UNIVERSITY POLICY

SUBJECT:	HEALTH AND SAFETY			**TITLE:**	LABORATORY SAFETY
CODING:	00-01-45-55:00	**ADOPTED:**	10/18/95	**AMENDED:**	03/05/03

I. PURPOSE

This policy sets forth the standards for proper practices, procedures and safety equipment to protect laboratory personnel from potential health and safety hazards presented by chemicals, biological materials and equipment used in the laboratory workplace.

This policy is designed to comply with: a) The Public Employees Occupational Safety and Health (PEOSH) standard 29 CFR l9l0.l450, the NIH Guidelines for Research Involving Recombinant DNA Molecules; b) The Biosafety guidelines set out in NIH's publication "Biosafety in Microbiological and Biomedical Laboratories; and c) Federal requirements for Facilities Possession, Use, and Transfer of Select Agents and Toxins; 42CFR part 73; d) USA Patriot Act 2001,Public Law 107–56; e) Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107–188 and f) Guidelines of the Center for Disease Control. Copies of the standards a-f cited above are available on the EOHSS website by following "Laboratory Safety" links.

II. ACCOUNTABILITY

A. Under the direction of the President and the Senior Vice President for Academic Affairs, the Deans, Vice Presidents, Presidents/CEOs of the Healthcare Units and Executive Director for Materials Management shall implement this policy. The Department of Environmental and Occupational Health and Safety Services (EOHSS), in conjunction with the appropriate laboratory safety committees at each school, shall develop laboratory safety standards and shall monitor compliance with these standards. EOHSS shall notify the appropriate Dean, Vice President, President/CEO of the Healthcare Unit or Executive Director of Materials Management of any situation in laboratories that pose an imminent hazard, and of any safety deficiencies in laboratories that are not corrected in a timely manner.

B. Laboratory Safety Committee is a freestanding committee or a sub-committee of a larger unit to be established to address issues of laboratory safety and implementation of the Laboratory Safety Program as described in this policy. The Committee will include Responsible Investigators, clinical laboratory representatives, representatives from the School/Unit/Department and EOHSS.

C. Institutional Biosafety Committee is a freestanding committee or a sub-committee of a larger unit whose composition meets the requirements of the NIH "Guidelines for Research Involving Recombinant DNA Molecules" to be established to review, approve and oversee protocols involving recombinant DNA molecules, select agents, and pathogenic microorganisms or potentially infectious materials requiring work at the Biological Safety Level 2 or greater. Smaller schools may utilize the services of another UMDNJ school's Institutional Biosafety Committee rather than having their own Committee, as long as there is adequate means to provide oversight and as long as the chair of the Committee agrees.

III. APPLICABIITY

This policy applies to all laboratories being used for research or clinical purposes under the auspices of the University by all Schools/Units/Departments located in all UMDNJ owned, leased or operated facilities.

IV. DEFINITIONS

A. Laboratory - a facility where relatively small quantities of hazardous chemicals or biological agents are used on a non-production basis for research or clinical purposes.

B. Laboratory Personnel - employees, students and other persons conducting research and clinical activities in UMDNJ laboratories, regardless of UMDNJ employment status.

C. Minimum UMDNJ Laboratory Safety Standards - The Laboratory Safety Plan sets forth minimum UMDNJ Laboratory Safety Standards which are mandatory for every laboratory. Minimum safety standards are denoted by directive phrases such as:

1. "shall"
2. "must"
3. "is prohibited"
4. "is required"
5. "is not permitted"

D. Particularly Hazardous Substance - any substance which meets the criteria defined in the PEOSH Laboratory Safety Standard of "select carcinogen," reproductive toxin, or substance with a high degree of acute toxicity (rat oral LD50 less than 50 mg/kg.).

E. Responsible Investigator - UMDNJ faculty member who has been assigned laboratory space.

F. Responsible Facility Official (RFO) ensures management oversight of the transfer of select agents, consistent with the CDC Guidelines.

G. Recombinant DNA Molecules - Consistent with the NIH Guidelines, recombinant DNA molecules are either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (ii) molecules that result from the replication of those described in (i) above.

H. Select Agent - Select agents are specific pathogens and toxins as defined by Title 42 CFR Parts 73.4 and 73.5. Registration with the Secretary of the Department of Health and Human Services and approval by the Institutional Biosafety Committee is required before Possession, Use, and Transfer of Select Agents and Toxins.

V. REFERENCES

A. The Public Employees Occupational Safety and Health Act, (PEOSHA) 29 CFR l9l0-l450, as implemented by the New Jersey Department of Labor, NJAC l2:l00-4.2

B. The NIH Guidelines for Research Involving Recombinant DNA Molecules

C. The Biosafety guidelines set out in NIH's publication "Biosafety in Microbiological and Biomedical Laboratories"

D. Federal requirements for Facilities Possession, Use, and Transfer of Select Agents and Toxins, 42 CFR Part 73; Code of Federal Regulations, Title 42, Section, Part 72, Interstate Shipment of Etiologic Agents, Additional Requirements for Facilities Transferring or Receiving Select Agents

E. USA Patriot Act 2001,Public Law 107–56

F. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107–188, (g) Guidelines of the Center for Disease Control

G. Possession by Restricted Persons of Select Biological Agents or Toxins 00-01-10-10:00

The following policies provide additional and related information:

H. NJ Workers and Community Right-To-Know 00-01-45-25:00

I. Hazardous Waste Management 00-01-45-35:00

J. Chemical Spill Prevention & Mitigation 00-01-45-45:00

K. Bloodborne Pathogens 00-01-45-50:00

L. Fire and Life Safety 00-01-45-60:00

VI. POLICY

UMDNJ provides a comprehensive health and safety program for all University laboratories which is described in the Laboratory Safety Plan. The program will be coordinated with other University health and safety policies, including those outlined in Section V. to ensure comprehensive, customized and non-redundant coverage. Pursuant to this program, minimum laboratory safety standards, which comply with applicable Federal and State regulations and guidelines, are established in a written Laboratory Safety Plan for each School/Unit/Department. The exact requirements of such plans are decided by EOHSS, in conjunction with representatives from each School/Unit/Department. The Laboratory Safety Plan contains minimum UMDNJ safety standards which apply to all University laboratories. In addition to the Laboratory Safety Plan, the Select Agents Program, described in Section VI.B.1., and the minimum UNDNJ Laboratory Safety Design Guidelines, described in Section VI.B.2., are additional components of the Laboratory Safety Program.

A. Requirements:

1. Laboratory Safety Plan

EOHSS and representatives from each School/Unit/Department shall establish a Laboratory Safety Plan for each School/Unit/Department. Each plan shall include all of the required components listed in Section VI.B.1., and shall be prominently displayed and made available to all laboratory personnel who work in laboratories and/or who provide support services that involve laboratories. If desired, Schools/Units/Departments may use an alternative plan as long as it includes all of the components listed in Section VI.1., as well as the UMDNJ Minimum Laboratory Safety standards. All such plans, including alternative plans, must be reviewed and updated annually by the School/Unit/Department, in conjunction with EOHSS to reflect any pertinent changes.

2. Required Components of the Plan

a. Designating a Laboratory Safety Officer:

Each Laboratory/Department/Division shall appoint an employee who is qualified by training or experience to provide technical guidance in the implementation of the plan. More than one Laboratory Safety Officer per department or division may be appointed depending on the scope of the

laboratory investigations. Schools/Units/Departments with a small number of laboratories may jointly appoint a single Laboratory Safety Officer.

b. Establishing Standard Operating Procedures:

Written procedures must be developed about common topics, such as working alone, vacating laboratories, conducting laboratory safety audits, storing chemicals, using refrigerators and cold rooms, allowing visitors in laboratories, and permitting unattended operations. Copies of such procedures will be available to all laboratory personnel and to EOHSS and will be used in employee training.

c. Controlling Exposure:

Preventative measures must be designed to ensure that exposure of employees to chemical substances is minimized and kept within professionally recognized standards. Such measures will include an appropriate combination of engineering controls, work practices and personal protective equipment.

d. Training:

All employees shall receive initial and subsequent periodic instruction in those safety topics specifically described in the Laboratory Safety Plan.

e. Requiring Prior Approval:

A prior approval process must be established for those activities, specified in the plan, which may pose an increased risk to laboratory personnel and others who may be present. Examples of activities which may require prior approval include working with a particularly hazardous chemical, or working alone during off-hours.

f. Ensuring Medical Consultation:

Medical consultation attention must be available when laboratory personnel develop symptoms associated with exposure to hazardous chemicals, and/or when air monitoring indicates that laboratory personnel have received chemical exposures over regulatory limits, and/or when a spill or other incident results in an acute exposure.

g. Personnel Working with Particularly Hazardous Substances:

Special procedures must be established which set out requirements governing the use of particularly hazardous chemicals, as defined by this policy, Section IV.D.

h. Establishing Emergency Procedures and Equipment:

Written emergency procedures for fires, spills, exposures and other likely laboratory accidents must be written and prominently displayed. Emergency equipment such as fire extinguishers, safety showers, and eyewashes shall be readily accessible and kept in usable condition.

i. Maintaining Properly Functioning Protective Equipment:

Protective equipment, such as chemical fume hoods, safety showers, eyewashes, and biological safety cabinets shall be maintained and tested in accordance with any and all applicable regulations and with the manufacturer's recommendations. The Laboratory Safety Plan shall clearly specify who will be responsible for properly maintaining this equipment and for documenting in writing such maintenance.

j. Monitoring Exposure:

Laboratory personnel who, either have been exposed or who exhibit symptoms consistent with exposure, shall be regularly assessed and monitored by EOHSS in accordance with applicable regulations. Whenever possible, laboratory personnel will be notified of the results of monitoring within three (3) working days of the receipt of results. The PEOSH mandated maximum allowable time of fifteen (l5) days between receipt of the results and notification, shall at no time be exceeded.

k. Keeping Records: Records associated with the Laboratory Safety Program will be maintained as follows:

i. Records maintained by EOHSS:

1. Exposure monitoring records, (including exposure incident reports), shall be maintained for the duration of employment and thirty (30) years thereafter.

2. Training records shall be maintained for the duration of employment.

ii. Records maintained by the relevant Campus Student/Employee Medical Services Provider will be maintained as follows:

1. Results of medical tests and examinations, including written opinions as required by the PEOSH Laboratory Safety Standard shall be maintained for the duration of employment or length of study and thirty (30) years thereafter.

2. Analysis derived from the use of medical or exposure data shall be maintained for the duration of employment or length of study and thirty (30) years thereafter.

B. Responsibilities:

1. Select Agents Program

a. An entity may not possess or use in the United States, receive from outside the United States, or transfer within the United States, any select agent or toxin unless the entity has been granted a certificate of registration by the HHS Secretary or the USDA Secretary. In conjunction with EOHSS, each School/Unit/Department shall develop procedure and standards for researchers to follow when transferring, obtaining or possessing, using and disposing of select agents. See University policy, 00-01-10-10:00, Possession by Restricted Persons of Select Agents or Toxins. These standards/procedures must ensure:

i. proper training in appropriate skills for laboratory personnel and

ii. appropriate measures for the access and security of select agents.

b. The Institutional Biosafety Committee shall ensure that such procedures and standards meet biosafety level requirements for working with the particular biological agent before it can be ordered, possessed or transferred.

c. Schools/Units/Departments which possess, transfer or obtain select agents must register with the Secretary of HHS and obtain a registration number to be used to validate Possession, Use, and Transfer of Select Agents and Toxins.

d. The Dean of Research or other senior management representative for the Dean of the School/Unit/Department will serve as the RFO, see Section IV.F. The RFO must sign each request certifying that:

i. the requestor of the agent is officially affiliated with the facility,

ii. the laboratory meets guidelines for working with the requested agent, and

iii. the receiving facility holds a currently valid registration number.

e. Exemptions:

i. Exemption regarding diagnosis, verification, or proficiency testing - § 73.6 (a). Clinical Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 using select agents for diagnostic, reference or verification of proficiency testing purposes.

ii. Exemption regarding products cleared, approved, licensed, or registered under certain laws - § 73.6 (b) Laboratories using attenuated strains of select agents approved for human vaccination purposes by FDA or other recognized national or international organizations.

2. EOHSS, in conjunction with Physical Plant, Facilities Planning and Construction (FP&C) and the Laboratory Safety Committees of each School/Unit/Department shall develop Minimum UMDNJ Laboratory Safety Design Guidelines for new/renovated laboratories. The architect/engineer affiliated with the project must bring potential departures from the guidelines to the attention of the FP& C Project Manager who shall ensure that it is brought to the attention of Physical Plant, EOHSS and the end user and discussed at a planning meeting before being accepted. FP&C shall provide the Architect/Engineer with a copy of the guidelines in the beginning of the planning stage and shall advise them of the above requirement.

By Direction of the President:

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Senior Vice President for Administration and Finance