

DATE: September 3, 2015

TO: All Schools, Centers and Divisions of the University & Saint Louis University

Hospital

SUBJECT: Policy on Radiation Safety Committee (RSC)

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I. POLICY

Saint Louis University ("the University") and Saint Louis University Hospital ("the Hospital") endeavor to provide for the safe use of radioactive materials and machine produced radiation used in the diagnosis and treatment of patients in University and Hospital facilities, and in research. Key objectives of these safety functions are minimizing radiation dose to patients, clinical and research faculty and staff, and the general public. To meet these important radiation safety objectives, the Saint Louis University Radiation Safety Committee (RSC) exists to facilitate comprehensive oversight of the use of radioactive materials and machine produced ionizing radiation.

II. SCOPE OF POLICY

This policy applies to all clinical and research units of the University and the Hospital where radioactive materials and/or machine produced ionizing radiation are used. It extends to all faculty, physicians, including residents, medical students, nurses, technologists and other clinical and research staff and students involved in the use of radioactive materials and/or machine produced ionizing radiation.

III. <u>AUTHORITY</u>

The President of the University has conferred upon the Vice President for Medical Affairs the authority to appoint members to the Radiation Safety Committee (RSC) for Saint Louis University. The RSC reports through its Chairperson to the University President through the Vice President for Medical Affairs and to Saint Louis University Hospital senior management. The authority to comprehensively review and approve, or disapprove, all radiation safety aspects of clinical and research uses of radioactive materials and machine produced ionizing radiation is vested in the RSC, and its subcommittees, as applicable. The RSC and its subcommittees also serve as technical resources for the radiation safety program involving radioactive materials and machine produced radiation, including but not limited to:

- 1. The drafting, review, approval and implementation of specific radiation safety procedures, policies, manuals, and other documents intended to serve as tools in implementing the radiation safety program.
- 2. Review of personnel radiation dose reports exceeding ALARA thresholds.
- 3. Radiation Safety Education
- 4. X-ray, fluoroscopy and all other x-ray machine purchases, including accelerators.

The RSC is empowered to develop all of the necessary oversight tools and documents essential to facilitate review and education functions. Specific duties and responsibilities are further delineated in Section IV.

IV. MISSION & IMPLEMENTATION

The RSC provides administrative and technical oversight over the use of radioactive materials at Saint Louis University and Saint Louis University Hospital. The RSC also provides administrative and technical oversight over the use of machine (device) produced radiation used for diagnostic imaging, therapeutic, and/or research purposes. These oversight functions may be directly administered by the RSC or through one of its subcommittees. Specific RSC duties and responsibilities include:

A. Radioactive Materials Oversight: All aspects of Radioactive Materials use as described in the broad scope NRC license issued to Saint Louis University are governed by the RSC. These include all authorizations for possession and clinical or research use of radioactive materials. Specific RSC radioactive materials oversight duties and responsibilities include:

- 1. Authorization: The RSC is authorized by the Executive Management to oversee all uses of NRC licensed materials at Saint Louis University and Saint Louis University Hospital.
- **2. Communication to Management:** The RSC informs the Vice President for Medical Affairs and other Institutional administrators as applicable, of the radiation safety program operations, changes, incidents and all situations that have or may result in regulatory intervention.
- **3. Establishment of Policy:** The RSC establishes the institutional policy on radiation protection matters that will ensure that radioactive materials are safely used. This includes review of training programs, equipment, facilities, supplies, procedures and the performance of individuals with radiation safety program responsibilities.
- **4. Familiarity with Regulatory Framework:** The RSC is familiar with pertinent regulations, license conditions and commitments to regulatory agencies and ensures that radioactive materials are used in compliance with the institution's obligations.
- **5. ALARA** (<u>As Low As Reasonably Achievable</u>): The RSC ensures that licensed materials are used consistent with the ALARA philosophy and program.
- **6. Application/Protocol Review:** The RSC reviews and approves or denies, on the basis of safety and the prior training and/or experience of the applicant, all requests to use radioactive materials within the University or Hospital.
- **7. Maintenance of NRC License:** The RSC ensures that the license is amended prior to implementing changes that require license amendments.
- **8. Interim Authorizations by the RSO:** The RSC empowers the RSO and establishes delegation of authority procedures that allow the RSO to review and issue interim authorizations, and to review and approve certain changes to authorizations on behalf of the RSC. All interim authorizations issued by the RSO will be reviewed and approved by the RSC at the next Committee meeting.
- **B.** Machine Produced Radiation Oversight: The RSC is responsible for oversight of radiation safety in the clinical and research use of x-ray devices, i.e. machine-produced radiation at University and Saint Louis University Hospital facilities. This includes the use of x-ray, fluoroscope, accelerator and other ionizing radiation equipment purchases for the University and the Hospital. Elements of oversight include related communication to University and Hospital management, review of institutional policy on radiation protection matters involving machine produced radiation, training programs, and the performance of individuals with radiation safety program responsibilities.

V. COMMITTEE MEMBERSHIP

Appointments shall be made to the Radiation Safety Committee by the University Vice President for Medical Affairs. Hospital members may be recommended by the Hospital President.

- **A. Selection of Membership:** Membership shall include, but is not limited to, the following positions and at least one representative from the specified areas (listed alphabetically):
 - 1. Administration Saint Louis University (SLU)
 - a. Vice President for Research, or his/her designee.
 - b. Director, Office of Environmental Health and Safety
 - 2. Administration SLU Hospital
 - a. Nursing Management
 - b. Associate Administrator or Equivalent
 - 3. Clinical Departments (SLU)
 - a. Nuclear Medicine Authorized User
 - b. Radiation Medicine Medical Physicist and/or Authorized User
 - c. Radiology Medical Physicist and/or Interventional Radiologist
 - **4. Radiation Safety Officer** (SLU Office of Environmental Health and Safety)
 - **5. Research Departments** (**SLU**) may include faculty users of radioactive materials from three or more of these departments:
 - a. Biology
 - b. Biochemistry and Molecular Biology
 - c. Chemistry
 - d. Internal Medicine
 - e. Molecular Microbiology and Immunology/Institute of Molecular Virology
 - f. Pathology
 - g. Pediatrics
 - h. Pharmacological and Physiological Sciences
 - i. Surgery
 - **6.** Other ad hoc Members/Consultants: Additional individuals with technical expertise or relevant institutional responsibility will be utilized as consultants or ad hoc members of the committee on an as-needed basis.
- **B.** Chairperson and Vice Chairperson: The University Vice President for Medical Affairs shall appoint a Committee Chairperson and a Vice Chairperson. The Vice Chairperson shall be selected from among the members to fulfill the role of Acting Chairperson if the Chairperson is not available.

C. Alternate RSC Members: Under some circumstances alternate RSC members may be appointed for certain RSC members. Alternate members may attend all RSC meetings, but only have voting privileges when the Primary RSC member that they represent is absent from the meeting.

VI. RSC MEETING FREQUENCY

- **A. Regular Meetings**: Monthly meetings are scheduled to facilitate timely review and approval of research and clinical protocols, including IRB protocols, authorized users, ALARA reports, equipment acquisitions and to conduct other committee business. Notwithstanding cancellation of one or more monthly meetings, the RSC shall meet at least quarterly.
- **B.** Ad hoc Meetings: Ad hoc meetings may be convened to expedite investigation and reporting of abnormal occurrences (e.g., medical events, spills or other contamination events, missing or lost sealed sources, deliberate misconduct, etc.), should they occur. Ad hoc meetings may also be scheduled as needed to facilitate expedited review of research protocol application submissions or resubmissions between regularly scheduled meetings, taking into consideration RSC membership availability.
- C. Cancellation of Regular Meetings: In the event there is no committee business to discuss, the regularly scheduled RSC meeting may be cancelled prior to the meeting without notice to the University & Hospital communities. Notwithstanding cancellation of a regularly scheduled meeting, ad hoc meetings will be scheduled if needed.
- **D. Quorum**: A quorum is required in order to conduct routine committee business. In order to establish a quorum:
 - a. The number of voting committee members present must equal at least six.
 - b. The Committee Chairperson or Vice Chairperson must be present.
 - c. The Radiation Safety Officer must be present.
 - d. A University Management representative must be present.
- **E. Electronic Mail Balloting/Voting:** The RSC may implement an electronic mail (Email) ballot procedure when it is necessary to act on matters between committee meetings. Discussions made via Email ballot shall be discussed and ratified during the next regular meeting. These Email ballot decisions do not constitute a meeting.

VII. RSC REPORTING

- **A. Meeting Minutes:** Minutes of the RSC Meetings shall be provided to the University Vice President for Medical Affairs, and to the RSC Membership, inclusive of the designated Hospital Management representative.
- **B.** Annual Audits: Annual RSC audits of the radiation safety program shall be provided to the Vice President for Medical Affairs and School of Medicine Dean, and the designated Hospital Management representative.

VIII. RSC SUBCOMITTEES

Subcommittees of the Radiation Safety Committee may be established to provide specialized focus in certain areas that may require more in depth treatment of a specific matter on a short-term or long-term basis than can be accomplished at regular Radiation Safety Committee meetings.

- **A.** Ad-Hoc RSC Subcommittees: Ad hoc subcommittees to provide in depth focus on a particular matter on a finite short-term timeline may be established by the RSC Chairperson. The scope of such ad-hoc subcommittees shall be defined by the RSC Chairperson and members shall be appointed by the RSC Chairperson. Ad hoc subcommittee minutes and decisions are brought to the RSC for review and final approval.
- B. Standing RSC Subcommittees: A standing subcommittee to provide in depth focus to a specialized radiation safety area on a long-term basis may be established upon the recommendation of the Radiation Safety Committee through its chairperson and approval by the Vice President for Medical Affairs and Dean School of Medicine. Standing RSC Subcommittees require a written policy document defining the scope, authority, mission and implementation, subcommittee membership positions, subcommittee meeting frequency, etc., to be approved by the Vice President for Medical Affairs and Dean, School of Medicine. Standing subcommittees may issue final approvals consistent with the authority delineated in the written policy for that subcommittee. Standing subcommittee minutes are brought to the RSC for review and ratification.

IX. <u>CONFIDENTIALITY</u>

Each member of the Radiation Safety Committee, and of its respective subcommittees, will adhere to a written confidentiality agreement.

X. <u>CONFLICT OF INTEREST</u>

Each member of the Radiation Safety Committee is subject to the provisions of applicable University and/or Hospital Conflict of Interest Policies.

XI. <u>MEMBERSHIP TERMS</u>

Appointments to the Radiation Safety Committee shall generally be for three-year renewable terms.

XII. <u>REFERENCES</u>

- 1. Code of Federal Regulations (CFR), Title 10, Part 35
- 2. NRC License Renewal Application dated June 4, 2013

XIII. <u>RECISSION</u>

Policy on Radiation Safety Committee (RSC) dated February 1, 2013 and approved February 22, 2013.

XIV. <u>REVIEW DATE</u>

This policy letter will be reviewed every 3 years or as-needed. In all cases, current Nuclear Regulatory Commission (NRC) regulations, the most recent NRC license or license amendment issued to Saint Louis University, and other federal and state requirements take precedence over particular provisions of this policy.

APPROVED:

(Signed Copy on File)				
Fred P. Pestello, Ph.D.				
President				
Saint Louis University				
Date Approved:	September 10, 2015			