	215-895-2222	Dial “80” or 7111
Queen Lane	215-895-2222	Dial “80”
University City	215-895-2222	----------

7. In order to asses the situation be prepared to provide the following information:

- Name and call back number
- The location of the spill (campus, building and room number)
- Type of material spilled
- The amount of material that spilled

8. Remain on or near the telephone until you have received instructions from the emergency operator or Public Safety or Security or the University Department of Environmental Health and Safety.

D. Minor Spill Response Procedures

In the event of a minor spill the following emergency procedures shall be implemented:

1. If injured or contaminated with hazardous substances immediately proceed with personal decontamination procedures.
2. Laboratory personnel will be responsible for the containment and clean up of all **minor** spills.

3. Proper personal protection equipment shall be donned during the clean up of all **minor** spills. If the laboratory occupants do not have the proper personal protective equipment then contact the University Department of Environmental Health and Safety for assistance at 215-895-5892 or 215-778-4278 or 215-895-5919 or Public Safety at 215-895-2822 to contact a representative from the Department of Environmental Health and Safety.
4. Contain spilled material(s) using absorbent pads and/or socks. Paper Towels cannot be used for containment of spill nor shall they be used for clean up.
5. Neutralize spilled material(s) using the appropriate neutralizing agent.
6. Clean up neutralized material using dustpan and/or plastic scoop.
7. Place neutralized material in hazardous waste bags. Dispose of as hazardous waste.
8. Wash area where spill has occurred with distilled water several times making sure no residue was left behind. Dispose of any towels used as hazardous waste.
9. All emergency equipment shall be decontaminated and stored.
10. All non-disposable personal protective equipment shall be decontaminated and stored.
11. All disposable personal protective equipment and clean up materials shall be disposed of as hazardous waste.
12. Always use extreme caution when cleaning up hazardous substances.
13. If the material spilled is not covered under the **minor** spill definition (< 500 gm or 500 ml of non-acutely hazardous material) then laboratory personnel shall implement the **major spill procedures.**

E. Personal Decontamination Procedures

Please be advised that these procedures are general decontamination procedures. These procedures might not be appropriate for certain types of hazardous materials. In effort to ensure proper decontamination consult the Material Safety Data Sheet prior to conducting any experiments.

If injured or contaminated with a hazardous substance these procedures will be implemented **immediately** prior to cleaning up or reporting spill.

- <u>For spills contacting the of skin, follow these procedures:</u>

1. Immediately flush with flowing water for at least 15 minutes (i.e. sink or safety shower).
2. If there is no visible burn, wash with warm water and soap, removing any jewelry to facilitate clearing of any residual material.
3. Check the material safety data sheet to see if any delayed effects should be expected. If the MSDS is not available contact the University Department of Environmental Health and Safety immediately at 215-895-5892 or 215-778-4278 or 215-895-5919 or go to www.hazard.com.
4. Seek medical attention for even minor chemical burns.
5. Do not use creams, lotions, or salves.

- <u>For spills on clothing, follow these procedures:</u>

1. Do not attempt to wipe the clothes.
2. Quickly remove all contaminated clothing, shoes, and jewelry while using the safety shower.
3. Seconds count, so do not waste time because of modesty
4. Take care not to spread the chemical on the skin or, especially, in the eyes.
5. Use caution when removing pullover shirts or sweaters to prevent contamination of the eyes; it may be better to cut the garments off.
6. Immediately flood the affected body area with warm water for no less than 15 minutes. Resume if pain returns.
7. Get medical attention as soon as possible.
8. Discard contaminated clothes as hazardous waste or have them laundered separately from other clothing.

- <u>For splashes into the eye, take these steps:</u>

1. Using the eyewash immediately flush for at least 15 minutes.
2. Hold the eyelids away from the eyeball, and move the eye up and down and sideways to wash thoroughly behind the eyelids.
3. Get medical attention immediately. Follow first aid by prompt treatment by a member of a medical staff or an ophthalmologist who is acquainted with chemical injuries.

Exhibits

DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

Exhibit II-a
RIGHT TO KNOW GUIDELINES

Note: This section is required to be reviewed and signed upon acceptance of a position **or** before the employee begins working at Drexel University and Drexel University College of Medicine.

Biological and Chemical research often requires the use of hazardous materials including radioisotopes, infectious agents, and hazardous chemicals. While working at Drexel and Drexel University College of Medicine, it is likely that you will be required to handle such materials. In this regard it will be your specific right and obligation to know, before using a hazardous material in an experiment, what is the nature of the material, its specific hazard and the proper procedures for its use.

Prior to utilizing any substance, each employee of Drexel University and Drexel University College of Medicine has the right and obligation to be educated to the proper use of substance and any risk associated with the substance. If, as an employee of Drexel University and Drexel University College of Medicine, you have any questions about any substance you work with, you should contact the laboratory director or the Drexel University's Department of Safety and Health, (chemical hazards, general life safety), the Drexel University Biosafety Officer (biohazards), or Drexel and Drexel University College of Medicine's Radiation Safety Office (radiation hazards). See "Frequently Used Contact Numbers" of the Laboratory Safety Manual.

With your right to know come specific responsibilities for your protection and the protection of others. Adherence to all government and Drexel University and Drexel University College of Medicine's guidelines and regulations for the use and disposal of any hazardous materials is mandatory. In addition, all reasonable precautions to assure the safety of yourself and others must be taken. This may include vaccination.

If you are ever in doubt or have a problem with the use of any materials or have a complaint about experiments done by others, the following procedures are to be followed:

1. Discuss the problem with your immediate supervisor.
2. If you are not satisfied, discuss with the department chair.
3. If you are not satisfied, then discuss the problem with the Safety Office.
4. If still unsatisfied, discuss the problem with the University Biosafety Officer.
5. If still unsatisfied, contact the University Biosafety Committee Chair.
6. If still not satisfied, request a meeting with the Assistant Provost of Research.

I have read, understood and will adhere to these guidelines

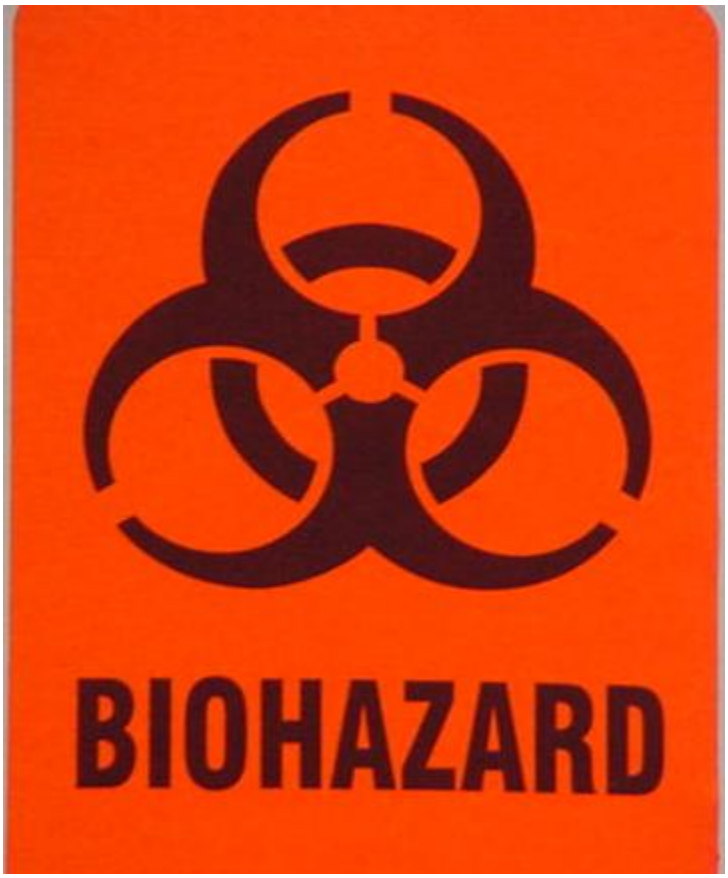
_____ _____

Signature Date

DREXEL UNIVERSITY
AND
DREXEL UNIVERSITY COLLEGE OF MEDICINE

EXHIBIT IV-A1

BIOHAZARD WARNING SIGN



DREXEL UNIVERSITY
AND
DREXEL UNIVERSITY COLLEGE OF MEDICINE

EXHIBIT IV-A3

RADIATION WARNING SIGN

DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

Exhibit IV.b – LABORATORY BIOLOGICAL WASTE DISPOSAL GUIDE

Infectious Waste Containers:

The University Department of Environmental Health and Safety will supply the following containers for proper disposal of biological waste:

- Red biohazard sharps container that are rigid, tightly lidded and puncture resistant. A seventeen gallon floor container will be supplied unless otherwise specified.
- Red biohazard bags.
- Biohazard cardboard boxes to store the red biohazard bags (only upon request).

Infectious Waste Container Request:

The University Department of Environmental Health and Safety will determine the number of containers to be supplied. The outside vendor will only replace the same number of containers that are removed. Additional containers can only be requested through the Department of Environmental Health and Safety. The contractor will not supply any additional containers without receiving a confirmation from the Safety and Health office.

New laboratories

- Contact the University Department of Environmental Health and Safety at 215-895-5919.

University City Campus Laboratories

- Red Biohazard Sharps Containers – replaced during weekly pickup by outside contractor. If not on the list for pickup please contact the Department of Environmental Health and Safety at 215-895-5919.
- Red Biohazard Infectious Waste Bags – replaced during weekly pickup by outside contractor. If not on the list for pickup please contact the Department of Environmental Health and Safety at 215-895-5919.

Center City Campus Laboratories

- Red Biohazard Sharps Containers – replaced during weekly pickup by outside contractor. If not on the list for pickup please contact the Department of Environmental Health and Safety at 215-895-5919.
- Red Biohazard Infectious Waste Bags – contact Facilities Management at 215-762-6500 at any time to request replacement bags.

Queen Lane Campus Laboratories

- Red Biohazard Sharps Containers – replaced during weekly pickup by outside contractor. If not on the list for pickup please contact the Department of Environmental Health and Safety at 215-895-5919.
- Red Biohazard Infectious Waste Bags – replaced during pickup by custodial services. Contact custodial services at 215-991-8484 to request replacement bags.

Infectious Waste Pick-up Procedure:

- Infectious waste containers **MUST** remain inside the laboratory at all times prior to pick-up. Containers must not be placed in the hallway at any time.
- Laboratory personnel must be present at the time of the pick-up. The contractor does not have keys to access the laboratories to remove the materials. If you are not present at the time of pick-up then the material will not be removed until the next scheduled pick-up.

Infectious Waste Pick-up Schedule (Animal Waste Excluded See Disposal Guideline):

The pick-up schedule for each campus is as follows:

University City Campus

- Biohazard Sharps - the contractor is on site every Friday between the hours of 9:00 am and 1:30 pm.
- Red Biohazard Infectious Waste Bag – the contractor is on site every Friday between the hours of 9:00 am and 1:30 pm.

Center City Campus

- Biohazard Sharps – the contractor is on site every Thursday between the hours of 9:00 am and 1:30 pm.
- Red Biohazard Infectious Waste Bag – the building custodial staff will remove this material at any time upon request. Contact Facilities Management at 215-762-6500.

Queen Lane Campus

- Biohazard Sharps – the contractor is on site every Friday between the hours of 8:30 am and 9:30 am.
- Red Biohazard Infectious Waste Bag – the building custodial staff will remove this material at any time upon request. Contact custodial services at 215-991-8145.

Disposal Guideline:

CATEGORY	DESCRIPTION	EXAMPLES	DISPOSAL
Infectious Sharps Waste	A sharp is considered any object that is capable of penetrating the skin. Used sharps, regardless of whether they are infectious, may be stored in the same container.	All Needles, sutures, syringes, and blades (i.e. scalpels, razors, etc.), Pasteur pipettes, blood vials, culture plates, and glass slides. Any other broken or unbroken glass or plastic if it has been in contact with infectious agents or that has been used in animal or human patient care or treatment at medical or research laboratories.	Red Biohazard Sharps Containers (should be closed and picked up for disposal when ¾ full) Sharps containers should be rigid; tightly lidded; and puncture resistant.
Non-Contaminated Laboratory Glassware & Plasticware	Any item that does not meet the classification of "Infectious Sharps Waste" (described above), but could potentially break or puncture a regular trash bag and pose a hazard to custodial staff.	All pyrex, empty chemical bottles (after triple rinsing and defacing label), or other non-contaminated broken or fragile glass or plastic.	Red Biohazard Sharps Containers (should be closed and picked up for disposal when ¾ full) Sharps containers should be rigid; tightly lidded; and puncture resistant.
Regulated Infectious Waste	Any waste with the presence or the reasonably anticipated presence of blood or other	(1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid,	Solid Infectious Waste (non-sharps): Red Biohazard Infectious

	potentially infectious materials on an item or surface. Infectious waste shall be sorted at the point of origin in the generating facility into the following three classes, and each class shall be placed in a separate container: Used sharps; Fluid quantities greater than 20 cubic centimeters; and Other infectious waste	pericardial fluid, peritoneal fluid, amniotic fluid, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult to differentiate between body fluids; (2) Any unfixed human tissue or organ (other than intact skin); (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; (4) Microbiological cultures and stocks of infectious agents, including the following: cultures and stocks of infectious agents; wastes from the production of biologicals; and culture dishes, assemblies and devices used to transfer, inoculate and mix cultures.	Waste Bags (bags should be inside a hard plastic container labeled "Biohazard"). Liquid Infectious Waste (i.e. culture media, blood, body fluids): ** Dispose in sanitary sewer after chemical decontamination with a fresh solution of 10% bleach (wait 15-20 minutes prior to discharging down the drain)
Non-Regulated Waste	Waste from laboratories that is **not** a sharp and is **not** contaminated with an infectious agent, waste generated that does **not** contain human blood, body fluids, or blood products or animal blood, or blood products.	**Non-contaminated:** gloves, bench paper, packaging materials, foil, plastic bags, paper towels, weighing boats, bottle caps, fly media, filter flasks, etc. Non-contaminated refers to objects that are not known or reasonably expected to have the presence of blood or other potentially infectious materials on their surface.	Regular Lab Trash (removed by custodial staff)
Infectious Animal Waste	Contaminated animal materials known to have been exposed to zoonotic infectious agents or non-zoonotic human pathogens during research.	Contaminated animal carcasses, body parts, blood, blood products, secretions, excretions and bedding of animals that were known to have been exposed to zoonotic infectious agents or non-zoonotic human pathogens.	Red Biohazard Infectious Waste Bags – Sent to Animal Facility for Disposal
Non-Infectious Animal Waste	Animal carcasses and body parts from animals that have **not** been exposed to zoonotic infectious agents or human pathogens during research.	Animal carcasses or body parts from animals that have not been exposed to infectious agents.	Red Biohazard Infectious Waste Bags – Sent to Animal Facility for Disposal

** Once liquid infectious waste has been decontaminated with a fresh solution of 10% bleach for 15-20 minutes, the waste is no longer considered to be regulated infectious waste, and can therefore be discharged down the drain.

You may contact the Department of Environmental Health and Safety with any questions. Contact: Martin Bell at 215-895-5892 or Jeff Nemetz at 215-895-5913

DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

Exhibit IV-c
AUTOCLAVE OPERATION

WHAT TO DO	HOW TO DO IT	KEY POINTS WHY
Prepare for start-up	• Remove plug screen from bottom of chamber and clean	If plugged with debris, will interfere with free flow of steam
Arrange load	• Place flat packs of supplies on edge. If several tiers, place alternate tiers crosswise	To insure adequate flow of steam
Loading containers of liquid	• Do not mix loads of liquids with other supplies	
	• Use only vented closures	Sealed bottles may explode
	• Use only type 1 borosilicate (Pyrex) glass bottles Rupture ordinary glass	Stress of temperature and pressure may
	• Use sterilizer slow exhaust only	Fast exhaust causes rapid boiling within the bottles with loss of fluids. Do not place flammable chemicals or chemical which are unstable at high temperatures in the sterilizer
	• Moisten loads of cloth or fabric	Dry fabrics remove moisture from steam, causing superheating which chars the fabric

Exhibit IV-c
AUTOCLAVE OPERATION

WHAT TO DO	HOW TO DO IT	KEY POINTS WHY
Close autoclave door	• Turn handle clockwise until arms are within rim of door- continue turning handle until snug • To sterilize all materials: • Turn timer to desired exposure period • Turn selector to appropriate position: "slow exh" for liquids "fast exh" if drying not required "fast exh and dry" for wrapped supplies, etc. • Turn operating handle (clockwise only) to "Ster"	Time required for sterilization varies with load
Open sterilizer	• Turn hand wheel counterclockwise • Open sterilizer door no more than a few inches	
When load is completely processed, sterile light will come on and alarm will sound	• Wait a few minutes before unloading sterilizer	Rapid boiling will occur if door is opened too soon

DREXEL UNIVER AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

Exhibit IV-f

EXPOSURE CONTROL PLAN for RESEARCH LABORATORIES

It is the policy of Drexel University and Drexel University College of Medicine to provide a safe working environment for personnel. To provide documentation of the policies and procedures which have been implemented to eliminate or reduce employee exposure to bloodborne pathogens. Procedures have been developed to identify those individuals with occupational exposure, those whom may have occupational exposure and those not expected to have occupational exposure to human blood, bodily fluids, pathogenic bacteria and viral agents, recombinant DNA and other potentially infectious or pathogenic materials.

These individuals will be provided with training, appropriate personal protective equipment, vaccination against Hepatitis B (free of charge), and post exposure follow-up and prophylaxis in accordance with OSHA's Standard on Occupational Exposure to Bloodborne Pathogens 29 CFR 1910.1030.

All research laboratories are required to complete the enclosed Bloodborne Pathogen Exposure Control Plan. This plan must be kept in each laboratory and a photocopy of the completed plan must be returned as soon as possible to the Department of Environmental Health and Safety at:

Drexel University
400 N. 31st Street
Philadelphia, PA 19104

This plan must be updated annually, photocopied and sent to the Department of Environmental Health and Safety.

BLOODBORNE PATHOGEN

EXPOSURE CONTROL PLAN

OCTOBER 2009

Introduction

Each employer having an employee(s) with occupational exposure as defined by:

---

a reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties

shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

The Exposure Control Plan shall contain at least the following elements:

- An Exposure Determination

- The schedule and method of implementation for

    1. Methods of Compliance,
    2. HIV and HBV Research Laboratories and Production Facilities,
    3. Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up,
    4. Communication of Hazards to Employees, and
    5. Record keeping, of this standard, and

- The procedure for the evaluation of circumstances surrounding exposure incidents

The Exposure Control Plan must be accessible to employees at all times

The Exposure Control Plan must be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

The Exposure Control Plan must be made available to OSHA upon request for examination and copying.

Definitions

Assistant Secretary	means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.
Blood	means human blood, human blood components, and products made from human blood.
Bloodborne Pathogens	means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens

include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Clinical Laboratory means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Engineering Controls means controls (e.g., sharps disposal containers, self-sheathing needles) that isolate or remove the bloodborne pathogens hazard from the workplace.

Exposure Incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials those results from the performance of an employee's duties.

Handwashing Facilities means a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

Licensed Healthcare Professional is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

Other Potentially Infectious Materials (OPIM) means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment (PPE) is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

Production Facility means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research Laboratory means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may

	produce high concentrations of HIV or HBV but not in the volume found in production facilities.
Source Individual	means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.
Sterilize	means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.
Universal Precautions	is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.
Work Practice Controls	means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

Exposure Control Plan (EPC)

A) Exposure Determination

Each employer who has an employee(s) with occupational exposure as defined by:

A reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties

Shall prepare an exposure determination.

This exposure determination shall be as follows:

List all job classifications in your area, which **will have** occupational exposure

_____

_____

_____

_____

List job classifications in your area, which **may have** occupational exposure

_____
_____
_____

List **all tasks** and procedures that result in occupational exposure

_____
_____
_____

Exposure determination shall be made without regard to the use of personal protective equipment.

B) Schedule and Method of Implementation

Methods of Compliance

Standard (Universal) Precautions

Treat all bodily fluids / materials as infectious, including any and all instrumentation and materials which may have come in contact with body fluids such as paper, gauze, bandages, sponges, gloves, etc.

Engineering Controls

Handwashing facilities must be present in every lab / clinical area. Hand washing shall be performed prior to and after the use of gloves and/or patient contact.

Sharps containers must be used for the disposal of all syringes, glass ware (broken and intact, petri dishes, pipettes, hard plastic which has the ability to shatter under pressure, and any other materials which may have become contaminated and has the ability to cut, scratch or pierce the skin and /or breach mucus membranes. Sharps containers should not be moved unless properly closed to prevent spillage.

Sharps containers must be inspected daily. The person performing this inspection will close all containers which are more than 2/3 full and check for adequate labeling. Full containers will be removed, disposed and replaced by an outside contractor. If removal and replacement has not been performed appropriately, close the container and contact the Department of Environmental Health and Safety at (215) 895-5919.

The removal of full sharps containers and red bag waste will be performed routinely. Full sharps containers and red bag waste will not remain in temporary storage for more than 7 days.

List additional engineering controls here. Include needleless syringes, needleless blood draw kits, shatter proof plastic, etc.

_____
_____
_____
_____
_____

Work Practice Controls

Standard (Universal) Precautions will be observed at all times.

Eating, drinking, smoking, applying cosmetics, etc. will not be tolerated in any lab at any time.

Mouth pipetting / suctioning is not permitted under any circumstance.
All specimens shall be placed in leak proof, puncture resistant and labeled containers.

Syringes are not to be recapped, bent or purposely broken.

List additional work practice controls here. Include one handed techniques, sterilization, labeling, procedures to minimize needlesticks and splashing, etc.

_____
_____
_____
_____
_____

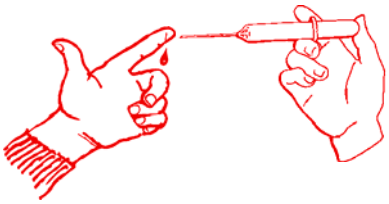
Cleaning and Decontaminating Blood Spills

- Always wear gloves
- First wipe with a towel and dispose of the towel as infectious waste
- Apply a biocide / germicide or 10% bleach in water solution over entire area
- Repeat for manufactures recommended exposure time (usually 5-10 minutes)
- Allow surface to air dry
- If the surface is a floor, demarcate with slippery when wet signs

Laundry

- Laundry contaminated with blood or other potentially infectious materials should be placed in a designated container that prevents leakage.
- Laundry in this area is processed by_____
- Phone number for service is _____

Infectious Sharps Waste

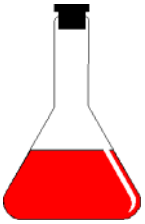


- *Do not recap or bend used syringes*
- *Lids are to be kept on containers*
- *Close container prior to moving*
- *Do not fill containers more than 2/3 full*
- *Do not ever reach into container for any reason*
- *Do not dispose of sharps in regular trash*
- *Do not dispose non-sharps in sharps container*
- *Do not use cardboard containers for disposal of sharps*

All sharps containers are inspected daily by_____
If primary inspector is absent, sharps containers will be inspected by_____
All sharps are removed and disposed of by an outside contractor.
Frequency of removal is _____ one times per week.

Please refer to the University's Laboratory Biological Waste disposal guideline for proper disposal of infectious waste. The guideline can be accessed in the University's Laboratory Safety Manual.

Infectious Non-Sharps Waste

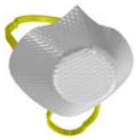


- **All infectious waste will be disposed of in red labeled bags**
- Red Labeled bags will be contained in designated, labeled hard plastic or metal containers – No cardboard containers are to be utilized
- Containers used to hold red bags will be routinely cleaned with a 10% (min.) bleach solution
- **Do not dispose of Sharps in Red Bags.**
- **Do not use cardboard containers for the disposal of infectious waste**

Please refer to the University's Laboratory Biological Waste disposal guideline for proper disposal of infectious waste. The guideline can be accessed in the University's Laboratory Safety Manual.

Personal Protective Equipment (PPE)

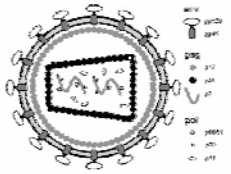




List all protective equipment available (at no cost to employees) in your work area. Include safety glasses and/or goggles, splash shields, gloves (chain mail, latex, PVC, etc.), chemical aprons, masks, etc.

_____
_____
_____

PPE is stored at_____
PPE is routinely inspected by _____
Frequency of PPE Inspection _____
Additional PPE can be obtained by _____



HIV and HBV Research Laboratories and Production Facilities

These facilities will follow all policies and procedures outlined in the biosafety manual. A biosafety manual has been developed and approved by the Drexel University biosafety committee. A copy of this manual is located in each of the HIV, HBV and other biological research laboratories. If you would like a copy of this manual please contact Jonathan M. Chase, MS at (215) 762-6506.

Hepatitis B Vaccination

Names of vaccinated individuals in your area:

_____ _____
_____ _____
_____ _____
_____ _____

Names of individuals which declined vaccination:

_____	_____
_____	_____
_____	_____
_____	_____

Post-Exposure Evaluation and Follow-up

When an incident occurs, it should be immediately reported to the employee's supervisor and/or PI. An incident report should be initiated and faxed within 24hrs to the Department of Environmental Health and Safety.

Supervisors must offer post-exposure evaluation and follow-up

Follow-up will include the following:

- Documentation of route of exposure and circumstances related to the incident
- Identification and status of the source individual. If consent is given the source individual will be tested.
- HIV test results of source individual will be made available only if negative
- Employees will be offered blood tests for HIV, HBV, HCV and HIV seroligical agents.
- Employees will be offered post-exposure prophylaxis
- Counseling will be given to employee(s) on precautions after the exposure, potential illnesses and reporting procedures

Communication of Hazards to Employees

Training

Training content will cover the following topics

- An explanation of the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030
- The Drexel University Exposure Control Plan for Clinical Practice Groups
- Standard Precautions
- Work Practice Methods
- Engineering Controls
- Management of regulated waste such as sharps and infectious waste
- Epidemiology and symptomology of Hepatitis B,C and HIV
- Modes of transmission of HBV, HCV and HIV

- Review of procedures which may result in exposure to potentially infectious materials
- Use of Personal Protective Equipment
- **An explanation of labels and signs used**
- The Drexel University Hepatitis B Vaccine Program
- Post-exposure evaluation and follow-up procedures

Frequency of Training

New Hire – All new employees will be trained on the contents of the bloodborne pathogen standard 29cfr1910.1030 and information specific to there individuals work areas. Training is provided online at www.drexel.edu/facilities/healthSafety/.

Annual – Refresher training will be provided to all employees. The training can be accessed online at www.drexel.edu/facilities/healthSafety/. This training session will review items covered in the initial new hire training but will also include changes in regulations and any new policies adapted by the University.

Labels

- Labels must be present on all doors leading to areas containing potentially contaminated materials (i.e. laboratory doors).
- Labels must be placed on all vessels or containers containing bio-waste or other potentially contaminated materials, including transport containers, refrigerators, freezers, centrifuge, etc.
- Labels must be placed on all containers used for holding red Bio-waste bags.
- Labels must be placed on all sharps containers.

Record Keeping

Medical Records

Complete records must be retained for at least 30 years after the last day of employment of any individuals which had an occupational exposure. These records must be kept confidential.

Medical records must be made available to subject employee and/or subject employees representative (with written consent), OSHA and NIOSH.

Training Records

Training records must be retained for three years. These records must include dates, name and qualifications of trainer, individuals trained and their job titles. The Department of Environmental Health and Safety will maintain these records.

University City Campus - Emergency Contact Numbers

Department	Name	Office Number	Mobile Number
Public Safety		215-895-2222	
Emergency Room	HUP	215-662-3920	
Student Health	Drexel	215-895-5800	
Occupational Health	Worknet	215-467-5800	
Univ. Safety	Jon Chase	215-895-5891	215-669-6122
Univ. Safety	Martin Bell	215-895-5892	215-778-4278
Univ. Safety	Phil Leo	215-895-5909	215-768-1624
Univ. Safety	Diana Dukes	215-895-5907	215-778-4279
Radiation Safety	Kent Lambert	215-255-7860	215-651-2211
Facilities		215-895-2808	
Maintenance		215-895-2808	
Environmental Services		215-895-2808	

Center City Campus - Emergency Contact Numbers

Department	Name	Office Number	Mobile Number
Emergency Operator		80	
Emergency Room	HUH	215-762-7963	
Student Health		215-762-8590	
Occupational Health	Worknet	215-762-8590	
Univ. Safety	Jon Chase	215-895-5891	215-669-6122
Univ. Safety	Martin Bell	215-895-5892	215-778-4278
Univ. Safety	Phil Leo	215-895-5909	215-768-1624
Univ. Safety	Diana Dukes	215-895-5907	215-778-4279
Hospital Safety	Steve Morrissey	215-762-6133	
Radiation Safety	Kent Lambert	215-255-7860	215-651-2211
Facilities	Patricia Lewis	215-762-6500	215-783-2672
Security		215-762-7110	
Maintenance		215-762-3000	
Environmental Services		215-762-4700	

Queen Lane Campus - Emergency Contact Numbers

Department	Name	Office Number	Mobile Number
Public Safety		215-895-2222	
Student Health		215-895-5800	
Occupational Health	Worknet	215-762-8590	
Univ. Safety	Jon Chase	215-895-5891	215-669-6122
Univ. Safety	Martin Bell	215-895-5892	215-778-4278
Univ. Safety	Phil Leo	215-895-5909	215-768-1624
Univ. Safety	Diana Dukes	215-895-5907	215-778-4279
Radiation Safety	Kent Lambert	215-255-7860	215-651-2211
Facilities	Ray Stoffel	215-991-8484	215-651-1321
Security		215-991-8102	
Maintenance		215-991-8500	
Environmental Services		215-991-8500	

DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

Exhibit V-a
Classification of Human Etiologic Agents on the Basis of Hazard

This section includes those biological agents known to infect humans as well as selected animal agents that may pose theoretical risks if inoculated into humans. Included are lists of representative genera and species known to be pathogenic; mutated. Recombined, and non-pathogenic species and strains are not considered. Non-infectious life cycle stages of parasites are excluded. This section reflects the current state of knowledge and should be considered a resource document. Included are the more commonly encountered agents and is not meant to be all inclusive. Information on agent risk assessment may be found in the Agent Summary Statements of the CDC/NIH publication, Biosafety in Microbiological and Biomedical Laboratories. Further guidance on agents not here may be obtained through: Centers for Disease Control and Prevention, Biosafety Branch, Atlanta, Georgia 30333, Phone:(404) 639-3883, Fax: (4tz4) 639-2294; National institutes of Health, Division of Safety, Bethesda, Maryland 20892, Phone: (301) 496-1357; National Animal Disease Center, U.S. Department of Agriculture, Ames, Iowa 50010, Phone: (515) 862-8258.

Classification of Biohazardous Agents by Risk Group (RG)

Risk Group 1 (RG1)
Agents that are not associated with disease in healthy adult humans

Risk Group 2 (RG2)
Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available

Risk Group 3 (RG3)
Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk)

Risk Group 4 (RG4)
Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available (high individual risk and high community risk)

Risk Group 1 (RG1) Agents
RGI agents are not associated with disease in healthy adult humans. Examples of RGI agents include asporogenic Bacillus subtilis or Bacillus lichenifomlis, Escherichia coli-K12 and adeno-associated virus types I through 4.

Those agents not listed in Risk Groups (rgs) 2, 3 and 4 are not automatically or implicitly classified in RG l; a risk assessment must be conducted based on the known and potential properties of the agents and their relationship to agents that are listed.
Risk Group 2 (RG2) Agents

RG2 agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

Risk Group 2 (RG2) - Bacterial Agents including Chlamydia
--Acinetobacter baumannii (formerly Acinetobacter calcoaceticus)
--Actinobacillus
--Actinomyces pyogenes (formerly Corynebacterium pyogenes)
--Aeromonas hydrophila
--Amycolata autotrophica
--Archanobacterium haemolyticum (formerly Corynebacterium haemolyticum)
--Arizona hinshawii - all serotypes
--Bacillus anthracis
--Bartonella henselae, B. Quintana, B. Vinsomi
--Bordetella including B. Pertussis
--Borrelia recurrentis, B. Burgdorferi
--Burkholderia (formerly Pseudomonas species)
--Campylobacter coli, C. Fetus, C. Jejuni
--Chlamydia psittaci, C. Trachomatis, C. Pneumoniae
--Clostridium botulinum, Cl. Chauvoei, Cl. Haemolyticum, Cl. Histolyticum, Cl. Novyi, Cl. Septicum, Cl. Tetani
--Corynebacterium diphtheriae, C. Pseudotuberculosis, C. Renale
--Dermatophilus congolensis
--Edwardsiella tarda
--Erysipelothrix rhusiopathiae
--Escherichia coli - all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including E coli 0157:H7
--Haemophilus ducreyi, H. Influenzae
--Helicobacter pylori
--Klebsiella- all species except K. Oxytoca (RGI)
--Legionella including L. Pneumophila
--Leptospira interrogans - all serotypes
--Listeria --Moraxella
--Mycobacterium including M. Avium complex, M. Asiaticum, M. Bovis BCG vaccine strain, M. Chelonei, M. Fortuitum, M. Kansasii, M. Ieprae, M. Malmoense, M. Marinum, M. Paratuterculosis, M. Scrofulaceum, M. Simiae, M. Szulgai, M. Ulcerans, M. Xenopi
--Mycoplasma, except M. Mycoides and M. Agalactiae which are restricted animal pathogens
--Neissena gonorrhoeae, N. Meningitidis
--Nocardia asteroides, N. Brasiliensis, N. Otitidiscaviarum, N. Transvalensis
--Rhodococcus equi
--Salmonella including S. Arizonae, S. Cholerasuis, S. Ententidis, S. Gallinarum-pullorum, S. Meleagridis, S. Paratyphi, A, B. C, S. Typhi, S. Typhimurium
--Shigella including S. Boydii, S. Dysenteriae, type 1, S. Flexneri, S. Sonnei
--Sphaerophorus necrophorus
--Staphylococcus aureus
--Streptobacillus moniliformis - Streptococcus including S. Pneumoniae, S. Pyogenes
--Treponema pallidum, T. Carateum
--Vibrio cholerae, V. Parahemolyticus, V. Vulnificus

--Yersinia enterocolitica

Risk Group 2 (RG2) - Fungal Agents
--Blastomyces dermatitidis
--Cladosponum bautianum, C. (Xylohypha) trichoides
--Cryptococcus neoformans
--Dactylaria galopava (Ochroconis gallopavum)
--Epidermophyton
--Exophiala (Wangiella) dermatitidis
--Fonsecaea pedrosoi
--Microsporum
--Paracoccidioides brazi liensis
--Penicillium mameffei
--Sporothrix schenckii
--Tnchophyton

Risk Group 2 (RG2) - Parasitic Agents
--Ancylostoma human hookworms including A duodenale, A. Ceylanicum
--Ascaris including Ascaris lumbricoides suum
--Babesia including B. Divergens, B. Microti
--Brugia filaria worms including B. Malayi, B. Timori
--Coccidia
--Cryptosporidium including C. Parvum
--Cysticercus cellulosae (hydatid cyst, larva of T. Solium)
--Echinococcus including E. Granulosis, E. Multiloculans, E. Vogeli
--Entamoeba histolytica
--Enterobius
--Fasciola including F. Gigantica, F. Hepatica
--Giardia including G. Lamblia
--Heterophyes
--Hymenolepis including H. Diminuta, H. Nana
--Isospora
--Leishmania including L braziliensis, L. Donovani, L. Ethiopia, L. Major, L. Mexicana, L. Peruvania, L. Tropica --Loa loa filaria worms
--Microspondium
--Naeglena fowlen
--Necator human hookworms including N. Amencanus
--Onchoerca filaria worms including, O. Volvulus
--Plasmodium including simian species, P. Cynomologi, P. Falciparum, P. Malariae, P. Ovale, P. Vivax
--Sarcocystis including S. Sui hominis
--Schistosoma including S. Haematobium, S. Intercalatum, S. Japonicum.S. Mansoni, S. Mekongi
--Strongyloides including S. Stercoralis
--Taenia solium
--Toxocara including T. Canis
--Toxoplasma including T. Gondii
--Trichinella spiralis

--Trypanosoma including T. Brucei brucei, T. Brucei gambiense, T. Brucei rhodesiense, T. Cruzi
--Wuchereria bancrofti filaria worms

Risk Group 2 (RG2) - Viruses
Adenoviruses, human - all types

Alphaviruses (Togaviruses) - Group A Arboviruses
--Eastern equine encephalomyelitis virus
--Venezuelan equine encephalomyelitis vaccine strain TC-83
--Western equine encephalomyelitis virus

Arenaviruses
--Lymphocytic chonomeningitis virus (non-neurotropic strains)
--Tacaribe virus complex
--Other viruses as listed in the reference source

Bunyaviruses
-Bunyamwera vinus
--Rib Valley fever virus vaccine strain MP-12
--Other viruses as listed in the reference source

Cal civiruses

Coronaviruses

Flaviviruses (Togaviruses) - Group B Arboviruses
--Dengue virus serotypes 1, 2, 3, and 4
--Yellow fever virus vaccine strain 17D
--Other viruses as listed in the reference source

Hepatitis A, B. C, D, and E viruses

Herpesviruses - except Herpesvirus simiae (Monkey B virus)
--Cytomegalovirus
--Epstein Banr virus
--Herpes simplex types I and 2
--Herpes zoster
--Human herpesvirus types 6 and 7

Orthomyxoviruses
--Influenza viruses types A, B. And C
--Other tick-borne orthomyxoviruses as listed in the reference source

Papovaviruses
--All human papilloma viruses

Paramyxoviruses

--Newcastle disease virus
--Measles virus
--Mumps virus
--Parainfluenza viruses types 1, 2, 3, and 4
--Respiratory syncytial virus

Parvoviruses
--Human parvovirus (Bl9)

Picornaviruses
--Coxsackie viruses types A and B
--Echoviruses - all types
--Polioviruses - all types, wild and attenuated
--Rhinoviruses - all types

Poxviruses - all types except Monkeypox virus and restricted poxviruses including Alastrim, Smallpox, and
Whitepox

Reoviruses - all types including Coltivirus, human Rotavirus. And Orbivirus (Colorado tick fever virus)

Rhabdoviruses
--Rabies virus - all strains
--Vesicular stomatitis virus - laboratory adapted strains including VSV-Indiana, San Juan, and Glasgow
Togaviruses (see Alphaviruses and Flaviviruses)
--Rubivirus (rubella)

Risk Group 3 (RG3) Agents
RG3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.

Risk Group 3 (RG3) - Bacterial Agents Including Rickettsia
--Bartonella
--Brucella including B abortus, B. Canis, B. Suis
--Burkholderia (Pseudomonas) mallei, B. Pseudomallei
--Coxiella burnetii
--Francisella tularensis
--Mycobacterium bovis (except BCG strain, Risk Group 2 (RG2) - Bactenal Agents including Chlamydia),
M. Tuberculosis
--Pasteurella multocida type B -"buffalo" and other virulent strains
--Rickettsia akari, R. Australis, R. Canada, R. Conorii, R. Prowazekii, R. Nckettsii. R. Sibenca, R.
Tsutsugamushi, R. T phi (R. Moosen)
--Yersinia pestis

Risk Group 3 (RG3) - Fungal Agents
--Coccidioides immitis (sporulating cultures; contaminated soil)
--Histoplasma capsulatum, H. Capsulatum var.. Duboisii

Risk Group 3 (RG3) - Parasitic Agents
None

Risk Group 3 (RG3) - Viruses and Prions
Alphaviruses (Togaviruses) - Group A Arboviruses
--Semliki Forest virus
—St. Louis encephalitis virus
--Venezuelan equine encephalomyelitis virus (except the vaccine strain TC-83)

Arenaviruses
--Flexal
--Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)

Bunyaviruses
--Hantaviruses including Hantaan virus
--Rift Valley fever virus

Flaviviruses (Togaviruses) - Group B Arboviruses
--Japanese encephalitis virus
--Yellow fever virus
--Other viruses as listed in the reference source

Poxviruses
--Monkeypox virus

Prions
--Transmissible spongioform encephalopathies (TME) agents (Creutzfeldt-Jacob disease and kuru agents)

Retroviruses
--Human Immunodeficiency virus (HIV) types 1 and 2
--Human T. Cell lymphotropic virus (HTLV) types 1 and 2
--Simian immunodeficiency virus (SIV)

Rhabdoviruses
--Vesicular stomatitis virus

Risk Group 4 (RG4) Agents
RG4 agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

Risk Group 4 (RG4) - Bacterial Agents
None

Risk Group 4 (RG4) - Fungal Agents
None

Risk Group 4 (RG4) - Parasitic Agents
None

Risk Group 4 (RG4) - Viral Agents
Arenaviruses
--Guananto virus
--Lassa virus
--Junin virus
--Machupo virus
--Sabia

Bunyaviruses (Nairovirus)
--Crimean-Conoo hemorrhagic fever virus

Filoviruses
--Ebola virus

--Marburg virus

Flaviruses (Togaviruses) - Group B. Arboviruses
--Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian spring-summer encephalitis viruses

Herpesviruses (alpha)
--Herpesvirus simiae (Herpes B or Monkey B virus)

Paramyxoviruses
--Equine morbillivirus

Hemorrhagic fever agents and viruses as yet undefined

Animal Viral Etiologic Agents in Common Use

The following list of animal etiologic agents is appended to the list of human etiologic agents. None of these agents is associated with disease in healthy adult humans; they are commonly used in laboratory experimental work. Acontainment level appropriate for RGI human agents is recommended for their use. For agents that are infectious to human cells,

e.g., amphotropic and xenotropic strains of murine leukemia virus, a containment level appropriate for RG2 human agents is recommended.

Baculoviruses

Herpesviruses
--Herpesvirus ateles
--Herpesvirus saimiri
--Marek's disease virus
--Murine cytomegalovirus

Papovaviruses
--Bovine papilloma virus
--Polyoma virus
--Shope papilloma virus
--Simian virus 40 (SV40)

Retroviruses
--Avian leukosis virus
--Avian sarcoma virus
--Bovine leukemia virus
--Feline leukemia virus
--Feline sarcoma virus
--Gibbon leukemia virus
--Mason-Pfizer monkey virus
--Mouse mammary tumor virus
--Murine leukemia virus
--Murine sarcoma virus
--Rat leukemia virus

Murine Retroviral Vectors
Murine retroviral vectors to be used for human transfer experiments (less than 10 liters) that contain less than 50% of their respective parental viral genome and that have been demonstrated to be free of detectable replication competent retrovirus can be maintained, handled, and administered, under BLI containment.

DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

Exhibit V-b:
Importation Permits for Etiologic Agents

Centers for Disease Control and Prevention
Office of Health and Safety/Biosafety
Date Last Rev'd: March 9, 1995

GENERAL

If you question whether your situation requires an importation permit, the safe alternative is to complete the application and let us make the decision. CDC's Department of Biosafety tries to process applications within 10 working days.

INTRODUCTION

Etiologic agents are those microorganisms that cause disease in humans and include bacteria, bacterial toxins, viruses, fungi, rickettsia. Protozoans, and parasites. These disease causing microorganisms may also be referred to as infectious agents or infectious substances and the materials, such as body fluids and tissues that contain them, are referred to as infectious materials. Organisms such as mosquitoes that may transmit infectious diseases to other humans are called vectors.

Etiologic agents and the vectors and other materials that may contain them, are recognized by the federal government and state governments as hazardous materials. Infectious materials are regularly transported from one location to another by common land and air carriers . Containers of infectious materials must be carefully packaged to prevent breakage or leakage to avoid exposure of the package handlers, transporters, and the general public to the package contents. The package must be labeled with the universal biohazard sign to warn package handlers of the hazardous contents. When a package of infectious material is being imported into the United States it should be accompanied by an importation permit.

IMPORTATION PERMITS

Many etiologic agents, infectious materials or vectors containing infectious agents are imported from foreign locations into the United States for domestic use and study. Packages containing etiologic agents originating in these foreign locations must have an importation permit issued by the United States Public Health Service. Importation permits are issued only to the importer, who must be located in the United States. The importation permit, with the proper packaging and labeling, will expedite clearance of the package of infectious materials through the United States Public Health Service Division of Quarantine and release by U.S. Customs.

The importer bears responsibility for assuring that the foreign shipping personnel pack and label the infectious materials according to USPHS regulations. Transfers of previously imported material within the U.S. also require a permit for the same reason.

Shipping labels containing the universal biohazard symbol, the address of the importer, the permit number, and the expiration date, are also issued to the importer with the permit. The importer must send the labels and one or more copies of the permit to the shipper. A label must be secured to each package, and a copy of the permit should also be attached to the package. The permit and labels inform the U.S. Customs Service and U.S. Division of Quarantine Personnel of the package contents.

FEDERAL REGULATION

The importation of etiologic agents is governed by the following federal regulation:

USPHS 42 CFR - Pan 71 Foreign Quarantine. Pan 71.54 Etiologic agents, hosts, and vectors.

A. A person may not import into the United States, nor distribute after importation, any etiologic agent or any arthropod or other animal host or vector of human disease. Or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director.

B. Any import coming within the provisions of this section will not be released from custody prior to receipt by the Port Director of U.S. Customs Service of a permit issued by the Director (Centers for Disease Control and Prevention).

See Appendix A for actual text.

ITEMS REQUIRING PERMITS

Etiologic agents

It is impractical to list all of the several hundred species of etiologic agents. In general, an import permit is needed for any infectious agent known to cause disease in man. This includes, but is not limited to, bacteria, viruses, rickettsia, parasites, yeasts and molds. In some instances, agents which are suspected of causing human disease also require a permit.

Biological materials

Unsterilized specimens of human and animal tissue (including blood), body discharges, fluids, excretions or similar material. When known or suspected of being infected with disease transmissible to man require a permit under these provision in order to be imported.

Animals

Any animal known or suspected of being infected with any disease transmissible to man. Importation of turtles of less than 4 inches in shell length and all non-human primates requires an importation permit issued by the Division of Quarantine. Telephone (404) 639-1437 for further information.

Insects

Any living insect, or other living arthropod, known or suspected of being infected with any disease transmissible to man. Also, if alive, any fleas, flies, lice, mites, mosquitoes, or ticks, even if uninfected. This includes eggs, larvae, pupae, and nymphs as well as adult forms.

Snails

Any snails capable of transmitting schistosomiasis. No mollusks are to be admitted without a permit from either Centers for Disease Control and Prevention or the Department of Agriculture. Any shipment of mollusks with a permit from either agency will be cleared immediately.

Bats

All live bats. Bats may also require a permit from the U.S. Department of Interior, Fish and Wildlife Services.

LETTERS OF AUTHORIZATION

After review of an "Application to Import an Etiological Agent" the issuing of officer may issue a "Letter Authorization" rather than an importation permit. The Letter of Authorization is issued for materials that are judged to be non-infectious, but which might be construed to be infectious by U.S. Customs inspection personnel.

Letters of Authorization may be issued for items such as formalin fixed tissues, sterile cell cultures, clinical materials such as human blood, serum, plasma, urine, cerebrospinal fluid, and other tissues or materials of human origin when there is no evidence or indication that such materials contain an infectious agent.

A copy of a Letter of Authorization should be attached to the package, and also should be furnished to the courier or importation broker. Letters of Authorization are in effect for two years, and do not require a shipping label to be issued by this office.

PACKAGING REQUIREMENTS

Infectious materials imported into this country must be packaged to withstand breakage and leakage of contents, and labeled, as specified in the following federal regulations: USPHS 42 CFR Pan 72 - interstate Shipment of Etiologic Agents. DOT 49 CFR PART 173 - Transportation of Etiologic Agents

For international shipments, the international Air Transport Association (IATA) Dangerous Goods Regulations should be consulted.

OTHER PERMITS

United States Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) permits are required for infectious agents of livestock and biological materials containing animal, particularly livestock material.

Tissue (cell) culture techniques customarily use bovine material as a stimulant for cell growth. Tissue culture materials, and suspensions of cell culture grown viruses or other etiologic agents containing growth stimulants of bovine or other livestock origin are, therefore, controlled by the USDA due to the potential risk of introduction of exotic animal diseases into the U.S. Further information may be obtained by calling the USDA/APHIS at (301) 436-7885.

United States Department of Interior (USDI) permits are required for certain live animals and all live bats. Call (800) 358-2104 for further information.

EXPORTS OF INFECTIOUS MATERIALS

The export of infectious material may require a license from the Department of Commerce. Call (202) 482-0896 for further information.

Centers for Disease Control and Prevention
Of five of Health and Safety
Biosafety Branch
1600 Clifton Road l MS F-05
Atlanta, Georgia 30333
Phone (404) 639-3235 FAX (404) 639-2294

Completing the "Application to import or Transport Agents or Vectors of Human Disease"

INTRODUCTION

Importation permits and Letters of Authorization are issued by the Biosafety Branch, Office of Health and Safety, Centers for Disease Control and Prevention after review of a completed application form An application form may be obtained from the Fax information System [404 639-3883] and requesting document # 101001. (For the entire Application Package, request document #101000). Completed application forms may be returned to the Biosafety Branch by mail or FAX.

Application for the importation permit should be made 10 working days in advance of the shipment date to allow time for processing, issuance and delivery of the permit and shipping labels to the permittee.

Application forms may be handwritten or typed. Handwritten forms must be readable. Unreadable forms or incomplete information will delay permit issuance. If more space is needed for a block, use additional sheet(s). Noting the block number.

BLOCK I

The person requesting the permit (applicant) should be (1) knowledgeable and skilled in the handling of the infectious agent or biological material, (2) be directly responsible for work with the infectious material, and (3) should be located at the address within the U.S. where work with the infectious material will be performed. Regulatory affairs of fixers or other general administrative personnel are generally not acceptable as permittees.

Enter your complete name and address. Failure to include the telephone and FAX numbers where you can be reached during the day will result in prolonged delays if we have to contact you. The name appearing in this block, and in Block 10 should be the same. One or more names may be used here. For each name used in Block 1, there must be a corresponding signature in Block 10.

BLOCK 2

Enter complete name and address of the sender. Multiple sources may be listed on an attached sheet as needed. Indicate which source is supplying which infectious material.

BLOCK 3

Complete as indicated. This block determines whether a permit or a Letter of Authorization will be issued. Importation permits will be issued for infectious agents or materials known, or suspected, to contain infectious materials.

Letters of Authorization will be issued for biological materials that are not infectious. Please state here if the material is not infectious.

Owe will issue both infectious agents and Letters of Authorizations to the same person if needed and requested.

BLOCK 4

An importation into the U.S. refers to the package as passing through the Port of entry to the applicant's address.

Moving imported material from one air carrier to another at the Point of Entry on the way to its domestic destination is not considered a transfer for the purposes of this permit. A transfer within the U.S. refers to shipping from one address within the U.S. to another address within the U.S.

Permits for single importations are valid for six months. Permits for multiple importations are valid for one year. Letters of Authorization are valid for two years.

For multiple shipments, enter the number of shipments you expect to receive in the next 12 months. One importation label is issued per shipment.

BLOCK 5 - Complete as specified

BLOCK 6 - Complete as specified

BLOCK 7

In describing objectives. Please state the intended use(s): infectious disease research or diagnosis, genetic studies or analysis, chemical or biochemical analysis, enzyme assays, population profiles, hit development, etc.

BLOCK 8

Explain the biosafety level of the laboratory where the work will occur and any other information pertinent to available facilities.

BLOCK 9 - Complete as specified

BLOCK 10

Remember to sign the form before it is FAXED or mailed. The signature (block 10) should be by the person requesting the permit (Block 1). Type or print the name(s) in the "applicant" section of the person(s) who signs in the "signature" section.

U.S. Department of Health and Human Services
Form Approved Public Health Service OMB No. 0920 0199
Centers for Disease Control and Prevention CDC 0.753 (formerly 13.29)
Office of Health and Safety F05 Rev. 9
Atlanta, Georgia 30333
Fax information System: 404 639-3883

Appendix A

Importation Permit Federal Regulation
Federal Register Vol. 50 No. 8/ Friday, January 11, 1985
Rules and Regulations
Department of Health and Human Services
Public Health Service 42 CFR Part 71
Foreign Quarantine
Agency: Centers for Disease Control and Prevention, Public Health Service, HHS
Action: Final Rule

SUMMARY: This rule amends the regulations in 42 CFR Part 71 necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. In 1967, the public Health Service was reorganized and the Quarantine

Program was transferred to the Centers for Disease Control and Prevention (CDC). Since the transfer, the Quarantine Program has been modernized and streamlined The regulations have been updated to reflect current concepts of disease surveillance, investigation, and control.

EFFECTIVE DATE: February 11, 1985.

Part 71.54 Etiological agents, hosts, and vectors

A. A person may not import into the United States, nor distribute after importation, any etiological agent or any arthropod or other animal host or vector of human disease, or any exotic living arthropod or other animal capable of being a host or vector of human disease unless accompanied by a permit issued by the Director.

B. Any import coming within the provisions of this section will not be released from custody prior to receipt by the District Director of the U.S. Customs Service of a permit issued by the Director.

Part 71.55 Dead Bodies

The remains of a person who died of a communicable disease listed in 71.32 may not be brought into a U.S. port unless the body is (a) properly embalmed and placed in a hermetically sealed casket, (b) cremated or (c) accompanied by a permit issued by the Director.

Exhibit V-c

Biological Materials Shipping Guide

Last Modified: January 2009

TABLE OF CONTENTS

CLASSIFICATION DEFINITIONS

Patient Specimens

Patient specimens are those collected directly from humans or animals, including, but not limited to excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

Infectious Substances

Infectious substances are substances which are known or reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

Note: Classification of infectious substances must be based on known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgment concerning individual circumstances of the source human or animal.

- **Category A:** An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.

- **Category B:** An infectious substance which does not meet the criteria for inclusion in Category A.

Genetically Modified Microorganisms and Organisms

Genetically modified micro-organisms (GMMOs) and genetically modified organisms (GMOs) are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

Genetically modified organisms and micro-organisms which meet the definition of infectious substances (e.g., can cause disease in humans or animals) must be classified as infectious substances.

SHIPPING SUMMARY TABLE

Shipment Classification	Proper Shipping Name	UN Number	Hazard Class	Packing Group	Packing Instruction (PI)	Hazard Label	Max. Net Quantity per Package for Passenger Aircraft	Max. Net Quantity per Package for Cargo Aircraft	Special Provisions (**)
Category A infectious substance, affecting humans	Infectious substance, affecting humans, (*)	UN 2814	6.2	-	602	Infectious substance	50mL / 50g	4L / 4 kg	A81, A140
Category A infectious substance, affecting animals	Infectious substance, affecting animals, (*)	UN 2900	6.2	-	602	Infectious substance	50mL / 50g	4L / 4kg	A81, A140
Category B infectious substance	Biological substance, category B	UN 3373	6.2	-	650	UN 3373	4L / 4kg	4L / 4kg	-
Genetically modified micro-organisms & organisms (non-infectious)	Genetically modified micro-organisms	UN3245	9	-	913	Miscellaneous	No Limit	No Limit	A47
Patient Specimens	Exempt human specimen *or* Exempt animal specimen	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Dry Ice	Dry Ice	UN 1845	9	III	904	Miscellaneous	200kg	200kg	A48

*** Identify technical name of agent in parenthesis**

**** Special Provisions:**

A81 – The quantity limits do not apply to body parts, organs or whole bodies. Transport in accordance with this Special Provision must be noted on the Shipper's Declaration for Dangerous Goods.

A47 – Genetically modified micro-organisms and genetically modified organisms, which meet the definition of an infectious substance and the criteria for inclusion in Division 6.2, must be transported as UN 2814, UN 2900 or UN 3373, as appropriate.

A48 – Packaging tests are not considered necessary.

A140 – For the purposes of documentation, the proper shipping name must be supplemented with the technical name. Technical names need not be shown on the package. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in Category A and assigned to UN 2814 or UN 2900, the words "suspected category A infectious substance" must be shown, in parentheses, following the proper name on the Shipper's Declaration of Dangerous Goods, but not on the outer packagings.

Patient Specimens
Checklist

Definition: Patient specimens are those collected directly from humans or animals, including, but not limited to excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

Note: This only includes specimens for which there is minimal likelihood that pathogens are present.

Specimen Packaging:

___ A leak-proof primary receptacle(s)
___ A leak-proof secondary packaging
___ An outer packaging of adequate strength for its capacity, mass and intended use, and withat least one surface having minimum dimensions of 100mm x 100mm

- For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material

- When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them

Labeling Outer Container:

___ Marked with the words "*Exempt human specimen*" or "*Exempt animal specimen*", as appropriate

Completing the Airbill:

___ Name and address of shipper and recipient
___ Check "Saturday Deliver" box if applicable
___ In Section 6 (Special Handling) of the airbill, indicate that the shipment is NOT a dangerous good
___ Shipper's signature (optional)

Note: In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions.

Examples:

- Blood or urine tests to monitor cholesterol levels, blood glucose levels, or hormone levels
- Tests required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases
- Biopsies to detect cancer
- Antibody detection in humans or animals

Category A Infectious Substances

Checklist: Packing Instruction 602

Specimen Packaging

___ Watertight primary receptacle(s)
___ A watertight secondary packaging
___ Other than for solid infectious substances, absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated so as to prevent contact between them
___ An itemized list of contents, enclosed between the secondary packaging and the outer packaging
___ A rigid outer packaging of adequate strength for its capacity, weight and intended use. The smallest external dimension must be not less than 100 mm (4 in.).

Note: Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa and temperatures in the range of -40°C to 55°C (-40°F to 130°F).

Labeling Outer Container

___ Class 6 Infectious Substance label
___ *"Infectious Substance, Affecting Humans, UN 2814"* or *"Infectious Substance, Affecting Animals, UN 2900"* and net quantity of infectious substance
___ Name and telephone number of a person responsible (marked durably and legibly)
___ If shipment includes > 50mL or 50g of a Category A infectious substance, then add a *"Danger, Do Not Load On Passenger Aircraft"* label to the outer container

Note: If packaged with dry ice, include Miscellaneous Class 9 label, UN 1845 and net weight (kg) of dry ice.

Dangerous Goods Declaration Form

___ Name, address and telephone number of shipper and recipient
___ Mark out the non-applicable "Aircraft Box"
___ Mark out the non-applicable "Radioactive" box
___ "Nature and Quantity of Dangerous Goods" section of Declaration Form – complete this section using information provided in SHIPPING SUMMARY TABLE
___ 24-hour emergency response telephone number
___ Name and title of signatory, place, and date
___ Shipper's signature

PI 602 (2007 Change) – Revised to add provision for a quantity of 30 mL or less of dangerous goods in Classes 3, 8 or 9 to be permitted in each primary receptacle containing infectious substances when used to maintain viability, stabilize or prevent degradation or neutralize the hazard of the infectious substances.

Category B Infectious Substances
Checklist: Packing Instruction 650

Specimen Packaging

___ The primary receptacle(s) must be leakproof and must not contain more than 1 L
___ The secondary packaging must be leakproof
___ If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them
___ Absorbent material must be placed between the primary receptacle and the secondary packaging. The absorbent material must be in sufficient quantity to absorb the entire contents of the primary receptacle(s)
___ An itemized list of contents must be enclosed between the secondary packaging and the outer packaging
___ At least one surface of outer packaging must have a minimum dimension of 100mm x 100mm (4in. x 4in.)

Note: The outer packaging must not contain more than 4L or 4kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep the specimens cold.

Labeling Outer Container

___ Name and address of the shipper and recipient
___ Name, and telephone number of a person responsible must be provided on the air waybill or on the package
___ "UN 3373" label must be displayed on a background of a contrasting color and clearly visible and legible
___ Statement *"BIOLOGICAL SUBSTANCE, CATEGORY B"* adjacent to UN 3373 label

Note: If packaged with dry ice, include Miscellaneous Class 9 label, UN 1845 and net weight (kg) of dry ice.

Completing the Airbill

___ Name and address of the shipper and recipient
___ Name, and telephone number of a person responsible must be provided on the air waybill or on the package
___ The "Nature and Quantity of Goods" box should show "UN 3373" and the text *"BIOLOGICAL SUBSTANCE, CATEGORY B"*
___ Shipper's signature (optional)

Note: A Shipper's Declaration for Dangerous Goods in not required.

PI 650 (2007 Change) – Revised to add provision for a quantity of 30 mL or less of dangerous goods in Classes 3, 8 or 9 to be permitted in each primary receptacle containing infectious substances when used to maintain viability, stabilize or prevent degradation or neutralize the hazard of the infectious substances.

Genetically Modified Micro-organisms
Checklist: Packing Instruction 913

Specimen Packaging

___ Watertight primary receptacle(s)
___ A watertight secondary packaging
___ Other than for solid infectious substances, absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated so as to prevent contact between them.
___ An itemized list of contents, enclosed between the secondary packaging and the outer packaging
___ A rigid outer packaging of adequate strength for its capacity, weight and intended use. The smallest external dimension must be not less than 100 mm (4 in.).

Labeling Outer Container

___ Name and address of shipper and recipient
___ Miscellaneous Class 9 label
___ *"Genetically Modified Microorganisms, UN 3245"*, and net quantity
___ Name and telephone number of a person responsible (marked durably and legibly)

Note: If packaged with dry ice, include UN 1845 and net weight (kg) of dry ice.

Dangerous Goods Declaration Form

___ Name, address and telephone number of shipper and recipient
___ Mark out the non-applicable "Aircraft Box"
___ Mark out the non-applicable "Radioactive" box
___ "Nature and Quantity of Dangerous Goods" section of Declaration Form – complete this section using information provided in SHIPPING SUMMARY TABLE
___ 24-hour emergency response telephone number
___ Name and title of signatory, place, and date
___ Shipper's signature

Carbon Dioxide, Solid (Dry Ice)
Checklist: Packing Instruction 904

Specimen Packaging:

___ Dry ice must be in packaging designed and constructed to permit the release of carbon dioxide gas and to prevent a build-up of pressure that could rupture the packaging.

___ Arrangements between shipper and operator(s) must be made for each shipment, to ensure ventilation safety procedures are followed.

Labeling Outer Container:

___ Class 9 label

___ Proper shipping name (**Dry ice** or **Carbon dioxide, solid**)

___ UN 1845

___ Net weight used in "kg" units

Completing the Airbill:

The Shipper's Declaration requirements are only applicable when the dry ice is used as a refrigerant for dangerous goods that require a Shipper's Declaration.

When a Shipper's Declaration is not required, the following information should be contained in the "Nature and Quantity of Goods" box on the air waybill:

___ UN 1845

___ Proper shipping name (**Dry ice** or **Carbon dioxide, solid**)

___ Class 9 label

___ Number of packages

___ Net quantity of dry ice in each package

SHIPPING LABELS

Class 6 Label – Infectious Substance

Class 9 Label – Dry Ice

"Danger, Do Not Load on Passenger Aircraft" Label

UN 3373 Label – Biological Substance, Category B

Completing Dangerous Goods Declaration
Top-Half of Form

SHIPPER'S DECLARATION OF DANGEROUS GOODS

<table>
<tr><td colspan="2">Shipper

A</td><td>Air Waybill No.

Page of Pages

Shipper's Reference Number</td></tr>
<tr><td colspan="2">Consignee

B</td><td></td></tr>
<tr><td colspan="2">Two completed and signed copies of this Declaration must be handed to the operator

TRANSPORT DETAILS</td><td rowspan="2">WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.</td></tr>
<tr><td>This shipment is within the limitations prescribed for: (delete non-applicable)

PASSENGER AND CARGO AIRCRAFT | CARGO AIRCRAFT ONLY

C</td><td>Airport of Departure</td></tr>
<tr><td>Airport of Destination</td><td colspan="2">Shipment type: (delete non-applicable) D

NON-RADIOACTIVE | RADIOACTIVE</td></tr>
</table>

A – Shipper: Enter your full name, address and telephone number.

B – Consignee: Enter full name and address of recipient. When shipping infectious substances, include the text, "Person responsible:" plus his/her name and telephone number at the bottom of "Consignee" box.

C – Transport Details: Indicate here if your shipment is restricted to cargo aircraft only (i.e. if it is > 50mL or 50g of a Category A infectious substance). Using the capital letter "X", enter X's to block out "Passenger and Cargo Aircraft Only" (for shipments which must travel on Cargo Aircraft Only) or to block out "Cargo Aircraft Only" (for shipments which may travel on either Passenger or Cargo aircraft).

D – Shipment Type: Using the capital letter "X", enter X's to block out "NON-RADIOACTIVE" (for shipments which contain radioactive material) or to block out "RADIOACTIVE" (for shipments which do not contain radioactive material).

Completing Dangerous Goods Declaration
Bottom-Half of Form

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification				Quantity and Type of Packaging	Packing Instructions	Authorization
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group			
E	**F**	**G**	**H**	**I**	**J**	**K**
Additional Handling Information **L** Emergency Telephone Number						
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable International and National Governmental Regulations. I declare that all of the applicable air transport requirements have been met.				Name / Title of Signatory Place and Date **M** Signature *(see warning above)*		

E – UN or ID Number: Enter the appropriate UN number (i.e. UN 2814 or UN 3245)

F – Proper Shipping Name: Enter the proper shipping name with the technical name in parentheses – i.e. "Infectious substance, affecting humans (Hepatitis B virus)".

G – Class or Division: Enter appropriate hazard class (i.e. "6.2" or "9")

H – Packing Group: For dry ice, enter "III" in this column. Biological materials are not assigned packing groups.

I – Quantity and Type of Packaging: Enter the net quantity for each material here. Use only metric units. At the bottom of this column, indicate the number and type of packages used (usually, "All packed in one fibreboard box"). Do not spell like "fiberboard". If using an overpack, indicate here with "Overpack Used".

J – Packing Instructions: Enter appropriate packing instruction number. The packing instruction for infectious substances is 602. The packing instruction for dry ice is 904. The packing instruction for genetically modified micro-organisms or organisms is 913.

K – Authorization: Note any Special Provisions, if applicable (i.e. if you choose to not include the technical name for an infectious substance on the outer package, you must list A140 in this column).

L – Additional Handling Information: In the space following "Emergency Telephone Number" include a 24-hour emergency telephone response number where the shipper can be reached.

M – Sign and date each copy of your Shipper's Declaration.

Manufacturers

Certified Shipping Containers & Labels

Air Sea Atlanta 1234 Logan Circle Atlanta, GA 30318 Phone: 404-351-8600 http://www.airseaatlanta.com/	**All-Pak** Corporate One West 1195 Washington Pike Bridgeville, PA 15017 Phone: 800-245-2283 http://www.all-pak.com/
DG Supplies, Inc 4 Corporate Drive Suite D, Bldg. 4 Cranbury, NJ 08512 http://www.dgsupplies.com/	**EXAKT-PAK** 7002 N. Broadway Extension Oklahoma City, OK 73116 Phone: 405.848.5800 | 800.866.7172 http://www.exaktpak.com/
Inmark, Inc. 675 Hartman Road, Suite 100 Austell, GA 30168 Phone: 770-373-3300 / 800-646-6275 http://www.inmarkinc.com/	**Centurion Scientific** 1740 Fenpark Drive Fenton, MO 63026 USA Phone: 636-349-1261 / 800-962-8636 http://www.jitcertified.com/
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DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

Exhibit V-d
Final Rule: Additional Requirements for Facilities Transferring or Receiving Select Agents

This section is a summary of the Final Rule, as stated in the Federal Register 42 CFR Part 72

SUMMARY

On June 10, 1996, the Centers for Disease and Prevention (CDC), the Department of Health and Human Services (HHS), issued a Notice of Proposed Rulemaking (NPRM) to implement Section 511 of Public Law 104-132, "The Antiterrorism and Effective Death Penalty Act of 1996," which requires the Secretary of HHS to regulate the transfer of select agents. CDC requested comments on the NPRM and provided 30 days for individuals to submit their written comments. CDC considered the comments received and is issuing this final regulation in light of those comments. Current regulations specify requirements for the packaging, labeling, and transport of select agents shipped in interstate commerce. This final rule places additional shipping and handling requirements on facilities that transfer or receive select agents listed in the rule that are capable of causing substantial harm to human health.

EFFECTIVE DATE

April 15, 1997. Incorporation by reference of certain publications listed in the final rule is approved by the Director of the Federal Register as of October 24, 1996 . All transfers of select agents must comply with the complete documentation and registration requirements contained in this final rule on or after April 15, 1997. CDC has already begun efforts to inform and educate affected parties about the registration and transfer process for select agents. Within the next 60 days, CDC anticipates providing additional detailed information to interested parties in order to initiate the registration process.

FOR FURTHER INFORMATION CONTACT Dr. Jonathan Y. Richmond, Director, Office of Health Safety, Centers for Disease Control and Prevention, 1600 Clifton Road, Mail stop FO5, Atlanta, GA 30333; telephone (404) 639-2453.

SUPPLEMENTARY INFORMATION

This rule finalizes the rule entitled "Additional Requirements for Facilities Transferring or Receiving Select Infectious Agents," which was published in the Federal Register on June 10, 1996 (61 FR 29327). It has been retitled, "Additional Requirements for Facilities Transferring or Receiving Select Agents."

Section 5 11 of Public Law 104-132, enacted on April 24, 19965 stipulated that HHS issue a proposed regulation within 60 days and a final regulation within 120 days. The NPRM was published on June 10 (13 days earlier than required) and provided 30 days for public review and comment. The subject matter, and subsequent comments responding to the

NPRM, raised highly- complex issues that demanded careful consideration and significant discussion with numerous other involved Federal agencies Thus, the publication of this final rule extended beyond 120 days.

Description

The Antiterrorism and Effective Death Penalty Act of 1996 (Public Law 104 132) authorizes the Secretary of Health and Human Services (HHS) to regulate the transfer of certain agents harmful to humans. The Centers for Disease Control and Prevention (CDC) is the agency within the Department responsible for promulgating this regulation This rule is designed to ensure that select agents are not shipped to parties who sue not equipped to handle them appropriately, or who otherwise lack proper authorization for their requests, and to implement a system whereby scientists in research institutions may continue transferring and receiving these agents without undue burdens. Respondents include facilities such as those operated by government agencies, universities, research institutions, and commercial entities.

Those facilities requesting select agents listed in the regulation must register with the Secretary of HHS, or with registering entities authorized by the Secretary, as capable and equipped to handle the select agents in accordance with requirements of this regulation.

Once registered, facilities must complete a federally-developed form. CDC Form EA-101, for each transfer of an agent covered by this rule. Information on this form will include the name of the requestor and requesting facility, the name of the transferor and transferring facility, the name of the responsible facility official for the transferor and requester, the requesting facility's registration number, the transferring facility's registration number, the name of the agent(s) being shipped, the quantities of the agent(s) being transferred (number of containers being transferred and amount per container), and the proposed use of the agent. As a result of the information collection requirements of this regulation, CDC expects that respondents will incur only minimal routine administrative costs, such as those associated with telephone calls, mailing, and facsimile transmission. CDC does not expect that respondents will incur any capital costs, or even significantly increased operating costs.

Description of Respondents:

Commercial suppliers of these select agents, as well as government agencies, universities, research institutions, and private companies that transfer or obtain these agents, or that wish to work with these agents. Estimated Annual Reporting Burden CFR Section Number of Respondents Frequency of Responses Total Annual Responses Hours per Response Total Hours 72.6(a) 1,000 1 1,000 .25 25072.6(d) 1.000 3 3,000 i .05 3,150 72.6(e) 120 21 27520.17 42872.6(0 1,000 3 3,000 .11 330Total 4,158 Reporting or Disclosures: The above citations are currently cleared under 30 CFR Part 11 as OMB control Number 0920-0199.
List of Subjects in 42 CFR Part 72

Additional requirements for facilities transferring or receiving select agents.

A. **Registration of facilities**

(1) Prior to transferring or receiving a select agent listed in Appendix A of this part, a facility shall register with a registering entity authorized by the Secretary (paragraph (c) of this section) or be approved by the Secretary as equipped and capable of handling the covered agent at Biosafety Level (BL) 2, 3, or 4, depending on the agent.

(2) Registration will include:

(i) Sufficient information provided by the responsible facility official indicating that the applicant facility, and its laboratory or laboratories, are equipped and capable of handling the agents at BL 2, 3, or 4, depending upon the agent, and the type of work being performed with the agents:

(ii) inspection of the applicant facility at the discretion of the Secretary or the registering entity in consultation with the Secretary;

(iii) issuance by the registering entity of a registration number unique to each facility;

(iv) Collection of a periodic site registration fee by the registering entity or the Secretary. A schedule of fees collected by the Secretary to cover the direct costs (e.g., salaries, equipment, travel) and indirect costs (e.g., rent, telephone service and a proportionate share of management and administration costs) related to administration of this part will be published in the Federal Register and updated annually.

(v) Follow-up inspections of the facility by the registering entity or the Secretary, as appropriate, to ensure the facility continues to meet approved standards and record keeping requirements.

(3) Such registration shall remain effective until relinquished by the facility or withdrawn by the Secretary or the registering entity.

(4) The registration may be denied or withdrawn by the registering entity or the Secretary based on:

(i) Evidence that the facility is not or is no longer capable of handling covered agents at the applicable biosafety level;

(ii) Evidence that the facility has handled covered agents in a manner in contravention of the applicable biosafety level requirements;

(iii) Evidence that the facility has or intends to use covered agents in a manner harmful to the health of humans;

(iv) Evidence that the facility has failed to comply with any provisions of this part or has acted in a manner in contravention of this part; or

(v) Failure to pay any required registration fee.

(5) The requirements for BSL-2, 3. And 4 operations pertaining to this section are contained in the CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories," Third Edition, May 1993 which is hereby incorporated by reference. The Director of the Federal Register has approved under 5 U.S.C. 552 (a) and I C.F.R. Part 51 the incorporation by reference of the above publication. Copies may be obtained from the Superintendent of Documents, U.S . Government Printing Office, Washington D.C. 20402 Copies may be inspected at the Centers for Disease Control and Prevention 1600 Clifton Road, Atlanta Georgia, or at the Office of the Federal Register, 800 North Capitol Street NW, Suite 700, Washington D.C. Additional specific requirements for handling toxins subject to this part must be met and are found in 29 CFR 1910.1450, "Occupational Exposure to Hazardous Chemicals in Laboratories."

B. **Appeals**

A decision made by the Secretary or a registering entity to deny or withdraw registration of a particular facility may be appealed to the Secretary. An application for appeal must be received by the Secretary no later than 14 days after the appealing party's application for registration was denied or no later than 14 days after the appealing party's registration was withdrawn. The application must clearly identify the issues presented by the appeal and fully explain the appealing party's position with respect to those issues. The Secretary may allow the filing of opposing briefs, informal conferences, or whatever steps the Secretary considers appropriate to fairly resolve the appeal.

C. **Authorized Registering Entities**

(1) The Secretary may authorize a state agency or private entity to register facilities under paragraph (a) of this section, if the Secretary determines that the registering entity's criteria for determining the biosafety standards for facilities handling select agents are consistent with the requirements contained in the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories," Third Edition.

(2) A registering entity shall maintain:

(i) A database of all facilities formerly and currently registered as BL 2, 3 or 4 and capable of working with agents in Appendix A of this part. The database shall include the name and address of the registered facility, the date the facility was registered, the facility's registration number, and the name and phone number of the responsible facility official.

(ii) A copy of each CDC Form EA-IOI transmitted by each transferor registered by that registering entity. Such forms shall be made readily accessible to the Secretary and to appropriate federal law enforcement authorities and/or authorized local law enforcement authorities.

(3) In the event the Secretary authorizes more than one registering entity, or if other wise necessary, the Secretary may require the establishment of a consolidated database to carry out the provisions of 72.6(c)(2).

D. **Requests For Agents**

(1) Prior to the transfer of any agent contained in Appendix A of this part, a CDC Form EA-IOI must be completed for each transfer sought. As specified in CDC Form EA-IOI, the information provided must include:

(i) The name of the requester and requesting facility;
(ii) The name of the transferor and transferring facility;
(iii) The names of the responsible facility of finials for both the transferor and requester;
(iv) The requesting facility's registration number;
(v) The transferring facility's registration number;
(vi) The name of the agent(s) being shipped;
(vii) The proposed use of the agent(s); and
(viii) The quantity (number of containers and amount per container) of the agent(s) being shipped.

(2) The form must be signed by the transferor and requester, and the responsible facility officials representing both the transferring and requesting facilities.

(3) A copy of the completed CDC Form EA-IOI must be retained by both transferring and requesting facilities for a period of five (5) years after the date of shipment or for five (5) years after the agents are consumed or properly disposed, whichever is longer.

(4) All CDC forms EA-101 must be produced upon request to appropriate federal and authorized local law enforcement authorities, officials authorized by the Secretary, and officials of the registering entity

E. **Verification of Registration**

(1) Prior to transferring any agent covered by this part, the transferor’s responsible facility official must verify with the requestor's responsible facility official, and as appropriate, with the registering entity:

(i) That the requesting facility retains a valid, current registration;
(ii) That the requestor is an employee of the requesting facility; and
(iii) That the proposed use of the agent by the requester is correctly indicated on CDC Form EA-IOI.

(2) In the event that any party is unable to verify the information required in paragraph (e)(l) of this section, or there is suspicion that the agent may not be used for the requested purpose, then the party shall immediately notify CDC

F. **Transfer**

(1) Upon completion of the CDC Form EA-l0l and verification of registration, the transferring facility must comply with the packaging and shipping requirements in this part or other applicable regulations when transferring the agent.

(2) The requesting facility's responsible official must acknowledge receipt of the agent telephonically or otherwise electronically within 36 hours of receipt and provide a paper copy or facsimile transmission of receipt to the transferor within 3 business days of receipt of the agent.

(3) Upon telephonic acknowledgment of receipt of the agent, the transferor shall provide a completed paper copy or facsimile transmission of CDC Form EA-IOI within 24 hours to the registering entity (holding that facility's registration), in accordance with 6(c)(2) for filing in a centralized repository.

G. **Inspections**

(1) Registering entities or the Secretary may conduct random or for cause inspections of registered facilities to assure compliance with this part. All CDC forms EA-101 and records deemed relevant by inspecting officials must be produced upon request to authorized personnel conducting these inspections. Inspections may also include review of the mechanisms developed by a facility to track intrafacility transfers as well as the facility's agent disposal procedures.

(2) In addition, the Secretary may conduct inspections of registering entities, and/or any consolidated database established in accordance with 6(c)(3), to assure compliance with this part.

H. **Exemptions**

(1) Exemptions for certain select agents: Select agents otherwise covered by this part are exempt from its provisions if:

(i) The agent is part of a clinical specimen intended for diagnostic, reference, or verification purposes. Isolates of covered agents from clinical specimens shall be disposed of in accordance with °72.6(i) after diagnostic, reference, or verification procedures have been completed;

(ii) The agent is a toxin having an LD50 for vertebrates of more than 100 nanograms per kilogram of body weight which is used for legitimate medical purposes or biomedical research or is one of the listed toxins which has been inactivated for use as a vaccine or otherwise detoxified for use in biomedical research procedures; or

(iii) The agent(s) is an exempted strain specified in Appendix A of this part and/or CDC Form EA- I OL Additional exemptions for otherwise covered strains will be considered when CDC reviews and updates the list of select agents (Appendix A of this part). Individuals seeking additions to the list of exemptions 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 changes to the list of exemptions will be published in the Federal Register for review and comment prior to inclusion on Appendix A of this part.

(2) Exemption of Clinical Laboratory Improvement Amendments of 1988, (42 U.S.C.0 263a) (CLIA). CLIA certified laboratories: Clinical laboratories certified under the Clinical Laboratory Improvement Amendments of 1988, (42 U.S.C.0 263a) (CLIA), that utilize these select agents for diagnostic, reference, verification, or proficiency testing purposes are exempt from the provisions of 72.6.

(3) Procedures for facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory: Facilities that are not CLIA laboratories but are transferring or receiving select agents to or from a CLIA laboratory must comply with the following provisions. (No additional paperwork on behalf of CLIA laboratories is required by this section.)

(i) Prior to transferring a select agent subject to this part to a CLIA laboratory for diagnostic. Reference, verification, or proficiency testing purposes, the transferor must:

(A) Provide the following information on CDC Form EA-IOI:

1) The name of the requestor and requesting facility;
2) The name of the transferor and transferring facility;
3) The name of the transferor's responsible facility

4) The requesting facility's CLIA certification number (which the transferor must verify as valid and current with the registering entity);
5) The transferring facility's registration number;
6) The name of the agent(s) being shipped;
7) The proposed use of the agent(s); and
8) The quantity (number of containers and amount per container) of the agent(s) being shipped .

(B) Verify receipt of the agent with the CLIA laboratory and note such receipt on CDC Form EA-101;

(C) Transmit a copy of the form, signed by the transferor and the responsible facility official representing the transferring facility, to the registering entity holding the transferring facility's registration; and

(D) Retain a copy of CDC Form EA-IOI in accordance with 72.6(d)(3) and 6(d)(4).

(ii) Prior to receiving a select agent listed in Appendix A of this part from a CLIA laboratory, the requester must be registered in accordance with 72.6(a) and comply with the following requirements:

(E) Comply with the disposal requirements of ~7 ' 6(i) and all other sections of this part when subsequently transferring the agent.

I. **Agent Disposal**

Upon termination of the use of the agent, all cultures and stocks of it will be

(i) Securely stored in accordance with prudent laboratory practices,
(ii) Transferred to another registered facility in accordance with this part, or
(iii) Destroyed on-site by autoclaving, incineration, or another recognized sterilization or neutralization process.
(iv) When an agent, previously transferred to a facility in accordance with this part, is consumed or destroyed, the responsible facility official must formally notify the registering entity. Formal notification must be on CDC Form EA-IOI and a copy kept on record by the responsible facility official for a period of five (5) years and is subject to paragraph (g) of this section.

J. **Definitions. As used in this section:**

Facility means any individual or government agency, university, corporation, company, partnership, society, association, firm, or other legal entity located at a

single geographic site that may transfer or receive through any means a select agent subject to this part.

Registering entity means an organization or state agency authorized by the Secretary to register facilities as capable of handling select agents at Biosafety Level 2, 3, or 4, depending on the agent, in accordance with the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories."

Requestor means any person who receives or seeks to receive through any means a select agent subject to this part from any other person.

Responsible facility official means an official authorized to transfer and receive select agents covered by part on behalf of the transferor and/or requestor's facility. This person should be either a safety of fixer, a senior management official of the facility, or both. The responsible facility official should not be an individual who actually transfers or receives an agent at the facility.

Secretary means the Secretary of the Department of Health and Human Services or her or his designee.

Select agent means a microorganism (virus, bacterium. Fungus, rickettsia) or toxin listed in Appendix A of this part. The term also includes:

(1) Genetically modified microorganisms or genetic elements from organisms on Appendix A of this part, shown to produce or encode for a factor associated with a disease, and

(2) Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins on Appendix A of this part, or their toxic subunits.

Single geographic site means a building or complex of buildings at a single mailing address.

Transfer means:
The conveyance or movement from a point of origination to a point of destination either

(i) From one state or territory to another or
(ii) Entirely within one contiguous state or territory.

(3) Intrafacility transfers within a registered facility located at a single geographic site are not covered by the provisions of Section 72.6 (d), (e), and (f provided that:

(i) The intended use of the agent remains consistent with that specified in the most current transfer form and

(ii) For each intrafacility transfer, the facility maintains records that include the name and location of the recipient; the amount of agent transferred, and the date transferred. Such records must be maintained for a period of five (5) years after the date of transfer or for five (5) years after the agents are consumed or properly disposed, whichever is longer.

Transferor means any person who transfers or seeks to transfer through any means a select agent subject to this pan to any other person.

72.7 Penalties

Individuals in violation of this pan are subject to a fine of no more than $250,000 or one year in jail, or both. Violations by organizations are subject to a fine of no more than $500,000 per event. A false, fictitious, or fraudulent statement or representation on the Government forms required in the part for registration of facilities or for transfers of select agents is subject to a fine or imprisonment for not more than five years, or both for an individual. And a fine for an organization.

Appendix A to Pan 72-Select Agents

Viruses

1. Crimean-Congo hemorrhagic fever virus
2. Eastern Equine Encephalitis virus
3. Ebola viruses
4. Equine Morbilhvirus
5. Lassa fever virus
6. Marburg virus
7. Rift Valley fever virus
8. South American Hemorrhagic 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. Burkholdena (Pseudomonas) mallei
4. Burkholderia (Pseudomonas) pseudomallei

5. Clostridium botulinum
6. Francisella tularensis
7. Yersinia pestis

Exemptions: vaccine strains as described in Title 9 CFR, Pan 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. Staphloccocal 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 sub units.

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

I. Products subject to regulation under the Federal insecticide Fungicide and Rodenticide Act (7 U.S.C. ° 136 et seq.) And the Toxic Substances Control Act (15 U.S.C. ° 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.

Exhibit V-e
Research involving Recombinant DNA: Section 111. Experiments Covered by the NIH Guidelines and Appendix C-VI: The Purchase or Transfer of Transgenic Rodents

This section describes six categories of experiments involving recombinant DNA: (i) those that require Institutional Biosafety Committee (IBC) approval, RAC review, and NIH Director approval before initiation (see Section m-A). (ii) those that require NIH/ORDA and institutional Biosafety Committee approval before initiation (see Section E-B), (iii) those that require Institutional Biosafety Committee and Institutional Review Board approvals and NIH/ORDA registration before initiation (see Section III-C), (iv) those that require Institutional Biosafety Committee approval before initiation (see Section III-D), (v) those that require Institutional Biosafety Committee notification simultaneous with initiation (see Section III-E), and (vi) those that are exempt from the NIH Guidelines (see Section III-F).

Note: if an experiment falls into Sections E-A m-B, or m-c and one of the other sections, the rules pertaining to Sections III-A, III-B, or III-C shall be followed. If an experiment falls unto Section III-F and into either Sections III-D or III-E as well, the experiment is considered exempt from the NIH Guidelines.

Any change in containment level, which is different from those specified in the NIH Guidelines, may not be initiated without the express approval of NIII/ORDA (see Section IV-C- I -b-(2) and its subsections, Minor Actions).

Section III-A. Experiments that Require institutional Biosafety Committee Approval, RAC Review, and NIH Director Approval Before initiation (See Section IV-C-I -by 1), Major Actions).

Section III-A-I. Major Actions under the NIH Guidelines

Experiments considered as Major Actions under the NIH Guidelines cannot be initiated without submission of relevant information on the proposed experiment to the Office of Recombinant DNA Activities, National Institutes of Health/MSC 7010, 6000 Executive Boulevard Suite 302, Bethesda, Maryland 20892-7010, (301) 496-9838, the publication of the proposal in the Federal Register for 15 days of comment, review by RAC, and specific approval by NIH the containment conditions or stipulation requirements for such experiments will be recommended by RAC and set by NIH at the time of approval. Such experiments require Institutional Biosafety Committee approval before initiation. Specific experiments already approved are included in Appendix D, Major Actions Taken under the NIH Guidelines, which may be obtained from the Office of
Recombinant DNA Activities, National institutes of Health MSC 701 0, 6000 Executive Boulevard
Suite 302, Bethesda Maryland 20892-7010 (301) 496-9838.

Section III-A-I-a. The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally (see Section V-B, Footnotes and References of Sections l-IV), if such acquisition could compromise the use of the drug to control disease agents m humans, veterinary medicine, or agriculture, will be reviewed by RAC.

Section III-B. Experiments That Require NIH/ORDA and institutional Biosafety Committee Approval Before initiation

Experiments in this category cannot be initiated without submission of relevant information on the proposed experiment to NIH/ORDA. The containment conditions for such experiments will be determined by NIH/ORDA in consultation with ad hoc experts. Such experiments require Institutional Biosafety Committee approval before initiation (see Section l~'-B-2-b{l), institutional Biosafety Committee).

Section III-B-I. Experiments involving the Cloning of Toxin Molecules with LD50 of Less than 100 Nanograms per Kilogram Body Weight

Deliberate formation of recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight (e.g., microbial toxins such as the botulinum toxins, tetanus toxin, diphtheria toxin, and Shigella dysentariae neurotoxin) Specific approval has been given for the cloning in Escherichia coli K-12 of DNA containing genes coding for the biosynthesis of toxic molecules which are lethal to vertebrates at 100 nanograms to 100micrograms per gram body weight. Specific experiments already approved under this section may be obtained from the Office of Recombinant DNA Activities, National Institutes of Health MSC 7010, 6000 Executive Boulevard, Suite 302, Bethesda, Maryland 20892-7010, (301) 496-9838.

Section III-C. Experiments that Require institutional Biosafety Committee and institutional Review Board Approvals and NIHIORDA Registration Before initiation

Section III-C-1. Experiments involving the Deliberate Transfer of Recombinant DNA or DNA or RNA Derived from Recombinant DNA into One or More Human Subjects

Research proposals involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA, into human subjects (human gene transfer) will be considered through a review process Involving both NIH/ORDA and RAC. Investigators shall submit relevant information on the proposed human gene transfer exponents to NIH/ORDA. Submission of human gene transfer protocols to NIH will be is the format described in Appendix M-l, Submission Requirements -- Human Gene Transfer Experiments Submission to NIH/ORDA shall be for registration purposes and will ensure continued public access to roles ant human gene transfer information in compliance with the NIH Guidelines . Investigational New Drug (IND) applications should be submitted to FDA in the format described in 21 CFR, Chapter 1, Subchapter D, Part 312, Subpart B. Section 23, IND Content and Format.

Institutional Biosafety Committee approval must be obtained from each institution at which recombinant DNA material will be administered to human subjects (as opposed to each institution involved m the production of vectors for human application and each institution

at which there is ex vivo transduction of recombinant DNA material into target cells for human application).

RAC prefers that submission to NIH/ORDA in accordance with Appendix M-l, Submission Requirements --Human Gene Transfer Experiments, contain no proprietary data or trade secrets, enabling all aspects of the review to be open to the public. Following receipt by NIH/ORDA, relevant information shall be entered into the NIH human gene transfer database for registration purposes. Summary information pertaining to the human gene transfer protocol will be forwarded to RAC members. NIH/ORDA summary information shall include comparisons to previously registered protocols. Specific items of similarity to previous experiments include (but are not limited to): (i) gene delivery vehicle; (ii) functional gene, (iii) marker gene, (iv) packaging cell (if applicable), (v) disease application, (vi) route of administration, and (vii) patent selection criteria.

RAC members shall notify NIH/ORDA within 15 working days if the protocol has been determined to represent nose cl characteristics requiring further public discussion.

Full RAC review of an individual human gene transfer experiment can be initiated by the NIH Director or recommended to the NIH Director by: (i) three or more RAC members, or (ii) other Federal agencies. An individual human gene transfer experiment that is recommended for full RAC review should represent novel characteristics deserving of public discussion RAC recommendations on a specific human gene transfer experiment shall be forwarded to the NIH Director, the Principal investigator, the sponsoring institution, and other DHHS components, as appropriate.

Note: For specific directives concerning the use of retroviral vectors for gene delivery, consult Appendix B-V-lr Murine Retroviral Vectors.

Section III-D. Experiments that Require Institutional Biosafety Committee Approval Before Initiation

Prior to the initiation of an experiment that falls into this category, the Principal investigator must submit a registration document to the Institutional Biosafety Committee which contains the following information: (i) the source(s) of DNA; (u) the nature of the inserted DNA sequences; (iii) the host(s) and vector(s) to be used: (iv) if an attempt will be made to obtain expression of a foreign gene, and if so, indicate the protein that still be produced: and (v) the containment conditions that will be implemented as specified m the NIH Guidelines. For experiments m this category, the registration document shall be dated, signed by the Principal investigator, and filed with the institutional Biosafety Committee. The institutional Biosafety Committee shall review and approve all experiments m this category prior to their initiation Requests to decrease the level of containment specified for experiments in this category will be considered by NIH (see Section IV-C-I -b{2)~c), Minor Actions).

Section III-D-1. Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems (See Section II-A, Risk Assessment)

Section III-D-1-a. Experiments involving the introduction of recombinant DNA into Risk Group 2 agents will usually be conducted at Biosafety Level (BL) 2 containment. Experiments with such agents will usually be conducted with whole animals at BL2 or BL2-N (Animals) containment.

Section III-D-1-b. Experiments evolving the introduction of recombinant DNA unto Risk Group 3 agents will usually be conducted at BL3 containment. Experiments with such agents will usually be conducted with whole animals at BL3 or BL3-N containment.

Section III-D-1-c. Experiments involving the introduction of other DHHS co DNA into Risk Group 4 agents shall be conducted at BL4 containment. Experiments with such agents shall be conducted with whole animals at BL4 or BL4-N containment.

Section III-D-1-d. Containment conditions for experiments involving the Introduction of recombinant DNA into restricted agents shall be set on a case-by-case basis following NIH/ORDA review. A U.S. Department of Agriculture permit is required for work with plant or animal pathogens (see Section V-G and V-L, Footnotes and References of Sections l-IV). Experiments with such agents shall be conducted with whole animals at BL4 or BL4-N containment.

Section III-D-2. Experiments in Which DNA From Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems

Section III-D-2-a. Experiments m which DNA from Risk Group 2 or Risk Group 3 agents (see Section II-A, Risk Assessment) is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BL2 containment. Experiments m which DNA from Risk Group 4 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes may be performed under BL2 containment after demonstration that only a totally and irreversibly defective fraction of the agent's genome is present in a given recombinant. In the absence of such a demonstration BL4 containment shall be used. The Institutional Biosafety Committee may approve the specific lowering of containment for particular experiments to BL 1. Many experiments m this category are exempt from the NIH Guidelines (see Section III-F, Exempt Experiments). Experiments involving the formation of recombinant DNA for certain genes coding for molecules toxic for vertebrates require NIH/ORDA approval (see Section III-B-I, Experiments Involving the Cloning of Toxin Molecules with LD50 of Less than 100 Nanograms Per Kilogram Body Weight) or shall be conducted under NIH specified conditions as described in Appendix F. Containment Conditions for Cloning of Genes Coding for the Biosynthesis of Molecules Toxic for Vertebrates.

Section III-D-2-b. Containment conditions for experiments in which DNA from restricted agents is transferred into non pathogenic prokaryotes or lower eukaryotes shall be determined by NIIL'ORDA following a case-by-case review (see Section V-L, Footnotes and References of Sections l-IV). A IU S Department of Agriculture permit is required for work with plant or animal pathogens (see Section V-G. Footnotes and References of Sections l-IV).

Section III-D-3. Experiments Involving the Use of infectious DNA or RNA Viruses or Defective DNA or RNA Viruses m the Presence of Helper Virus in Tissue Culture Systems

Caution: Special care should be used m the evaluation of containment levels for experiments which are likely to either enhance the pathogenicity (e.g., insertion of a host oncogene) or to extend the host range(e.g., introduction of novel control elements) of viral vectors under conditions that per nit a productive infection in such cases. Serious consideration should be given to Increasing physical containment by at least one level

Note: Recombinant DNA or RNA molecules derived there from, which contain less than two-thirds of the genome of any eucharistic virus (all viruses from a single Family (see Section V-J, Footnotes and References of Sections l-IV) being considered identical (see Section V-Kg Footnotes and References of Sections l-IV), are considered defective and may be used in the absence of helper under the conditions specified in Section III-E- I, Experiments involving the Formation of Recombinant DNA Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus.

Section III-D-3-a. Experiments involving the use of infectious or defective Risk Group 2 viruses (see Appendix B-II, Risk Group 2 Agents) in the presence of helper virus may be conducted at BL2.

Section III-D-3-b. Experiments involving the use of infectious or defective Risk Group 3 viruses (see Appendix BASED, Risk Group 3 (RG3) - Viruses and Prions) in the presence of helper virus may be conducted at BL3.

Section III-D-3-c. Experiments involving the use of infectious or defective Risk Group 4 viruses (see Appendix B-IV-D, Risk Group 4 (RG4) - Viral Agents) in the presence of helper virus may be conducted at BL4.

Section III-D-3-d. Experiments involving the use of infectious or defective restricted pox viruses (see Sections V-A and V-L, Footnotes and References of Sections I-IV) in the presence of helper virus shall be determined on a case-by-case basis following NIH/ORDA review. A U. S . Department of Agriculture permit is required for work with plant or animal pathogens (see Section V-G, Footnotes and References of Sections l-IV).

Section III-D-3-e. Experiments involving the use of infectious or defective viruses m the presence of helper virus which are not covered in Sections III-D-3-a through 111-D-3-d may be conducted at BLI .

Section III-D-4. Experiments involving Whole Animals
This section covers experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived there from, into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals. For the latter, other than viruses which are only vertically transmitted, the experiments may not be conducted at BLI-N containment. A minimum containment of BL2 or BL2-N is required.

Caution - Special care should be used m the evaluation of containment conditions for some experiments with transgenic animals. For example, such experiments might lead to the creation of novel mechanisms or increased transmission of a recombinant pathogen or production of undesirable traits m the host animal. In such cases, serious consideration should be given to increasing the containment conditions.

Section Ill-D4-a Recombinant DNA or DNA or RNA molecules derived there from, from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BLI or BLI-N and appropriate to the organism under study (see Section V-B, Footnotes and References of Sections l-IV)

Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BLI or BLI-N and appropriate to the organism under study.

Experiments involving the introduction of other sequences from eukaryotic viral genomes into animals are covered under Section III-D-4-b, Experiments involving Whole Animals. For experiments involving recombinant DNA-modified Risk Groups 2, 3, 4, or restricted organisms, see Sections V-A, V G. And V-L.

Footnotes and References of Sections l-IV. It is important that the investigator demonstrate that the fraction of the viral genome being utilized does not lead to productive infection. A U. S . Department of Agriculture permit is required for work with plant or animal pathogens (see Section V-G, Footnotes and References of Sections l-IV).

Section III-D4-b. For experiments involving recombinant DNA, or DNA or RNA derived there from involving whole animals, including transgenic animals, and not covered by Sections III-D-I, Experiments Using Human or Animal Pathogens (Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems, or S-D-4-a Experiments involving Whole Animals, the appropriate containment shall be determined by the institutional Biosafety Committee.

Section III-D-4-c. Exceptions under Section III-D4, Experiments involving Whole Animals

Section III-D-4-c-(1) Experiments involving the generation of transgenic rodents that require BL1 containment are described under Section III-E-3, Experiments involving transgenic Rodents.

Section III-D-4-c-(2). The purchase or transfer of transgenic rodents is exempt from the NIH Guidelines under Section III-F, Exempt Experiments (see Appendix C-VI, The Purchase or Transfer of Transgenic Rodents).

Section III-D-5. Experiments involving Whole Plants. Experiments to genetically engineer plants by recombinant DNA methods, to use such plants for there experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing recombinant DNA, may be conducted under the

containment conditions described in Sections III-D-5-a through 111-D-5-e. If experiments involving whole plants are not described in Section III-D-5 and do not fall under Sections III-A, III-B, III-D or III-F, they are included m Section III-E.

NOTE - For recombinant DNA experiments falling under Sections III-D-5-a through 111-D-5-d, physical containment requirements may be reduced to the next lower level by appropriate biological containment practices such as conducting experiments on a virus with am obligate insect vector m the absence of that vector or using a genetically attenuated strain.

Section III-D-5-a. BL3-P (Plants) or BL2-P + biological containment is recommended for experiments involving most exotic (see Section V-W, Footnotes and References of Sections l-IV)
Infectious agents with recognized potential for serious detrimental impact on managed or natural ecosystems when recombinant DNA techniques are associated with whole plants.

Section III-D-5-b. BL3-P or BL2-P + biological containment is recommended for experiments involving plants containing cloned genomes of readily transmissible exotic (see Section V-W. Footnotes and References of Sections l-IV) infectious agents with recognized potential for serious detrimental effects on managed or natural ecosystems in which there exists the possibility of reconstituting the complete and functional genome of the infectious agent by genomic complementation in plants.

Section III-D-5-c. BL4-P containment is recommended for experiments with a small number of readily transmissible exotic (see Section V-W. Footnotes and References of Sec ions l-IV) infectious agents. Such as the soybean rust fungus (Phakospora pachyrhizi) and maize streak or other viruses m the presence of their specific arthropod vectors, that have the potential of being serious pathogens of major I J S crops.

Section III-D-9d. BL3-P containment is recommended for experiments involving sequences encoding potent vertebrate toxins introduced unto plants or associated organisms. Recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of < 100 nanograms per kilogram body weight fall under Section E-B-I, Experiments involving the Cloning of Toxin Molecules with LD50 of Less than 100 Nanograms Per Kilogram Body Weight, and require NIH/ORDA and institutional Biosafety Committee approval before initiation.

Section III-D-5-e. BL3-P or BL2-P + biological containment is recommended for experiments with microbial pathogens of insects or small animals associated with plants if the recombinant DNA-modified organism has a recognized potential for serious detrimental impact on managed or natural ecosystems.

Section III-D-6. Experiments Involving More than 10 Liters of Culture

The appropriate containment will be decided by the Institutional Biosafety Committee. Where appropriate, Appendix K, Physical Containment for Large Scale Uses of Organisms Containing Recombinant DNA Molecules, shall be used Appendix K describes containment conditions Good Large Scale Practice through BL3-Large Scale.

Section III-E. Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation

Experiments not included m Sections III-A, III-B, III-C, III-D, III-F, and their subsections are considered in Section III-E. All such experiments may be conducted at BL I containment. For experiments m this category, a registration document (see Section III-D, Experiments that Require Institutional Biosafety Committee Approval Before initiation) shall be dated and signed by the Investigator and filed with the local institutional Biosafety Committee at She time the experiment is initiated. The institutional Biosafety Committee reviews and approves all such
Proposals, but institutional Biosafety Committee review and approval prior to initiation of the experiment is not required (see Section IV-A Policy). For example, experiments in which all components derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes fall under Section III-E and may be conducted at BLI containment.

Section III-E-I. Experiments involving the Formation of Recombinant DNA Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus

Recombinant DNA molecules containing no more than avo-thirds of the genome of any eukaryotic virus (all viruses from a single Family (see Section V-Q, Footnotes and References of Sections l-IV) being considered identical (see Section V-S, Footnotes and References of Sections l-IV)) may be propagated and maintained in cells m tissue culture using BLI containment. For such experiments, it must be demonstrated that the cells lack helper virus for the specific Families of defective viruses being used if helper virus is present, procedures specified under Section III-D-3, Experiments Involving the Use of infectious Animal or Plant DNA or RINA Viruses or Defective Animal or Plant DNA or RNA Viruses m the Presence of Helper Virus m Tissue Culture Systems, should be used. The DNA may contain fragments of the genome of viruses from more than one Family but each fragment shall be less than two-thirds of a genome

Section III-E-2. Experiments involving Whole Plants
This section covers experiments involving recombinant DNA-modified whole plants, and or experiments involving recombinant DNA-modified organisms associated with whole plants, except those that fall under Section III-A, III-B, III-D, or III-F. It should be emphasized that knowledge of the organisms and judgment based on accepted scientific practices should be used in all cases m selecting the appropriate level of containment. For example, if the genetic modification has the objective of increasing pathogenicity or converting a non-pathogenic organism into a pathogen, then a higher level of containment may be appropriate depending on the organism, its mode of dissemination, and its target organisms. By contrast, a lower level of containment may be appropriate for small animals associated with many types of recombinant DNA-modified plants.

Section III-E-2-a. BLI-P is recommended for all experiments with recombinant DNA-containing plants and plant-associated microorganisms not covered m Section III-E-2-b or other sections of the NIH Guidelines. Examples of such experiments are those involving recombinant DNA-modified plants that are not noxious weeds or that cannot interbreed with noxious weeds m the immediate geographic area, and experiments involving whole

plants and recombinant DNA-modified non-exotic (see Section V-M. Footnotes and References of Sections l-IV) microorganisms that have no recognized potential for rapid and widespread dissemination or for serious detrimental impact on managed or natural ecosystems (e.g., Rhizobium spp. And Agrobacterium spp.).

Section III-E-2-b. BL2-P or BLI-P + biological containment is recommended for the following experiments:

Section III-E-2-b-(1). Plants modified by recombinant DNA that are noxious weeds or can Interbreed with noxious weeds m the immediate geographic area.

Section III-E-2-b-(2). Plants m which the introduced DNA represents the complete genome of a non-exotic infectious agent (see Section V-W, Footnotes and References of Sections I-IV).

Section III-E- 2-b-(3). Plants associated with recombinant DNA-modified non-exotic microorganisms that have a recognized potential for serious detrimental impact on managed or natural ecosystems (see Section V-W Footnotes and References of Sections l-IV).

Section III-E-2-b-(4). Plants associated with recombinant DNA-modified exotic microorganisms that have no recognized potential for serious natural ecosystems (see Section V-W, Footnotes and References of Sections l-IV).

Section III-E-2-b-(5). Experiments with recombinant DNA-modified arthropods or small animals associated with plants, or with arthropods or small animals with recombinant DNA-modified microorganisms associated with them if the recombinant DNA-modified microorganisms have no recognized potential for serious detrimental impact on managed or natural moss stems (see Section V-W, Footnotes and References of Sections l-r~)

Section III-E-3. Experiments involving Transgenic Rodents

This section covers experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived there from, into the germ-line (transgenic rodents). Only experiments that require BLI containment are covered under this section; experiments that require BL2, BL3, BL4 containment are covered under Section m-D4, Experiments Involving Whole Animals.

Section III-F. Exempt Experiments

The following recombinant DNA molecules are exempt from the NIH Guidelines and registration with the Institutional Biosafety Committee is not required:

Section III-F-1. Those that are not m organisms or viruses.

Section III-F-2. Those that consist entirely of DNA segments from a single non-chromosomal or viral DNA source, though one or more of the segments may be a synthetic equivalent.

Section III-F-3. Those that consist entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well established physiological means.

Section III-F-4. Those that consist entirely of DNA from am eukaryotic host including its chloroplasts, mitochondria or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).

Section III-F-5. Those that consist entirely of DNA segments from different species that exchange DNA b) known physiological processes, though one or more of the segments may be a Synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director math advice of the RAC after appropriate notice and opportunity for public comment (see Section IV-C-I-b-(l)-(c), Major Actions). See Appendices A-l through A-VI, Exemptions Under Section lii-F-5--Sublists of Natural Exchangers, for a list of natural exchangers that are exempt from the NIH Guidelines.

Section III-F-6. Those that do not present a significant risk to health or the environment (see Section IV-C- I -b-(I)-(c), Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C, Exemptions under Section III-F-6 for other classes of experiments which are exempt from the NIH Guidelines

Appendix C-VI. The Purchase or Transfer of Transgenic Rodents.

The purchase or transfer of transgenic rodents for experiments that require BL I containment (See Appendix G-II-M, Footnotes and References of Appendix G) are exempt from the NIH Guidelines.

Appendix C-VII. Footnotes and References of Appendix C

Appendix C-VII-A-1. The NIH Director, with advice of the RAC, may revise the classification for the purposes of these N1H Guidelines (see Section IV-C- I -b{2)~(b), NIH Director--Specific Responsibilities). The revised list of organisms in each class is reprinted m Appendix B.

FOR YOUR INFORMATION

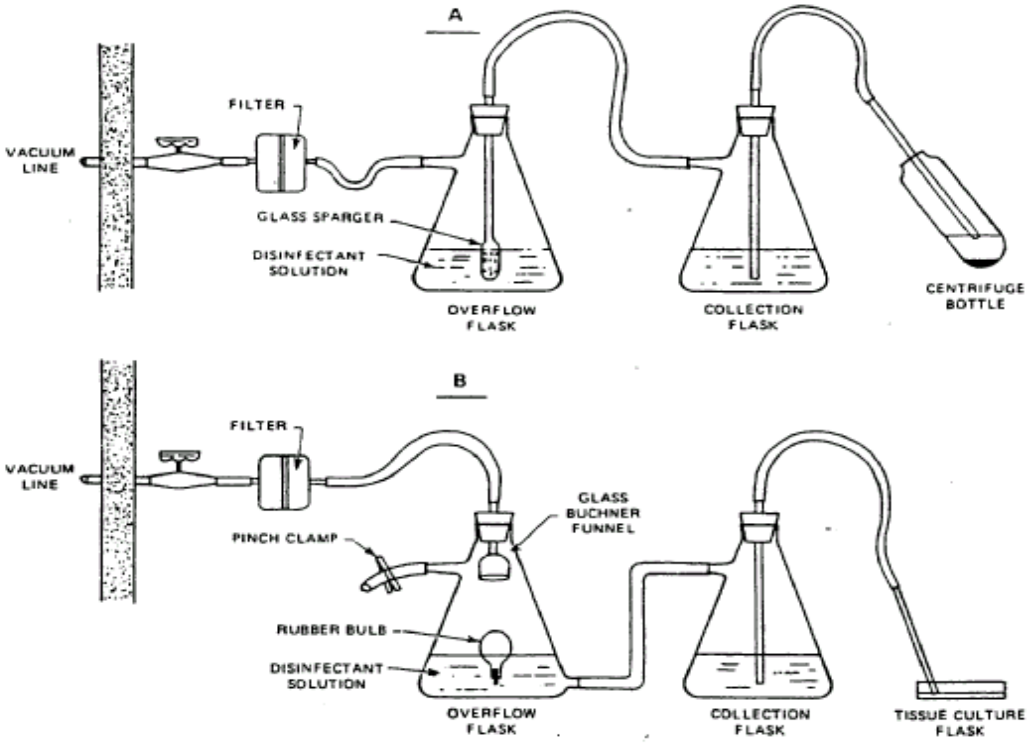
Summary of the changes in NIH Guidelines for Recombinant DNA in relation to transgenic rodents:

1) Purchase or transfer of transgenic animals (from commercial or non-commercial sources) are exempt from the NIH guidelines and approval of the Institutional

biosafety committee, provided the animals and experiments can be carried out at BL- I containment.

2) Generating new transgenic animals requires notification of the IBC at the initiation of the experiment. The lack of requirement for prior approval here also assumes the experiments can be carried out at BL-1. Generating transgenics using DNA sequences from risk group 2, 3, or 4 agents will require prior IBC approval at the appropriate contaminment level.

EXHIBIT V-f
Two Techniques for Protecting Vacuum Systems from Contamination



TWO TECHNIQUES FOR PROTECTING VACUUM SYSTEM FROM CONTAMINATION

DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

Exhibit V-g

Occupational Health and Safety Program for All Personnel Handling and Working Near Laboratory Animals
July 1, 1999

REGULATORY AUTHORITY

The Occupational Health and Safety (OHS) program for personnel working with or near laboratory animals follows the guidelines set forth in the Guide for the Care and Use of Laboratory Animals (the Guide, 1996 and subsequent revisions), as well as other pertinent documents. The PHS Policy on Humane Care and Use of Laboratory Animals (IV,A,1,f) requires a "health program for personnel who work in laboratory animal facilities or have frequent contact with animals." The same PHS Policy (IV,A,1) requires institutions receiving PHS financial support to use the Guide in developing its various animal care and use programs. The Guide itself (pp.14-18) discusses many aspects of an occupational health and safety program. Our accreditation agency (AAALAC) also uses the Guide as a basis for its review of our program of animal care and use, including our occupational health and safety program. Other appropriate documents (e.g., those of OSHA) also apply to aspects of the animal care and use program.

WHO IS INCLUDED?

This program includes all persons, both university and non-university employees, who work with laboratory animals, and in certain instances, work near laboratory animals. As examples, this policy includes (but is not limited to) animal care technicians, veterinarians, veterinary technicians, supervisors of animal care, researchers, graduate students, postdoctoral students, research technicians, maintenance personnel, and outside contractors.

WHAT IS INCLUDED?

The OHS program for persons working with laboratory animals includes zoonotic diseases; human diseases potentially transmissible through laboratory animals or their tissues (e.g., human tissues implanted into immunocompromised animals), teaching or product safety testing with animals; physical hazards such as (but not limited to) lifting heavy objects, animal bites, needle sticks, burns, falls and noise; ionizing and non-ionizing radiation hazards; chemical hazards such as (but not limited to) toxins, carcinogens, and cage cleaning chemicals; and allergens. This is outlined in Table 2.

OVERSIGHT

General oversight of the entire OHS program for persons using laboratory animals is the responsibility of the Institutional Animal Care and Use Committee (IACUC).

OPERATIONAL RESPONSIBILITY

Physical examinations will be provided by the Office of Employee and Student Health at Hahnemann University Hospital. Table 1 lists those persons who must have a physical examination before initiating any work with laboratory animals. Persons refusing necessary vaccinations will be required to sign a release. Table 1 lists those persons who must provide a health history form to an OHS physician so that the physician can determine if a physical examination is necessary. Health history forms are available from the Office of Employee and Student Health or the Office of Research.

Any person working with or near laboratory animals may voluntarily submit a health history form to the OHS or private physician for evaluation of the need for a physical examination.

Any person listed on an IACUC protocol as working with or near laboratory animals, or any University Laboratory Animal Resources (ULAR) employee working with laboratory animals, shall have written health approval from an OHS or private physician to do so. Any limiting conditions set by the physician must be written on that approval. The IACUC shall assure that this approval is present prior to a person's participation on an IACUC approved protocol. The Attending Veterinarian shall assure that this approval is present prior to a ULAR employee being assigned work with or near laboratory animals.

All persons listed in Table 1 as needing "Required Training" must partake in the basic OHS training program provided by the university's Biosafety Officer. Topics to be included are listed in Table 2 and may be modified by the Biosafety Officer as he or she deems appropriate. Satisfactory completion of the program shall be assured by the issuance of a Certificate of Completion. The IACUC shall assure that this approval is present prior to a person's participation on an IACUC approved protocol.

Other forms of training, as mandated by either the IACUC, University Biosafety Committee, Radiation Safety Committee, or other appropriate university committees or offices will be provided as detailed by those entities.

Areas marked "maybe" in Table 1 will be based upon the closeness of animal contact, known risks from zoonotic or other infectious diseases, etc. This decision will be made by the University Veterinarian in consultation (if appropriate) with an OHS physician.

Table 1. Basic Requirements by Risk Category

Risk Category	Required Training History	Health History	Physical Exam	TB Test	Vaccination
Maintenance personnel	Maybe	Maybe	Maybe	Yes	No
Office assistants in animal facility, etc.	No	Maybe	Maybe	Maybe	No
ULAR animal and veterinary care staff	Yes	Yes	Yes	Tetanus	Maybe Rabies
Non-ULAR persons having direct contact with non-human primates	Yes	Yes	Yes	Yes	Tetanus
Non-ULAR persons having direct and frequent contact with lab rodents/rabbits	Yes	Yes	Determined by OHS physician	No	Tetanus
Non-ULAR persons having direct but infrequent contact with animals other than non-human primates	Yes	Maybe	Maybe	Maybe	Maybe

Conditions listed in Table 2 are used to supplement, not replace the OHS training program provided by the university's Biosafety Officer. For example:

- University Laboratory Animal Resources veterinary technicians who provide Species Specific Certification and training will advise persons they are testing or training about the potential for allergies to develop to laboratory animals, and to rodents in particular. They will advise these people to see an OHS physician, or their private physician, if allergy symptoms develop.

  It is the responsibility of the Principal Investigator (PI) to assure that all research personnel under his/her responsibility partake in the appropriate parts of this OHS program. The Supervisors of Animal Care and Attending Veterinarian will assume the same responsibility for those persons who report to them.

- The IACUC is responsible for assuring that employees and other persons (e.g., volunteers, students) receive a health examination prior to initially working with laboratory animals.

- Persons handling or coming into close contact with either nonhuman primates, animals known to harbor a zoonotic disease, or animals with a reasonable potential for having a zoonotic disease (e.g., a pregnant sheep is at risk for harboring Q-fever) will receive additional information and training on those zoonotic diseases and their prevention. This information, both oral and written, will be provided by the University Veterinarian or his/her delegate. The veterinarian will inform the IACUC, in writing, when this process has been completed.

The University Biosafety Committee shall be responsible for providing oversight of specific OHS precautions required for those unique biosafety concerns that often occur during the course of biomedical research. For example: an investigator desiring to work with nitrosomethylurea, a carcinogen capable of producing mammary cancer in rats and other animals, must, in addition to the general requirements of this OHS program, abide by the more specific requirements of the University Biosafety Committee concerning the safe use of this chemical.

UNIVERSITY COMMITTEE REQUIREMENTS

Prior to the initiation of any procedure using animals with either ionizing or non-ionizing radiation (excluding diagnostic x-rays), the PI must complete the Radioactive Materials in Laboratory Animals Questionnaire of the Radiation Safety Committee, and obtain approval from the Radiation Safety Committee and the IACUC.

Prior to the initiation of any procedure using a biohazard in laboratory animals, the Principal Investigator must complete the Animal Addendum of the University Biosafety Committee form, and obtain that committee's approval, and approval of the IACUC. Biohazards to humans include (but are not limited to) infectious organisms, chemical carcinogens, recombinant DNA, and toxins.

The IACUC form requires that an investigator identify any potential biohazard to humans, as well as the use of radiation and recombinant DNA.

ANIMAL ACQUISITION

All animal purchases or other means of animal acquisition are made through ULAR. ULAR will attempt to obtain animals known to be free from zoonotic diseases. The University Biosafety Committee has established a policy wherein any acquired nonhuman primates must have a reasonable certainty (as determined by the University Veterinarian) of being free from cercopithecine herpes virus-1 (Herpes-B virus). A quarantine program and testing program for various zoonotic diseases of nonhuman primates is part of the ULAR Standard Operating Procedures. Other quarantine and testing programs, as necessary, are the responsibility of the University Veterinarian.

Table 2. Continuing responsibility for oversight of selected conditions. "P" indicates primary, "S" indicates secondary responsibility for assuring either appropriate training, use or health care

Condition	Vet. Tech	ULAR Supv.	Attending Vet	P. I.	Biosafety Officer	OHS Physician	Biosafety Comm.	Radiation Safety Comm.	IACUC
Allergies	P					P			
Anesthetic gases	S		S	S	S		P		P
Autoclave hazards	S	S		S	P				
Bites	P	S				P			
Blood borne pathogens				P	S	P	P		S
Chemical hazards		P		P		S	P		S
Euthanasia hazards			S	P			S		S
Health exams		S		P		P			P
Immunizations				P		P	S		P
Infectious disease, human		S		P		P	P		S
Laundry		P		P			S		
Lifting		P			P				
MSDS		P		P	S		S		
Noise		S			P				
Radiation Hazards				S				P	S
Risk assessment			P	P	S	P	S		
Sharps	S	S		S	S		P		
Tuberculosis testing	S	S	S	S		P			P
Zoonoses		S	P	P	S	P	P		S

DETAILS OF THE TUBERCULOSIS (TB) TEST REQUIREMENT

Tuberculin skin testing will be provided to all ULAR animal and veterinary care employees who do not have a history of a reactive test, at their initial physical examination at the time of hire, and no less often than every twelve months thereafter. It will be given as medically indicated for those with known or suspected exposure. Any other person working with nonhuman primates, nonhuman primate blood (or other body fluids) or nonhuman primate tissues also must be tested no less often than annually, and prior to first working with those animals or their tissues. Exceptions include those who have had BCG vaccine administered within the previous 3 years or who have had a previous TB infection and treatment. These latter people must undergo an annual health screening by the university's Occupational Health and Safety physicians, or another physician acceptable to the university.

Personnel who had a positive skin test and did not receive medical treatment must have their entry into nonhuman primate colonies and interactions with (or near) nonhuman primates evaluated and approved on an individual basis by the IACUC. Likewise, any person having a positive TB test (other than with BCG vaccine as noted above) must have their entry into nonhuman primate colonies and interactions with (or near) nonhuman primates (or their tissues) evaluated and approved on an individual basis by the IACUC.

Existing policy for maintenance workers is that they must have an annual TB test.

DETAILS OF THE INITIAL PHYSICAL EXAMINATION

1. A physical examination, including a health history evaluation, will be performed by an OHSA physician or a person designated by a physician.

2. Tuberculin skin testing will be provided as described previously.

3. A history of tetanus immunization will be determined at the time of the initial physical examination. If necessary, tetanus immunization will be provided according to the current recommended schedule.

4. Rabies vaccination will be available and is recommended for individuals exposed to dogs and cats and certain other high risk animals (e.g., raccoons).

5. Hepatitis B vaccination is available to all university employees.

6. The physician, along with ULAR or an academic department, will collaborate (if appropriate) to determine the need or advisability of other immunizations or tests.

Individuals with allergies or at risk or developing allergies (history of asthma, eczema, preexisting allergies) shall have that information recorded as part of the physical examination and medical history and provided with further instructions or testing, at the discretion of the physician.

7. The physician shall provide a written health approval, if appropriate, indicating that the individual may work with laboratory animals. Any restrictions shall be noted on the approval.

DETAILS OF PERIODIC MEDICAL SURVEILLANCE

1. Any person having direct contact with nonhuman primates, their blood or other tissues, must have a TB test no less often than annually.

2. All persons approved by the IACUC to work with our near laboratory animals shall annually submit an Annual Health Review form to the Office of Employee Health or a private physician. The physician shall provide a written assurance to the IACUC that the person may continue to work with laboratory animals, and list restrictions, if any. The physician shall determine if a physical examination or other diagnostic procedures are required.

3. The IACUC shall assure that this approval is present prior to a person's continuing participation on an IACUC approved protocol. The IACUC shall annually inform the Attending veterinarian of the need for ULAR employees to submit an Annual Health Review form.

4. The IACUC shall be responsible for including information about the need for annual health approval along with the IACUC Periodic Report form used to renew IACUC protocols.

INJURIES AND ILLNESSES

ULAR, as part of its Standard Operating Procedures (SOP's), requires that all work related injuries be immediately reported to the appropriate Supervisor of Animal Care. Details of actions to take are also included in the sops. Each Principal Investigator should establish appropriate written sops for injury or illness relating to the use of laboratory animals, their blood, or other tissues. The University Biosafety Committee's Animal Addendum form already requests some of this information.

PREGNANCY

The developing fetus is at greater risk for injury from biohazards. Women are encouraged to report pregnancy to their supervisor as soon as possible. Consideration should be given to reassign these persons to areas of less risk. In particular, a pregnant person should avoid nonhuman primates, cats, chemicals (especially carcinogens and teratogens) and all forms of radiation.

BIOSAFETY MANUAL

The University Biosafety Committee provides all Principal Investigators and other interested persons with a Biosafety Manual which denotes many additional items that can potentially be part of an Occupational Health and Safety program for persons using laboratory animals. All employees and other persons using laboratory animals are encouraged to obtain this manual through the Office of Research.

DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE **Exhibit VI-a.1**	
Chemical Carcinogens Regulated by the University Biosafety Committee	**Quantity Requiring UBSC Approval**
BenezeneXCarbon tetrachlorideX Chloroform X1.2-Dibromo,-3ChloropropaneX 1.1-DimethylethylenimineX p-DioxaneX Ethylene DibromideX Propylenime	>.1 liter
EthionineX 3'-methyl-4-aminoazobenzeneX Urethane	>10 gram
Bromoethyl methanesulfonateX Chloromethyl methyl etherX DiepoxbutaneX 1.1-DimethylhydrazineX 1.2-DimethylhydrazineX EthylenimineX Ethyl methanesulfonateX HydrazineX MethylhydrazineX Methyl methanesulfonateX N-NitorsodiethylamineX N-NitrosodimethylamineX N-Nitrosodi-n-butylamineX N-Nitrosodi-n-propylamineXN-Nitroso-N-ethylurethaneX N-Nitroso-N-methylurethaneX N-NitrosopiperidineX Polychlorinated biphenylsX β-Propiolactone	>.01 liter
N-Acetoxy-2-acetylaminofluoreneX 2-AcetylaminofluoreneX AflatoxinsX AminoazotolueneX 2-AminofluoreneX Benz[a]anthraceneX Benzo[a]pyreneX ChlorambucilX CycasinX DiazomethaneX Dibenz[a,h]anthraceneX 7.12-Dimethylbenz[a]anthraceneX 4-DemethylaminazabenzeneX 3-3'-DimethylbenzidineX 1.4-DinitrosopiperazineX N-Hydrozy-2-acetylaminofluoreneX 3-MethycholanthreneX 4.4-Methylene bis(2-Chloroaniline)X1-Methyl-3-nitro-1-nitrosoguanidineX 1-NapthyamineX N-[4-(5-Nitro-2-furyl)-2-thiazoyl]-formamideX N-Nitroso-N-EthylureaX N-Nitroso-N-methylureaX 4-Nitroquinoline-1-oxideX ProcarbazineX 1.3-Propane sultoneX m-ToluenediamineX Uracil mustardX Vinyl	>1 gram

chloride	
Bis(chloromethyl)ether	<.01 liter
4-AminobiphenylX BenzidineX 3.3'-DimethoxybenzidineX 4-Nitrobiphenyl ◆ Ethidium Bromide (crystals)	<1 gram

Asbestos	LIMITS AS STATED IN 29CFR …
Formaldehyde	1910.1001
4-Dimethylaminioazobenzene	1910.1048
Coke oven emissions	1910.1015
Acrylonitrile	1910.1029
Cadmium	1910.1045
Inorganic Arsenic	1910.1027
Ethylene Oxide	1910.1450
3,3’-Dichlorobenzidine (and its salts)	1910.1450
Napthylamine Benzidine	1910.1450
	1910.1450

DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

Exhibit VI-c

Philadelphia Fire Prevention Code
CHAPTER 32

FLAMMABLE AND COMBUSTIBLE LIQUIDS – (Include variance for New College Building allowing 60 gallons per lab properly stored in flammable cabinets and 1.5 gallons bench top, including waste.)

Section F-3201.0 GENERAL

F-3201.1 Scope: The provisions of this chapter, the mechanical code and NFIPA 30 and 30A listed in Chapter 44 shall apply to the storage, handling and processing of flammable and combustible liquids in addition to the requirements of Chapter 23. The installation, repair and removal of fuel oil burner equipment and tanks shall be in accordance with NFIPA 31 listed in Chapter 44.

F-3201.2 Permit required: A permit shall be required for any of the following purposes:

1. To install, remove, repair or alter a stationary tank for the storage of flammable or combustible liquids or modify or replace any line or dispensing device connected thereto.
2. For the storage, handling or use of Class liquids exceeding 5 gallons (0.019 m3) in an institutional or residential occupancy, or exceeding 10 gallon (0.038 m3) in any other occupancy, or exceeding 60 gallons (0.23 m3) outside of any building, except that a permit shall not be required for the following purposes:
   - 2.1 For the storage or use of flammable liquids in the fuel tank of a motor vehicle, aircraft, motorboat, mobile power plant or mobile heating plant.
   - 2.2 For the storage or use of paints, oils, varnishes or similar mixtures when such liquids are stored for painting, maintenance, or similar purposes on the premises and are not stored for a period exceeding 30 days.
3. Storage, handling or use of Class II *combustible liquids* or Class III *combustible liquids* exceeding 25 gallons (0.095 m3) in a structure, except for fuel oil in the amount of less than 660 gallons (2.5 m3) utilized in connection with permanently installed heating equipment.
4. For the manufacture, processing, blending or refining of flammable or combustible liquids.
5. For the storage of flammable or combustible liquids in stationary tanks.
6. For placing any *flammable or combustible liquid* stationary tank temporarily or permanently out-of-service and to place a tank back into service (see Section F-3208.11).

7. For any structure utilized for servicing or repairing a motor vehicle therein.
8. For the testing of flammable and combustible liquid underground storage tanks.

F-3201.3 Permit application: The application for a permit shall be submitted in such form as the code official prescribes and accompanied by drawings and any additional information required by the code official. Permit and inspection fees required by ordinance shall accompany all applications.

F-3201.31 Stationary tank information: The application to install, remove, repair or alter any stationary tank for the storage of *flammable or combustible liquids* shall contain a general description of the proposed work and include two copies of a drawing indicating the location, use, capacity piping arrangement of all existing and proposed tanks located, or which are located, on the premises and all adjacent structures and property lines. Information confirming that the tank complies with the design requirements of Section F3203.2 shall be attached to or made a part of the application.

F-3201.4 Use group classification: The storage of *flammable and combustible liquids* exceeding the exempt amounts per control area indicated in Table F-3201.4 shall be classified as Use Group H-2.

Exception: The storage of Class III B liquids shall be classified as Use Group H-3 materials.

F-3201.5 Flammable and combustible liquid piping system: The piping systems for *flammable and combustible liquids* shall comply with NFIPA 30, 30A and the mechanical code listed in Chapter 44.

SECTION F-3202.2 DEFINITIONS

F-302.1 General: The following words and terms shall, for the purposes of this chapter and as stated elsewhere in this code, have the meanings shown herein.

Class IIIB Solvents – Liquids having a flash point at or above 200 degrees F. (93 degrees C).
Class IV Solvents – Liquids classified as nonflammable.

SECTION F-3203.0 FIRE SAFETY REQUIREMENTS

F-3203.1 General: The layout, arrangement and construction of structure sin which *flammable or combustible liquids* in any quantity are used or stored shall comply with the building code listed in Chapter 44 and be provided with fire protection and fire

protection systems as required by that code. Structures and their service equipment shall be maintained as required by this code.

F-3203.2 Containers, tanks, equipment and apparatus: Containers, tanks, equipment and apparatus and all piping, fittings and appliances utilized or intended to be utilized for the storage, handling, use or movement of flammable or combustible liquids shall be constructed and tested in accordance with NFIPA 30 listed in Chapter 44, and approved.

> **F-3203.21 Warning labels for containers**: All cans, containers and vessels containing flammable liquids or flammable liquid compounds or mixtures offered for sale shall be provided with a warning label painted or printed on the container, stating the liquid is flammable and shall be kept away from heat and an open flame. All portable cans, containers and vessels which are empty and offered for sale and intended for the conveyance or storage of flammable liquids or flammable liquid compounds or mixtures shall be conspicuously marked with the name of the product which the cans, containers or vessels are intended to contain.

F-3203.3 Hazardous appliances: The sale or utilization of any heating, lighting or cooking appliance which utilizes a flammable or combustible liquid presenting a hazard shall be prohibited.

F-3203.4 Unlawful sale for cleaning: Class I flammable liquids shall not be sold or offered for sale for the purpose of domestic cleaning.

F-3203.5 Dispensing: All flammable or combustible liquids shall be dispensed in accordance with Sections F –3203.5.1 through F-3203.5.4.

> **F-3203.5.1 Dispensing type**: Flammable liquids shall not be dispensed by gravity from tanks, drums, barrels or similar containers. Approved pumps taking suction from the top of the container shall be utilized, except when the viscosity of the liquid makes such a restriction impractical. Combustible liquids shall be drawn from tanks, drums or barrels by gravity through an approved self-closing valve or faucet affixed directly on the container or a rigid closed piping system attached thereto.
>
> **F-3203.5.2 Movable tanks**: The temporary use of movable tanks in conjunction with the dispensing of flammable or combustible liquid into the fuel tanks of motor vehicles or other motorized equipment on premises to which the public does not have access or permitted, provided such installation is approved.
>
> **F-3203.5.3 Pressurization**: Flammable or combustible liquids shall not be dispensed by a device operating through pressure within a storage tank, drum or container, unless the tank, drum or container has been approved as a pressure

vessel for the intended purpose. Additionally, air or oxygen shall not be utilized to pressurize the approved vessel.

F-3203.5.4 Prohibited dispensing: All portable or stationery tanks, drums and containers into which flammable or combustible liquids are dispensed shall comply with the requirements of this code.

F-3203.6 Disposal of Waste: The discharge of flammable or combustible liquids or any waste liquid containing petroleum or petroleum products shall be prohibited into or on any street, pavement, highway, drainage canal ditch, storm or sanitary drain or flood control channel, lake or waterway, or the ground. All waste petroleum products shall be stored and disposed by an approved method.

F-3203.7 Cleaning: Both Class I and II flammable and combustible liquids shall not be used within a structure for washing parts or removing grease or dirt unless used in a labeled machine for such purpose or in a separately ventilated room constructed in accordance with the building code listed in Chapter 44. Machines shall be utilized and installed in accordance with Sections F-3203.71-F-3203.7.6.

F3203.7.1 Installation: Machines and equipment shall be installed in accordance with the manufacturer's installation instructions for the labeled equipment.

F3203.7.2 Ventilation: Machines and equipment shall be located in areas ventilated to prevent the accumulation of vapors in accordance with the mechanical code listed in Chapter 44.

F-3203.7.3 Solvents: Solvents shall be compatible with machines in which the solvents are used.

F-3203.7.4 Accessibility: Machines shall not be located in areas open to the public.

F-3203.7.5 Separation from ignition sources: Machines shall be separated from ignition sources in accordance with the manufacturer's installation instructions or by a distance of 3 feet, whichever is greater.

F-3203.7.6 Quantity limits: The quantity of both Class I and II liquids used in machines shall not exceed the design capacity of such machines, and the following requirements:

1. The quantity of both Class I and II liquids used in machines without remove solvent reservoirs shall not exceed 10 gallons.

2. The quantity of Class II liquids used in machines with remove solvent reservoirs shall not exceed 35 gallons per machines. The

aggregate quantity shall not exceed 240 gallons in structures not protected with an approved automatic sprinkler system and 480 gallons in structures protected with an approved automatic sprinkler system.

3. The remove solvent reservoirs shall be permitted to be integral with the machine that the reservoir services, or separated and connected by hoses, tubing, piping or similar devices complying with section F-3203.2.

4. Remote solvent reservoirs shall comply with the container requirements of Section F-3203.2.

F-3203.8 Sources of ignition: Precautions shall be taken to prevent ignition by eliminating or controlling sources of ignition in locations where flammable vapors are capable of existing. Sources of ignition shall include: open flames, lighting, smoking, cutting and welding, hot surfaces, frictional heat, sparks (static, electrical, and mechanical), spontaneous ignition, chemical and physical-chemical reactions and radiant heat. Where proper precautionary measures are not taken, either the devices shall not be utilized or the operation shall be suspended.

F-3203.9 Spills and leaks: Flammable and combustible liquid spills and leaks shall be promptly reported to the code officials.

F-3203.9(r) Contamination remediation: All soil and ground water contamination resulting from spills from storage tanks or containers shall be reported to the Pennsylvania Department of Environmental Resources and clean-up procedures established by that agency shall be followed. After remediation is completed, a copy of the assure report documenting satisfactory remediation shall be sent to the Commercial and Industrial Fire Inspection Unit of the Department of Licenses and Inspections.

F-3203.1 Valves: All new and existing above-ground Class I flammable and Class II combustible liquid tanks located inside of a structure shall be provided with either an approved automatic-closing, heat-actuated valve or a normally closed, remotely activated valve or other approved device on each liquid transfer connection located by the liquid level, except for connections utilized for emergency disposal. The valve shall be located within 2 feet of the shell of the tank.

Exception: Flammable or combustible liquid tanks with a capacity of less than 500 gallons and located in one-story structures designed and protected for flammable or combustible liquid storage.

F-3203.11 Prohibited change of use: The seasonal conversion of a gasoline tank or any other tank containing flammable liquids for the storage or dispensing of home heating oils, such as kerosene for retail sales, shall be prohibited.

F-3203.12 Emergency coordination: Chemical plants and refineries shall maintain a liaison with the Fire Department and other city agencies to establish and maintain operating procedures and equipment to be used during fires or other emergencies at a facility.

F-3203.12.1 Facilities with in-plant fire brigades: All major petroleum refineries and chemical plants with in-plant fire brigades shall assign knowledgeable personnel to act as the plant's emergency coordinators on all operating shifts, and they or their designees shall be responsible for providing a liaison with the Fire Department and other emergency officials who may be called upon to render assistance during a fire or other emergency.

F-3203.12.1.1 Review of emergency procedures: Annually, the designated liaison of a faculty equipped with an in-plant fire brigade shall meet with the Deputy Commissioner of Operations of the Fire Department, or designee, to review and coordinate their fire fighting and emergency procedures are acceptable to the Fire Department. Plans and training shall be consistent with Section 5-6.4 of NFIPA 320 listed in Chapter 44.

F-3203.12.1.2 Communications during an emergency: Facilities with in-plant brigades shall have at least two portable radios capable of receiving and transmitting on the Fire Department's fire ground radio frequencies.

Table F-23.18.1(1)

EXEMPT AMOUNTS OF HAZARDOUS MATERIALS PRESENTING A PHYSICAL HAZARD MAXIMUM QUANTITIES PER CONTROL AREA h

		Closed Systemsg			Open systemsg	
MATERIAL	CLASS	Solid pounds	Liquid Gallons (pounds)	Gas (cubic feet)	Solid pounds (cubic feet)	Liquid gallons (pounds)
Combustible liquid	II IIIA IIIB	Not applicable	120a 330a 13,200b	N/A	N/A	30a 80a 3,300b
Combustible dust pounds per 1,000 cubic feet		1c	N/A	N/A	1c	N/A
Combustible fiber	Loose Baled	(100) (1,000)	N/A	N/A	(20) (200)	N/A
Cryogenics Flammable or oxidizing		N/A	45a	N/A	N/A	10a
Explosives		1/4d	(1/4)d	N/A	1/4d	(1/4)d
Flammable gas	Gaseous Liquefied	N/A	N/A	750a.e N/A	N/A	N/A
Flammable liquid	1A 1B 1C	N/A	30a 60a 90a	N/A	N/A	10a 15a 20a
Combination (IA,IB,IC)		N/A	120a.f	N/A	N/A	30a.f
Flammable solid		25a	N/A	N/A	25a	N/A
Organic peroxide	Unclassified detonable I II III	1/4d 1a 50a 125a	1/4d (1)a (50)a	N/A	1/4d 1a 10a 25a	(1/4)d (1)a (10)a (25)a

		Closed Systemsg			Open Systemsg	
MATERIAL	CLASS	Solid pounds (cubic feet)	Liquid gallons (pounds)	Gas (cubic feet)	Solid pounds (cubic feet)	Liquid gallons (pounds)
Oxidizer	4 3 2 1	1/4d 2a 250a 1,000a	1/4d (2)a (250)a (1,000)a	N/A	1/4d 2a 50a 200a	(1/4)d (2)a (50)a (200)a
Oxidizer – gas	Gaseous Liquified	N/A	N/A 15a.e	1,500a.e N/A	N/A	N/A
Pyrophoric		1d	(1)d	10d.e	0	0
Unstable (reactive)	4 3 2 1	1/4d 1a 50a (125)b	(1/4)d (1)a (50)a (125)b	2d.e 10a.e 250a.e 750a.e	1/4d 1a 10a 25b	1/4d (1)a (10)a (25)b
Water-reactive	3 2	5a 50a	(5)a (50)a	N/A	1a 10a	(1)a (10)a

Note a. The maximum quantities shall be increased 100 percent in buildings equipped throughout with an approved automatic sprinkler system in accordance with the building code listed in Chapter 44. Where Note e also applies, the increase for both notes shall be applied accumulatively.

Note b. The permitted quantities shall not be limited in a building equipped throughout with an approved automatic sprinkler system in accordance with the building code listed in chapter 44.

Note c. A dust explosion potential is considered to exist where 1 pound or more of combustible dust per 1,000 cubic feet of volume is normally in suspension or is capable of being placed into suspension in all or a portion of an enclosure, including dust inside pieces of equipment. This also includes combustible dust which accumulates on horizontal surfaces inside buildings or equipment and which is capable of being placed into suspension by an accident, sudden force or small explosion.
Note d. Permitted in buildings equipped throughout with an approved automatic sprinkler system in accordance with the building code listed in Chapter 44.
Note e. The maximum quantity shall increase 10.0 percent when dispenses or used inside approved exhaust gas cabinets, exhausted enclosures or fume hood. Where NOTE a also applies, the increase for both notes shall be applied accumulatively.
Note f. Containing not more than the exempt amounts of Class IA, IB, or IC flammable liquids.
Note g. The aggregate quantity in use and storage shall not exceed the exempt amount per control area indicated in Chapter 24 through 43.

Note h. Quantities in parenthesis indicate quantity units in parenthesis at the head of each column 1 cubic foot – 0.028 m3, 1 pound – 0.454 kg: 1 gall on = 0.00379m3.

Table F-2318.1(2)
EXEMPT AMOUNTS OF HAZARDOUS MATERIALS PRESENTING A HEALTH HAZARD MAXIMUM QUANITITES PER CONTROL AREA f

Material	Solid poundsa	Liquid gallons (pounds)a	Gas Cubic feet	Solid Poundsa	Solid gallons (pounds)a
Corrosive	5,000	500b	810a.e	1,000	100b
Highly toxic	1	(1)	20c	¼	(1/4)
Irritant	5,000	500	810a.e	1,000	100
Radioactive (See Chapter 41)		100 rem-sealed source		25 rem-sealed source	
Sensitizer	5,000	500	810a.e	1,000	100
Toxic	500	(500)	810a.e	125	(125)
Other health hazards	5,000	500	810a.e	1,000	100

Note a. A maximum quantities shall be increased 100 percent in buildings equipped throughout with an approved sprinkler system in accordance with the building code listed in Chapter 44. Where Note e also applies, the increase for both notes shall be applied accumulatively.
Note b. Containment shall be provided and arranged so sprinkler discharge will not overflow and mix non-compatible materials.
Note c. Permitted only where stored in approved gas cabinets or exhausted enclosures in accordance with Section F-2319.3.6.
Note d. The aggregate quantity in use and storage shall not exceed the exempt amount per control area indicated in Chapter 24 through 43.
Note e. the maximum quantity shall be increased 100 percent when dispensed or used inside approved exhausted gas cabinets, exhausted enclosures or fume hoods.
Where Note a also applies, the increase for both notes shall be applied accumulatively.
Note f. Quantities in parentheses indicate quantity units in parenthesis at the head of each column. 1 cubic foot – 0/028 m3, 1 pound – 0.454 kg: 1 gallon – 0.00379 m3.

F-2319.2.4 Spill control and drainage: Rooms or areas where hazardous material liquids are dispensed or used shall be provided with a means to control spills and drainage in accordance with Section F-2315.2 and F-2315.3.

Exceptions

1. Containers not exceeding 1 gallon (0.00379 m3) in capacity.
2. Hazardous material systems containing 5 gallons (0.019m3) or less capacity.

F-2319.3 Closed systems: Use of hazardous materials in closed containers or systems shall comply with Sections F-2319.3.1 through F-2319.3.6.

F-2319.3.1 System design: Systems shall be suitable for the intended purpose and designed by persons competent in such design. Where approved practices or standards have been established for the processes employees, such practices or standards shall be followed in the design. Controls shall be designed to prevent materials from entering or leaving process or reaction systems at other than the intended time, rate or path. Automatic controls, where provided, shall be designed to be fail-safe.

F-2319.3.2 Ventilation: Where closed systems are designed to be opened as part of normal operations, ventilation shall be provided in accordance with Section F-2319.2.2.

F-2319.3.3 Explosion control: Where an explosion hazard is capable of occurring as a result of the dispensing or use process, explosion control shall be provided in accordance with the building code listed in Chapter 44.

> **Exception:** Process vessels designed to fully contain the worst case explosion anticipated within the vessel under process conditions considering the most likely failure.

F-2319.3.4 Spill control, drainage and containment: Rooms or areas where hazardous materials liquids are used, individual tank or containers exceeding 55 gallons (0.21 m3) shall be provided with a means to control spills in accordance with Section F-2315.1.

F-2319.3.5 Secondary containment: Secondary containment shall be provided in accordance with Section F-2315.4 where the aggregate of multiple tanks or containers exceeds 1,000 gallons (3.8 m3).

Table F-3201.4
EXEMPT AMOUNTS OF FLAMMABLE AND COMBUSTIBLE LIQUIDS

Conditions	Class	Exempt amounts (gallons)b
Inside Storage Unprotected by sprinklers, approved cabinet or safety containers	IA IB IC Combination (IA, IB, IC) II IIIA IIIB	30 60 90 120a 120 330 13,200
Within approved cabinet or safety containers in unsprinklered structure	IA IB IC Combination (IA, IB, IC) II IIIA IIIB	60 120 180 240a 240 600 26,400
In sprinklered structure, not approved cabinet or safety containers	IA IB IC Combination (IA, IB, IC) II IIIA IIIB	60 120 180 240a 240 660 Untitled
In sprinklered structure, not approved cabinet or safety containers	IA IB IC Combination (IA, IB, IC) II IIIA IIIB	120 240 360 480a 480 1,320 Unlimited
Outside storage	IA IB IC Combination (IA, IB, IC) II IIIA IIIB	60 120 180 240a 240 660 Unlimited

Note a. Containing not more than the exempt amounts of Class IA, IB, or IC flammable liquids.
Note b. 1 gallon = 0.00379 m3.

Boiling point: The temperature at which the vapor pressure of a liquid equals the atmospheric pressure of 14.7 pounds per square inch (psia) (101 kPa) or 760 mm of mercury. Where an accurate boiling point in unavailable of the materials in question, or for mixtures which do not have a constant boiling point, for the purposes of this classification, the 10 percent of a distillation performed in accordance with ASTM D86 listed in Chapter 44 shall be used as the boiling point of the liquid.

Combustible liquids: Any liquids having a flash point at or above 100 degrees F. (38 degrees C.) shall be known as Class II or III liquids. Combustible liquids shall be divided into the following classifications:

Class II. Liquids having flash points at or above 100 degrees F. (38 degrees C.) and below 140 degrees F. (60 degrees C.).

Class IIIA. Liquids having flash points at or above 140 degrees F. (60 degrees C.) and below 200 degrees F. (93 degrees C).

Class IIIB. Liquids having flash points at or above 200 degrees F. (93 degrees C.).

Flammable liquids: Any liquids having a flash point below 100 degrees F. (38 degrees C.), and having a vapor pressure not exceeding 40 psia (276 kPa) at 100 degrees F. (38 degrees C.). Flammable liquids shall be known as Class liquids and shall be divided into the following classifications:

Class IA. Liquids having a flash point below 73 degrees F. (23 degrees C.). and having a boiling point below 100 degrees F. (38 degrees C.).

Class IB. Liquids having a flash point below 73 degrees F. (23 degrees C.) and having a boiling point at or above 100 degrees F. (38 degrees C.).

Class IC. Liquids having a flash point at or above 73 degrees F. (23 degrees C.) and below 100 degrees F. (38 degrees C.).

(See Combustible liquids for Class II or III liquids.)

Flash point: The minimum temperature in degrees Fahrenheit at which a flammable liquid will give off sufficient vapors to form an ignitable mixture with air near the surface or in the container, but will not sustain combustion. The flash point of a liquid shall be determined by appropriate test procedure and apparatus as specified in ASTM D56 and D93 listed in Chapter 44.

Remote solvent reservoir: A liquid solvent container enclosed against evaporative losses to the atmosphere during periods when the container is not being utilized, except for a solvent return opening not larger than 16 square inches (10,322 mm2). Such return allows pump-cycled used solvent to drain back into the reservoir from a separate solvent sink or work area.

Solvent or liquid classifications: A method for classifying solvents or liquids according to the following classes:

Class I Solvents – Liquids having a flash point below 100 degrees F.(38 degrees C.).

Class II Solvents – Liquids having a flash point at or above 100 degrees F. (38 degrees C.). and below 140 degrees F. (60 degrees C.).

Class IIIA Solvents – Liquids having a flash point at or above 140 degrees F. (60 degree C.) and below 200 degrees F. (93 degrees C.).

DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

Exhibit VII-a
General Radiation Safety in the Laboratory

- Eating, drinking, application of cosmetics, manipulation of contact lenses are NOT permitted.
- Smoking or chewing of tobacco products are NOT permitted.
- Do not store food or drinks for human consumption within the laboratory.
- Mouth pipetting is NOT permitted.
- Careful experimental planning, including dry runs, shielding considerations, source handling tools, contamination control and monitoring should be performed to minimize exposure and chance of spills or other incidents.
- Wear laboratory coat while in the laboratory.
- Wear disposable gloves, and change them frequently.
- Use plastic backed absorbent paper on all work areas where radioactive materials will be used. Use drip trays where practical.
- Label radioactive work areas and containers of radioactive material with radioactive warning tape.
- Use appropriate (e.g., shielded, labeled) containers for storing or carrying radioactive material.
- Seal containers of radioactive material when vortexing, centrifuging and incubating.
- Use a secondary trap flask in series with collection flask for vacuum aspiration.
- Wear radiation monitoring badge(s) if assigned.
- Do NOT wear someone else radiation monitoring badge. If yours is missing contact the Radiation Safety Office.
- Post the following notices in the laboratory:
  1. NRC Form 3 – "Notice to Employees"
  2. General Radiation Safety Rules
  3. Emergency Procedures
- Label the laboratory and equipment, as applicable, with "Caution Radioactive Material" sign.
- Maintain record of receipt, use and disposal of radioactive material.
- Monitor hands, shoes and clothing frequently.
- Wash hands after using radioactive material, before eating or smoking, and when leaving the work area. Survey yourself (hands, body, feet) and work area before leaving the laboratory for lunch, breaks and/or the end of the day; and after each high level use (i.e. Alliquoting from stock solution) of radioactive material.
- Dispose of waste according to guidelines as found in the Drexel University and Drexel University College of Medicine' Radiation Safety Manual.
- Follow the procedures for receiving radioactive material packages.
- Use Plexiglas shielding where practical and appropriate when manipulating 32P or other high energy beta emitter.

- Use approved fume hoods or glove boxes when required in licensing conditions to control possible airborne contamination.
- Prevent unauthorized access to radioactive material by challenging unauthorized individuals, locking radioactive material in refrigerators, freezers or storage cabinets, or locking the laboratory when no one is physically present.
- Follow the approved protocol and any conditions of authorization.
- The RSO must be notified in the event of:
    1. Personnel contamination;
    2. Any accident resulting in direct exposure to personnel;
    3. Unexpected loss of RAM to air or sewer; or loss of RAM

DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

Exhibit VII-b
Policy and Procedures: Protection and Monitoring of Personnel-Pregnant Workers

Background

State and federal regulations limit the radiation dose to the embryo/fetus of an occupationally exposed declared pregnant woman to 0.5 rem (500 millirem) for the entire gestation. A declared pregnant woman is defined in the regulations as "a woman who has voluntarily informed the licensee, in writing, of her pregnancy and the estimated date of conception."

The dose limit is only for occupational exposures. Any radiation exposure received as a patient from medical diagnosis or treatment, and exposures received from natural background radiation are not controlled by this limit.

The woman must provide the declaration of pregnancy in writing to impose the more restrictive limit.

The declaration of pregnancy is strictly voluntary.

In effect, a pregnant woman has the choice of declaring her pregnancy, thereby imposing a more restrictive dose limit to her embryo/fetus. To comply with the more restrictive radiation dose limits, Drexel University and Drexel University College of Medicine may require the use of additional protective equipment (i.e. Additional shielding, lead aprons, etc.), increased monitoring (i.e. Extra film badges, pocket dosimeters, etc.), or re-assign duties. Note that most activities involving exposure to radiation at Drexel University and Drexel University College of Medicine result in annual radiation exposures of less than 500 millirem.

Policy and Procedures

To comply with this regulation, the Drexel University and Drexel University College of Medicine' Radiation Safety Office has implemented the following policy/procedures:

- The pregnant woman who wishes to impose radiation dose limits for her embryo/fetus must provide a written declaration to the Radiation Safety Officer. The attached form provides such written notification.
- Declaration of pregnancy is strictly voluntary.
- A pregnant woman who plans to declare her pregnancy is encouraged to do so promptly upon discovering her pregnancy so that the appropriate precautions can be taken early in the gestation period.
- The declaration of pregnancy will be kept confidential. The declaration of pregnancy will only be disclosed to Drexel University and Drexel University

College of Medicine' employees with a legitimate need to know (i.e. Immediate supervisor).

- A declared pregnant woman may "undeclare" her pregnancy. The intent of the regulation and this policy is to give the pregnant woman the right to choose whether or not to impose dose limits. She may revoke her choice but her right to choose is irrevocable.
- A pregnant woman may seek recommendations from the Radiation Safety Office to reduce radiation exposure to her embryo/fetus without declaring her pregnancy.
- Any woman may request additional information on the risks associated with radiation exposure to the embryo/fetus from the Radiation Safety Office.
- The declared pregnant worker will notify the Radiation Safety Office of the end of her pregnancy so that the special precautions can be terminated.
- The radiation dose limit to the embryo/fetus of a declared pregnant woman is 0.5 rem (500 millirem). The radiation dose limit applies only to occupational exposure of the declared pregnant woman. It does not apply to radiation exposure from medical diagnosis or treatment, nor does is apply to background radiation exposures.
- Restrictions may be imposed to prevent radiation exposures from exceeding 500 millirem during the gestation. These restrictions may include a temporary change in work assignments, the use of additional protective equipment, and increased monitoring.
- If the embryo/fetus radiation exposure has exceeded 450 millirem before the pregnancy is declared, a dose limit of 50 millirem will be in effect for the remainder of the pregnancy.

Confidential

To : Radiation Safety Officer

From : _____

Subject: Declaration of Pregnancy

Date : _____

Pursuant to the requirements of the U.S. Nuclear Regulatory Commission regulations and Drexel University and Drexel University College of Medicine' policy, I am declaring my pregnancy. I understand that by declaring my pregnancy, a dose limit of 500 millirem to the embryo/fetus (10% of the annual radiation exposure limit to a radiation worker) is imposed. I also understand that Drexel University and Drexel University College of Medicine may need to institute engineering controls, administrative controls, additional personal protective equipment, and/or additional monitoring to assure compliance with the dose limits.

I certify that I am making this declaration voluntarily.

The estimated date of conception (month/year) is _____ .

Signature : _____ Date : _____

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Exhibit VII-c
Radiation Emergency Instructions

MINOR SPILLS - involving no radiation hazard to personnel.

1. Notify all other persons in the room or area that a spill has occurred.
2. Prevent spread of contamination by covering the spill with absorbent paper.
3. Decontaminate the area. Using paper towels or absorbent pads, clean towards the center of the spill. Place all waste into plastic bags and dispose of as radioactive waste. Disposable gloves, lab coat, and if necessary, appropriate shoe covers should be worn. Cleansing agents may be used after initial decontamination attempt.
4. Survey the area and all contaminated and potentially contaminated individuals with a G-M survey meter. Survey for removable contamination using wipe samples.
5. Report the incident to the Radiation Safety Office by telephone. (See numbers at bottom of page)

MAJOR SPILLS – involving potential radiation hazard to personnel, involving personal contamination, involving actual or potential uptake of radioactive material, or which threatens to restrict the use of the facility.

1. **Clear the area:** Notify all persons not involved with or near the spill to vacate the room.
2. **Prevent spread of contamination:** cover the spill with absorbent paper. Do NOT attempt to clean it up. Assemble all potentially contaminated personnel near the room entrance.
3. **Close the room:** prevent entry into the room.
4. **Call for help**: Immediately contact the Radiation Safety Office.
5. **Decontaminate personnel:** Survey personnel for contamination. Contaminated clothing should be removed and stored for evaluation by Radiation Safety. Contaminated skin should be flushed thoroughly and then washed with mild soap and lukewarm water.

FIRES – (R.A.C.E.)

Rescue persons in immediate danger
Alarm – activate manual pull station and call security (Dial “80”) with the fire location.
Contain the fire by closing the room.
Evacuate the area. Do not attempt to extinguish the fire unless:

a. The fire presents an immediate risk of injury to you or someone else in the area, or
b. The fire is very small in size, easily extinguished, and you have had fire extinguisher training.

Do NOT attempt to extinguish the fire if radioactive materials are directly involved. **Evacuate** the area; **contact** Radiation Safety; and notify the fire fighters that radioactive materials are involved.

After hours, call the Hospital Emergency Operator (dial “80”-DUCOM or “215-895-2222”-Drexel) and request the radiation emergency call list. **A spill is defined as leaving the confines of the experiment. A discharge onto absorbent paper or a drip tray is not a spill.**

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Exhibit VII-d
RADIATION EXPOSURE LIMITS*

TYPE OF EXPOSURE	LIMITS
Total Effective Dose (Sum of internal and external dose)	5,000 millirem per year
Lens of eye	15,000 millirem per year
Skin	50,000 millirem per year
Extremities	50,000 millirem per year
Single organ or tissue (except lens of eye)	50,000 millirem per year
Minors (Under age 18)	10% of adult limit
Embryo / Fetus of declared pregnant woman	500 millirem per year
Member of the public	100 millirem per year per licensee

**U.S.N.R.C. regulations, Title 10, Part 20, Code of Federal Regulations (1-1-84).*
NOTE: Certain states and other regulatory agencies may use limits that are different from the above.

Exhibit VII-e
ISOTOPE TABLE

					Half Life	
Isotope	**Decay Type**	**Energy (MeV)**	**Target Organ**	**ALI**	**Radioactive**	**Biological**
H-3	Beta	0.0186	Body Tissue	80,000 uCi	12.26y	12d
C-14	Beta	0.156	Body fat	2,000 uCi	5730y	12d
Na-24	Beta Gamma	1.389 1.369 2.754	Total body	4,000 uCi	14.96h	11d
P-32	Beta	1.71	Bone	600 uCi	14.28d	1155d
S-35	Beta	0.167	Total body	400 uCi	87.90d	623d
Cr-51	Gamma	0.32	Total body	40,000 uCi	27.80d	616d
I-125	Gamma	0.028	Thyroid	40 uCi	60.20d	138d
I-131	Beta Gamma	0.606 0.637 0.364	Thyroid	90 uCi	8.05d	138d

TARGET ORGAN: Organ in which the radioactive material tends to concentrate or delivers the most dose..

ALI (Allowable Limit of Intake): The amount of a radioisotope inhaled or ingested that would result in a whole body dose equivalent of 5 rem or a dose to an individual organ of 50 rem.

RADIOACTIVE HALF LIFE: The amount of time required for one-half of the radioactive material to undergo radioactive transformations.

BIOLOGICAL HALF LIFE: The time required for one-half of the material to be removed from the target organ or body by biological processes.

APPENDICES

APPENDIX A

DOT HAZARD CLASSIFICATION LIST

HAZARD CLASSIFICATIONS	EXAMPLE
EXPLOSIVE A & B	DYNAMITE
EXPLOSIVE C	FIREWORKS
BLASTING AGENTS	PLASTIC EXPLOSIVES
RADIOACTIVE MATERIAL	CO-60 OR I-125
FLAMMABLE LIQUIDS	ALCOHOL
PYROPHORIC LIQUIDS	PHOSPHORUS HYBRIDS
NON-FLAMMABLE COMPRESSED GASES	NITROGEN
FLAMMABLE GASES	OXYGEN
COMBUSTIBLE LIQUIDS	KEROSENE
FLAMMABLE SOLIDS	PICRIC ACID/10% WET
OXIDIZER	NITRIC ACID
CORROSIVE MATERIAL	HYDROCHLORIC ACID
IRRITATING MATERIAL	LACRAMATOR
POISON A	HEPTACHLOR
POISON B	PHENOL
ORGANIC PEROXIDE	BENZOYL PEROXIDE
*ORM-A	FORMALDEHYDE
ORM-B	MERCURY
ORM-C	ASBESTOS
ORM-D	BLEACH
ORM-E	FERRIC SULFATE
ETIOLOGICAL AGENTS	MICROORGANISMS (E. COLI)

*ORM = OTHER REGULATED MATERIAL

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APPENDIX B

EPA HAZARD CLASSIFICATION LIST

1. IGNITABLE WASTE-

FLASH POINT <140 F
FLAMMABLE SOLIDS (10)
OXIDIZERS (11)
FLAMMABLE GASES (8)
SOME COMBUSTIBLE LIQUIDS (9)
FLAMMABLE LIQUIDS (5)
PYROPHORIC LIQUIDS (6)

2. CORROSIVES-

ANY LIQUID OF PH$\leq$2 OR $\geq$12.5 (12)

3. REACTIVE-EXPLOSIVES A, B, OR C (1, 2, OR 3)

WATER REACTIVE
CYANIDE OR SULFIDE
ORGANIC PEROXIDES (16)
POISON B (15)

4. EXTRACTION PROCEDURE (EP) TOXIC

8 METALS:

ARSENIC	SILVER
CADMIUM	LEAD
CHROMIUM	BERYLLIUM
MERCURY	THALLIUM

4 PESTICIDES:

LINDANE	TOXAPHENE
ENDRIN	METHOXYCHLOR

2 HERBICIDES:

2,4 D	2,4,5 T

POISON A AND SOME POISON B (14 AND 15)
IRRITATING MATERIAL (13)
RADIOACTIVE MATERIAL (4)
ORM-A-B-C (17,18, AND 19)
ORM-E (21)

NOTE: NUMERALS IN PARENTHESES INDICATED CHEMICAL CATEGORIES ON THE DOT LIST.

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APPENDIX C

CHEMICAL INVENTORY FORM **PAGE ___OF ___**

CHEMICAL PRODUCT OR TRADE NAME	MAJOR HAZARDOUS COMPONENTS	QUANTITY	PHYSICAL STATE L, S, G	NFPA/HMIS HAZARD CLASS				DATE PURCHASE	SHELF LIFE	MSDS PRESENT Y OR N	COMMENTS
				H	F	R	SH				

***HAZARD CLASS RATING AS PER NATIONAL FIRE PREVENTION ASSOCIATION (NFPA)**

(H) = HEALTH HANDING **(F) = FLAMMABILITY** **(R) = REACTIVITY** **(SH) = SPECIAL**

4 DEADLY ACID	**4 FLASH PT.<730F**	**4 MAY /DETONATE**	**ACID-ACID**
3 EXTREME DANGER	**3 FLASH PT.<1000F**	**3 SHOCK/HEAT MAY DETONATE**	**ALKALINE -AKL**
2 HAZARDOUS CORROSIVE	**2 FLASH PT.>1000F**	**2 VIOLENT CHEMICAL CHANGE**	**CORROSIVE - COR**
1 SLIGHTLY HAZARDOUS	**1 FLASH PT.>2000F**	**1 UNSTABLE IF HEATED**	**OXIDIZER - OXY**
0 NORMAL MATERIAL	**0 WILL NOT BURN**	**0 STABLE**	**RADIATION-RAD**

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APPENDIX D

SAMPLE MSDS REQUEST LETTER

TO: CHEMICAL MANUFACTURER, IMPORTER, OR DISTRIBUTOR

AS YOU ARE AWARE, OSHA REQUIRES EMPLOYERS TO PROVIDE TRAINING TO THEIR EMPLOYEES CONCERNING THE HAZARDS OF CHEMICALS OR OTHER HAZARDOUS MATERIALS. TO PROPERLY TRAIN OUR EMPLOYEES, WE NEED A MATERIAL SAFETY DATA SHEET (MSDS) FOR ONE OR MORE OF YOUR PRODUCTS.

YOUR PROMPT ATTENTION IS NECESSARY TO MAINTAIN A PROPER LEVEL OF SAFETY FOR OUR EMPLOYEES. PLEASE SEND THE MSDS FOR CHEMICALS ON THE ATTACHED LIST NO LATER THAN .

SINCERELY,
NAME
TITLE

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APPENDIX E

MSDS EXAMPLE

ANY COMPANY
MATERIAL SAFETY DATA SHEET
ISSUE DATE: AUGUST 1, 1990

ANY COMPANY
P.O. BOX 1234
ANYTOWN, USA

SECTION I-GENERAL INFORMATION

PRODUCT/CHEMICAL NAME — 10% NEUTRAL BUFFERED FORMALIN, V/V

CHEMICAL FAMILY-ALDEHYDE

BUSINESS TELEPHONE — (314) 555-1235

SECTION II-HAZARDOUS INGREDIENTS

	%	TLV	ACCREDITING AGENCY	
37% FORMALDEHYDE-STABILIZED WITH METHANOL (11% V/V) (PROBABLE CARCINOGEN)	10 V/V	1 PPM-	TWA	OSHA
		2 PPM-	STEL	OSHA
METHANOL	1	200 PPM		OSHA

SECTION III-PHYSICAL DATA

APPEARANCE	CLEAR COLORLESS LIQUID
ODOR	PUNGENT ODOR
BOILING POINT (°F)	204° TO 211° F
EVAPORATION RATE (BUTYL ACETATE=1)	0.43
PERCENT VOLATILE BY VOL.	98%
SOLUBILITY IN WATER	100%-COMPLETE
SPECIFIC GRAVITY (WATER=1)	1.109 @ 21° C
VAPOR DENSITY (AIR=1)	1.1
VAPOR PRESSURE (MM OF HG)	19

SECTION IV-FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (METHOD USED: PENSKY-MARTENS):
NONE OBSERVED BELOW 180° F (82° C)

FLAMMABLE LIMITS IN AIR, % BY VOLUME:
LOWER 7 UPPER 73%

EXTINGUISHING MEDIA:
ALCOHOL FOAM, DRY CHEMICALS, CARBON DIOXIDE, WATER SPRAY.

UNUSUAL FIRE AND EXPLOSION HAZARDS:
MAY GENERATE FORMALDEHYDE GAS.

FIRE-FIGHTING PROCEDURES:
COOLING CONTAINER WITH WATER SPRAY OR FOG WILL HELP TO ABSORB ESCAPING FUMES. EVACUATE AFFECTED AREAS. STAY UPWIND AND AVOID CONTACT WITH SMOKE AND FUMES. IF CONTACT CANNOT BE AVOIDED, WEAR PERSONAL PROTECTIVE EQUIPMENT INCLUDING CHEMICAL SPLASH GOGGLES AND AIR MASK WITH BREATHING AIR SUPPLY. RUNOFF FROM FIRE CONTROL MAY CAUSE POLLUTION.

SECTION V-REACTIVITY DATA

STABILITY:
STABLE

INCOMPATIBILITY:
REACTION WITH PHENOL, STRONG ACIDS OR ALKALIS MAY BE VIOLENT. FORMALDEHYDE AND HYDROCHLORIC ACID MAY FORM BIS-CHLOROMETHYL ETHER, AN OSHA-REGULATED CARCINOGEN.

HAZARDOUS DECOMPOSITION:
OCCURS SLOWLY AT ELEVATED TEMPERATURES, RELEASING FORMALDEHYDE GAS.

HAZARDOUS POLYMERIZATION:
NONE.

SECTION VI-HEALTH DATA

INHALATION:
MAY CAUSE SORE THROAT, COUGHING, AND SHORTNESS OF BREATH. CAUSES IRRITATION TO THE RESPIRATORY TRACT. MAY BE FATAL IN HIGH CONCENTRATIONS.

INGESTION:
CAN CAUSE SEVERE ABDOMINAL PAIN, VIOLENT VOMITING, HEADACHES, AND DIARRHEA. LARGER DOSES MAY PRODUCE DECREASED BODY TEMPERATURE, PAIN IN THE DIGESTIVE TRACT, SHALLOW RESPIRATION, WEAK IRREGULAR PULSE, UNCONSCIOUSNESS, AND DEATH. METHANOL COMPONENT AFFECTS THE OPTIC NERVE AND MAY CAUSE BLINDNESS.

SKIN CONTACT:
TOXIC. MAY CAUSE IRRITATION TO SKIN WITH REDNESS, PAIN AND POSSIBLE BURNS. SKIN ABSORPTION MAY OCCUR WITH SYMPTOMS PARALLELING THOSE FROM INGESTION.

EYE CONTACT:
VAPOR CAUSES IRRITATION TO THE EYES WITH REDNESS, PAIN, AND BLURRED VISION. HIGHER CONCENTRATIONS OR SPLASHES MAY CAUSE IRREVERSIBLE EYE DAMAGE.

SECTION VII-FIRST AID PROCEDURES

INHALATION:
REMOVE TO FRESH AIR. IF NOT BREATHING, GIVE ARTIFICIAL RESPIRATION. IF BREATHING IS DIFFICULT, GIVE OXYGEN. CALL A PHYSICIAN.

INGESTION:

IF SWALLOWED, INDUCE VOMITING IMMEDIATELY BY GIVING TWO GLASSES OF WATER AND STICKING FINGER DOWN THROAT. NEVER GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON. CALL PHYSICIAN IMMEDIATELY.

SKIN CONTACT:

IN CASE OF CONTACT, IMMEDIATELY FLUSH SKIN WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES WHILE REMOVING CONTAMINATED CLOTHING AND SHOES. WASH CLOTHING BEFORE REUSE. THOROUGHLY CLEAN SHOES BEFORE REUSE. GET MEDICAL ATTENTION IMMEDIATELY.

EYE CONTACT:

WASH EYES WITH PLENTY OF WATER FOR AT LEAST 15 MINUTES, LIFTING LOWER AND UPPER EYELIDS OCCASIONALLY. GET MEDICAL ATTENTION IMMEDIATELY.

SECTION VIII-SPECIAL PROTECTION

VENTILATION:

VENTILATION ADEQUATE TO KEEP FORMALDEHYDE CONCENTRATIONS BELOW INDICATED EXPOSURE LIMITS SHOULD BE PROVIDED. IF LIMITS MAY BE EXCEEDED, USE A FULL FACE AIR PURIFYING RESPIRATOR WITH CARTRIDGES APPROVED FOR FORMALDEHYDE (UP TO 500 PPM) OR SUPPLIED AIR RESPIRATOR.

PERSONAL PROTECTIVE EQUIPMENT:

USE CHEMICAL SPLASH GOGGLES, NEOPRENE OR POLYVINYL CHLORIDE GLOVES AND COVERALLS WITH LONG SLEEVES. USE BREATHING AIR SUPPLY FROM AIRLINE MASK OR SELF-CONTAINED BREATHING MASK IF EXPOSURE LIMITS ARE EXCEEDED.

SECTION IX-SPILL PROCEDURES

STEPS TO TAKE IN CASE OF RELEASE OR SPILL:

KEEP UPWIND OF LEAK; EVACUATE AREA UNTIL GAS HAS DISPERSED. SOAK UP SMALL LEAKS WITH RAGS OR OTHER ABSORBENT AND REMOVE IN COVERED METAL CONTAINERS OR DRUMS. DIKE LARGE SPILLS. MAY BE NEUTRALIZED WITH DILUTE (5%) SOLUTIONS OF AMMONIA SODIUM SULFITE OR SODIUM BISULFITE AND REMOVED. FLUSH SPILL AREA WITH PLENTY OF WATER.

WASTE DISPOSAL METHOD:

COMPLY WITH FEDERAL, STATE, AND LOCAL REGULATIONS. IF APPROVED, FLUSH TO CHEMICAL SEWER, INCINERATE, DISPOSE IN HAZARDOUS MATERIAL LANDFILL, OR FLUSH TO WASTE WATER TREATMENT SYSTEM. VERY DILUTE SOLUTIONS CAN BE HANDLED BY BIOCHEMICAL ACTION IN FORMALDEHYDE-ADAPTED WASTE TREATMENT SYSTEMS; WATER SPRAY OR FOG WILL HELP ABSORB ESCAPING FUMES.

SECTION X-SHIPPING INFORMATION

STORAGE CONDITIONS:

KEEP CONTAINER CLOSED. KEEP AWAY FROM HEAT AND OPEN FLAMES. DO NOT STORE BELOW 15°C (59° F).

TRANSPORTATION:

DOT SHIPPING NAME-FORMALDEHYDE OR FORMALIN SOLUTION. DOT HAZARD CLASS-ORM-A (IN CONTAINERS OF 110 GALLONS OR LESS).

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APPENDIX F

CONCENTRATIONS OF CHEMICALS IMMEDIATELY DANGEROUS TO LIFE OR HEALTH

Documentation for Immediately Dangerous to Life or Health Concentrations (IDLHs)

NIOSH CHEMICAL LISTING AND DOCUMENTATION OF REVISED IDLH VALUES (AS OF 3/1/95)

SUBSTANCE	ORIGINAL IDLH VALUE	REVISED IDLH VALUE
Acetaldehyde	10,000 ppm	2,000 ppm
Acetic acid	1,000 ppm	50 ppm
Acetic anhydride	1,000 ppm	200 ppm
Acetone	20,000 ppm	2,500 ppm[LEL]
Acetonitrile	4,000 ppm	500 ppm
Acetylene tetrabromide	10 ppm	8 ppm
Acrolein	5 ppm	2 ppm
Acrylamide	Unknown	60 mg/m3
Acrylonitrile	500 ppm	85 ppm
Aldrin	100 mg/m3	25 mg/m3
Allyl alcohol	150 ppm	20 ppm
Allyl chloride	300 ppm	250 ppm
Allyl glycidyl ether	270 ppm	50 ppm
2 Aminopyridine	5 ppm	5 ppm [Unch]
Ammonia	500 ppm	300 ppm
Ammonium sulfamate	5,000 mg/m3	1,500 mg/m3
n-Amyl acetate	4,000 ppm	1,000 ppm
sec-Amyl acetate	9,000 ppm	1,000 ppm
Aniline	100 ppm	100 ppm [Unch]
o-Anisidine	50 mg/m3	50mg/m3 [Unch]
p-Anisidine	50 mg/m3	50 mg/m3[Unch]

Antimony compounds (as Sb)	80 mg Sb/m3	50 mg Sb/m3
ANTU	100 mg/m3	100mg/m3[Unch]
Arsenic (inorganic compounds,as As)	100 mg As/m3	5 mg As/m3
Arsine	6 ppm	3 ppm
Azinphosmethyl	20 mg/m3	10 mg/m3
Barium (soluble compounds, as Ba)	1,100mg Ba/m3	50 mg Ba/m3
Benzene	3,000 ppm	500 ppm
Benzoyl peroxide	7,000 mg/m3	1,500 mg/m3
Benzyl chloride	10 ppm	10 ppm [Unch]
Beryllium compounds (as Be)	10 mg Be/m3	4 mg Be/m3
Boron oxide	N.E.	2,000 mg/m3
Boron trifluoride	100 ppm	25 ppm
Bromine	10 ppm	3 ppm
Bromoform	Unknown	850 ppm
1,3-Butadiene	20,000 ppm[LEL]	2,000 ppm[LEL]
2-Butanone	3,000 ppm	3,000 ppmUnch]
2-Butoxyethanol	700 ppm	700 ppm [Unch]
n-Butyl acetate	10,000 ppm	1,700ppm [LEL]
sec-Butyl acetate	10,000 ppm	1,700 ppm[LEL]
tert-Butyl acetate	10,000 ppm	1,500 ppm[LEL]
n-Butyl alcohol	8,000 ppm	1,400 ppm[LEL]
sec-Butyl alcohol	10,000 ppm	2,000 ppm
tert-Butyl alcohol	8,000 ppm	1,600 ppm
n-Butylamine	2,000 ppm	300 ppm
tert-Butyl chromate	30mg/m3(asCrO3)	15mgCr(VI)/m3
n-Butyl glycidyl ether	3,500 ppm	250 ppm
n-Butyl mercaptan	2,500 ppm	500 ppm
p-tert-Butyltoluene	1,000 ppm	100 ppm

Cadmium dust (as Cd)	50 mg Cd/m3	9 mg Cd/m3
Cadmium fume (as Cd)	9 mg Cd/m3	9mgCd/m3[Unch]
Calcium arsenate (as As)	100 mg As/m3	5 mg As/m3
Calcium oxide	Unknown	25 mg/m3
Camphor (synthetic)	200 mg/m3	200mg/m3[Unch]
Carbaryl	600 mg/m3	100 mg/m3
Carbon black N.E.	1,750 mg/m3	
Carbon dioxide	50,000 ppm	40,000 ppm
Carbon disulfide	500 ppm	500 ppm [Unch]
Carbon monoxide	1,500 ppm	1,200 ppm
Carbon tetrachloride	300 ppm	200 ppm
Chlordane	500 mg/m3	100 mg/m3
Chlorinated camphene	200 mg/m3	200mg/m3[Unch]
Chlorinated diphenyl oxide	Unknown	5 mg/m3
Chlorine	30 ppm	10 ppm
Chlorine dioxide	10 ppm	5 ppm
Chlorine trifluoride	20 ppm	20 ppm [Unch]
Chloroacetaldehyde	100 ppm	45 ppm
alpha-Chloroacetophenone	100 mg/m3	15 mg/m3
Chlorobenzene	2,400 ppm	1,000 ppm
o-Chlorobenzylidene malononitrile	2 mg/m3	2 mg/m3 [Unch]
Chlorobromomethane	5,000 ppm	2,000 ppm
Chlorodiphenyl (42% chlorine)	10 mg/m3	5 mg/m3
Chlorodiphenyl (54% chlorine)	5 mg/m3	5 mg/m3 [Unch]
Chloroform	1,000 ppm	500 ppm
1-Chloro-1-nitropropane	2,000 ppm	100 ppm
Chloropicrin	4 ppm	2 ppm
beta-Chloroprene	400 ppm	300 ppm
Chromic acid and chromates	30mg/m3asCrO3)	15 mg r(VI)/m3
Chromium (II) compounds [as Cr(II)]	N.E.	250mgcr(II)/m3
Chromium (III) compounds [as Cr(III)]	N.E.	25mgcr(III)/m3
Chromium metal (as Cr)	N.E.	250 mg Cr/m3
Coal tar pitch volatiles	700 mg/m3	80 mg/m3

Cobalt metal, dust and fume (as Co)	20 mg Co/m3	20mgCo/m3[Unch]
Copper (dusts and mists, as Cu)	N.E.	100 mg Cu/m3
Copper fume (as Cu)	N.E.	100 mg Cu/m3
Cotton dust (raw)	N.E.	100 mg/m3
Crag (r) herbicide	5,000 mg/m3	500 mg/m3
Cresol (o, m, p isomers)	250 ppm	250 ppm [Unch]
Crotonaldehyde	400 ppm	50 ppm
Cumene	8,000 ppm	900 ppm [LEL]
Cyanides (as CN)	50mg/m3(as CN)	25 mg/m3(asCN)
Cyclohexane	10,000 ppm	1,300 ppm[LEL]
Cyclohexanol	3,500 ppm	400 ppm
Cyclohexanone	5,000 ppm	700 ppm
Cyclohexene	10,000 ppm	2,000 ppm
Cyclopentadiene	2,000 ppm	750 ppm
2,4-D	500 mg/m3	100 mg/m3
DDT	N.E.	500 mg/m3
Decaborane	100 mg/m3	15 mg/m3
Demeton	20 mg/m3	10 mg/m3
Diacetone alcohol	2,100 ppm	1,800 ppm[LEL]
Diazomethane	2 ppm	2 ppm [Unch]
Diborane	40 ppm	15 ppm
Dibutyl phosphate	125 ppm	30 ppm
Dibutyl phthalate	9,300 mg/m3	4,000 mg/m3
o-Dichlorobenzene	1,000 ppm	200 ppm
p-Dichlorobenzene	1,000 ppm	150 ppm
Dichlorodifluoromethane	50,000 ppm	15,000 ppm
1,3-Dichloro 5,5-dimethylhydantoin	Unknown	5 mg/m3
1,1-Dichloroethane	4,000 ppm	3,000 ppm
1,2-Dichloroethylene	4,000 ppm	1,000 ppm
Dichloroethyl ether	250 ppm	100 ppm
Dichloromonofluoromethane	50,000 ppm	5,000 ppm
1,1-Dichloro 1-nitroethane	150 ppm	25 ppm
Dichlorotetrafluoroethane	50,000 ppm	15,000 ppm
Dichlorvos	200 mg/m3	100 mg/m3

Dieldrin	450 mg/m3	50 mg/m3
Diethylamine	2,000 ppm	200 ppm
2-Diethylaminoethanol	500 ppm	100 ppm
Difluorodibromomethane	2,500 ppm	2,000 ppm
Diglycidyl ether	25 ppm	10 ppm
Diisobutyl ketone	2,000 ppm	500 ppm
Diisopropylamine	1,000 ppm	200 ppm
Dimethyl acetamide	400 ppm	300 ppm
Dimethylamine	2,000 ppm	500 ppm
N,N-Dimethylaniline [Unch]	100 ppm	100 ppm
Dimethyl 1,2-dibromo 2,2-dichlorethyl phosphate	1,800 mg/m3	200 mg/m3
Dimethylformamide	3,500 ppm	500 ppm
1,1-Dimethylhydrazine	50 ppm	15 ppm
Dimethylphthalate	9,300 mg/m3	2,000 mg/m3
Dimethyl sulfate	10 ppm	7 ppm
Dinitrobenzene (o, m, p isomers)	200 mg/m3	50 mg/m3
Dinitroocresol [Unch]	5 mg/m3	5 mg/m3
Dinitrotoluene	200 mg/m3	50 mg/m3
Di sec-octyl phthalate	Unknown	5,000 mg/m3
Dioxane	2,000 ppm	500 ppm
Diphenyl	300 mg/m3	100 mg/m3
Dipropylene glycol methyl ether	Unknown	600 ppm
Endrin	2,000 mg/m3	2 mg/m3
Epichlorohydrin	250 ppm	75 ppm
EPN	50 mg/m3	5 mg/m3
Ethanolamine	1,000 ppm	30 ppm
2-Ethoxyethanol	6,000 ppm	500 ppm
2-Ethoxyethyl acetate	2,500 ppm	500 ppm
Ethyl acetate [LEL]	10,000 ppm	2,000ppm
Ethyl acrylate	2,000 ppm	300 ppm
Ethyl alcohol [LEL]	15,000 ppm	3,300ppm
Ethylamine	4,000 ppm	600 ppm
Ethyl benzene [LEL]	2,000 ppm	800 ppm
Ethyl bromide	3,500 ppm	2,000 ppm
Ethyl butyl ketone	3,000 ppm	1,000 ppm
Ethyl chloride ppm[LEL]	20,000 ppm	3,800
Ethylene chlorohydrin	10 ppm	7 ppm

Ethylenediamine	2,000 ppm	1,000 ppm
Ethylene dibromide	400 ppm	100 ppm
Ethylene dichloride	1,000 ppm	50 ppm
Ethylene glycol dinitrate	500 mg/m3	75 mg/m3
Ethyleneimine [Unch]	100 ppm	100 ppm
Ethylene oxide [Unch]	800 ppm	800 ppm
Ethyl ether	19,000ppm[LEL]	1,900ppm[LEL]
Ethyl formate	8,000 ppm	1,500 ppm
Ethyl mercaptan	2,500 ppm	500 ppm
N-Ethylmorpholine	2,000 ppm	100 ppm
Ethyl silicate	1,000 ppm	700 ppm
Ferbam	N.E.	800 mg/m3
Ferrovanadium dust	N.E.	500 mg/m3
Fluorides (as F)	500 mg F/m3	250 mg F/m3
Fluorine [Unch]	25 ppm	25 ppm
Fluorotrichloromethane	10,000 ppm	2,000 ppm
Formaldehyde	30 ppm	20 ppm
Formic acid [Unch]	30 ppm	30 ppm
Furfural	250 ppm	100 ppm
Furfuryl alcohol	250 ppm	75 ppm
Glycidol	500 ppm	150 ppm
Graphite (natural)	N.E.	1,250 mg/m3
Hafnium compounds (as Hf)	Unknown	50 mg Hf/m3
Heptachlor	700 mg/m3	35 mg/m3
n-Heptane	5,000 ppm	750 ppm
Hexachloroethane [Unch]	300 ppm	300 ppm
Hexachloronaphthalene [Unch]	2 mg/m3	2 mg/m3
n-Hexane	5,000 ppm	1,100 ppm[LEL]
2-Hexanone	5,000 ppm	1,600 ppm
Hexone	3,000 ppm	500 ppm
sec Hexyl acetate	4,000 ppm	500 ppm
Hydrazine	80 ppm	50 ppm
Hydrogen bromide	50 ppm	30 ppm

Hydrogen chloride	100 ppm	50 ppm
Hydrogen cyanide [Unch]	50 ppm	50 ppm
Hydrogen fluoride (as F) [Unch]	30 ppm	30 ppm
Hydrogen peroxide [Unch]	75 ppm	75 ppm
Hydrogen selenide (as Se)	2 ppm	1 ppm
Hydrogen sulfide	300 ppm	100 ppm
Hydroquinone	Unknown	50 mg/m3
Iodine	10 ppm	2 ppm
Iron oxide dust and fume (as Fe) Fe/m3	N.E.	2,500 mg
Isoamyl acetate	3,000 ppm	1,000 ppm
Isoamyl alcohol primary and secondary)	10,000 ppm	500 ppm
Isobutyl acetate [LEL]	7,500 ppm	1,300ppm
Isobutyl alcohol	8,000 ppm	1,600 ppm
Isophorone	800 ppm	200 ppm
Isopropyl acetate	16,000 ppm	1,800 ppm
Isopropyl alcohol ppm[LEL]	12,000 ppm	2,000
Isopropylamine	4,000 ppm	750 ppm
Isopropyl ether ppm[LEL]	10,000 ppm	1,400
Isopropyl glycidyl ether	1,000 ppm	400 ppm
Ketene	Unknown	5 ppm
Lead compounds (as Pb) Pb/m3	700 mg Pb/m3	100 mg
Lindane	1,000 mg/m3	50 mg/m3
Lithium hydride	55 mg/m3	0.5 mg/m3
L.P.G. 2,000ppm[LEL]	19,000ppm[LEL]	
Magnesium oxide fume	N.E.	750 mg/m3
Malathion	5,000 mg/m3	250 mg/m3
Maleic anhydride	Unknown	10 mg/m3
Manganese compounds (as Mn) Mn/m3	N.E.	500 mg
Mercury compounds [except (organo) alkyls as Hg]	28 mg Hg/m3	10 mg Hg/m3

Mercury (organo) alkyl compounds(as Hg)	10 mg Hg/m3	2 mg Hg/m3
Mesityl oxide	5,000 ppm	1,400 ppm[LEL]
Methoxychlor	N.E.	5,000 mg/m3
Methyl acetate	10,000 ppm	3,100 ppm[LEL]
Methyl acetylene	15,000ppm[LEL]	1,700 ppm[LEL]
Methyl acetylenepropadiene mixture	15,000 ppm	3,400 ppm[LEL]
Methyl acrylate	1,000 ppm	250 ppm
Methylal	15,000ppm[LEL]	2,200 ppm[LEL]
Methyl alcohol	25,000 ppm	6,000 ppm
Methylamine	100 ppm	100 ppm [Unch]
Methyl (namyl) ketone	4,000 ppm	800 ppm
Methyl bromide	2,000 ppm	250 ppm
Methyl Cellosolve (r)	2,000 ppm	200 ppm
Methyl Cellosolve (r) acetate	4,000 ppm	200 ppm
Methyl chloride	10,000 ppm	2,000 ppm
Methyl chloroform	1,000 ppm	700 ppm
Methylcyclohexane	10,000 ppm	1,200 ppm[LEL]
Methylcyclohexanol	10,000 ppm	500 ppm
o-Methylcyclohexanone	2,500 ppm	600 ppm
Methylene bisphenyl isocyanate	100 mg/m3	75 mg/m3
Methylene chloride	5,000 ppm	2,300 ppm
Methyl formate	5,000 ppm	4,500 ppm
5-Methyl 3-heptanone	3,000 ppm	100 ppm
Methyl hydrazine	50 ppm	20 ppm
Methyl iodide	800 ppm	100 ppm
Methyl isobutyl carbinol	2,000 ppm	400 ppm
Methyl isocyanate	20 ppm	3 ppm
Methyl mercaptan	400 ppm	150 ppm
Methyl methacrylate	4,000 ppm	1,000 ppm
Methyl styrene	5,000 ppm	700 ppm
Mica	N.E.	1,500 mg/m3
Molybdenum(insoluble compounds, as Mo)	N.E.	5,000 mg Mo/m3
Molybdenum (soluble compounds, as Mo)	N.E.	1,000 mg Mo/m3
Monomethyl aniline	100 ppm	100 ppm [Unch]

Morpholine	8,000 ppm	1,400 ppm[LEL]
Naphtha (coal tar)	10,000ppm[LEL]	1,000ppm[LEL]
Naphthalene	500 ppm	250 ppm
Nickel carbonyl (as Ni)	7 ppm	2 ppm
Nickel metal and other compounds(as Ni)	N.E.	10 mg Ni/m3
Nicotine	35 mg/m3	5 mg/m3
Nitric acid	100 ppm	25 ppm
Nitric oxide	100 ppm	100 ppm [Unch]
p-Nitroaniline	300 mg/m3	300mg/m3[Unch]
Nitrobenzene	200 ppm	200 ppm [Unch]
p-Nitrochlorobenzene	1,000 mg/m3	100 mg/m3
Nitroethane	1,000 ppm	1,000ppm[Unch]
Nitrogen dioxide	50 ppm	20 ppm
Nitrogen trifluoride	2,000 ppm	1,000 ppm
Nitroglycerine	500 mg/m3	75 mg/m3
Nitromethane	1,000 ppm	750 ppm
1-Nitropropane	2,300 ppm	1,000 ppm
2-Nitropropane	2,300 ppm	100 ppm
Nitrotoluene (o, m, p isomers)	200 ppm	200 ppm [Unch]
Octachloronaphthalene	Unknown	Unknown [Unch]
Octane	5,000 ppm	1,000 ppm[LEL]
Oil mist (mineral)	N.E.	2,500 mg/m3
Osmium tetroxide (as Os)	1 mg Os/m3	1mgOs/m3[Unch]
Oxalic acid	500 mg/m3	500mg/m3[Unch]
Oxygen difluoride	0.5 ppm	0.5 ppm [Unch]
Ozone	10 ppm	5 ppm
Paraquat	1.5 mg/m3	1 mg/m3
Parathion	20 mg/m3	10 mg/m3
Pentaborane	3 ppm	1 ppm

Pentachloronaphthalen [Unch]	Unknown	Unknown
Pentachlorophenol	150 mg/m3	2.5 mg/m3
n-Pentane ppm[LEL]	15,000 ppm[LEL]	1,500
2-Pentanone	5,000 ppm	1,500 ppm
Perchloromethyl mercaptan [Unch]	10 ppm	10 ppm
Perchloryl fluoride	385 ppm	100 ppm
Petroleum distillates (naphtha) ppm[LEL]	10,000 ppm	1,100
Phenol [Unch]	250 ppm	250 ppm
p-Phenylene diamine	Unknown	25 mg/m3
Phenyl ether (vapor)	N.E.	100 ppm
Phenyl etherbiphenyl mixture (vapor)	N.E.	10 ppm
Phenyl glycidyl ether	Unknown	100 ppm
Phenylhydrazine	295 ppm	15 ppm
Phosdrin [Unch]	4 ppm	4 ppm
Phosgene [Unch]	2 ppm	2 ppm
Phosphine	200 ppm	50 ppm
Phosphoric acid mg/m3	10,000 mg/m3	1,000
Phosphorus (yellow)	N.E.	5 mg/m3
Phosphorus pentachloride	200 mg/m3	70 mg/m3
Phosphorus pentasulfide	750 mg/m3	250 mg/m3
Phosphorus trichloride	50 ppm	25 ppm
Phthalic anhydride	10,000 mg/m3	60 mg/m3
Picric acid	100 mg/m3	75 mg/m3
Pindone	200 mg/m3	100 mg/m3
Platinum (soluble salts, as Pt) Pt/m3	N.E.	4 mg
Portland cement mg/m3	N.E.	5,000
Propane ppm[LEL]	20,000ppm[LEL]	2,100
n-Propyl acetate	8,000 ppm	1,700 ppm
n-Propyl alcohol	4,000 ppm	800 ppm
Propylene dichloride	2,000 ppm	400 ppm
Propylene imine	500 ppm	100 ppm
Propylene oxide	2,000 ppm	400 ppm
n-Propyl nitrate	2,000 ppm	500 ppm
Pyrethrum 35,000mg/m3[Unch]	5,000 mg/m	
Pyridine	3,600 ppm	1,000 ppm

Quinone	300 mg/m3	100 mg/m3
Rhodium (metal fume and insoluble compounds, as Rh)	N.E.	100 mg Rh/m3
Rhodium (soluble compounds, as Rh)	N.E.	2 mg Rh/m3
Ronnel	5,000 mg/m3	300 mg/m3
Rotenone	Unknown	2,500 mg/m3
Selenium compounds (as Se)	Unknown	1 mg Se/m3
Selenium hexafluoride	5 ppm	2 ppm
Silica, amorphous	N.E.	3,000 mg/m3
Silica, crystalline (respirable dust)	N.E.	
cristobalite/tridymite:		25 mg/m3
quartz/tripoli:		50 mg/m3
Silver (metal dust and soluble compounds, as Ag)	N.E.	10 mg Ag/m3
Soapstone	N.E.	3,000 mg/m3
Sodium fluoroacetate	5 mg/m3	2.5 mg/m3
Sodium hydroxide	250 mg/m3	10 mg/m3
Stibine	40 ppm	5 ppm
Stoddard solvent	29,500 mg/m3	20,000 mg/m3
Strychnine	3 mg/m3	3 mg/m3 [Unch]
Styrene	5,000 ppm	700 ppm
Sulfur dioxide	100 ppm	100 ppm [Unch]
Sulfuric acid	80 mg/m3	15 mg/m3
Sulfur monochloride	10 ppm	5 ppm
Sulfur pentafluoride	1 ppm	1 ppm [Unch]
Sulfuryl fluoride	1,000 ppm	200 ppm
2,4,5-T	Unknown	250 mg/m3
Talc	N.E.	1,000 mg/m3
Tantalum (metal and oxide dust, as Ta)	N.E.	2,500 mg Ta/m3
TEDP	35 mg/m3	10 mg/m3

Tellurium compounds (as Te)	N.E.	25 mg Te/m3
Tellurium hexafluoride	1 ppm	1 ppm [Unch]
TEPP	10 mg/m3	5 mg/m3
Terphenyl (o, m, p isomers)	Unknown	500 mg/m3
1,1,1,2-Tetrachloro 2, 2-difluoroethane	15,000 ppm	2,000 ppm
1,1,2,2-Tetrachloro 1, 2-difluoroethane	15,000 ppm	2,000 ppm
1,1,2,2-Tetrachloroethane	150 ppm	100 ppm
Tetrachloroethylene	500 ppm	150 ppm
Tetrachloronaphthalene	Unknown	Unknown [Unch]
Tetraethyl lead (as Pb)	40 mg Pb/m3	40mg Pb/m3[Unch]
Tetrahydrofuran	20,000ppm[LEL]	2,000ppm[LEL]
Tetramethyl lead (as Pb)	40 mg Pb/m3	40mg Pb/m3[Unch]
Tetramethyl succinonitrile	5 ppm	5 ppm [Unch]
Tetranitromethane	5 ppm	4 ppm
Tetryl	N.E.	750 mg/m3
Thallium (soluble compounds, as Tl)	20 mg Tl/m3	15 mg Tl/m3
Thiram	1,500 mg/m3	100 mg/m3
Tin (inorganic compounds, as Sn)	400 mg Sn/m3	100 mg Sn/m3
Tin (organic compounds, as Sn)	Unknown	25 mg Sn/m3
Titanium dioxide	N.E.	5,000 mg/m3
Toluene	2,000 ppm	500 ppm
Toluene 2,4-diisocyanate	10 ppm	2.5 ppm
o-Toluidine	100 ppm	50 ppm
Tributyl phosphate	125 ppm	30 ppm
1,1,2-Trichloroethane	500 ppm	100 ppm
Trichloroethylene	1,000 ppm	1,000 ppm [Unch]
Trichloronaphthalene	Unknown	Unknown [Unch]
1,2,3-Trichloropropane	1,000 ppm	100 ppm
1,1,2-Trichloro 1,2, 2-trifluoroethane	4,500 ppm	2,000 ppm
Triethylamine	1,000 ppm	200 ppm

Trifluorobromomethane	**50,000 ppm**	**40,000 ppm**
2,4,6-Trinitrotoluene	**1,000 mg/m3**	**500 mg/m3**
Triorthocresyl phosphate [Unch]	**40 mg/m3**	**40 mg/m3**
Triphenyl phosphate	**N.E.**	**1,000 mg/m3**
Turpentine	**1,500 ppm**	**800 mg**
Uranium (insoluble compounds, as U)	**30 mg U/m3**	**10 mg U/m3**
Uranium (soluble compounds, as U)	**20 mg U/m3**	**10 mg U/m3**
Vanadium dust	**70 mg/m3(as V2O5)**	**35 mg V/m3**
Vanadium fume	**70 mg/m3(as V2O5)**	**35 mg V/m3**
Vinyl toluene	**5,000 ppm**	**400 ppm**
Warfarin	**350 mg/m3**	**100 mg/m3**
Xylene (o, m, p isomers)	**1,000 ppm**	**900 ppm**
Xylidine	**150 ppm**	**50 ppm**
Yttrium compounds (as Y)	**N.E.**	**500 mg Y/m3**
Zinc chloride fume	**4,800 mg/m3**	**50 mg/m3**
Zinc oxide	**2,500 mg/m3**	**500 mg/m3**
Zirconium compounds (as Zr)	**500 mg Zr/m3**	**50 mg Zr/m3**

DREXEL UNIVERSITY AND DREXEL UNIVERSITY COLLEGE OF MEDICINE

APPENDIX G
TARGET ORGAN POSTER

A list of target organ effects shall be posted in a central location for access by all employees as follows:

HEPATOTOXINS
Chemicals that produce liver damage
Jaundice; liver enlargement
Carbon tetrachloride; nitrosamines

NEPHROTOXINS
Chemicals that produce kidney damage
Edema; proteinuria
Halogenated hydrocarbons; uranium

NEUTROTOXINS
Chemicals that produce their primary toxic effects on the nervous system
Narcosis; behavioral changes; decrease in motor functions
Mercury; carbon disulfide

AGENTS THAT ACT ON THE BLOOD OR HEMATOPOETIC SYSTEM
Decrease hemoglobin function; deprive body tissues of oxygen
Cyanosis; loss of consciousness
Carbon monoxide; cyanides

AGENTS THAT DAMAGE THE LUNG
Chemicals that irritate or damage the pulmonary tissue
Cough; tightness in chest; shortness of breath
Silica: asbestos

REPRODUCTIVE TOXINS
Chemicals that affect the reproductive capabilities including chromosomal damage (mutations) and effects on fetuses (teratogenesis)
Birth defects; sterility
Lead

CUTANEOUS HAZARDS
Chemicals that affect the dermal layer of the body
Defatting of the skin; rashes; irritation
Ketones; chlorinated compounds

EYE HAZARDS
Chemicals that affect the eye or visual capacity
Conjunctivitis; corneal damage
Organic solvents; acids

APPENDIX H

ODOR AS AN AID TO CHEMICAL SAFETY*

CHEMICAL	TLV (PPM)	AOT (PPM)
ACETONE	750	13
AMMONIA	25	5.2
ARSINE	0.05	0.5
CARBON MONOXIDE	50	100,000
CHLORINE	1	0.31
CHLOROFORM	10	85
P-DICHLOROBENZENE	75	0.18
ETHYL ALCOHOL	1000	84
ETHYL ETHER	400	8.9
HYDROGEN SULFIDE	10	0.008
METHYL ALCOHOL	200	100
METHYLENE CHLORIDE	100	250
NAPHTHALENE	10	0.084
OZONE	0.1	0.045
PHENOL	5	0.04
TOLUENE	100	2.9
VINYL CHLORIDE	5	3000
M-XYLENE	100	1.1

EXTRACTED FROM THE JOURNAL OF APPLIED TOXICOLOGY. VOL. 3 (6), 1983