

Facility Safety Plan

State University of New York Upstate Medical University

A. Research Operations / Standard Operating Procedure

The State University of New York Upstate Medical University maintains two safety departments to address the institutional needs of complying with the federal, state, and local laws regulating safety and health. In addition, research compliance is generally handled through the Vice-Provost for Research, the Research Administration Office and the primary committees outlined below.

Safety Departments:

Environmental Health & Safety: addresses the following regulations:

- 29 CFR (General Standards) 1910.1000, subpart Z
- 29 CFR 1910.1200 Hazard Communication Standard
- 29 CFR 1910.1030 Bloodborne Pathogens Standard
- 29 CFR 1910.1450 Chemical Hygiene Plan/Laboratory Standard
- 40 CFR Hazardous Waste Management (6NYCRR-NYS)
- 49 CFR 171.172 D.O.T. Regulations/Haz Waste Transport SARA – Title III
- Guidelines for Research Involving Recombinant DNA—Molecules / NIH
- CDC-NIH Biosafety in Microbiological and Biomedical Laboratories

Environmental Health & Safety: serves as the institution's compliance and education agency with respect to safety and health concerns associated with biomedical research. The Office consists of four occupational health and safety professionals who have areas of experience and practice in general and fire safety, biosafety and environmental health and safety.

In general, the following list demonstrates the areas that Environmental Health & Safety operates in:

- General Safety
- Fire Safety
- Biosafety
- Hazardous Waste Management
- Hazardous Materials Management
- HAZ-MAT Emergency Response
- Industrial Hygiene Services
- Accident Investigation/mitigation

Radiation Safety: Ensures compliance with safety and health regulations and oversees ordering, storage and disposal of radioactive waste in accordance with Nuclear Regulatory Commission and New York State Department of Health requirements. Addressed in the following regulations:

- 10 CFR 20 Standards for Protection Against Radiation
- 10 CFR 30 Rules of General Applicability to Domestic Licensing of Byproduct Material
- 10 CFR 35 Medical Use of Byproduct Material
- 10 CFR 71 Packaging and Transporting of Radioactive Materials
- 49 CFR 100 to 177 Transportation
- Chapter I – Part 16 New York State Department of Health, Regulation on Ionizing Radiation
- 6 NYCRR Part 380 Rules and Regulations for Prevention and Control of Environmental Pollution by Radioactive Materials. A full description of activities is included below. (See “Radiation Safety”)

Departments/ Committees Governing Research:

Research Compliance Office: Assures that all research conducted at Upstate Medical University and/or by faculty of Upstate Medical University involving human subjects, laboratory animals, radiation, toxic and infectious agents, human tissues and recombinant DNA complies with government regulations and Research Foundation/Upstate Medical University institutional policies.

Institutional Review Board for the Protection of Human Subjects (IRBPHS or IRB): Is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Upstate. The IRB operates in compliance with the U.S. Code of Federal Regulations, Department of Health and Human Services (DHHS) Title 45 Part 46, as well as the Food and Drug Administration (FDA) regulations on human subjects research. Upstate policy and federal regulations require that all research involving human subjects, human tissue, surveys of human subjects, or medical records be reviewed and approved by the Upstate IRB prior to initiation of the research. This requirement applies to all human subject research conducted by faculty, on- and off-campus, whatever the funding support for the project.

Committee for the Humane Use of Animals (CHUA): As required by the Animal Welfare Act, Public Health Service Guidelines and New York State regulations, any investigator planning to use live vertebrate animals for research or education must secure prior approval of an Institutional Animal Care and Use Committee (IACUC).

Radiation Safety Committee: The possession and use of radioactive materials or devices producing ionizing radiation is authorized by the New York State Department of Health. Any individuals wishing to purchase, use and dispose of radioactive materials or devices at Upstate must obtain approval from the Radiation Safety Officer and the Radiation Safety Committee to ensure the maximum beneficial use of radiation with the minimum practical risk to patients, research subjects, employees and the general public.

Institutional Biosafety Committee (IBC): All research involving infectious agents, fresh human tissue or recombinant DNA must be reported to the Institutional Biosafety Committee (IBC) for review.

Specific elements of this plan are outlined below:

Biological Safety Program

- (a) EHS reviews laboratory spaces annually.
- (b) Each principal investigator must prepare a Biosafety Manual for any research involving human blood, body fluid, tissue or pathogenic organism. The manual must be reviewed and approved by the Institutional Biosafety Committee prior to initiating any research project.
- (c) Spaces used for biological research are audited using a multidisciplinary team made up of Institutional Biosafety Committee members prior to initiating any research project.
- (d) Principal investigators must certify annually that all approved research is in compliance with all regulations and institutional policies.
- (e) Training and Instruction for the Upstate Bloodborne Pathogen/Exposure Control Plan
- (f) Training and Instruction in biosafety for all faculty, staff, medical students and post-docs
- (g) Spill Response
- (h) Accident Investigation

Chemical Safety Program

- (a) Annual inspection of laboratories for compliance with Upstate's Chemical Hygiene Plan requirements.
- (b) Training and instruction for Chemical Hygiene Plan/Exposure Control Plan for all Faculty and staff.
- (c) Ensures material safety data sheet collection and dissemination.
- (d) Chemical waste storage, packaging and recycling/disposal in accordance with US EPA, NYSDEC and DOT Regulations.
- (e) Reactive hazard mitigation, and “**unknown**” chemical identification by external consultant.
- (f) Chemical spill/incident response procedure and remediation.
- (g) Activate Institution’s Emergency notification system.
- (h) NYS DEC, USEPA RCRA, EPCRA, CERCLA, FIRFRA compliance activities and audits are conducted by EHS.

Radiation Safety

Radiation Safety Office: A group of trained health physicists and technicians who are responsible for enforcing the regulations, statutes and policies of the institution, federal and state agencies as applicable, and for interfacing with these regulatory agencies. They also provide support services such as personnel monitoring (TLDs, etc.), centralized ordering of radioactive materials, waste disposal, centralized record repository, safety surveys, and educational activities. In summary, they are responsible for education, documentation, training and enforcement regarding all ionizing radiation used on the SUNY Upstate campus.

Radiation Safety Officer Responsibilities and Qualifications:

The responsibility for radiation protection procedures is assigned to the Radiation Safety Officer. The Radiation Safety Officer should be certified by the American Board of Health Physics, the American Board of Medical Physics or the American Board of Radiology or Licensed by the State of New York. The responsibilities of the Radiation Safety Officer (RSO) include the following:

1. Supervise the centralized procurement, receipt, calibration, storage, issuance and disposal of all radioactive materials entering or leaving SUNY Upstate Medical University.
2. At SUNY Upstate Medical University, the RSO must be consulted and plans for radiation protection in advance of the purchase of any source of radiation.
3. Make personnel monitoring devices available to all staff members whose department chairs, section chief, or individuals request them.
 - a) Instructions on the correct use of dosimeters will be provided.
 - b) Complete records of all personnel exposures will be maintained.
4. Survey areas where radiation is employed:
 - a) Determine the exposure levels in occupied areas.
 - b) Specify appropriate working conditions

5. Perform and document appropriate bioassay measurement(s) on employees on a routine and, if necessary, emergency basis.
6. Formulate regulations governing the use of radiation sources (including radioactive materials as well as radiation producing machines).

In general, such regulations will be in conformance with those recommended by the National Council on Radiation Protection (NCRP) and Measurements, the New York State Department of Health and other regulatory agencies having jurisdiction.
7. Require the posting of appropriate warning signs in radiation areas.
8. Review plans for the proposed use of radiation from the point of view of radiation protection and make appropriate recommendations to the user and the Radiation Safety Committee (RSC).
9. Supervise the decontamination of individuals or property and the disposal of radioactive waste.
10. By means of periodic statements, the RSO reports to the administration on the amount and identify of all radioactive materials or other sources of radiation entering the medical center.
11. The Radiation Safety Officer reports to the administration of Upstate Medical University any unusual or major radiation hazards or accidents.
12. Formulates policy with regard to handling of radiation sources. Major new policies are submitted to the Radiation Safety Committee and the Administration for their endorsement.
13. General surveillance of all health physics activities, including both personnel and environmental monitoring.
14. Monitoring all therapy and X-ray machines, including teletherapy units, capable of producing ionizing radiations.
15. Instructing personnel in proper procedures for the use of radioactive materials.
16. Storage of all radioactive materials not in current use.
17. These provisions are intended to assist department chairs and individuals in maintaining good radiation protection practices in their departments, clinics, and laboratories and do not decrease their responsibility in this regard.

B. Facility Equipment and Description (Related to the Research Environment)

SUNY Upstate Medical University operates 300 research laboratories, distributed over five buildings in Syracuse, New York. Each Principal Investigator is requested to prepare a laboratory safety manual specifically for the research facilities and activities in their spaces and submit a copy to the department or governing committees outlined in *Part A.* above. Within the manual, specific hazardous agents i.e. toxic, carcinogenic chemicals, select agent materials and biohazards are addressed with respect to safe use, storage and disposal.

All laboratories are 100% in 100% out ventilated spaces, with approximately 250 laboratories having fume hoods available in continuous operation mode.

Personal Protective Equipment is specified for each researcher in the departmental compliance policy, and within specific standard operating procedures prepared by the principal investigator for his/her projects. EHS evaluates PPE and proper use on a case by case basis.

Biological safety cabinets are required for biological safety level 2 and higher activities. Access to steam autoclaves is also required for biological safety level 2 and higher activities.

C. Radioactive Materials

A copy of SUNY Upstate Medical University's Radioactive Materials License is attached.

D. Hazard Analysis (Related to the Research Environment)

Adverse Event

Control Activities

Detonation / Deflagration
chemicals in use/storage

Chemical hygiene training for faculty and staff and rigorous inspection of laboratories for unstable reactives, unknown, improper storage practices by EHS.

Chemical Spills

Specific policy to report all spills to EHS and evacuate area. EHS to evaluate hazards on case by case basis. Affected personnel sent to Emergency Department for evaluation and treatment. Training and auditing of faculty and staff for proper chemical use/storage practices. EHS maintains equipment and is trained to respond to incidental spills and agreements are in place with qualified outside response vendors for any chemical spills beyond internal capabilities.

Fire / Bomb-threat /
Catastrophic Events

Total alarm and evacuate procedure using facility-wide alarm systems. Full contingency plan developed and distributed internally and externally to government agencies.

Toxic Chemical Exposure

Removal/support of victim by Syracuse Fire Department Hazmat team. EHS supports Paramedics and ED with required information on associated hazards.

Biological Agent Exposure

Depending on agent and dose, responses can range up to similar procedure as outlined for toxic chemical exposure (above). Spills are handled by EHS.

Suspected over-exposure
to chemicals in use

EHS provides industrial hygiene evaluation and practice review for lab research activities. Recommendations are made, enforced if warranted, to reduce exposure levels to acceptable levels based on OSHA, EPA, ACGIH Standards and Guidelines.

E. Biological Defense Research Program Requirements

We have no Biological Defense Research Program activities.