



POLICY ON RADIATION SAFETY PROGRAM COMPLIANCE

Dated: August 4, 2015

Supersedes: Policy on Radiation Safety Program Compliance dated August 8, 2014

I. PURPOSE

New York Medical College (NYMC) is required by the New York State Department of Health (NYSDOH) to maintain a Radiation Safety Program Manual, which must convey NYMC's official policies relating to the control of radioactive materials and satisfy the regulatory requirements for a written radiation protection program that includes provisions for keeping doses "as low as reasonably achievable" (ALARA).

II. POLICY

In order to assure compliance with applicable federal and state regulations, this policy establishes NYMC's Radiation Safety Manual as the official institutional body of policies and procedures regarding the control and use of radioactive materials at NYMC. This policy also establishes the authority of the Radiation Safety Officer ("RSO") to utilize such procedures as are necessary to correct specific items and/or repeated incidents of noncompliance, including the temporary suspension of an authorized user's permit to possess and/or use radioactive materials at NYMC.

III. SCOPE

This policy applies to all faculty, staff, and students who work with radioisotopes under New York Medical College's Radioactive Materials License (Number 1727).

IV. DEFINITIONS

Authorized User ("AU") - an individual approved by both NYMC and the NYSDOH for the possession and use of radioisotopes, and to supervise use by radiation workers under his/her supervision. Authorization for the use of any radiation source is conditional upon compliance with regulations, permit conditions and the policies and procedures outlined within the NYMC Radiation Safety Manual. Because of the responsibilities and liabilities involved, an authorized user must be a NYMC employee, and is normally a Principal Investigator (PI) and/or faculty member who has primary scientific, financial and legal responsibility for a research program, and signature authority on at least one NYMC account.

Permitted Laboratory - laboratory space under the control of an Authorized User that has been internally permitted by the RSO for the possession and use of radioactive materials. An AU is issued a permit based on the understanding that s/he will abide by all applicable regulations, policies and procedures.

Radiation Safety Officer ("RSO") - an individual (approved by NYSDOH and named on the institutional license) who administers a radiation protection program in accordance with Part 16 of New York State Sanitary Code (Ionizing Radiation), as well as with NYMC policies and procedures.

Radiation Worker - any individual whose official duties or authorized activities include the handling of radioactive materials under an Authorized User.

V. PROCEDURES

Certain categories of non-compliance as well as repeated findings of non-compliance will automatically result in the suspension of the AU's permit to use radioisotopes. The reporting of violations is not limited to formal laboratory inspections; violations may be noted at any time.

A. **Category One Violations.** The most serious instances of non-compliance with respect to the security of radioactive materials and/or the safety of the use thereof. Consequently, an AU's permit will be suspended after a single finding. Category One violations include:

1. Radioactive material detected in an unlabeled trash container;
2. Evidence of liquid radioactive waste disposal into laboratory sinks;
3. Radioactive material not secured against removal (including but not limited to source vials, aliquots, working solutions and waste);
4. Loss of radioactive material(s);
5. Falsifying survey results and/or inventory records;
6. Working with radioactive materials under a suspended or inactive permit or in an unposted area;
7. Use of radioactive materials by an untrained individual;
8. Failure to report a radioactive spill;
9. Purposeful irradiation of an individual and/or the use of radioactive materials to purposefully harm an individual.

B. **Category Two Violations.** Considered to be less serious than Category One violations; however, it is the repetition of such violations that results in a permit suspension, such that the AU may devote time and attention to correcting the root causes of the infractions (i.e. a need for further training). Suspension will

occur after three (3) documented findings within a 12-month period. (Note: a suspension may occur after three different violations or three repeats of the same violation have been documented over the course of a calendar year.) Category Two violations include:

1. Evidence of eating, drinking, or smoking in permitted laboratories;
2. Failure to maintain an accurate and up-to-date inventory of radioactive material (including the failure to make regular decay corrections, as well as instances where total activity present in waste plus stock vials does not agree with initial activity received);
3. Mouth-pipetting of radioactive materials;
4. Not wearing the appropriate personal protective clothing while working with radioactive materials;
5. Poor radiological housekeeping;
6. Improper waste segregation;
7. Not performing and/or documenting required surveys (within the time limits prescribed by NYMC's Radiation Safety Manual).

- C. **Permit Suspension.** If the RSO finds cause for the suspension of an authorized user's permit (from either a single "Category One" violation, or documentation of four or more instances of "Category Two" violations within one calendar year), EHS will remove all radioisotopes (including waste products) from the AU's possession and all work with radioactive materials must be immediately suspended.
- D. **Reinstatement of Permits Following a Suspension.** The AU's permit will be suspended while the RSO conducts a complete review to determine the root cause(s) for the repeated violations. This review will be documented and sent to the AU. The AU must provide a written response to the RSO's report, detailing the corrective action(s) that will be taken in order to curtail the behavior that led to the violations. If the RSO finds the corrective action plan and the timetable for compliance to be adequate, s/he may restore the AU's permit. The RSC will receive a report regarding the case at the next regularly scheduled meeting of the RSC. If, however, the RSO considers that further disciplinary action may be warranted (particularly in the case of repeat suspensions and/or in the case of certain Category One violations), s/he may refer the case to the RSC chairperson, who will then review the case and recommendations regarding how to proceed. If warranted, the AU may be requested to appear before the RSC.
- E. **Examples of Possible Recommended Corrective or Disciplinary Actions**

1. Temporary suspension of an specific individual's authorization to use radioactive materials pending refresher training;

2. Permanent suspension of a specific individual's authorization to use radioactive materials at NYMC;
3. Mandatory refresher training for all personnel listed under a radioactive materials permit;
4. Suspension of AU's permit for periods of time up to one year;
5. Complete revocation of AU's permit and the ability of specific individuals to use radioactive materials under any other permit at NYMC;
6. Financial penalty;
7. Termination

VI. EFFECTIVE DATE

This policy shall be effective as of the date signed.

VII. POLICY RESPONSIBILITIES

A. Radiation Workers

1. Comply with all radiation safety program requirements;
2. Complete all required training.

B. Authorized User

1. Ensures that all radiation safety program requirements are fulfilled for all posted areas under his/her permit;
2. Ensures that all radiation workers working under his/her permit receive the appropriate initial training and remain current in all refresher training requirements.

C. Department of Environmental Health & Safety

1. Monitors conditions at NYMC for radiation safety program compliance;
2. Provides advice and guidance with respect to the interpretation and administration of this policy.

D. Radiation Safety Officer

1. Administers a radiation protection program in accordance with Part 16 of New York State Sanitary Code (Ionizing Radiation), as well as with NYMC policies and procedures;

2. Investigates all reports of radiation safety program non-compliance and takes the appropriate actions to correct non-compliance (including, but not limited to, permit suspension).

E. Radiation Safety Committee

1. Reviews all instances of permit suspensions;
2. Recommends corrective and/or disciplinary actions for permit suspensions when requested by the RSO.

VIII. POLICY MANAGEMENT

Responsible Executive: Vice President of Operations

Responsible Officer: Director, Environmental Health & Safety

Responsible Department: Environmental Health & Safety

APPROVED:



Edward C. Halperin, M.D., M.A.
Chancellor for Health Affairs and
Chief Executive Officer



Date