STATEMENT OF AUTHORITY

Upon publication of these procedures, the Radiation Safety Committee of the Medical University of South Carolina is hereby authorized to act as agent for the Institution involving matters of review, control and mediation arising from the use or proposed use of radioactive materials and/or ionizing or non-ionizing radiation at the Medical University of South Carolina. A statement of the composition of the Council and a delineation of authority is included in the pages of this manual.

Furthermore, it is hereby declared that the Radiation Safety Officer of the Medical University of South Carolina derives his authority directly from the Office of the President of the Medical University of South Carolina in all matters involving radiation safety and/or violations of accepted rules of practice as described herein. The scope of the authority of the Radiation Safety Officer shall include, but not be limited to, the authority to identify radiation safety problems; initiate, recommend, or provide corrective actions; stop unsafe operations; and verify implementation of corrective actions.

Raymond S. Greenberg, M.D., PhD.
President, Medical University of South Carolina

Revised, July 2011
ACKNOWLEDGMENTS

The technical information contained in this manual has been obtained from many sources. It is based mainly on general scientific information and the rules, regulations, and guidelines of the Nuclear Regulatory Commission, and recommendations of the National Council on Radiation Protection and Measurements.

Thanks are given to all who have provided help with this revision.

Radiation Safety Officer
**Section I: Administration and Procedures**

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GLOSSARY

1. MEDICAL UNIVERSITY OF SOUTH CAROLINA: As referred to in the text of this manual, Medical University is defined as the entity for which the University is legally responsible and all ancillary facilities for which the University becomes legally responsible through an action by the Radiation Usage Committee.

2. BIOASSAY: The determination of the kind, quantity, or concentration, and location of radionuclides in the human body by direct (in vivo) measurements or by in vitro analysis of material excreted or removed from the body.

3. CONTAMINATION, RADIOACTIVE: Deposition of radioactive material at any place where it is not desired, and particularly in any place where its presence may be harmful. The harm may be in vitiating the validity of an experiment or procedure, or in actually being a source of danger to personnel.

4. CUMULATIVE DOSE (RADIATION): The total dose resulting from repeated exposure to radiation of the same region, or of the total body.

5. EXTERNAL RADIATION: Exposure to ionizing or non-ionizing radiation when the radiation source is located outside the body and the radiation must then penetrate into the superficial or deep tissues. Exposure to external radiation is reported as "shallow" or "deep".

6. FILM BADGE: A packet of photographic film used for approximate measurement of ionizing radiation exposure for personnel monitoring purposes. The badge may contain two or three films of differing sensitivity, and it may contain a filter which shields part of the film from certain types of radiation.

7. HALF-LIFE, BIOLOGICAL: The time required for the body to eliminate one-half (½) of the administered dose of any substance by regular processes of elimination. This time is the same for both stable and radionuclides of a particular element.

8. HALF-LIFE, EFFECTIVE: The time required for a radioactive material fixed in the tissues of the body to be diminished by a factor of two (2), as a result of the combined action of radioactive decay and biological elimination, i.e.,

\[
\frac{1}{T_{\text{eff}}} = \frac{1}{T_{\text{phy}}} + \frac{1}{T_{\text{bio}}}
\]

9. HALF-LIFE, RADIOACTIVE: The time required for a radioactive substance to lose one-half (½) of its activity by decay.

10. INTERNAL RADIATION: Exposure of ionizing radiation where the radiation source is in the body as a result of radionuclides contained in the body tissues or cavities.

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11. RADIATION: The emission and propagation of energy through space or through a material medium. The term radiation, or radiant energy when unqualified, usually refers to electromagnetic radiation; such radiation commonly is classified, according to frequency, as Hertzian, infrared, visible (light), ultraviolet, x-ray, and gamma ray.

   a) Ionizing Radiation: Radiation capable of ionizing material by interactions of particular or electromagnetic radiation; refers to ultraviolet, x-ray, gamma-ray, alpha, beta, neutron, etc. radiations.

   b) Non-ionizing Radiation: All electromagnetic radiation which does not ionize matter; however, it may cause damage by thermal effects, etc.; includes radiofrequency, visible, infrared, microwave, and ultrasound radiations.

12. RADIATION THERAPY: Treatment of disease with any type of radiation (ionizing or non-ionizing).

13. RADIOACTIVITY: The process whereby certain nuclides undergo spontaneous disintegration in which energy is liberated, generally resulting in the formation of a new nuclide. The process is accompanied by the emission of one or more types of radiation, such as alpha particles, beta particles and gamma photons. The property of radioactivity is exhibited by more than fifty naturally occurring radionuclides (natural radionuclides) and is commonly referred to as natural radioactivity. The property of radioactivity can be induced in certain elements under controlled conditions and, in such instances, the resultant radioactivity is referred to as artificial radioactivity.

14. RADIATION SURVEY: Evaluation of the radiation hazards incident to the production, use or existence of radioactive materials or other sources of radiation under specific conditions. Such evaluation customarily includes a physical survey of the disposition of materials and equipment, measurements or estimates of the levels of radiation which may be involved, and a sufficient knowledge of processes using or effecting these materials to predict any hazards resulting from expected or possible changes in materials or equipment.

15. RELATIVE BIOLOGICAL EFFECTIVENESS (RBE): The ratio of gamma ray or x-ray dose to the dose which is required to produce the same biological effect of the radiation in question. For example, the RBE of alpha radiation is 10. This means that 10 mGy of alpha radiation will produce a biological response to the same degree as will 100 mGy of x or gamma radiation.

16. WIPE TEST: A one (1) inch disc of paper is used to wipe approximately 100 cm$^2$ of accessible surface in a radionuclide laboratory to determine the quantity if any, of removable radioactive contamination which might exist. This knowledge will enable the person working with the material to determine if a decontamination of the area is in order.

17. GRAY (GY): The unit of radiation absorbed dose. One gray is the amount of energy absorbed per unit mass of tissue due to any type of ionizing radiation, and is equal to 1.0 Joules per kilogram.

   \[
   1 \text{ Gray (Gy)} = 100 \text{ rad}
   \]
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18. SIEVERT (SV): The unit of dose equivalent. One sievert is the biological effective dose due to any type of ionizing radiation. One sievert is the equivalent to 1.0 Joules per kilogram of x-ray. The relationship between the sievert and the Gray is given by:

Dose equivalent (Sv) = Absorbed Dose (Gy) x Quality Factor (QF)

where QF is a quality factor dependent upon the type of ionizing radiation. For beta, x and gamma radiation, QF = 1, for alpha radiation, QF = 1 - 20, and for neutron radiation, QF = 3 - 10. The millisievert (mSv) is one-thousandth (0.001) of a sievert.

1 Sievert (Sv) = 100 rem

19. COULOMB PER KILOGRAM: The unit of exposure of x and gamma radiation. Exposure rate of x and gamma radiation is measured in coulombs per kilogram per hour (kg\(^{-1}\) h\(^{-1}\)). 1 C kg\(^{-1}\) = 3.88 x 10\(^3\) R = 3.88 x 10\(^6\) mR.

20. BECQUEREL (Bq): The unit of radioactivity. One becquerel (Bq) is the activity corresponding to a disintegration rate of 1 disintegration per second (dps). The Megabecquerel is one million (10\(^6\)) becquerels.

1 Bq = 27 pCi

21. RADIATION AREA: Any accessible area in which an individual may receive a dose in excess of 50 μSv (5 millirems) in any one hour or a dose in excess of 1 mSv (100 millirems) in any 5 consecutive days.

22. HIGH RADIATION AREA: Any accessible area in which an individual may receive a dose in excess of 1 mSv (100 millirems) in any one hour.

**********************************************************************************

PREVIOUS TERMINOLOGY

A. RAD: The unit of radiation absorbed dose. One rad is the amount of energy absorbed per unit mass of tissue due to any type of ionizing radiation, and is equal to 100 erg per gram or 0.01 Joules per kilogram. 1 rad = 10 mGy

B. REM: The unit of dose equivalent. One rem is the absorbed dose due to any type of ionizing radiation. One rem is the dose equivalent to 0.01 Joules per kilogram. The relationship between the rem and rad is given by:

Dose equivalent (rem) = Absorbed Dose (rad) x Quality Factor (QF) where QF is a quality factor dependent upon the type of ionizing radiation. For beta, x - and gamma radiation, QF = 1, for alpha radiation, QF = 1 - 20, and for neutron radiation, QF = 3 - 10. The millirem (mRem) is one-thousandth (0.001) of a rem. 1 rem = 10 mSv

C. ROENTGEN: The unit of exposure of x and gamma radiation. One roentgen (R) is the quantity of x or gamma radiation that produces an electrical charge of 2.58 x 10\(^{-4}\) coulombs per kilogram of air at standard temperature and pressure. The milliroentgen (mR) is one-thousandth (0.001) of a roentgen. Exposure rate of x and gamma radiation is measured in mR per hour. 1 R = 2.58 x 10\(^{-4}\) C kg\(^{-1}\)

D. CURIE: The unit of radioactivity. One curie (Ci) is the activity corresponding to a disintegration rate of 3.7 x 10\(^{10}\) disintegrations per second (dps). The millicurie (mCi) is one-thousandth (0.001) of a curie. The microcurie (μCi) is one-millionth (0.000001) of a curie. 1 Ci = 37 GBq

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CHAPTER I

ADMINISTRATION AND PROCEDURES

Radiation Safety Officer

It is the responsibility of the Radiation Safety Officer to ascertain that the policies and procedures adopted by the Radiation Control Council are followed by all individuals at the Medical University of South Carolina whose work involves the use of radioactive materials and/or ionizing or non-ionizing radiation. He and/or his staff will review the plans of the experiments involving the use of radioactive materials and/or ionizing or non-ionizing radiation with the purpose of minimizing hazards which would not be entirely covered under the scope of routine good housekeeping. The Radiation Safety Officer is available for consultation to all investigators using radioactive materials and/or ionizing or non-ionizing radiation. The Radiation Safety Office(r) will supervise decontamination procedures and advise investigators of the necessity for decontamination of an area. The Radiation Safety Officer will have the authority to suspend any operation involving radiation which constitutes a health hazard or which is in violation of regulations set forth in the Radiation Safety Manual of the Medical University of South Carolina, until he deems that proper corrections have been made.

In brief, the duties of the Radiation Safety Officer are:

1. He shall derive his authority directly from the Office of the President of the Medical University of South Carolina in all matters involving radiation safety and/or violations of accepted rules of practice as described herein.

2. Under his supervision, his staff will approve all University procedures which could involve radiation exposure and all changes in such procedures except irradiation of a patient for medical diagnosis or therapy.

3. He will act in a supervisory capacity in all aspects of radiation measurement and protection activities, including monitoring, maintenance of exposure records, survey methods, radioactive waste disposal, and radiological safety practices.

4. Under his supervision, his staff will ensure that all users of radioactive materials perform routine radiation monitoring and keep records on approved forms in accordance with the requirements of Chapters II - V of this Manual.

5. Under his supervision, his staff will consult with all potential users of radioactive materials and/or ionizing or non-ionizing radiation and advise on radiological safety procedures.

6. He will suspend any operation causing an excessive radiation hazard as rapidly and safely as possible.

7. Under his direction, staff will be responsible for keeping all Health Physics records for the Medical University of South Carolina. These include:

   a) A list of all users of radioactive materials and/or ionizing or non-ionizing radiation,
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the material(s) being used, and the area of use.
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b) A record of all radioactive materials ordered and received by the Medical University of South Carolina. The Radiation Safety Office will counter-sign each requisition for radioactive materials before the Purchasing Department will order the material, unless other arrangements are made. He must also sign any requisition for x-ray producing equipment and non-ionizing radiation equipment prior to purchasing.

c) A record of all disposal of radioactive material. A form for receipt, use and disposall will be given to each user with each specific order of radioactive material. This will be turned in to the Radiation Safety Office when completed.

d) A record of all survey instrument calibrations.

e) A record of the monitoring and wipe tests from each laboratory using radioactive materials.

f) A record of all personnel exposure histories and current exposure profiles. These will include monthly badge reports and any bioassays which may be required.

g) A record of any contaminations which may have occurred and a list of all personnel involved in such an incident.

h) A record of all losses or thefts of radioactive materials.

i) A record of all leak tests of sealed radioactive sources.

8. Under his direction, staff will perform monthly (*changed from weekly*) surveys and audits of Nuclear Pharmacy, Nuclear Medicine, Cesium Storage Room and Radiation Safety Radioactive Storage Building. Quarterly surveys shall be performed on Radiation Safety Workroom and related areas. Biannual audits of Nuclear Pharmacy, Nuclear Medicine, Radiation Oncology and Investigator labs shall ensure compliance.

9. He will supervise and be responsible for the performance of the Assistant Radiation Safety Officers and may delegate those responsibilities which come within the scope of their training and experience.

10. He will keep the records of meetings of the Radiation Safety Committee.

11. He and/or his staff will be responsible for ensuring that all records desired by the Council or Committee, as set up and maintained in accordance with this manual, are kept accurately and up-to-date. If necessary, he will suspend any operation in non-compliance until the records are in order.

12. He and/or his staff will ensure that all aspects of radiation safety are in compliance with all State and Federal regulations as detailed in the Rules and Regulations for Radiation Control for the State of South Carolina, Title 10 of the Code of Federal Regulations (10 CFR 20 - Standards for Protection Against Radiation), and, where applicable, the Occupational Safety and Health Act, 1970 (OSHA), and Title 21 Code of Federal Regulations, Part 812.

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The Radiation Safety Committee is a standing committee of MUSC. Members will be appointed by the President of the Medical University of South Carolina. The Council shall be composed of thirteen (13) members and consist of administrative representatives of those University organizational units in which radioactive materials are used as. All members unable to attend a given meeting are empowered to send a designated representative who will have full voting privileges. The University President has a standing invitation to attend any scheduled meeting as a non-voting participant.

The Committee shall serve as the general policy making and regulatory body for all University activities involving the use of radioactive materials and/or ionizing or non-ionizing radiation. It is the responsibility of the Committee to maintain updated knowledge and awareness of technological progress, as well as, associated usage and safety procedures, serve as final arbiter in procedural questions involving internal usage of radioactive compounds, conduct any investigations necessary in whole or part because of internal radionuclide usage, assure ongoing University cooperation/coordination with appropriate local, State and Federal authorities, make recommendations for Committee memberships, make recommendations for a University Radiation Safety Officer, and promote safe usage of radioactive materials at the University.

This committee will have the responsibility under the Institution's broad radioactive materials license for issuance of licenses to individual University employees desiring the privilege of using such materials for research and/or clinical purposes. In discharging this responsibility, the Committee shall meet at least bi-annually as specified in its charter and shall serve as a peer group to evaluate all applications by Medical University of South Carolina employees for licensure, maintain updated awareness of current procedures and methods for safe radionuclide handling, be capable of evaluating the effectiveness of the use of radionuclides in any proposed experimental designs, and, as required, report.

Procedures for Training of Personnel

Any personnel shall be adequately trained in the handling and use of radioactive materials prior to beginning work in laboratories that utilize radioactive materials. It is the responsibility of the principal investigator (authorized user) to ensure that his/her personnel are properly instructed in the safe use of radioactive materials and emergency procedures. The Radiation Safety Office requires proof of adequacy of training. A completed “Certificate of Training” (pg. 128) must be in the licensed investigator’s file and on file with the Radiation Safety Office prior to an individual beginning work with radioactive material. With the exception of authorized users, M.D.’s, Ph.D.’s, and residents, any personnel working with or around radioactive materials shall take an annual refresher course in a related field of radiation. A list of the persons who attend the class shall be kept in the licensed investigator’s file and on file with the Radiation Safety Office. See Appendix H – Notices, Instructions, Reports to Workers, and Emergency Numbers.

Procedure for Obtaining Authorization

Any request for authorization to use radioactive materials and/or ionizing or non-ionizing radiation equipment should be prepared on the forms shown in Appendix B. An appointment to meet with Radiation Safety should be arranged prior to completing an application (extension 4255). The
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completed form(s) should be sent to the Radiation Safety Office which will review the safety aspects of the application and will expedite it to the Radiation Usage Committee except for applications for non-human use of sealed sources, such as gas chromatographs, detector standards, etc. The request for authorization shall include, but not limited to, the following:

1. Training and experience of the principal investigator, including medical experience where applicable.

2. Nature of proposed investigation or usage.

3. Description of the facilities in which the work will be performed.

4. Safety aspects of the proposed use.

5. Statement of required possession limit in becquerels.

When an application has been approved (by three members of the Radiation Usage Committee to whom the application was sent) the Radiation Safety Office will notify the principal investigator by sending him/her a copy of the authorization. This license will expire two years after the issue date. Renewal notices will be sent approximately 60 days prior to expiration.

The criteria for licensing will be on the following basis.

Any individual desiring to use radioactive materials and/or ionizing or non-ionizing radiation will be required to have general knowledge of the subject. He/She may have obtained the necessary training in residency, formal training course or collaboration in a program using by-product material. To qualify as adequately trained, the individual's background should include:

1. A working knowledge of:
   a) Principles and practices of radiological health safety and health physics.
   b) Radioactivity measurements, standardization, monitoring techniques, and instruments.
   c) Mathematics and calculations basic to the use and measurement of radioactivity.
   d) Biological effects of radioactive materials and/or ionizing or non-ionizing radiation.

2. Experience in the use of by-product material for the types of quantities for which the application is being made, or equivalent experience. A minimum of one (1) year experience shall be considered adequate.

These criteria will serve as an evaluation of those individuals desiring to use radionuclides and/or ionizing or non-ionizing radiation in non-human research and procedures, as well as, in the use of radionuclides and/or ionizing or non-ionizing radiation in routine clinical procedures. Individuals desiring to use radionuclides clinically will be required to have the following training in addition to the above:

1. Supervised examination of patients to determine the suitability for diagnosis and/or treatment and recommendation on dosage to be prescribed.

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2. Collaboration in calibration of the dose and actual administration of the dose to the patient, including calibration of the radiation dose, related measurements and plotting of data.

3. Adequate period of training to enable the physician to manage radioactive patients and to follow patients through diagnosis and/or the course of treatment.

4. Study and discussion with preceptor of case histories to establish most appropriate diagnostic and/or therapeutic procedures, limitation, contradictions, etc.

The criteria for specific training in the use of radionuclides and/or ionizing or non-ionizing radiation in well established medical procedures regarding patients will be based on the criteria outlined in Appendix C of the NRC's Medical Licensing Guide. Those procedures regarded as routine are those listed in Appendix D of the NRC's Medical Licensing Guide.

Experimental and non-routine medical uses of by-product materials and/or ionizing or non-ionizing radiation include all human uses not specified in Appendix D of the NRC's Medical Licensing Guide. Those uses are classified into two areas:

1. Clinical Research - This will apply to a new use of a by-product material and/or ionizing or non-ionizing radiation in humans for which little is known or published. The basis for proceeding with the procedure in humans is documented animal studies. These animal studies will be conducted to establish toxicity, biological half-life, distribution, and effectiveness. This phase would include the initial introduction into humans and initial trials on a limited number of patients.

2. Clinical Evaluation - This area of non-routine use applies to the planned testing of a new diagnostic or therapeutic procedure in an appropriate series of control and diseased humans. The procedures and results of clinical research will have been reported in the literature or at meetings.

The clinical research areas will be limited to those individuals who have broad experience in the use of radionuclides and/or ionizing or non-ionizing radiation and who have appropriate facilities and equipment available to conduct research. Research will be conducted by groups of competent individuals representing various disciplines rather than by single individuals. The individual physician who is the chief investigator and is primarily responsible for the research will be required to have broad and varied experience in the use of radionuclides and/or ionizing or non-ionizing radiation and in clinical research investigation.

The clinical evaluation area will be limited to those individuals with broad experience in clinical evaluation and the use of radionuclides and/or ionizing or non-ionizing radiation and with adequate resources available to conduct the trials.

Each application will be completed by the investigator and sent to the Radiation Safety Office for review and then to three members of the Radiation Safety (formerly Usage Committee) for approval (see Appendix B for a sample application form).

Note that these applications are also evaluated by the Human Research Committee of the Medical University of South Carolina. This Committee makes recommendations concerning the use
Section I: Administration and Procedures of human subjects in clinical research and evaluation. The Human Research Committee will follow the evaluation and recommendations of the Radiation Usage Committee and the Radiation Safety Officer.

Regulations of the Food and Drug Administration are also followed for all applications which involve the use of new drugs and new uses for previously approved drugs, as well as, use of non-ionizing radiation.

Procedure for Transfer of Radioactive Material(s) from/to Outside Institutions

When an investigator is transferring employment to the Medical University of South Carolina and transferring material from his/her previous employment, he/she must first notify the Radiation Safety Office. The Radiation Safety Office will require information regarding the type and quantity of radioactive material being transferred. An application for authorization to use radioactive material must be completed. The Radiation Safety Office will hold all transferred radioactive material until the application has been approved. Any unauthorized material(s) brought into the Medical University is subject to confiscation by the Radiation Safety Office.

When an investigator is leaving the Medical University of South Carolina, an appropriate transfer form must be completed and sent to the Radiation Safety Office prior to leaving. All radioactive material must be accounted for prior to an investigator leaving the Medical University.

TRANSFERS TO OUTSIDE INSTITUTIONS MUST BE ARRANGED THROUGH THE RADIATION SAFETY OFFICE.
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Procurement of Radioactive Materials

The following procedure will be used, except in cases where prior arrangements have been made with the Radiation Safety Office and the Director of Purchasing. Each investigator MUST ensure that personnel preparing purchase requisitions for materials are informed of the following procedures.

1. Each requisition must show the license number and name of the investigator (see sample requisition on page 117).

2. All requisitions for radioactive materials MUST be sent to the Radiation Safety Office for approval BEFORE going to Procurement/Grants Accounting.
   a) Send or bring requisitions to the Radiation Safety Office. After approval, the requisition will be forwarded to purchasing via campus mail.
   b) All confirming/emergency orders should be brought to the Radiation Safety Office BEFORE sending to Procurement. Any additions to orders (blanket, standing, etc.) must be approved by Radiation Safety before being ordered.
   c) All personnel MUST use the appropriate shipping address noted below when placing telephone orders.

    **RESEARCH INVESTIGATORS**

    Medical University of South Carolina
    Radiation Safety
    Mark for # ____ (Investigator's license #)
    276W Main Hospital
    169 Ashley Avenue
    Charleston, SC 29425

    **NUCLEAR MEDICINE**

    Medical University of South Carolina
    Nuclear Pharmacy
    H313, Main Hospital
    169 Ashley Avenue
    Charleston, SC 29425

    **LABORATORY MEDICINE**

    Medical University of South Carolina
    Laboratory Medicine
    169 Ashley Avenue
    Charleston, SC 29403

d) Departmental Orders (DO's) **SHALL NOT** be used for procurement of radioactive materials.

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3. The Radiation Safety Office will make certain all information needed by Procurement and the vendor is included on the requisition.

4. The Procurement Department will not process any requisition for radioactive material which has not been approved by Radiation Safety unless prior arrangements have been made by the investigator with the Radiation Safety Office and Director of Procurement.

Procedure for Receiving Radioactive Materials

When a shipment of radioactive material is received, it shall be delivered promptly to the Radiation Safety Office unless permission is granted by the Radiation Safety Office to deliver elsewhere. A copy of the packing slip will be made for Radiation Safety records and the shipment will be checked for correctness of type and quantity of radioactive material ordered. If any discrepancy is noted with respect to a shipment (e.g. wrong materials, wrong quantities, materials for which the investigator is not authorized, etc.) the Radiation Safety Office will notify the investigator as to the disposition of the shipment.

When a shipment is received, Radiation Safety will monitor the package for possible contamination caused by leakage of the radioactive contents and to verify the transport index is correct. A wipe test will then be performed on exterior and on the interior of all packages with the exception of RIA kits. The procedure for the survey and wipe test is as follows:

1. Radiation Survey
   a) Hold the probe of the survey instrument against the outside surface of the shipping container;
   b) observe the highest reading in C kg⁻¹ h⁻¹ (mRh⁻¹) on all faces or sides of the container;
   c) record the maximum reading obtained.

2. Wipe Test
   a) Using a 2.3 cm paper disc or filter paper, wipe approximately 100 cm² of the outside of the shipping container;
   b) repeat procedure 2.a) for the inside of the carton, wiping the exterior packaging of the source.
   c) the wipes obtained by the above procedures shall be counted in a suitable radiation detector and the readings recorded on the worksheet.

If the wipe tests indicate removable contamination in excess of 0.37 kBq (370 dps) per 100 cm² of package surface area on the external surface of the package, the Radiation Safety Office shall immediately notify the final delivery carrier and the Bureau of Radiological Health by telephone.

If radiation levels are found on the external surface of the package in excess of 5.16 x 10⁵ C kg⁻¹ h⁻¹ (200 mRh⁻¹), or at three feet from the external surface of the package in excess of 2.58 x 10⁻⁶ C kg⁻¹ h⁻¹ (10 mRh⁻¹), the Radiation Safety Office shall immediately notify by telephone, the Bureau
Section I: Administration and Procedures of Radiological Health and the final delivery carrier.

Packages requiring surveys shall be monitored and wipe tested as soon as possible after receipt, and to satisfy requirements of RHA 3.26.

All packages known to contain radioactive material shall be monitored for radioactive contamination and radiation levels if there is evidence of degradation of package integrity, e.g. crushed, wet, and/or damaged units.

If any unusual situation arises which is not covered by the above procedures, please call the Radiation Safety Office for specific instructions at extension 792-4255.

These procedures are for the benefit of all authorized users of radioactive materials at the Medical University of South Carolina; non-compliance can jeopardize the Broad License of the Institution and an investigator's authorization will be suspended.

Procurement of Electronic Devices Capable of Producing X-Radiation

All orders for electronic devices capable of producing X-radiation, including, but not limited to, diagnostic, dental, and therapeutic x-ray units, animal x-ray units, fluoroscopic x-ray units, electron microscopes, high energy microwave devices, shall be submitted to the Radiation Safety Office for approval before being sent to Procurement. The Director of Procurement will not honor any request for such equipment without authorization of the Radiation Safety Office. Prior to submitting such a requisition, the investigator must be approved by the Radiation Usage Committee for the operation of such equipment.

Radiation Survey of Electronic Equipment

Before any electronic equipment capable of producing X-radiation is placed in use, it shall be surveyed by the Radiation Safety Office to ascertain if a safety hazard exists from its use.

If after normal use of such electronic equipment, the operator suspects a radiation hazard may exist, he/she should request a radiation survey by the Radiation Safety Office.

Non-Ionizing Radiation Guidelines

The Medical University of South Carolina's Radiation Safety Officer will have jurisdiction over all aspects of non-ionizing radiation, as well as ionizing radiation. The guidelines for non-ionizing radiation will be the "INTERIM GUIDELINES ON LIMITS TO EXPOSURE TO RADIOFREQUENCY ELECTROMAGNETIC FIELDS IN THE FREQUENCY RANGE FROM 100 kHz to 300 GHz" promulgated by the International Non-Ionizing Radiation Committee of the International Radiation Protection Association (IRPA) on 8 July 1983. These guidelines will be used until such time as they are superseded by new ones of the IRPA, the National Council of Radiation Protection (NCRP), the South Carolina Department of Health and Environmental Control, or Federal Guidelines.

MUSC Radiation Safety Manual, December 2012
The exposure to radiofrequency (RF) electromagnetic radiation has been shown to produce a variety of adverse health effects ranging from eye cataracts, thermal injury, overloading of the thermoregulatory response, altered behavior, to convulsions. In order to protect the health of workers and the general public, the exposure limits in the above mentioned Guidelines will be adopted. These guidelines apply to exposures of workers and the general public to RF electromagnetic fields, except for deliberate exposures of patients undergoing medical treatment or diagnosis, i.e., diathermy, Nuclear Magnetic Resonance (NMR), etc.

Quantities and Units - The physical quantities for exposure to RF electro-magnetic fields in the frequency region of 10 MHz and above are expressed in terms of the specific absorption rate (SAR). The SI unit of SAR is watt per kilogram (W/kg). Additional information on quantities and units can be found in NCRP No. 67, "Radiofrequency Electromagnetic Fields, Properties, Quantities and Units, Biophysical Interactions and Measurements".

Exposure Limits - The occupational exposure to RF electromagnetic fields in the frequency region of 10 MHz and above should not exceed a SAR of 0.4 W/kg when averaged over any 6 minutes and over the whole body or 4 W/kg when averaged over any 6 minutes and any one gram of tissue.

The general public exposure to RF electromagnetic fields in the frequency region of 10 MHz and above should not exceed a SAR of 0.08 W/kg when averaged over any 6 minutes and over the whole body or 0.8 W/kg when averaged over any 6 minutes and one gram of tissue.

The exposure limits to RF electromagnetic fields in the frequency region of 10-30,000 MHz are given in Table 1 for the occupational limits and in Table 2 for the general public limits in the above mentioned IRPA Guidelines (see Appendix G).

Acquisition of RF Equipment - The acquisition of RF equipment operating in the frequency region of 10-30,000 MHz must have the approval of the Radiation Safety Office prior to purchase. The Radiation Safety Office will review the equipment characteristics and facility for potential health hazards before approval. The experience and expertise of the investigator desiring to utilize this equipment must be submitted to the Radiation Safety Office for approval. All equipment used to treat or diagnose human subjects must have a U.S. FDA IDE or pre-market approval and be approved by the MUSC I.R.B. before it may be used. Surveys of the facility and/or RF equipment by a qualified expert shall be performed before first use on human subjects. All RF equipment approved by the FCC for telecommunications or data transmission will not be required to be surveyed as long as it is used for its intended purposes or satisfies regulations promulgated by the FDA in 21 CFR 812.

The Radiation Safety Office shall suspend any operation utilizing RF electromagnetic fields that constitute a health hazard to occupational workers or the general public as defined in the IRPA Guidelines or any Federal, State or Local exposure limit guidelines. The decision of the Medical University of South Carolina Radiation Control Council shall be final in these matters.

Airborne Ultrasound Guidelines

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The Medical University of South Carolina Radiation Safety Officer shall have jurisdiction over all aspects of airborne ultrasound which produces high audible noise levels. This applies to ultrasonic equipment that emits airborne acoustic energy, not only at the ultrasonic operating frequency, but also at sub-harmonics which are audible. Devices that may fall in this category are intrusion alarms, door openers, remote controls, pest repellers, and guidance devices for blind people, as well as devices for cleaning, drilling, mixing, and emulsification.

The guidelines for airborne ultrasound shall be the "INTERIM GUIDELINES ON LIMITS OF HUMAN EXPOSURE TO AIRBORNE ULTRASOUND" promulgated by the International Non-Ionizing Radiation Committee of the International Radiation Protection Association (IRPA). The exposure of the general public to high levels of airborne ultrasound can produce nausea, headaches, tinnitus and fatigue, as well as hearing loss. The guidelines adopted are primarily aimed at protection from exposure from devices emitting ultrasound limited to frequencies having one-third-octave bands with mid-frequencies from 20 kHz to 100 kHz.

Quantities and Units - Airborne Ultrasound is quantified in terms of sound pressure level (SPL) in decibels (dB), such that

\[ \text{SPL(dB)} = 20 \log_{10} \left( \frac{p}{p_r} \right) \]

where \( p \) is the room mean square acoustic pressure and \( p_r \) is the reference pressure, equivalent to approximately the lowest level of audible sound perceived in humans at the most sensitive frequency (approximately 1 KHz), and is normally taken as equal to 20 micropascals (μPa). 20 μPa is equivalent to an acoustic intensity \( I_r \), equal to \( 10^{-12} \text{ W/m}^2 \) in air. The acoustic intensity \( I \) is proportional to the square of the acoustic pressure. The sound pressure level (SPL) is equivalently expressed by

\[ \text{SPL(dB)} = 10 \log_{10} \left( \frac{I}{I_r} \right) \]

Exposure Limits - Limits of exposure to airborne ultrasound for occupational exposure is given in Table 1 of Appendix G. The limits apply to continuous exposure to workers for an 8-hour working day. Limits in Table 1 may be increased in accordance with corrections given in Table 2, provided the total duration of exposure per day does not exceed 4 hours.

Acquisition of Ultrasound Equipment - The acquisition of ultrasound equipment operating in the frequency range of 20 kHz to 100 kHz and which is capable of producing airborne ultrasound in excess of the limits given in Tables 1, 2, and 3 of Appendix G, must have the approval of the Radiation Safety Officer prior to purchase. The Radiation Safety Officer will review the equipment characteristics and the facility for potential health hazards before approval. The Radiation Safety Officer shall suspend any operation utilizing ultrasound that constitutes a health hazard to occupational workers or the general public as defined in IRPA Guidelines, or any Federal, State or Local exposure limit guidelines subsequently enacted.

Laser Radiation Guidelines

The Medical University of South Carolina's Radiation Safety Officer shall have jurisdiction over all aspects of laser radiation-producing devices. This applies to, but is not limited to, devices used in surgical operations, manufacturing, research, education, and as optical positioning devices.
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The guidelines for exposure to laser radiation will be the American National Standards Institute (ANSI), "Standards for the Safe Use of Lasers" Z 136.1 - 1980 Z 136.3 - 1988 "Standards for the Safe Use of Lasers in Health Care Facilities", and any subsequent guidelines issued by ANSI, State or Federal agencies such as the FDA-BRH or OSHA.

Laser hazards may be classified as 1) radioactive, 2) electrical, 3) explosive, and 4) toxic. Radioactive hazards are those resulting from laser spectral radiation and include retinal damage and thermal damage to the skin. Electrical hazards are due to electrical shock and electrical burns from high voltage power supplies. Explosive hazards may exist due to explosions from laser flash lamps and capacitors, as well as laser rods themselves. Toxic hazards may arise due to thermal effects of high power laser beams, such as ozone produced by ionization of air and toxic substances produced by high temperatures due to vaporization by high power laser beams.

The FDA-BRH classifies lasers operating in the visible region of the spectrum into Class-1 (less than 4x10^{-7}W,cw), Class-2 (4x10^{-7}W,cw), Class-3 (10^{-3}W to 0.5 W, cw) and Class-4 (greater than 0.5 W, cw). Class-1 lasers require no control; Class-2 lasers require the caution label, "DO NOT STARE INTO BEAM"; Class-3 lasers require various controls, such as key master control, interlocks, mechanical beam blocks, and the caution label, "DO NOT STARE INTO BEAM OR VIEW WITH OPTICAL INSTRUMENTS"; Class-4 lasers require the label, "AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION".

Permissible Exposure Levels: The maximum permissible exposure (MPE) limits to laser radiation shall be those promulgated by the ANSI Standard designated Z 136.1-1980, Z 136.3 - 1988, or subsequent standards promulgated by ANSI or Federal or State regulations taking precedence over them. These standards apply to exposure to the eyes. Maximum permissible exposure limits for the skin and eyes are given in Appendix G.

Protective Measures: Operators of lasers should exercise caution in the use and handling of laser beams so as not to cause laser reflections that can harm anyone in the area. All areas of exposure to hazardous levels of laser radiation shall be posted with warning signs and access will be limited to authorized personnel. Laser safety goggles designed to attenuate the particular wavelength of laser radiation being used to safe levels shall be used, provided they have an attenuation equal to or greater than that required for that wavelength of laser radiation and the power level of the laser does not exceed that which would cause material failure of the goggles. Electrical hazards should be eliminated by enclosing all high voltage power sources. Explosive hazards should be eliminated by proper shielding of flash lamps and capacitors used for "pumping" the laser.

Acquisition of Laser Equipment: The acquisition of laser equipment must have the approval of the Radiation Safety Officer prior to purchase. He will review equipment specifications and facilities and make appropriate recommendations regarding its use. The Radiation Safety Officer shall suspend any operation using laser radiation that constitutes a hazard to operating personnel or the general public, or which exceeds that exposure limits defined in ANSI Z 133.1 - 1980, or subsequent standards.