2. INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM

2.1 EXECUTIVE MANAGEMENT

Executive responsibility and authority for administration of Washington University in St. Louis is assigned to the Chancellor. The Chancellor has delegated the responsibility and authority to oversee the implementation and management of the Washington University radioactive materials license to the Executive Vice Chancellor for Medical Affairs. This individual appoints the Radiation Safety Committee (RSC) chairman, vice chairman, members and any alternates for the members. The RSC membership meets the requirements of 10 CFR 35.24(f). The Executive Vice Chancellor for Medical Affairs also proposes to the Chancellor an individual who meets the qualifications for the position of Radiation Safety Officer (RSO). The Chancellor appoints the RSO. The management structure for the radiation safety program is shown in Figure 1-1, Radiation Safety Organization.

2.2 RADIATION SAFETY COMMITTEE (RSC)

Duties and Responsibilities

1. Authorized by the Executive Management to oversee all uses of NRC-licensed and State of Missouri-registered radioactive materials and radiation-producing machines at Washington University and Washington University Medical Center (WU/WUMC).

2. Responsible for overseeing the receipt and handling of radioactive materials used in human research involving radioactive drugs. [NOTE: The Washington University Radioactive Drug Research Committee (RDRC) is responsible for overseeing all research protocols involving the administration of radioactive drugs to human subjects, and functions for this purpose as a subcommittee for both the RSC and the Washington University Human Studies Committee, which is our Institutional Review Board (IRB). For those research studies subject to the requirements of 21 CFR 361.1, the RDRC functions in accordance with the applicable Food and Drug Administration (FDA) regulations.]

3. Inform the Executive Vice Chancellor for Medical Affairs, and other WU/WUMC administrators as applicable, of the radiation safety program operations, changes, incidents and all situations that have or may result in regulatory intervention.

4. Establish the WU/WUMC policy on radiation protection matters that will ensure that radiation and 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.

5. Be familiar with all pertinent regulations, license and registration conditions and commitments to regulatory agencies and ensure that radiation and radioactive materials are used in compliance with WU/WUMC obligations.
6. Ensure that radiation and radioactive materials are used consistent with the ALARA philosophy and program.

7. Review and approve or deny, on the basis of safety and the prior training and/or experience of the applicant, all requests to use radioactive materials within WU/WUMC.

8. Ensure that licenses or registrations are amended prior to implementing changes that require amendments.

9. Meet as often as necessary to conduct RSC business. Meeting quorum shall be half the membership, including a management representative and the RSO or their alternates.

10. Implement a mail ballot procedure, which includes electronic mail, when it is necessary to act on matters between Committee meetings. Decisions made via mail ballot shall be discussed and ratified during the next regular meeting. These mail ballot decisions do not constitute a meeting.

11. Maintain written minutes of all Committee meetings, including members in attendance and members absent, discussions, actions, recommendations, decisions and results of votes.

12. Empower subcommittee(s) and establish delegation of authority procedures to review and approve user authorizations in the name of the RSC.

13. Empower the RSO and establish delegation of authority procedures to review and issue interim authorizations, and to review and approve certain changes to authorizations in the name of the RSC. All interim authorizations issued by the RSO will be reviewed and approved at the next Committee/subcommittee meeting.

14. Appoint Temporary Radiation Safety Officer(s) and empower the individual(s) to function as the RSO over all or any portion of the radiation safety program as the individual is qualified and as the RSC deems is appropriate.

2.3 RADIATION SAFETY OFFICER AND STAFF

Responsibilities and Duties

1. Implement the radiation safety program, including policies and procedures of the RSC.

2. Review all applications for uses of radiation or radioactive material to ensure compliance with appropriate regulations and license or registration conditions.

3. Issue authorizations for the use of radioactive materials in the name of the RSC.

4. Restrict or suspend use and/or possession of radiation or radioactive materials whenever a significant deviation from established guidelines and procedures has occurred or there is threat to health or property.
5. Be the primary WU/WUMC liaison to the NRC and State of Missouri with regard to the radiation safety program and license or registrations.

6. Report incidents, as required, to the applicable regulatory agency and provide descriptions of these incidents to the RSC and to the Executive Management.

7. Regularly inspect the facilities of each Authorized User by the methods and frequency developed in collaboration with the RSC.

8. Supervise all ordering, receipt, survey, monitoring and delivery of all shipments of radioactive material arriving at WU/WUMC.

9. Personnel training is conducted as is commensurate with the individual’s duties regarding radioactive materials as required by 10 CFR 19.

10. Supervise and coordinate the radioactive waste storage and disposal program.

11. Maintain inventory of all licensed or registered materials or machines.

12. Supervise decontamination and recovery operations.

13. Perform or ensure performance of required leak tests on all sealed sources and calibration of radiation survey instruments.

14. Manage personnel dosimetry and ALARA programs.

15. Develop, distribute and implement up-to-date radiation protection procedures in the daily operation of the radiation safety program.

16. Ensure that individuals installing, relocating, maintaining, adjusting or repairing devices containing sealed sources are trained and authorized by NRC or Agreement State license.

17. Ensure radioactive material is properly secured.

18. Maintain documentation to demonstrate by measurement or calculation that the total effective dose equivalent to the individual likely to receive the highest dose from the licensed or registered operation does not exceed the applicable limit for members of the public.

19. Audit at least annually the radiation safety program, document findings and review with the RSC.

20. Ensure that effective corrective actions are developed, implemented, and documented if violations of regulations, or license or registration conditions, or program procedures are identified.

21. Ensure that radioactive material is transported, or offered for transport, in accordance with applicable DOT requirements.
22. Ensure the license and registrations remain up-to-date and submit to the NRC or State of Missouri, in a timely manner, all amendment and renewal applications.

23. Maintain appropriate license and registration records including minutes of all RSC meetings.