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RADIATION SAFETY PLAN

Part IV - (Ionizing) Radiation Safety Plan
of the Laboratory Safety Plan

This document is subject to review and approval by the State of Kansas Radiation Control Program.

March 1, 2021

THE UNIVERSITY OF KANSAS

LAWRENCE

KANSAS

Contents - Radiation Safety Plan

1) RADIATION PROTECTION PROGRAM

1.1) Introduction

The **Radiation Protection Program** encompasses administrative controls and provisions relating to organization and management; program policies and procedures; measurement and quality assurance methods; record keeping, material control and accounting; and management review **to ensure the maximum protection of the public health and the maximum safety to all persons at, or in the vicinity of campus sources of radiation.**

The Radiation Protection Program follows the practice of ALARA, which is a risk assessment, risk elimination, and risk management process, and is in place **to eliminate risks or to reduce risks as low as reasonably achievable,** and **to promote a positive safety culture**, teaching fundamentals, demonstrating practices, and inculcating safety, health and environmental protection into research, education, public service and work environments.

The **Radiation Protection Program** is comprised of three components. These are the

1) Type A Specific License of Broad Scope
2) Radiation Safety Plan
3) Radiation Protection Procedures

This **Radiation Safety Plan** uses to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are '**as low as is reasonably achievable' (ALARA).**

The **Radiation Safety Plan** is Part IV of the Laboratory Safety Manual. The Laboratory Safety Manual is a comprehensive safety plan for individuals in laboratories at the University of Kansas. The manual includes *general* universal safety requirements (Part I), and *specific* requirements of Chemical Hygiene (Part II), of Biosafety (Part III), and of Laser Systems Safety (Part V).

The University of Kansas is committed to safety, health, and environment as evidenced by the following principles:

1) Empowering our faculty, staff, and students to demonstrate individual and institutional leadership in inculcating safety, health and environmental protection into research, education, public service and work environments;
2) Emphasizing open communication with our community regarding safety, health and environmental issues;
3) Instilling the values of safety, health, and environmental stewardship and conservation of resources in our future leaders.

Members of the Lawrence Campus are required to uphold these values through the following requirements:

1) Assuring compliance with applicable federal, State of Kansas and local safety, health and environmental requirements;
2) Preventing and minimizing hazards, assessing and controlling risks, reducing pollution and continuously improving our practices regarding safety, health and environmental protection;
3) Protecting and maintaining safe and environmentally responsible facilities for teaching, research, public service, work and campus living.

1.2) Purpose

The **Radiation Safety Plan** describes the administrative controls, assigns responsibilities, and stipulates management review for the policies, procedures, and instrumentation methods that are developed and implemented to assure radiation exposures 'as low as reasonably achievable.'

The **Licensed Program** described herein sets forth and accomplishes the requirements of Kansas Regulations, K.A.R. 28-35-133 through K.A.R. 28-35-505, for all University of Kansas' uses of all radiation, radiation machines, and radioactive materials (1) **to ensure the maximum protection of the public health** and **the maximum safety to all persons** at, or in the vicinity of, the place of use, storage, or disposal of sources of radiation, and is intended (2) **to be consistent with the best use** of radiation machines and radioactive materials, and (3) **to encourage the constructive uses of radiation.**

1.3) Legal Requirements

1.3.1) Mandate

The Radiation Safety Plan (1) is mandated by Kansas Regulations, K.A.R. Agency 28, Article 35 as set forth in the Nuclear Regulatory Commission Regulation, Title 10, Code of Federal Regulations, (2) is addressed by the policies issued by the Provost of the University of Kansas Lawrence campus, and (3) is developed, documented, and implemented commensurate with the scope and extent of licensed activities to ensure compliance and best use and practice.

1.3.2) Stipulations and Limitations

The Radiation Safety Plan is submitted as part of the Radioactive Materials License Application as supplementary information and is subject to review and oversight by the Kansas Radiation Control Program. Any modifications or changes to the Radiation Safety plan must be approved by the Radiation Safety Committee.

Note: The Radiation Safety Plan references Parts I, II, III, and V of the Laboratory Safety Manual. Sections of those parts may be applicable to this Plan. The University of Kansas 'Environment, Health & Safety Policy' and the other parts of the Laboratory Safety Plan may be changed without RSC approval or license amendment provided that the changes in those documents comply with the reporting structure and program commitments and requirements set forth in the Radiation Safety Plan.

In addition, the procedures and guidance documents and other referenced materials that make up the Radiation Protection Procedures Manual are not part of the License nor are they specifically part of the Radiation Safety Plan. These documents and standard operating procedures are continually being modified and amended to document and to implement a radiation protection program appropriate to the scope and extent of the activities conducted under the license, to establish and maintain compliance with the regulatory provisions, and to achieve occupational doses and doses to members of the public that are as low as reasonably achievable.

1.4) Applicability

All use of all radiation, radiation machines, and radioactive materials at the University of Kansas is subject to the conditions and requirements set forth herein, and include Authorized Laboratory Supervisors, Authorized Users, Declared Pregnant Authorized Users, Laboratory Authorized Occupants, Services Authorized Occupants, Contract Service Occupants, and/or Members of the Public.

1.5) Scope

The Radiation Safety Plan and the Radiation Protection Program specifically address making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical consistent with the purposes for which the licensed activity is undertaken, and includes risk assessments for reducing exposures to chemical, infectious and biological, human tissue, animal, and other occupational health and safety hazards as used with radiation sources, and promotes the culture of being environmentally responsible and of achieving sustainability by working towards minimizing and eliminating the environmental and social impacts of daily activities.

2) ORGANIZATION OF THE RADIATION SAFETY PLAN

2.1) Units of the Program – Lawrence Campus

2.1.1) Introduction

The operating units of the Radiation Safety Plan consist of the Lawrence Campus Management, the Lawrence Campus Radiation Safety Committee, the Lawrence Campus Radiation Safety Service, and the Lawrence Campus Authorized Laboratory Supervisors.

The University of Kansas Lawrence Campus and the University of Kansas Medical Center and other University of Kansas campuses and centers are identified below to clearly document the scope of and line of authority from the Chancellor to the University of Kansas Lawrence Campus to the Radiation Safety Committee, to the Radiation Safety Service, and ultimately to the Authorized Laboratory Supervisor. Each specific campus is required to possess its own license for radiation sources as needed. Only the University of Kansas Lawrence Campus is addressed here.

2.1.2) Management at the University of Kansas

The Chancellor and Chief Executive Officer of the University of Kansas has:

2.1.2.1) Ultimate authority over all University of Kansas Campuses which includes Lawrence, Kansas City Medical Center, and Overland Park Edwards, Wichita, as well as research and educational centers in Garden City, Hays, Parsons, Pittsburg, Topeka and Yoder.

The Provost/Executive Vice Chancellor of the University of Kansas Lawrence Campus has:

2.1.2.2) Responsibility and authority for all programs at the University of Kansas on the Lawrence Campus.

Vice Provost, and Deans:

2.1.2.3) Have responsibilities for various aspects of operations at the University of Kansas under the Provost.

Unit Directors and Unit Chairs:

2.1.2.4) Have responsibilities to comply with the requirements of the operations.

2.1.3) Composition of the Radiation Safety Committee

The Radiation Safety Committee shall meet the qualifications and requirements of a Type A Broad Radioactive Materials License under the State of Kansas. The Committee shall be composed of at least five members to represent the following types of Authorized Users of radioactive materials and of other sources of ionizing radiations as follows:

2.1.3.1) An Authorized Laboratory Supervisor with training and experience with the chemical manipulation of radioactive materials.

2.1.3.2) An Authorized Laboratory Supervisor with training and experience in tracer metabolism in biological organisms.

2.1.3.3) Radiation Safety Officer.

2.1.3.4) Executive Management.

2.1.3.5) A Physician from Watkins Health Service or from Intercollegiate Athletics. The physician is medical consultant to and voting member of the Committee.

2.1.3.6) An Authorized Laboratory Supervisor with training and experience in the use of radiation producing devices may serve on the Committee or serve as a consultant to the Committee for radiation devices.

2.1.3.7) The Director of Environment, Health, and Safety may serve on the Committee.

Note: The Radiation Safety Committee functions independently from any other committee, but participates in campus efforts that coordinate all safety related programs efficiently and cohesively. Members of the RSC must demonstrate a strong commitment to laboratory safety and promoting safe use of radioactive materials and devices.

2.1.4) Composition of the Radiation Safety Service

2.1.4.1) The Radiation Safety Service is a unit of the Department of Environment, Health, and Safety.

2.1.4.2) The Radiation Safety Service (RSS) shall employ a Radiation Safety Officer (RSO). This person shall be eligible for certification by the American Board of Health Physics and shall have at least five years of professional

experience in Health Physics and should have a Master's degree or its equivalent in Health Physics. The responsibilities of the Radiation Safety Officer shall not be transferred to other individuals, and only the RSO may delegate or reassign any duties thereof.

2.1.4.3) The Radiation Safety Service (RSS) may consist of additional professionals in radiation safety as follows:

2.1.4.3.1) Acting and Assistant Radiation Safety Officer. The Health Physics professional who acts in the place of the Radiation Safety Officer must have a degree in Health Physics and should have experience under a specific license of broad scope.

2.1.4.3.2) Other personnel may be assigned to RSS to fulfil specific tasks as directed by the RSO. No personnel may represent or serve as RSS without requisite training and experience and without express approval of the RSO.

2.1.5) Composition of the Staff of an Authorized Laboratory

An **Authorized Laboratory** is any unit, the physical facilities and the associated Approved Users, that has been approved by the Committee to use any radiation, radiation machine, or radioactive material under a specific permit. All radiation, radiation machines, and radioactive materials may only be used by Authorized Laboratories at the University of Kansas. The staff of an Authorized Laboratory shall consist of the following as a minimum:

2.1.5.1) **Authorized Laboratory Supervisor**. The Authorized Laboratory Supervisor is an individual who has been approved by the Radiation Safety Committee and who is responsible for all operations with sources of ionizing radiation within the Authorized Laboratory subject to Kansas and federal regulations, and University of Kansas and RSS permit requirements. The Authorized Laboratory Supervisor must be an Authorized User.

In addition, an Authorized Laboratory may have one or more of the following:

2.1.5.2) **Authorized User**. An Authorized User is an individual certified by the Radiation Safety Officer to have the training and experience necessary to perform the operations authorized under a Radiation Safety Committee approved permit. Only Authorized Users may use sources of ionizing radiation at the University of Kansas and only as authorized under the certification of their training and as authorized under a permit.

2.1.5.3) A **Declared Pregnant Worker** or **Declared Pregnant**

Authorized User is a woman certified by the Radiation Safety Officer to have the training and experience necessary to perform the operations authorized under a Committee approved permit, and who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of delivery.

2.1.5.4) **Laboratory Authorized Occupant**. A Laboratory Authorized Occupant is an individual certified by the Radiation Safety Officer that has ongoing working responsibilities in an Authorized Laboratory but who is not authorized to handle or work with sources of radiation.

2.1.5.5) **Services Authorized Occupants**. A Services Authorized Occupant is an individual who performs either routine or requested services in the Authorized Laboratory, but who is not under the direct supervision of the Authorized Laboratory Supervisor, who has the requisite training by the Radiation Safety Service.

2.1.5.6) **Contract Services Authorized Occupants**. A Contract Services Authorized Occupant is an individual who performs requested services in the Authorized Laboratory, but who is not under the direct supervision of the Authorized Laboratory Supervisor nor employed by the University of Kansas, who has the requisite training by the Radiation Safety Service.

2.1.5.7) **Member of the Public**. Any visitor or any individual other than those specified in Sections 2.1.5.1 to 2.1.5.6 above who enters an Authorized Laboratory.

2.2) Relationships of the Units

2.2.1) Management.

The Provost:

2.2.1.1) Assigns the personnel that shall have the responsibility for ensuring that an effective Radiation Protection Program is implemented and supported. It is understood that, although the reporting and budgetary unit for the Radiation Protection Program is delegated to the Vice Provost and subsequently EHS, the Provost has ultimate responsibility for the Radiation Protection Program. The *reporting and budgetary unit* shall be an office whose authority is at least equivalent to that of Vice Provost.

2.2.1.2) Issues the policies under which the Radiation Protection Program is established and implemented.

Note: The Radiation Safety Committee reports to the Provost and Executive Vice Chancellor through the Vice Provost of Administration and Finance.

The Radiation Safety Service reports to the Provost and Executive Vice Chancellor through the Vice Provost of Administration and Finance by the Associate Vice Provost and Chief Procurement Officer. The operating budget for the Radiation Safety Service is provided by that office through the Department of Environment, Health, and Safety.

2.2.2) Radiation Safety Committee.

The Provost and/or Vice Provost:

2.2.2.1) Appoints the members of the Radiation Safety Committee and authorizes the Committee with the Radiation Safety Service to implement the Radiation Protection Program.

The Radiation Safety Committee is:

2.2.2.2) Responsible for the ongoing Radiation Protection Program and for future changes in the program. The Committee is bound by Kansas and federal regulations, and by University requirements in carrying out its responsibilities.

2.2.3) Radiation Safety Service (RSS).

A Search Committee selects:

2.2.3.1) the Radiation Safety Service staff. The individuals hired by the University under the recommendations of the search committee shall meet the minimum qualifications stated in Section 2.1.4 above.

Note: The search committee shall be duly constituted according to university regulations and will include two members of the Radiation Safety Committee.

The Radiation Safety Officer is:

2.2.3.2) The supervisor of the Radiation Safety Service.

The Radiation Safety Service is:

2.2.3.3) Responsible for administering and carrying out the Radiation Protection Program as specified on a day to day basis.

2.2.3.4) Authorized to issue a "stop work" order if conditions and/or operations endanger either individuals or facilities.

Note: Such an order by the Radiation Safety Officer may be appealed to the Radiation Safety Committee which then assumes responsibility for its directives to the Provost.

2.2.4) Authorized Laboratories.

2.2.4.1) No work with sources of ionizing radiation may be performed except as authorized under a specific permit issued by the Committee.

The Authorized Laboratory Supervisor shall:

2.2.4.2) Ensure that all State of Kansas and federal regulations, and University of Kansas and RSS permit requirements are met within the laboratory as specified by the Radiation Safety Committee.

Note: This includes the responsibility for ensuring that all individuals as listed in Section 2.1.5 above are qualified at the relevant level. The Radiation Safety Officer certifies individuals, and the Radiation Safety Service works closely with the laboratories, monitors the activities within the Authorized Laboratories, provides directives and makes recommendations for changes in safety practices, and keeps the Authorized Laboratory Supervisor in compliance.

Authorized Users and Authorized Occupants shall:

2.2.4.3) Carry out their activities within an Authorized Laboratory as specified by the Radiation Safety Committee. Authorized Users and Authorized Occupants are responsible for performing their work in keeping doses as low as reasonably achievable and in complying with State of Kansas and NRC regulations, and University of Kansas and RSS permit requirements.

3) POLICIES OF THE RADIATION SAFETY COMMITTEE AND THE RADIATION SAFETY SERVICE

3.1) Policies of the Radiation Safety Committee

The Radiation Safety Committee shall:

3.1.1) Implement a Radiation Protection Program appropriate to the scope and extent of the activities conducted under the license.

3.1.2) Establish and maintain compliance with the regulatory provisions applied in the use of all radiation, radiation machines, and radioactive materials to ensure the maximum protection of the public health and the maximum safety to all persons at, or in the vicinity of, the place of use, storage, or disposal of sources of radiation.

3.1.3) Support practices that are consistent with the best use of radiation machines and radioactive materials, and encourage the constructive uses of radiation.

3.1.4) Facilitate the safe use of all radiation, radiation machines, and radioactive materials in making every reasonable effort to maintain exposures to occupational radiation workers and to the members of the public as far below the dose limits specified in these regulations as is practical, consistent with the purpose for which the licensed or registered activity is undertaken, taking the following into account:

(1) the state of technology;
(2) the economics of improvements in relation to the state of technology;
(3) the economics of improvements in relation to benefits to public health and safety and to other societal and socioeconomic considerations; and
(4) the economics of improvements in relation to the utilization of nuclear energy and licensed or registered sources of radiation in the public interest, in keeping with the principle of keeping collective and individual radiation exposures **AS LOW AS REASONABLE ACHIEVABLE (ALARA)**.

3.1.5) Support the University *Environment, Health & Safety Policy*

3.2) Policies of the Radiation Safety Service

The Radiation Safety Service shall:

3.2.1) Serve, on a day to day basis, as the agent of the Radiation Safety Committee in carrying out the policies of the Committee as stated in Section 3.1 above

4) CONTROL OF RADIOACTIVE MATERIALS AND RADIATION PRODUCING DEVICES

4.1) Requirements

4.1.1) Introduction

This chapter describes the specific responsibilities of Authorized Laboratory Supervisors and the general responsibilities of Authorized Users of radioactive materials and radiation producing devices and the interaction of the Radiation Safety Committee and Radiation Safety with other departments, units and users at the University of Kansas. The responsibilities include managing the safe use of radioactive materials and radiation producing devices in compliance with applicable State of Kansas and federal regulations, and University of Kansas and RSS permit requirements, and achieving the objective of keeping exposures **as low as reasonably achievable (ALARA)**.

4.1.2) Authorized Laboratory Supervisors, Authorized Users, and Authorized Occupants

Individuals on the Lawrence campus shall:

4.1.2.1) **Not** possess, use or work with sources of ionizing radiation until an Authorized Laboratory Supervisor, an alternate, and an Authorized Laboratory have been approved under a specific permit by the Committee.

Note: An Authorized Laboratory Supervisor must also be an Authorized User.

4.1.2.2) **Not** work with sources of ionizing radiation unless users are carrying out that use under the specific conditions of a valid permit issued by the Committee.

4.1.2.3) **Not** work with sources of ionizing radiation in areas or rooms controlled for the purpose of radiation protection unless users have been appropriately trained by the Radiation Safety Officer and authorized for that use or occupancy by the Radiation Safety Committee.

Note: An individual properly trained to handle and manipulate radioactive materials or radiation producing devices is designated an **Authorized User** in this manual. An appropriately trained individual working in an area controlled for purposes of radiation protection, but not with the sources of ionizing

radiation contained therein, is an **Authorized Occupant** in this manual. There are different categories of Authorized Users. See Chapter 12, Radiation Safety Training.

Authorized Users shall:

4.1.2.4) Handle and/or use only sources of ionizing radiation for which they have been trained and authorized, and only in Authorized Laboratories.

4.2) Responsibilities of Authorized Users and Authorized Laboratory Supervisors

4.2.1) Actions by Authorized Users

Authorized Users shall:

4.2.1.1) Follow all applicable State of Kansas and federal regulations, and laboratory safety procedures adopted by the University of Kansas for the safe use of radioactive materials and radiation producing devices, including the requirements set forth in this Part.

4.2.1.2) Fulfill all conditions of a risk assessment permit applicable to the particular use and laboratory.

Note: No individual may handle sources of ionizing radiation until appropriate certification has been granted by the Radiation Safety Officer.

4.2.1.3) Keep individual and collective radiation exposures **AS LOW AS REASONABLY ACHIEVABLE (ALARA).**

4.2.2) Authorized Laboratory Supervisors

Authorized Laboratory Supervisors shall:

4.2.2.1) Follow all requirements of Authorized Users.

4.2.2.2) Prepare and submit risk assessments for permit applications, renewal applications, and amendment requests as needed or required.

4.2.2.3) Provide and maintain all required engineered safeguards specified in the applicable permit.

4.2.2.4) Implement the applicable standard operating procedures. This includes licensed procedures, standard permit conditions, and laboratory specific procedures.

4.2.2.5) Ensure that the conditions of the permit and this plan are achieved in the laboratory under the supervision of the Authorized Laboratory Supervisor. (Laboratory includes all rooms and facilities specified in the permit.)

4.2.2.6) Ensure that all individuals (except for Facilities Services Custodial and Operations personnel) carrying out activities in the permit-specified laboratories are appropriately trained for the level of involvement.

4.2.2.7) Escort and direct members of the public in areas controlled for the purpose of radiation protection so that measurable radiation exposures meet the University of Kansas Public ALARA values.

4.2.2.8) Keep all records required by these responsibilities.

4.2.2.9) Maintain secure control over all radioactive materials and radiation producing devices until they have been transferred to another unit in a Committee-approved fashion.

Note: No Radiation Producing Device, Electron Beam Device or radioactive material may be transferred to another individual, inclusive of any form of disposal, unless prior approval has been obtained from the RSS. This applies to radioactive sources in devices such as liquid scintillation counters, gas chromatography devices, etc. These items and their locations are registered with the State of Kansas.

4.3) Responsibilities of the Radiation Safety Committee

4.3.1) Actions by the Radiation Safety Committee.

The Radiation Safety Committee shall:

4.3.1.1) Specify adequate and reasonable health and safety regulations based upon prudent practice, upon regulatory guides, policy and guidance directives, radiological health protection publications, and upon State of Kansas and federal laws governing the use of sources of ionizing radiation. This is normally accomplished through recommendations made by the RSS.

4.3.1.2) Ensure that the University of Kansas prepares and maintains valid licenses as required by State of Kansas and federal regulations appropriate for the acquisition, possession and uses of sources of ionizing radiation as carried out on the Lawrence campus.

Note: The RSS has the responsibility to prepare the applications for review and submission by or for the Committee.

4.3.1.3) Ensure that all records and documentation required by State of Kansas and federal regulations are appropriately maintained and to keep applicable records of correspondence between Authorized Supervisors and the Committee.

Note: Many of these documents and records may be kept and maintained by the RSS for the Committee.

4.3.1.4) Ensure that appropriate procurement and disposal procedures for all sources of ionizing radiation are provided.

4.3.1.5) Provide consultation and make recommendations on the location and design of new laboratories and facilities or concerning modifications of existing facilities in which sources of ionizing radiation are to be used.

Note: If such recommendations are not solicited or followed, the Committee may refuse to issue a permit for the projected use or revoke an existing permit. See Section 4.3.1.2 above.

4.3.1.6) Assist University personnel in obtaining the qualifications necessary to use radioactive materials and/or other sources of ionizing radiation.

4.3.1.7) Receive and review permit applications and risk assessment proposals for the use of sources of ionizing radiation and approve, approve with added conditions, or disapprove these applications based only upon the adequacy of protection of health and safety and/or the protection of the other activities in adjoining facilities.

Note: For certain low level uses, the Committee delegates this authority to the RSS subject to Committee's post facto review. The RSS makes its recommendations to the Committee concerning all permit applications prior to action by the Committee. See Chapters 5 and 7.

4.3.1.8) Assist Authorized Users in obtaining the use of special facilities and services when these are needed for specific applications that require use of radioactive materials and/or sources of ionizing radiation.

4.3.1.9) Maintain contact, through the RSS, with Authorized Laboratory Supervisors for the purpose of ensuring that unnecessary hazards are avoided and that corrective actions are initiated and taken for any work in progress which is not performed in compliance with applicable State of Kansas and federal regulations, and University of Kansas and permit conditions and requirements.

Note: To accomplish this, the Committee may revoke permits if flagrant or repeated violations occur under a permit.

4.3.1.10) Provide consultation, advice and aid in solving problems of radiological health and safety encountered by individuals associated with Authorized Laboratories or by individuals in adjoining areas.

4.3.1.11) Review and, if appropriate, take action on investigative activities and reports submitted to the Committee by the RSS.

4.3.1.12) Make recommendations concerning the staffing of the RSS and the required budgetary support.

4.3.1.13) Review the performance of the staff of the Radiation Safety Service as deemed necessary or as directed by the Provost's Office.

4.3.1.14) Recommend medical examination of personnel who may have been exposed to hazardous levels of ionizing radiation or who may have been contaminated with radioactive isotopes in cooperation with a medical doctor.

4.3.1.15) Convene in person and/or electronically each semester to review pertinent issues in this section.

Note: The RSO communicates regularly electronically with the Committee. Committee voting for permit applications almost always occurs electronically. The Radiation Safety Officer and the Chair of the Committee routinely interact on program specifics. The Committee interacts with the Chair of the Committee on voting issues. The Radiation Safety Committee has established a quorum for meetings. A quorum consists of at least three individuals and represents the Chairperson of the Committee, the RSO, Executive Management and/or one representative from the area of use from which specific issues will be discussed, and as necessary, any other member whose field of expertise is

necessary for the discussion. Most permit reviews and all policy and procedure adoptions requires the vote of five Committee members.

4.4) Responsibilities of the Radiation Safety Service

4.4.1) Actions by the Radiation Safety Service

The Radiation Safety Service shall:

4.4.1.1) Authorize use and provide directive and guidance to Authorized Laboratory Supervisors and/or Authorized Users concerning their initial purchase, initial and continued use, and transfer or shipment of radioactive materials or radiation producing devices to ensure that all applicable State of Kansas and federal regulations, and safety standards and requirements, including engineered safety, are addressed for each use.

4.4.1.2) Certify and ensure that the Laboratory Supervisor listed in a permit application is qualified by training and experience to direct the activities associated with the permit. Certify and ensure all Laboratory Users and Occupants are qualified by training and/or experience to be associated with activities related to the permit.

4.4.1.3) Review and recommend to the Committee for approval, modification, or disapproval of permit applications for all activities involving radioactive materials and radiation producing devices. Approval shall be based upon criteria required by the Radioactive Materials License, and State of Kansas, federal, and local regulations. This includes certifying Authorized Users.

4.4.1.4) Approve all orders for radioactive materials, other sources of ionizing radiation, and radiation producing devices before they are placed based upon verification that Sections 4.4.1.1 to 4.4.1.3 have been satisfied.

4.4.1.5) Receive and inspect all shipments of radioactive materials shipped to campus for integrity, proper packaging and contents, and compliance with IATA/DOT shipping requirements and to approve and deliver the shipment to the approved Authorized Laboratory. Records of these inspections and approvals shall be kept.

4.4.1.6) Perform an initial radiation survey before a radiation producing device is placed into service and verify that all safety requirements for the operation of the radiation producing device, including the appropriate permits and

procedures, are met.

4.4.1.7) Perform initial radiation surveys and/or leak tests of radioactive materials before they are placed into service.

4.4.1.8) Perform periodic audits, announced and/or unannounced, of the Authorized Laboratories which use sources of ionizing radiation for compliance with the provisions of applicable permits and procedures.

4.4.1.9) Perform required leak tests on sealed sources at the required interval.

4.4.1.10) Perform periodic radiation and/or contamination surveys of radioactive sources and/or radiation producing device installations, as appropriate.

4.4.1.11) Perform decommissioning procedures to ensure that future occupants and the environment are not subjected to unacceptable risks from residual radioactivity when research activities are concluded in an Authorized Laboratory.

4.4.1.12) Approve and carry out proposed transfers of radioactive materials or radiation producing devices from one Authorized Laboratory Supervisor to another. Approval includes making sure that the materials to be transferred have been properly packaged for transfer, that the appropriate documentation has been prepared, and that an Authorized Laboratory receives the material or radiation producing devices. All transfers are to be completed by the Radiation Safety Service unless specific authorization has been granted by the RSS.

4.4.1.13) Evaluate accidents and/or incidents and implement actions designed to keep exposures ALARA.

4.4.1.14) Maintain a current inventory of radioactive materials and radiation producing devices within the facility and their locations.

4.4.1.15) Provide and ensure that Members of the Public, Authorized Occupants, and Authorized Users are provided training and retraining appropriate to the level of risk for the radioactive materials or sources of ionizing radiation in the areas to which they have access.

4.4.1.16) Require timely submission of renewal permits for review and approval.

4.4.1.17) Ensure that an adequate supply of appropriate portable and laboratory radiation measurement systems are available, functioning properly, and calibrated

as specified by the License with respect to frequency and method.

4.4.1.18) Establish and maintain a personnel dosimetry service that has NVLAP accreditation, perform required bioassays, and maintain all required dosimetry records.

4.4.1.19) Process all radioactive waste. See Section 4.9.

4.4.1.20) Arrange for external audits of the Radiation Protection Program if deemed necessary by the Committee.

4.4.1.21) Ensure that RSS personnel have continuing opportunities for professional development.

4.4.1.22) Ensure that the ALARA Program approved by the Committee is operational, and that the necessary reports associated with the operation of the program are generated.

4.4.1.23) Periodically review the Radiation Protection Program and recommend changes to the Committee that will improve the Program.

4.4.1.24) Ensure that auditable records as stipulated by State regulations are kept of all the activities described above.

4.4.1.25) Acquire the necessary permits, certifications, and licenses for activities involving the transfer of radioactive material/waste to other facilities.

4.4.1.26) Immediately terminate unsafe operations that would be in violation of licensing conditions under which the University is required to operate by State of Kansas and federal regulations. The Committee will be notified as soon as possible of such action.

4.4.1.27) Provide the Committee with pertinent information regarding new developments and changes in State of Kansas and federal regulations.

4.4.1.28) Provide immediate reports to the Committee for any flagrant violations, timely for other incidents, and annually or as necessary for summaries of permits and applications, noncompliance, remedial actions for contamination, investigation levels for personnel dosimetry, details of emergency actions, license status, untoward incidents, package and source receipts, trained personnel, active permits, new user permits, etc.

4.4.1.29) Supervise and provide operations responsibility at the Sunflower Remediation Facility to ensure the integrity of the cap, the upkeep of the groundwater treatment building, and the maintenance of the grounds.

4.4.1.30) Maintain required EPA, CDC, IATA, OSHA training and other certifications for hazardous waste operations and contingency plan, blood borne pathogens, select agents, KBI and FBI background checks, AAALAC Animal Care requirements, Lead Awareness, Lock-Out Tag-Out, emergency response, and other training as needed.

4.4.1.31) Maintain essential training for the National Incident Management System (NIMS) for preparedness, resource management, maintenance, communications, and command.

4.4.1.32) Provide assistance to the State of Kansas and its entities (schools, employees, and emergency responders) as needed.

4.5) RSS Specifics for Proposed Uses of Sources of Ionizing Radiation

4.5.1) The Radiation Safety Service

The RSS shall:

4.5.1.1) Provide design planning requirements, shielding plans, and engineering controls for proposed new and remodeled facilities to ensure the maximum protection of the public health and the maximum safety the for Recommendations are to be based upon applicable regulatory guides, NCRP and ICRP documents, ANSI standards, NFPA, etc. and prudent practice.

4.5.1.2) Provide guidance in the planning stages concerning engineered safeguards directly associated with the radiation producing devices or radioactive sources in the preparation of necessary permits, and in formulating specifications on the purchase requisitions.

4.5.1.3) Perform a safety review whenever radioactive sources and/or radiation producing devices are involved in proposals for the development of equipment. This would normally be accomplished during the review of the permit application covering the proposed use.

4.5.1.4) Perform a safety review whenever alterations in radiation producing devices are proposed.

4.6) RSS Role in the Continued Use of Sources of Ionizing Radiation and Related Facilities

4.6.1) Actions by the Radiation Safety Service

The RSS shall:

4.6.1.1) Upon providing design planning requirements, shielding plans, and engineering controls, perform an appropriate inspection to verify that RSS-mandated engineered radiation safety features have been appropriately incorporated.

NOTE: The permits specifying the nature of engineered safe-guards should have had prior RSS approval.

4.6.1.2) Upon receipt of notification that a radiation producing device has been received, inspect the radiation producing device and the installation for appropriate radiation safety features and perform an initial radiation survey and/or leak test (if appropriate) prior to approving the Radiation producing device for use within the facility.

4.6.1.3) Review and recommend approval, approval with modifications or disapproval of renewal requests for permits, requests for amendments to permits involving new uses of radiation producing devices or radioactive materials and/or any modification of radiation producing devices or their installations that might affect radiation safety.

4.6.1.4) Respond to any notification of concern by an individual that radiation safety might have been compromised--such as possible damage to sealed sources, possible impairment of radiation shielding, etc., and plan and execute appropriate remedial action.

4.6.1.5) Perform leak tests and/or radiation surveys according to the schedules given in the specific procedures for the performance of these activities.

4.6.1.6) Perform scheduled and/or unannounced audits as required by the specific procedures for the performance of the audits.

4.6.1.7) Approve the transfer of radioactive materials and/or radiation producing devices from one Authorized Laboratory to another **prior to the transfer**

based upon the possession of an appropriate permit by the proposed recipient.

4.6.1.8) Stop any activity that, in its judgment, has an immediate and unacceptable radiation risk associated with it. Report its findings to the Committee. Work shall not begin again until the issues have been resolved and RSS and/or Committee approval for resumption of activities has been given.

4.7) RSS Interaction with Procurement Services

4.7.1) Actions by the Radiation Safety Service

The RSS shall:

4.7.1.1) Ensure that Procurement Services' policies and procedures and that the campus software ordering and payment system provide for RSS approval prior to processing orders or purchase requisitions for radioactive materials and radiation producing devices.

4.7.1.2) Provide cooperation, assistance, and conformity with Procurement Services for campus purchasing policies and procedures.

4. 8) RSS Role in Packaging and Shipping Radioactive Material

4.8.1) Actions by the Radiation Safety Service

The RSS shall:

4.8.1.1) Acquire the required Dangerous Good's training necessary to ship hazardous materials.

4.8.1.2) Obtain the required Licenses, Export Controls, or Material Transfer Agreements.

4.8.1.3) Verify and secure documentation that the intended recipient has the necessary authorization to possess and use sources of radiation.

4.8.1.4) Approve and prepare packages and the required documentation for Authorized Laboratories and coordinate the shipment of radioactive materials and/or mixed hazard classes with the courier to ensure that Department of Transportation and International Air Transport Association Dangerous Goods

Regulations are achieved.

4.8.1.5) Review and approve purchase requisitions for the performance of paid services involving shipping of radioactive materials or other items in which radiation safety is a factor. Verify that all radiation safety standards will be met with respect to the transport services performed.

4.9) RSS Role in Radioactive Waste Management

4.9.1) Actions by the Radiation Safety Service

The RSS shall:

4.9.1.1) Prepare and maintain written procedures for the management of radioactive waste by the Authorized Laboratories to achieve license conditions, and State of Kansas and federal and local regulations.

4.9.1.2) Pickup and transport radioactive waste from laboratories and other locations following applicable license conditions, State of Kansas, local and federal guidelines.

4.9.1.3) Collect, appropriately accumulate, and obtain disposal capacity for the radioactive waste according to Licensed Conditions, and State of Kansas, federal, and local regulations.

4.9.1.4) Keep all required records with respect to the radioactive waste disposal.

Note: Authorized Laboratories will collect all waste for the Radiation Safety Service according to written procedures, except for tertiary aqueous rinses of glassware, etc. Any alternative procedure must be approved in the permit.

4.10) RSS Role in Transferring, Disposing, or Discontinuing Use of Radiation Producing Devices

4.10.1) Actions by the Radiation Safety Service

The RSS shall:

4.10.1.1) Ensure that any radiation producing device to be used for parts or to

be disposed of has been rendered fully inoperative and that it contains no radioactive sources before it is approved for disposal.

4.10.1.2) Ensure that any radiation producing device to be used for parts or to be disposed of has had all labels and markings removed, and that appropriate release surveys have been performed before it is approved for disposal.

4.10.1.3) Ensure that the recipient is appropriately authorized to receive the radiation producing devices if the devices are to be transferred to another laboratory or institution.

Note: Radiation Producing Devices are registered by the Radiation Safety Service with the State of Kansas and certification must be provided to Radiation Control for any decommissioning or disposal. The Radiation Safety Service will perform the decommissioning.

5) RISK ASSESSMENT PROCEDURES FOR OBTAINING A PERMIT TO POSSESS AND USE RADIOACTIVE MATERIALS

5.1) Introduction

The possession and use of **any source of radiation or radioactive material** is authorized and permitted only under an **Approved Permit** in an **Authorized Laboratory.** This chapter describes how such a permit may be obtained. Application materials are available through the RSS.

5.1.1) Check Sources, General License Sources, and Specific License Sources

All specifically licensed and all generally licensed sources used or proposed for use at the University of Kansas fall under this license and require registration with the Kansas Department of Health and Environment Radiation Control Program. Laboratory instruments that house radioactive sources are not exempt from the requirements of having an Approved Permit, even if they contain what is designated as a "generally licensed" radioactive source.

Radiological risks assessments are often not the only risk assessment needed for a protocol or use. The risk assessment by the Radiation Safety Officer will include not only a risk evaluation of radiolabel procedures, but will also assess chemical, infectious and biological materials, and animals, and other occupational health and safety risks.

Permits are valid only for one year and must be renewed annually. See Chapter 6 for renewal procedures.

Permits are approved for the specific uses and conditions specified in the risk assessment application and in the conditions attached to it by the RSS and the Committee. No significant changes may be made in the conditions of the permit until an amendment application covering those changes has been approved. See Chapter 6 for procedures and a partial list of significant changes.

5.1.2) Field Studies

Proposed tracer studies that would be conducted in the environment and would involve direct release of radioactive material to the environment require that (1) applicable environmental radiation standards be achieved, (2) an environmental assessment be prepared by the Radiation Safety Service, and (3) that a thorough review be completed and approval granted

by the Kansas Department of Health and Environment Radiation Control Program prior to any use. Researchers planning activities of this nature should contact the Radiation Safety Officer well in advance of any planned use.

Applicable environmental radiation standards are standards issued by the U.S. Environmental Protection Agency (EPA) under the authority of the Atomic Energy Act that impose limits on radiation exposures or levels, or concentrations or quantities of radioactive material, in the general environment outside the boundaries of locations under the control of persons possessing or using radioactive material.

An Environmental Assessment will be required and must provide sufficient evidence and analysis of impacts to support a determination of a finding of no significant impacts, and if not, then an Environmental Impact Statement will be required.

The assessment will include how the environmental resource (e.g., land or water) is used, how the resource would be affected by the proposed change, and the significance of the relationship between the environmental resource and proposed change. It will include an evaluation of radiological and nonradiological impacts. The potential impacts to cultural or historic resources and threatened and endangered species or critical habitat will also be addressed.

5.2) Types of Permits for the Use of Radioactive Materials

5.2.1) "Low Level" Permits.

5.2.1.1) To expedite the process for obtaining a permit to use low levels of radioactive materials, the Committee has authorized the Radiation Safety Officer to act on its behalf in approving a risk assessment application for a "Low Level" permit. A "Low Level" permit is sufficient, IF no more than the quantities listed in Appendix IV-A are to be used or possessed.

5.2.1.2) This low level permit is valid only for the specific procedures and for the specific isotope for which the request is made.

5.2.1.3) An Authorized Laboratory Supervisor so approved may not possess more than five (5) such specified quantities at any time.

5.2.1.4) The procedure for obtaining such a permit is given in Section 5.3 below. Such approvals may be reviewed and amended by the Committee, if the Committee chooses to do so.

5.2.2) Standard Permits.

The procedures for obtaining a standard permit are described in Section 5.4 for all other cases. An initial consultation with the Radiation Safety Service concerning the proposed use may be helpful in completing the application. The goal of the RSS and the Committee is to complete review of applications as quickly as possible.

5.3) Preparation of an Risk Assessment Application for a "Low Level" Permit

5.3.1) Actions by the Prospective Authorized Laboratory Supervisor

The prospective Authorized Laboratory Supervisor shall:

5.3.1.1) Determine whether or not the total activity (quantities) to be used under the proposed permit are within the limitations specified in Appendix IV-A of this part.

5.3.1.2) Satisfy the remaining parts of Section 5.3 if the quantities are within the limits of Appendix IV-A. If the quantities are greater than the limits of Appendix IV-A, proceed to Section 5.4 below and follow the steps described there.

5.3.1.3) Be certified by the Radiation Safety Service as having training appropriate for the "low levels" and types of radioactive materials to be used. See Chapter 12 for the procedures to become an Authorized Laboratory Supervisor" under a "low level" permit.

5.3.1.4) Submit to the Radiation Safety Service the names and signatures of all Authorized Users and Authorized Occupants under the proposed permit on the certified training documentation.

5.3.1.5) Ensure that all listed individuals are appropriately certified as having the required training by the Radiation Safety Service.

Note: No one may work in an Authorized Laboratory that has restrictions for the purpose of radiation protection until they have certified training appropriate to their involvement. Even individuals (Authorized Occupants) not using any radioactive materials must be given radiation protection instructions by the Radiation Safety Officer.

5.3.1.6) Contact the Radiation Safety Officer and describe the proposed use of the radioactive materials.

5.3.1.7) Establish, in consultation with the Radiation Safety Service, that the

proposed physical facilities are adequate for the proposed uses and have the required engineered safeguards. See Appendix IV-B for applicable design criteria for laboratories in which radioactive materials are to be used.

5.3.1.8) Based upon the advice provided by the Radiation Safety Officer, prepare an abbreviated application requesting approval to use the materials.

The application shall:

a.) Include the first and second page of the Application form (items 1- 8) which lists the supervisor, the alternate, the isotopes to be used, the location of use, the training and experience of the laboratory supervisor, and the radiation detection instrumentation.

b.) Provide a general description of the research that is being performed.

c.) Provide the experimental protocols and procedures that will be performed together with the levels and type of radioactive materials to be used subject to the "low level" limitations.

d.) Provide a brief description of the laboratory specific radiation protection program.

e.) Describe any required safety procedures or safeguards not addressed under the Standard Permit Conditions.

f.) Request and justify any condition of the Standard Permit Conditions for Permits Involving Radioactive Materials that cannot be met.

5.3.1.9) May possess and begin work with radioactive materials only after an approval letter (with possible added conditions) has been received from the Radiation Safety Officer **and** the Acknowledgment/Agreement Letter has been signed and returned to the Chair and to the RSS.

5.4) Preparation of an Risk Assessment Application for a Standard Permit

5.4.1) Actions by the Prospective Authorized Laboratory Supervisor

The prospective Authorized Laboratory Supervisor shall:

5.4.1.1) Be certified by the Radiation Safety Officer as having training

appropriate for the levels and types of radioactive materials to be used. See Chapter 12 for the procedures to obtain the certification necessary for an Authorized Laboratory Supervisor.

5.4.1.2) Establish, in consultation with the Radiation Safety Service that the proposed physical facilities are adequate for the proposed uses and have the required engineered safeguards.

5.4.1.3) Complete and submit to the Radiation Safety Service one electronic copy of all portions of the **Application Form for a Standard Radioactive Materials Permit**. This application includes a general description of the research that is being performed, and the experimental protocols and procedures that will be employed.

Note 1: The **Standard Permit Conditions** for the Use of Radioactive Materials is automatically part of every permit. The applicable Standard Permit Conditions may be incorporated into the permit recommendations and/or equivalent alternate conditions may be submitted with justification for any proposed changes.

Note 2: An initial consultation with the RSS concerning the proposed use may be very helpful in completing the application.

5.4.1.4) Submit to the Radiation Safety Service the names and signatures of all Authorized Users and Authorized Occupants under the proposed permit on the certified training documentation.

5.4.1.5) Ensure that all listed individuals are appropriately certified as having the required training by the Radiation Safety Service.

Note: No one may work in an Authorized Laboratory that has restrictions for the purpose of radiation protection until they have certified training appropriate to their involvement. Even individuals (Authorized Occupants) not using radioactive materials must be certified and given specific instructions.

5.4.1.6) May possess and work with radioactive materials only after the Acknowledgment/Agreement Letter has been signed and returned to the Chair of the Committee and to the Radiation Safety Service. See Section 5.5.3.5 below.

5.5) Review and Approval of Permits

5.5.1) Action of RSS on "Low Level" Permit Applications

The Radiation Safety Officer (RSO) shall:

5.5.1.1) Evaluate the abbreviated application for its adequacy in terms of risk based upon the requirements of this Part, the Specific License of Broad Scope, State of Kansas and federal regulations and recommendations of other applicable standards. (ANSI, and NCRP and ICRP publications.)

5.5.1.2) Provide consultation to the prospective Authorized Laboratory Supervisor concerning any deficiencies in the proposed radiation safety or administrative procedures.

5.5.1.3) Provide written approval of the application to the Authorized Laboratory Supervisor on behalf of the Committee when no unresolved safety or administrative issues remain.

The written approval shall contain:

a.) Applicable Standard Permit Conditions,

b.) Special conditions applicable to the permit, if any

c.) Completed Page 1 of the Permit Application.

d.) A copy of "Notice to Employees."

e.) A copy of "Emergency Procedures."

5.5.1.4) Submit copies of the permit application together with all associated commitments and documentation and the approval letter to the Chair of the Committee.

5.5.2) Action of RSS on "Standard Permit Applications"

The Radiation Safety Officer (RSO) shall:

5.5.2.1) Evaluate the application for its adequacy in terms of risk based upon the requirements of this Part, the Specific License of Broad Scope, State of Kansas and federal regulations and recommendations of other applicable standards. (ANSI, and NCRP and ICRP publications.)

5.5.2.2) Consult with the applicant concerning changes that need to be made in the application if any deficiencies are found.

Note 1: Depending upon the nature of the deficiencies, the RSO will request a revised application, submission of additional information in writing, or offer to incorporate additional conditions into the permit in the RSO's letter of recommendation which is sent with the application to the Committee.

Note 2: If there are disagreements between the applicant and the RSO with respect to identified "deficiencies", the applicant may request Committee review "as is.' The RSO shall document any concern to the Committee with the forwarding letter.

5.5.2.3) Forward a copy of the application, and the letter of recommendation to each member of the Committee.

5.5.3) Action of the Radiation Safety Committee on Permit Applications

The members of the Radiation Safety Committee shall:

5.5.3.1) Evaluate standard permit applications and associated materials for adequacy in radiation safety and in protecting other KU facilities using the same guidance listed in Section 5.5.2.1 above.

5.5.3.2) Send the Chair of the Committee the recommended action on the application for standard permit applications.

Note 1: The action may be approved, approved with additional conditions, or not approved.

Note 2: No action needs to be taken concerning Low Level permits unless a member identifies a safety concern. If there is a concern, the RSS and/or the Chair may be consulted directly. If the member is not satisfied with the results of the consultation, Section 5.5.3.3. should be followed.

5.5.3.3) Request a meeting of the Committee if the applicant feels that there are issues that need to be discussed.

The Chair of the Committee shall:

5.5.3.4) Approve the permit application with a majority vote.

5.5.3.5) Convene a meeting of the Committee if requested by the Chair or the Radiation Safety Officer.

5.5.3.6) Write a letter of approval to the prospective Authorized Laboratory Supervisor specifying any conditions added by the Committee upon receiving the votes from each of the Committee members.

Note: The letter shall require a signed acknowledgment/agreement (commitment to observe added conditions, if any) from the prospective Authorized Laboratory Supervisor. The letter shall contain all of the items listed in Section 5.5.1.3 above.

5.5.3.7) Complete any additional actions or agreements for the approved use by the Committee following the permit review and approval. Agreement is defined as a majority vote of the Committee members.

6) RENEWAL OF AND/OR AMENDMENTS TO RADIOACTIVE MATERIALS PERMITS

6.1) Expiration Date of Permits

6.1.1) All permits expire on November 30 of each year unless the **initial** permit was approved within the six months preceding the November 30 deadline.

6.2) Renewal of Permits

6.2.1) Recertification Training and Renewal of Permits **without** Projected Changes

The Authorized Laboratory Supervisor shall:

6.2.1.1) Ensure that each individual completes the required recertification materials provided by the RSS. The RSS will provide the appropriate recertification materials and/or 'open material' exams on or about October 1 of each year.

6.2.1.2) Complete the certified training documentation.

6.2.1.3) Sign the renewal application form.

6.2.1.4) Submit the appropriately signed certification of Section 6.2.1.2 with the signed renewal application form to the Radiation Safety Service **prior to November 30,** if **no** significant changes in the laboratory experiments are required for the next year. See Section 6.3.

6.2.1.5) Include an "amendment application" with the renewal if significant changes are anticipated. See Section 6.3.1.1 below.

Note: The permit continues to be valid for the Authorized Laboratory if the renewal request was submitted on time unless or until notified to the contrary by the RSS on behalf of the Committee. However, requests for changes in the permit (amendments) are not part of the permit until an approval letter from the Chair of the Committee has been acknowledged with a signature by the Authorized Laboratory Supervisor.

6.3) Amendment Applications for Approved Permits

6.3.1) Actions by the Authorized Laboratory Supervisor

The Authorized Laboratory Supervisor shall:

6.3.1.1) Evaluate the need for an "amendment application" **prior to initiating any new procedures or levels of use** that are not addressed in the permit.

6.3.1.2) Prepare an amendment application as specified in Section 6.3.1.3, if the anticipated changes involve any significant safety issues. Consultation with the RSS is encouraged if there is any doubt about whether or not the anticipated changes are covered under the existing permit. All of the following are considered significant changes. This list is not exhaustive.

Any change

a.) in the isotope being used.

b.) to a chemical form of the isotope with an increased biological hazard, or form that has not been approved in the approved permit.

c.) in the level of activities used in the procedures.

d.) in methods of chemical and physical manipulation that lead to increased or different hazards.

e.) in supervisory staff. An absence of greater than 60 days by the Authorized Laboratory Supervisor requires that the RSS be notified.

f.) in the location of use.

g.) in authorized users performing or handling radioactive material.

6.3.1.3) Submit to the RSS one electronic copy of the amendment application which contains the information relevant to the change being proposed for changes a. through d. above.

Note: All the information needed to evaluate adequacy of the training, engineered safeguards, and handling procedures as specified in the permit

application procedure of Chapter 5 needs to be submitted. The application may be in letter form if only one or two aspects are changed. The RSS may request that a full application form be completed IF the changes are substantial in all areas.

6.3.1.4) Submit to the RSS a letter which contains the information relevant to the change being proposed for supervisory staff (e.) and location of use (f.).

6.3.1.5) Begin work in keeping with the requested changes and attached conditions only after a signed acknowledgment/agreement of an approval letter from the Chair of the Committee has been returned both to the Chair and to the RSS.

6.4) Responsibilities of the RSS Concerning Renewal Applications

6.4.1) Actions of the Radiation Safety Service.

The Radiation Safety Service shall:

6.4.1.1) Send the Authorized Laboratory Supervisor copies of the permit renewal application form listing current approvals and amendments, the certified training documentation, and the recertification training materials. This should be accomplished by October 1 of each year.

The Radiation Safety Officer shall:

6.4.1.2) Upon receiving the renewal materials for a permit, review all the application materials, review the recertification materials, and sign the permit renewal application if all requirements are satisfied.

6.4.1.3) Notify the laboratory supervisor concerning issues that are not satisfactory, if any.

Note: If the recertification of training for any Authorized User cannot be given, arrangements must be made before work with radioactive materials continues.

6.4.1.4) Forward signed permit renewal applications to the Chair of the Committee for the Chair's signature and approval.

6.4.1.5) Follow the procedures in Section 6.5 below for any amendment applications that accompany a renewal request.

6.4.1.6) File the records on training and a copy of the final approved version of the renewal upon receiving it from the Chair of the Committee.

6.5) Responsibilities of the RSS Concerning Amendment Applications

6.5.1) Actions of the Radiation Safety Officer.

The Radiation Safety Officer shall:

6.5.1.1) Evaluate the amendment application for its adequacy in terms of risk based upon the requirements of this Part, the License, State of Kansas and federal regulations and recommendations of other applicable standards. (ANSI, and NCRP and ICRP publications.)

6.5.1.2) Consult with the applicant concerning changes that need to be made in the amendment application if any deficiencies are found.

6.5.1.3) Forward a copy of the application, and the letter of recommendation to each member of the Committee.

6.6) Responsibilities of the Radiation Safety Committee Concerning Renewal Applications

6.6.1) Actions by the Chair of the Committee

The Chair of the Committee shall:

6.6.1.1) Review the renewal applications forwarded by the RSS.

6.6.1.2) If the materials are satisfactory, sign the renewal application, and return the original copy to the RSS.

Note: The RSS will make electronic copies of the signed application, file the original, and send one copy to the Authorized Laboratory Supervisor.

6.6.1.3) Consult with the Authorized Laboratory Supervisor and the RSS if there is any issue that does not appear to be satisfactory.

6.6.1.4) Convene a meeting of the Committee if the issues are not satisfactorily resolved.

6.6.1.5) Carry out the directives agreed upon by any convened meeting of the Committee.

6.7) Responsibilities of the Radiation Safety Committee Concerning Amendment Applications

6.7.1) Actions by the Committee

The Radiation Safety Committee and Chair shall:

6.7.1.1) Follow the steps specified in Section 5.5.3 with respect to those issues addressed by the amendment application.

7) KDHE REGISTRATION and RISK ASSESSMENT PROCEDURES FOR OBTAINING A PERMIT TO POSSESS AND USE RADIATION PRODUCING DEVICES

7.1) Introduction

Radiation Producing Devices require (1) **registration** and **fee payment** to the State of Kansas Radiation Control Program with shielding plans and/or a request for medical wavier, and (2) **an approved permit** from the Radiation Safety Committee. **Approval must be granted by the RSS prior to purchase.**

Qualified experts in Radiation Safety prepare and submit the required shielding specifications and/or medical waiver requirements with the registration documents for the University of Kansas. Authorized Users assure compliance with the regulations by obtaining approval and by providing proper and timely notifications.

The devices listed below are radiation producing devices that require registration and approval.

ANALYTICAL	**Laboratory X-ray equipment** used for analysis of samples.
CABINET X-RAY	**Laboratory X-ray equipment** for analysis inside a cabinet
RADIOGRAPHIC	**Medical Diagnostic radiography equipment** used to produce stationary images (i.e. used in hospitals, clinics,)
WHOLE BODY DXA	Health fitness Dual Energy X-ray evaluations to determine body fat and mass and which require a **Medical Wavier** for use. DXA's are also considered BONE DENSITOMETERS and are used to measure bone density and mineral content**.**

Other registrable x-ray uses include,

INDUSTRIAL X-RAY, XRF	An x-ray device used to radiograph metal, equipment, or samples.
PARTICLE ACCELERATOR	Non-medical accelerator.
C-ARM	Diagnostic with tube head and film holder fixed in alignment.
FLUOROSCOPIC	Diagnostic radiography used to image moving structures.
RADIO/ FLUOROSCOPIC	Diagnostic equipment with both.
THERAPEUTIC X-RAY	An x-ray device used for superficial x-ray therapy.
THERAPEUTIC ACCELERATOR	An accelerator used for radiation therapy.
MAMMOGRAPHY	A device intended to be used to product radiographs of the breast.
COMPUTED TOMOGRAPHY	Diagnostic intended to produce cross-sectional images of the body.
DENTAL CEPHALOMETRIC	For alignment between bony and soft – film placed outside the mouth.
DENTAL INTRAORAL	Radiography of the teeth where the film is placed inside the mouth.
DENTAL PANORAMIC	Radiography of the teeth designed for images that show the entire jaw.
DENTAL CEPHAL/PANORAMIC	X-ray unit with both cephalometric and panoramic capabilities.

A Radiation Machine is any device that is primarily intended to produce, and is capable of

producing, ionizing radiation, or any device that is not primarily intended to produce, but does produce, ionizing radiation at a level greater than 0.5 mR/hr at any point five centimeters from its surface. Radiation machine is defined in K.A.R. 28-35-135r (e); Radiation Producing Devices are registered (K.A.R. 28-35-252).

The possession, use, and disposal of any radiation producing device are allowed only under an approved permit in an Authorized Laboratory. This chapter describes how such a permit may be obtained. Permits are valid only for one year and must be renewed annually. See Chapter 8 for renewal procedures.

Permits are approved for the specific uses and conditions specified in the risk assessment application and in the conditions attached to it by the RSS and the Committee. Significant changes may not be made in the conditions of the permit until an "amendment application" covering those changes has been approved. See Chapter 8 for procedures and a partial list of significant changes.

The procedures for obtaining a standard permit are described in this chapter. An initial correspondence to and/or consultation with the Radiation Safety Service describing needs and proposed plans is essential for obtaining approval to purchase, and subsequent communications are very valuable for completing the application and purchase.

Registration with the Kansas Department of Health and Environment by the RSS for a particular radiation producing device must be completed within thirty days (1) of purchase or (2) of obtaining such device, within thirty days (3) of making any changes to the installation, and within thirty days (4) of discontinuing or decommissioning such a device. All radiation producing devices are reregistered annually with KDHE by Radiation Safety.

7.2) Types of Machines & Devices Requiring a Radiation Producing Device Permit with Exclusions and Exemptions

7.2.1) Devices and machines requiring a Radiation Safety Committee-approved permit include:

7.2.1.1) **<u>All</u> machines designed to produce x-rays**, whether enclosed or not. This includes X-ray Diffraction units, Diagnostic X-ray units, Cabinet X-ray units, Industrial X-ray units, Handheld XRF units, and Medical X-ray units.

Note: Devices, machines, or instruments that contain radioactive sources require a radioactive materials permit. See Chapter 5 of this Part for the requirements. A unit that is both a radiation producing device and that contains a radioactive source must meet the requirements of this chapter and Chapter 5.

7.2.1.2) **All particle accelerators** including neutron generators with beams that produce external ionizing radiation hazards.

Note: See Section 7.7 below for requirements and procedures for obtaining the necessary permit.

7.2.1.3) All devices that use electron beams, but for which the production of ionizing radiation is incidental to their intended use. This includes electron microscopes, scanning electron microscopes, electron probes, etc.

Note: The procedure for obtaining permits and all the remaining requirements for prospective users of Electron Beam Devices are given in Chapter 9.

7.2.2) Television sets, video monitors and other appliances normally available in the home are not covered by this plan and are exempt from any of its requirements.

7.3) Procedure for Obtaining KDHE required Medical Wavier, Authorizations, and Permits to Possess and Use Whole Body DXA

A Medical Waiver must be granted for all DXA Use.

7.3.1) Total body measurements made by Dual-Energy X-ray Absorptiometry (DXA) fall under Part 5 K.A.R. 28-35-241 of the Kansas Radiation Protection Regulations, "**Use of X-rays in the Healing Arts.**" That part *establishes requirements for the diagnostic uses of x-rays in medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine*. 'The provisions of Part 5 are in addition to, and not in substitution for, other applicable provisions of the Radiation Protection Regulations.'

7.3.2) **"Healing arts"** Part 1, K.A.R. 28-35-135 h(e) means the activities authorized by K.S.A. 65-2801 et seq., and any amendments to those statutes, and is defined as any system, treatment, operation, diagnosis, prescription, or practice for the **ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, or injury,** and includes specifically but not by way of limitation the practice of medicine and surgery; the practice of osteopathic medicine and surgery; and the practice of chiropractic.

7.3.3) **Part 5 K.A.R 28-35-242c specifies the limitations on human use such that an individual shall not be exposed to the useful beam unless the exposure is for healing arts purposes, and each exposure has been authorized by a licensed practitioner of the healing arts,** or by an individual licensed to practice dentistry or podiatry within the authority granted to the individual

by Kansas licensing laws applying to dentists and podiatrists.

7.3.4) Part 5 K.A.R 28-35-242c **prohibits deliberate** (1) exposure of an individual for training, demonstration or other purposes **unless** there are also healing arts requirements and a proper prescription has been provided; and (2) exposure of an individual for the purpose of **healing arts screening** without prior written approval of the department. "Screening" means an exposure of a person without a prior examination by a licensed practitioner.

Note: An application for a healing arts screening program is not applicable; there is no screening of participants for diseases or conditions for which the x-ray examination are to be used in diagnosis.

7.3.5) Part 5 K.A.R. 28-35-242a **provides a waiver of requirements** for regulation K.A.R 28-35-242 (c) of the Kansas Radiation Protection Regulations for the proposed use of DXA since

a) the exposure is not for healing arts purposes,
b) each exposure will not be authorized by a licensed practitioner of the healing arts.

7.3.6) Participation involves human voluntary participation in a clinical or medical research program. As such, all of the requirements of the KU Institutional Review Board (IRB) will be achieved to protect the rights of those volunteers participating in such research, to protect research participants' rights and privacy, and to protect investigators from legal and ethical missteps and safeguards them from the repercussions of such missteps.

Such approval will include a consent statement to clearly inform the volunteer participant that the study uses x-rays, that the procedure is being performed for research purposes only, that there might be no direct benefit to the research participant, and that it is not being performed because the participant is sick and the procedure would help the volunteer feel better or because it would help the doctor diagnose the problem.

7.3.7) Actions by the Authorized Laboratory Supervisor

The prospective Authorized Laboratory Supervisor shall:

7.3.7.1) Provide the Radiation Safety Service all applicable information required by the regulations to obtain a medical waiver of requirements by the Secretary. **The Medical Wavier must be granted prior to purchase of any DXA.**

7.3.7.2) Complete the required IRB submittals in eCompliance. The Radiation

Safety Officer and the Assistant Radiation Safety Officer are reviewers in eCompliance and the requirements of the DXA Program and the Medical Wavier are achieved through this electronic compliance.

Note: The Office of Radiation Safety and the Radiation Safety Committee oversee the use of the whole body iDXA (Dual Energy X-ray Absorptiometry) as specified by the Kansas Department of Health and Environment, Radiation Control. The iDXA uses the ratio of two different x-ray energies and as such, human iDXA use must meet the same requirements as any other use of x-rays in the Healing Arts for medical x-ray device in Kansas. Deliberate exposure of an individual for training, demonstration, or other purposes outside the scope of the study is prohibited. DXA is approved under a Radiation Safety permit, and the work is reviewed monthly by the Radiation Safety office.

A licensed practitioner, M.D., is medical advisor and consultant to the program for those who voluntarily participate in the study and will be reviewing at least monthly, records of individuals who participate in the study. Operators are trained and certified to perform whole body scans under the authorized permit. These scans take five to seven minutes to complete and each use is recorded and documented.

Whole body or total body composition testing emerged as a new reference standard to study how lean body mass and body fat change during health and disease, and has provided a research tool to study the metabolic effects of aging, obesity, and acquired immune deficiency syndrome (AIDS). Lean tissue mass and total and regional body fat measurements aide in realistic weight management goals and in determining overall levels of fitness for a growing emphasis on nutrition and fitness. The **use of DXA as a diagnostic tool** for whole body assessments continues to expand rapidly for medical and research uses and its medical necessity is becoming more and more accepted and apparent.

Whole body composition or total body DXA is investigational or experimental and additional data are needed through well-designed studies with medical supervision to determine if whole body DXA for body composition leads to improved meaningful health outcomes. The University of Kansas is a major participant in designing studies and evaluating outcomes.

7.4) Procedure for Obtaining Medical Use Authorizations, and Permits to Possess and Use Radiographic Medical X-RAY Systems in the Healing Arts.

7.4.1) Part 5 K.A.R. 28-35-241 establishes requirements for the diagnostic use of X-rays

in medicine, dentistry, osteopathy, chiropractic, podiatry, and veterinary medicine.

7.4.2) An individual shall not be exposed to the useful beam unless the exposure is for healing arts purposes, and each exposure has been authorized by a licensed practitioner of the healing arts, or by an individual licensed to practice dentistry or podiatry within the authority granted to the individual by Kansas licensing laws applying to dentists and podiatrists. (K.A.R. 28-35-242)

The Medical Doctor or Radiologist shall:

7.4.3) Provide the Radiation Safety Service all applicable information required by the regulations to obtain approval for a healing arts installation.

7.4.4) Provide the Radiation Safety Service all applicable information to submit the radiation shielding plan. The shielding plan includes a floor plan that shows, at a minimum, the following for each room or device,

7.4.4.1) the location of the x-ray system's radiation port or diagnostic tube,
7.4.4.2) the port or diagnostic tube housing's travel and traverse limits,
7.4.4.3) the directions of the useful x-ray beam,
7.4.4.4) the locations of any windows and doors,
7.4.4.5) the location of the operator's booth,
7.4.4.6) the location of the x-ray control panel,
7.4.4.7) the dimensions of each room concerned,
7.4.4.8) the structural composition, thickness or lead equivalent of each room concerned, and primary or secondary barrier,
7.4.4.9) the type of occupancy factor of each adjacent room or area, inclusive of space above and below the rooms concerned. If there is an exterior wall, floor plan will show the distance to the closest areas where it is likely that individuals may be present

7.4.5) Be responsible for directing the administrative operation and control of each X-ray system and shall ensure that the requirements of Part 5 are achieved.

7.5) Procedure for Obtaining Shielding Plan Authorizations, and Permits to Possess and Use ANALYTICAL X-RAY Systems

7.5.1) Analytical X-ray systems include those components struck by X-rays, including radiation source housings, port and shutter assemblies, collimators, sample holders, cameras, goniometers, detectors, and shielding and may include power supplies,

transformers, amplifiers, readout devices, and control panels to determine the elemental composition or to examine the microstructure of materials.

7.5.2) Actions by the Authorized Laboratory Supervisor

The prospective Authorized Laboratory Supervisor shall:

7.5.2.1) Follow directives from the Radiation Safety Service concerning the engineered safety provisions that will be needed for use and to limit the impact of the radiation producing device placement on adjacent facilities and personnel.

7.5.2.2) Be certified by the Radiation Safety Service as having training appropriate for the radiation producing device to be used. See Chapter 12 for the procedures to become an Authorized Laboratory Supervisor.

7.5.2.3) Complete and sign the permit application for a radiation producing device.

Note: A provision is made for the submission of the manufacturer's name, model, and serial number after the unit is purchased. Unless specific waivers are requested and adequately justified, the permit is subject to all of the conditions of the standard permit conditions for users of radiation producing devices.

7.5.2.4) Ensure that all those who are to use the radiation producing device have received the required training including documented proficiency as specified in Chapter 12, Radiation Safety Training.

7.5.2.5) Complete the certified training documentation.

7.5.2.6) Submit an electronic copy of the permit application and copies of the certified training documentation to the Radiation Safety Service for its recommendations and distribution to the Committee.

7.5.2.7) Proceed with procurement and installation of the device only after receiving written approval of the permit application from the Chair of the Committee and the Acknowledgment/Agreement Letter has been signed and returned to the Chair and to the RSS.

7.5.2.8) Notify the RSS immediately after installation to schedule the required survey before use.

7.5.2.9) Operate the device according to the commitments made with the permit application and any special conditions specified by the Committee.

Note: The conditions and procedures of the Standard Permit Conditions for Users of Radiation Devices are part of every permit unless alternative safety provisions have been submitted and justified by the User and approved by the Committee.

7.6) Procedure for Obtaining Authorizations, and Permits to Possess and Use CABINET X-RAY SYSTEMS

7.6.1) Cabinet X-ray system means an X-ray system with the X-ray tube installed in an enclosure, called a "cabinet," that is independent from existing architectural structures except the floor on which the cabinet could be placed. The cabinet is intended for the following purposes:

(1) To contain at least that portion of a material being irradiated;
(2) to provide radiation attenuation; and
(3) to exclude personnel from the interior of the cabinet during the generation of X-rays.

Note 1: Cabinet X-ray systems may include all X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities.

Note 2: An X-ray tube that is used within a shielded part of a building, or X-ray equipment that may temporarily or occasionally incorporate portable shielding, shall not be considered a cabinet X-ray system.

7.6.2) Cabinet radiography using radiation machines mean industrial radiography that is conducted in an enclosed, interlocked cabinet that prevents the radiation machine from operating unless all openings are securely closed and that is sufficiently shielded so that every location on the cabinet's exterior meets the conditions for an unrestricted area as specified in K.A.R. 28-35-214a.

7.6.3) Actions by the Authorized Laboratory Supervisor

The prospective Authorized Laboratory Supervisor shall:

7.6.3.1) Consult with and follow directives from the Radiation Safety Service concerning the engineered safety provisions that will be needed and for an assessment of the impact of the radiation producing device placement on adjacent facilities and personnel.

7.6.3.2) Be certified by the Radiation Safety Service as having training

appropriate for the radiation producing device to be used. See Chapter 12 for the procedures to become an Authorized Laboratory Supervisor.

7.6.3.3) Complete and sign the permit application for a radiation producing device.

Note: A provision is made for the submission of the manufacturer's name, model, and serial number after the unit is purchased. Unless specific waivers are requested and adequately justified, the permit is subject to all of the conditions of the standard permit conditions for users of radiation producing devices.

7.6.3.4) Ensure that all those who are to use the radiation producing device have received the required training including documented proficiency as specified in Chapter 12, Radiation Safety Training.

7.6.3.5) Complete the certified training documentation.

7.6.3.6) Submit an electronic copy of the permit application and copies of the certified training documentation to the Radiation Safety Service for its recommendations and distribution to the Committee.

7.6.3.7) Proceed with procurement and installation of the device only after receiving written approval of the permit application from the Chair of the Committee **and** the Acknowledgment/Agreement Letter has been signed and returned to the Chair and to the RSS.

7.6.3.8) Notify the RSS immediately after installation to schedule the required survey before use.

7.6.3.9) Operate the device according to the commitments made with the permit application and any special conditions specified by the Committee.

Note: The conditions and procedures of the Standard Permit Conditions for Users of Radiation Devices are part of every permit unless alternative safety provisions have been submitted and justified by the User and approved by the Committee.

7.7) Procedure for Obtaining Authorizations, and Permits to Possess and Use Non-Human Use Particle Accelerators

7.7.1) Particle accelerators are machines capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of one mega

electron volt (MeV).

7.7.2) Actions by the Authorized Laboratory Supervisor

The prospective Authorized Laboratory Supervisor shall:

7.7.2.1) Provide the Radiation Safety Service all applicable information required by the regulations (K.A.R. 28-35-308) for the registration and use of particle accelerators. This includes the specifics for the proposed equipment and facilities, operating and emergency procedures, shielding and safety design requirements, controls and interlock systems, radiation monitoring instruments, and warning devices and security. **Authorization must be granted prior to the purchase of any particle accelerator.**

7.8) Review and Approval of Radiation Producing Device Permits

7.8.1) Actions by the Radiation Safety Officer

The Radiation Safety Officer (RSO) shall:

7.8.1.1) Evaluate the application for its adequacy in terms of risk based upon the requirements of this Part, the License, State of Kansas and federal regulations and recommendations of other applicable standards. (ANSI, and NCRP and ICRP publications.)

7.8.1.2) Consult with the prospective Authorized Laboratory Supervisor concerning changes that need to be made in the application if any deficiencies are found.

Note 1: Depending upon the nature of the deficiencies, the RSO will request a revised application, submission of additional information in writing, or offer to incorporate additional conditions into the permit in the RSO's letter of recommendation which is sent with the application to the Committee.

Note 2: If there are disagreements between the prospective Authorized Laboratory Supervisor and the RSO with respect to identified "deficiencies", the prospective Authorized Laboratory Supervisor may request Committee review "as is". The RSO would then document concerns to the Committee with the forwarding letter.

7.8.1.3) Forward a copy of the application, and the letter of recommendation to each member of the Committee.

7.8.2) Actions by the Radiation Safety Committee

The Radiation Safety Committee members shall:

7.8.2.1) Evaluate the application and associated materials for adequacy in radiation safety and in protecting other KU facilities using the same guidance listed in 7.4.1.1 above.

7.8.2.2) Send the Chair of the Committee action on the application. The action may be approved, approved with additional conditions, or not approved.

7.8.2.3) Request a meeting of the Committee if the prospective Authorized Laboratory Supervisor feels that issues need to be discussed.

7.8.3) Actions by the Chair of the Committee

The Chair of the Radiation Safety Committee shall:

7.8.3.1) Approve the permit application with a majority vote.

7.8.3.2) Convene a meeting of the Committee if requested by the Chair or the Radiation Safety Officer.

7.8.3.3) Write a letter of approval to the prospective Authorized Laboratory Supervisor specifying any conditions added by the Committee upon receiving the votes from each of the Committee members.

Note: The letter shall require a signed acknowledgment/agreement (commitment to observe added conditions, if any) from the prospective Authorized Laboratory Supervisor. The written approval shall contain:

a.) Applicable Standard Permit Conditions.
b.) Special conditions applicable to the permit, if any.
c.) A copy of "Notice to Employees."
d.) A copy of "Emergency Instructions."

8) RENEWAL OF RADIATION PRODUCING DEVICE PERMITS AND AMENDMENT APPLICATIONS

8.1) Expiration Date of Radiation Producing Device Permits

8.1.1) All permits expire on November 30 of each year unless the **initial** permit was approved within the six months preceding the November 30 deadline.

8.2) Renewal of Permits

8.2.1.) Actions by the Authorized Laboratory Supervisor.

The Authorized Laboratory Supervisor shall:

8.2.2.1) Ensure that each individual completes the required recertification materials provided by the RSS. The RSS will provide the appropriate recertification materials and/or "open material" exams on or about October 1 of each year.

8.2.2.2) Complete the certified training documentation.

8.2.2.3) Sign the permit renewal form after careful review of the uses of the radiation producing device(s) planned for the next year to ensure that significant changes are not required for the permit.

Note: No significant changes in use should have been made during the previous year unless an "amendment" application was first filed. See Section 8.3 below.

8.2.2.4) Go to Section 8.3 if significant changes are proposed.

Note: See the next section for a partial list of significant changes.

8.2.2.5) Submit the signed renewal form, and the certified training documentation to the RSS **prior to October 31** if **no** significant changes are required.

8.3) Procedure for Amendment Applications to Radiation Producing Device Permits

8.3.1) Actions by the Authorized Laboratory Supervisor.

The Authorized Laboratory Supervisor shall:

8.3.1.1) Make a prior review of any anticipated changes in personnel, procedures or engineered safeguards to identify significant impacts on radiation safety and/or protection of adjacent facilities.

Significant changes include all of the following:

a.) modification of the radiation producing device that may affect radiation safety.

b.) modification of required engineered safeguards.

c.) modification of radiation shielding

d.) change in supervisory personnel (note that this precludes the transfer of a radiation producing device to another individual without Committee approval.) An absence of 60 days by the Authorized Laboratory Supervisor requires that the RSS be notified.

e.) relocation of the radiation producing device (even within the same room)

f.) change in *open beam* procedures, such as *alignment*.

Note: This is not an exhaustive list of significant changes.

8.3.1.2) Submit an electronic copy to the RSS of an amendment application covering any changes which might have caused a significant change in radiation hazards.

8.3.1.3) Proceed with such changes only after receiving written approval from the Chair of the Committee **and** the Acknowledgment/Agreement Letter has been signed and returned to the Chair and to the RSS.

Note: The permit continues to be valid for the laboratory <u>if</u> the renewal request was submitted on time unless or until notified to the contrary by the Radiation Safety Service on behalf of the Committee. However, requests for changes in the permit (amendments) are not part of the permit until notified by the Chair.

8.4) Actions by the RSS Concerning Renewal Applications

8.4.1) Actions by the Radiation Safety Service or RSO

The Radiation Safety Service shall:

8.4.1.1) Send the Authorized Laboratory Supervisor copies of the permit renewal form listing current approvals and amendments, the certified training documentation, and the recertification training materials. This should be accomplished by about October 1 of each year.

The Radiation Safety Officer shall:

8.4.1.2) Upon receiving the renewal materials for a permit, review all the application materials, review the recertification materials, and sign the permit renewal application if all requirements are satisfied.

8.4.1.3) Notify the Authorized Laboratory Supervisor concerning issues that are not satisfactory, if any.

Note: If the recertification of training for any Authorized User cannot be given, arrangements must be made before the device may be continued to be used.

8.4.1.4) Forward signed permit renewal applications to the Chair of the Committee for the Chair's signature and approval.

8.4.1.5) Follow the procedures in Section 8.5 below for any amendment applications that accompany a renewal request.

8.4.1.6) File the records on training and a copy of the final approved version of the renewal upon receiving it from the Chair of the Committee.

8.5) Responsibilities of the RSS Concerning Radiation Producing Device Amendment Applications

8.5.1) Actions by the RSS or the RSO

The Radiation Safety Officer shall:

8.5.1.1) Evaluate the amended application for its adequacy in terms of risk based upon the requirements of this Part, the License, State of Kansas and federal regulations and recommendations of other applicable standards. (ANSI, and

NCRP and ICRP publications.)

8.5.1.2) Consult with the prospective Authorized Laboratory Supervisor concerning changes that need to be made in the amendment application if any deficiencies are found.

Note 1: Depending upon the nature of the deficiencies, the RSO will request a revised application, submission of additional information in writing, or offer to incorporate additional conditions into the permit in the RSO's letter of recommendation which is sent with the application to the Committee.

Note 2: If there are disagreements between the prospective Authorized Laboratory Supervisor and the RSO with respect to identified deficiencies, the prospective Authorized Laboratory Supervisor may request Committee review "as is". The RSO would then document concerns to the Committee with the forwarding letter.

8.5.1.3) Forward a copy of the amended application, and the letter of recommendation to each member of the Committee.

8.6) Responsibilities of the Chair of the Radiation Safety Committee Concerning Radiation Producing Device Renewals

8.6.1) Actions by the Chair of the Committee

The Chair of the Radiation Safety Committee shall:

8.6.1.1) Review the renewal applications forwarded by the RSS.

8.6.1.2) If the materials are satisfactory, sign the renewal application, and return the original copy to the RSS.

Note: The RSS will make copies of the signed application and file one copy, send one copy to the Authorized Laboratory Supervisor and return one copy to the Chair.

8.6.1.3) Consult with the Authorized Laboratory Supervisor and the RSS if there is any issue that does not appear to be satisfactory.

8.6.1.4) Convene a meeting of the Committee if the issues are not satisfactorily resolved.

8.6.1.5) Carry out the directives agreed upon by any convened meeting of the Committee.

8.7) Responsibilities of the Radiation Safety Committee Concerning Radiation Producing Device Renewal Applications

8.7.1) Actions by the Radiation Safety Committee concerning radiation producing device amendment applications

The Radiation Safety Committee and the Chair shall:

8.7.1.1) Evaluate the renewal application and associated materials for adequacy in radiation safety and in protecting other KU facilities.

8.7.1.2) Send the Chair of the Committee action on the application. The action may be approved, approved with additional conditions, or not approved.

8.7.1.3) Request a meeting of the Committee if the prospective Authorized Laboratory Supervisor feels that issues need to be discussed.

9) ACQUISITION AND USE OF ELECTRON BEAM DEVICES

9.1) Introduction

9.1.1.) Definition of Electron Beam Devices (EBDs)

All devices that use electron beams, **but for which the production of ionizing radiation is incidental to their intended use, and which are designed by the manufacturer to produce negligible external radiation fields are designated electron beam devices.**

Any unit that does not meet the above definition or is used in such a manner that the definition does not apply and/or is not a particle accelerator **is** a radiation producing device, and the radiation producing device requirements of Chapters 7 and 8 of this Part must be met.

Radiation machine or radiation producing device is any device that is primarily intended to produce, and is capable of producing, ionizing radiation, or any device that is not primarily intended to produce, but does produce, ionizing radiation at a level greater than 0.5 mR/hr at any point five centimeters from its surface.

Particle accelerators are machines capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually **in excess of one mega electron volt (MeV).** Particle accelerators, like electron beam tomography or electron beam irradiators, require a registration fee and are specifically covered in Chapter 7 of this part (7.7) and in K.A.R. 28-35-308 - Part 9, "Radiation Safety Requirements for Particle Accelerators."

Electron beam devices **includes transmission electron microscopes, scanning electron microscopes, electron probes**, Electron Beam Lithography, Electron Beam Welding (150 kVp), etc.

> Note 1: **Transmission electron microscopes** use an electron beam whose electrons are accelerated across a potential of 100 to 400 kV, and are transmitted through an ultra thin specimen, focused by electrostatic and electromagnetic lenses, and detected by an imaging device, such as a fluorescent screen, photographic film, or a CCD camera.
>
> Note 2: **Scanning electron microscopes** use an electron beam whose electrons are accelerated across a potential of 0.5 to 40 kV, and image the

surface by detecting low energy secondary electrons which are emitted from the surface of the specimen.

Note 3: Electronic equipment that produces radiation incidental to its operation for other purposes, if the dose equivalent rate averaged over an area of 10 square centimeters does not exceed five μSv (0.5 millirem) per hour at five centimeters from any accessible surface of the equipment, and radiation-producing equipment that is in transit or is in storage incident to transit; and domestic television receivers **need not be registered** with the State of Kansas.

Note 4: **Exemptions:** Electron beam devices that are part of household appliances or commercial electronic testing equipment are not subject to the requirements of this chapter **if** they are used only for the purposes for which they were manufactured and are not altered or modified in any way by the laboratory personnel. Examples are CRT TV and CRT PC monitors, and CRT oscilloscopes.

9.1.2) The acquisition and use of such a device requires an approved permit. See Section 9.2 below.

9.2) Procedure for Obtaining Electron Beam Device Permits

9.2.1) Actions by the Prospective Authorized Laboratory Supervisor

The prospective Authorized Laboratory Supervisor shall:

9.2.1.1) Complete and sign the permit application for an electron beam device.

Note: A provision is made for the submission of the manufacturer's name, model, and serial number after the unit is purchased. Prior consultation with the RSS is encouraged.

9.2.1.2) Submit an electronic copy to the Radiation Safety Service for distribution to the Radiation Safety Committee.

9.2.1.3) Proceed with procurement and installation of the device only after receiving written approval of the permit application from the Chair of the Committee **and** the Acknowledgment/Agreement Letter has been signed and returned to the Chair and to the RSS.

9.2.1.4) Request a radiation survey from the RSS immediately after installation.

9.2.1.5) Operate the device according to the conditions and requirements specified in:

a.) Permit conditions.

b.) Commitments made with the permit application.

c.) Any special conditions specified by the RSO or Committee.

Note: Permits are valid only for a period of one year. See section 9.3 below.

9.2.2) Actions of the RSO on electron beam device Permit Applications

The Radiation Safety Officer (RSO) shall:

9.2.2.1) Follow the procedures described under Section 7.8.

9.2.3) Actions by the Radiation Safety Committee and its Chair on electron beam device Permit Applications

The Radiation Safety Committee Members shall:

9.2.3.1) Follow the procedures described under Section 7.8

9.3) Procedure for the Annual Renewal of Electron Beam Device Permits

9.3.1) Actions by the Authorized Laboratory Supervisor

The Authorized Laboratory Supervisor shall:

9.3.1.1) Sign the renewal form provided by the RSS and return it to the RSS prior to October 31 of each year IF no changes in the initial permit are to be requested. (If the initial permit was granted within 6 months prior to October 31, a renewal is not required for that year.)

9.3.1.2) Submit an amendment request whenever needed because a significant change in the conditions of the permit are planned. **Such changes are not to be implemented until the proposed amendment has been approved in writing from the Committee and acknowledgment of the conditions of the updated permit has been returned to the Committee and the RSS.**

Significant changes include all of the following:

a.) Change in the approved laboratory supervisor.

b.) Change in the location of the electron beam device even within the same room.

c.) Any change that might affect the shielding integrity of the device.

d.) Any change that might result in a higher level of radiation exposure.

This is not an exhaustive list of significant changes.

Note: No electron beam device may be discarded or transferred to another person unless prior approval from RSS has been obtained. Before such devices may be discarded, the RSS must document that the capability for the production of the electron beam has been destroyed.

10) PLACING ORDERS FOR RADIOACTIVE MATERIALS

10.1) Introduction

10.1.1) Preparing a purchase order or request for radioactive materials shall only be initiated by users in laboratories authorized by the Committee to possess and to use specific radioisotopes or specific radiolabel compounds.

10.1.2) Only Authorized Users and/or individuals designated by the Authorized Laboratory Supervisor shall submit purchase orders or requests for radiolabeled chemicals to Radiation Safety for the Authorized Laboratory.

10.1.3) **All orders for radiochemicals or sources of radiation at the University of Kansas placed to a supplier or provider of radioactive materials or radiation sources shall be made by the RSS.** Authorized Users may arrange for special shipments directly from collaborative Laboratory Supervisors, etc., **only if** permission and approval have been granted by the RSS.

10.1.4) **All radioactive materials must be shipped directly to the Radiation Safety Service** unless a specific waiver of this requirement has been approved by the RSS. Waivers must have appropriate justification.

10.2) Procurement

10.2.1) Actions by the Authorized User and/or Designated Individual.

Note 1: The Designated Individual is an individual authorized by the Authorized Laboratory Supervisor to request that Radiation Safety place the order. This individual may be a Shared Service Center or Departmental accountant or an Authorized User. The order must be initiated by an Authorized User. The order must clearly note that the material is a radiochemical or radiation source.

Note 2: FITC is a software package for all University of Kansas purchases for all items that provides online electronic ordering from catalog and noncatalog vendors and from shopping to payment. Approvals and authorizations are an integral part of the ordering process, and include the staff of Radiation Safety in the approval process from beginning to ending.

The Authorized User with the assistance of the Radiation Safety Service should:

10.2.1.1) Verify that the permit authorizes the type and activity of material to be ordered.

10.2.1.2) Initiate the order through FITC with this information:

a.) the name of the Authorized Laboratory Supervisor for whom the order is being placed.

b.) the name of the Authorized User/Designated Individual placing the order.

c.) the radioisotope and chemical form.

d.) the name of the vendor and applicable catalog number.

e.) number of units to be ordered (and the total activity).

f.) date that the materials are needed.

10.2.1.3) FITC will create a Purchase Order Number

10.2.2) Actions by the RSS upon receiving a FITC notification.

The Radiation Safety Service should:

10.2.2.1) Verify that the type of radioisotope is authorized under the permit and that the possession limits of the Authorized Laboratory and of the University will not be exceeded by receipt of the order.

10.2.2.2) Enter the applicable information in the RSS records.

10.2.2.3) Approve the order in FITC and place the order to the vendor.

10.2.2.4) Notify the Authorized User of delays in shipment or of difficulties in obtaining the requested radioactive materials.

10.2.2.5) Coordinate the order with the appropriate personnel, if necessary.

10.3) Orders from Government Laboratories

10.3.1) Orders from government laboratories require special forms. Consult with RSS prior to preparing such an order.

10.4) Shipping and Receiving Instructions

10.4.1) All radioactive materials must be shipped to and received on campus by the RSS unless otherwise authorized by the RSS and/or the Committee.

10.4.2) All radioactive materials must be shipped to the following address:

University of Kansas
Radiation Safety Service
2330 Crowell Dr., 137 Kurata Building
Lawrence, KS 66047
Attn: 'RSO/Supervisor'

11) THE ALARA PROGRAM

11.1) Introduction

11.1.1) Radiation Doses As Low As Reasonably Achievable (ALARA)

Users of radiation sources under this specific Radiation Protection Program shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and public doses that are **As Low As Reasonably Achievable (ALARA)**. In addition to maintaining individual doses as far below the dose limits as is reasonably achievable, the sum of the doses received by all exposed individuals shall be maintained at the lowest practicable level.

In general, this means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical consistent with the purposes for which the licensed activity is undertaken.

Radiochemicals or Radiation Producing Devices are often combined with other materials of risk. ALARA includes risk assessments for reducing exposures to chemical, infectious and biological, human tissue, animal, and other occupational health and safety hazards as used with radiation sources, and promotes the culture of being environmentally responsible and of achieving sustainability by working towards minimizing and eliminating the environmental and social impacts of daily activities with a goal of having no environmental impact at all.

ALARA is defined as a professional standard of excellence, and is practiced by setting goals. The lower boundary of ALARA is background radiation exposure; the upper boundary of ALARA is the regulatory limit for occupational dose and for members of the public dose; to exceed an ALARA goal is not a violation of the regulations.

ALARA goals and levels of exposures or contamination requiring specific action are defined in this **ALARA Program**. The latter are called **reference or action levels** because they trigger the need for some specific response to the situation. Because references are made to these action levels throughout this chapter, the action levels are defined or stated first in Section 11.2 below.

A **remedial action** requires prompt and documented efforts to achieve the required levels.

An **investigational action** requires remedial action, and determination of causes and corrective actions to prevent recurrence.

An **interventional level** requires remedial action, investigational action, and direct involvement of the Radiation Safety Service to assess the incident.

The word **shall** is used for a **required procedure**. Failure to observe procedures and conditions introduced with a "shall" is "noncompliance" with permit conditions.

The word **should** is used for **highly recommended**, but not absolutely required, procedures and conditions.

An **unrestricted area** means an area to which access is neither limited nor controlled under the Radiation Protection Program. An uncontrolled area is considered an equivalent term. **Floors are considered unrestricted areas that may be located in ether a controlled area or restricted area.**

A **controlled area** is an area outside of a restricted area but inside the site boundary, access to which can be limited by the licensee.

A **restricted area** means any area to which the access is limited by the Radiation Protection Program to protect individuals against undue risks from exposure to sources of radiation. A labeled benchtop or labeled sink is considered a restricted area. The terms 'hot area' (or even 'hot spot') gives the wrong impression and is not used to describe restricted areas (or contamination) in the program.

This chapter constitutes the written **ALARA Program** approved by the Radiation Safety Committee and mandated by Kansas regulations. The ALARA Program commits all users of sources of ionizing radiation to the principle that all "unnecessary exposure" is to be avoided. Secondly, where potential or real exposures are unavoidable, every reasonable effort should be made to reduce the exposure.

The ALARA Program applies to all Authorized Users of sources of ionizing radiation at the University of Kansas unless an amendment to a specific permit grants alternative means of satisfying equivalent control.

11.1.2) Regulatory Dose Limits

The dose limits for **Authorized Users, Members of the General Public, Minors, and Declared Pregnant Women (Embryo/Fetus)** are those specified in K.A.R. 28-35-211 "**Part 4 of the Kansas' Standards for Protection Against Radiation."** These regulations also apply to exposure limits in unrestricted areas. Authorized Users are by definition radiation workers or occupationally exposed. The RSS will determine which Authorized Occupants (laboratory personnel) are included in the "occupationally exposed" category, and will provide appropriate

training.

11.1.3) ALARA Goals

The regulatory dose limits and the goals of the ALARA program for occupational dose and public dose non-occupational exposures are:

		Regulatory Limit	ALARA Goals
Whole Body	Adult - Radiation Worker	50 mSv	1 mSv (100 mrem)
Lens of Eye	Adult - Radiation Worker	150 mSv	3 mSv (300 mrem)
Skin, Extremities	Adult - Radiation Worker	500 mSv	10 mSv (1000 mrem)
Organ, Thyroid	Adult - Radiation Worker	500 mSv	10 mSv (1000 mrem)
Whole Body	Minor - Radiation Worker	5 mSv	0.1 mSv (10 mrem)
Whole Body	Embryo/ Fetus - Declared	5 mSv	0.1 mSv (10 mrem)
(Occupational Exposure of Declared Pregnant Worker)		(0.5 mSv/mo)	
Whole Body	Public - Individual	1 mSv	0.1 mSv 10 mrem
Whole Body	Public (Air Emission ex Rn)	0.1 mSv(10 mrem)	
Whole Body	Public (unrestr area)	0.02 mSv/hr - 0.50 mSv/yr	
Environmental	Public	App B, Tb II	0.02% App B, Tb II

Note 1: Whole body, for purposes of external exposure, means the head and trunk, including the male gonads, and shall include the arms above the elbow and the legs above the knee.

Note 2: Adult means an individual who is 18 or more years of age. Minor means an individual younger than 18 years of age.

Note 3: The total effective dose equivalent (TEDE) is the deep dose equivalent (DDE) and committed effective dose equivalent (CDE) for internal exposures. The Eye Dose Equivalent is LDE, the Shallow Dose Equivalent is SDE, (skin/extremity), the Total Organ Dose Equivalent is TODE, and the Public TEDE Exposure from Air Emissions excludes radon-222 and its daughters. Compliance with dose limits for individual member of the public can be demonstrated by evaluating the annual average concentrations released in gaseous and liquid effluents at the boundary of the unrestricted area.

11.1.4) Achievement of Dose Equivalent Goals and Limits

Authorized Users shall:

11.1.4.1) Plan and conduct all activities so that the ALARA dose goals specified in this chapter can be achieved. A Radiation Safety Committee-approved request (amendment to the permit) for a higher ALARA goal may be obtained. All approved ALARA goals shall be below the dose equivalent limits specified in the regulations.

11.1.4.2) Report to the Radiation Safety Service any accidental exposure, and assist the RSS in the investigation of such an incident.

11.1.4.3) Plan and conduct activities such that the average monthly dose does not lead to a dose in excess of the annual ALARA goals unless a documented analysis shows that a higher dose in a given month will be compensated by lower exposures in prior (preferable) or succeeding months.

11.2) Action Levels

11.2.1) Radiation Exposures

11.2.1.1) Action Levels for Exposure

a.) **Remedial Level (RL) for Exposure**

Any measurable skin contamination requires decontamination and documentation in the survey records of the laboratory.

Note: Causes should always be determined when feasible even at the lowest levels of contamination and corrective action implemented.

b.) **Investigation Level (IL) for Exposure**

Any whole body personnel dosimeter report in **excess of 8 mrem deep dose or eye dose in any one month and/or of 15 mrem shallow dose in any one month,** requires an investigation by the RSS. See Section 11.7. (Minimum measurable quantities – 1 mrem photon, 10 mrem beta, 30 mrem ring. IL of 8 mrem determined by ALARA goal of 100 mrem over twelve months)

11.2.2) Control of Contamination

11.2.2.1) KU ALARA Goals in Contamination Control

a.) The primary goal in contamination control is to have **no measurable contamination on any external surfaces that have the potential of being contacted by personnel and that might result in doses to Authorized Users, Occupants, or to the Members of the Public.** (i.e., outside surfaces of containers

and equipment, floors, bench tops, secondary containers, etc.)

b.) Minimize contamination when the primary goal is not feasible.

c.) Remove any level of contamination, whenever feasible and at the earliest possible time after detecting the contamination.

11.2.2.2) Action Levels in Contamination Control

a.) **Remedial Levels (RL) of Contamination**

Any removable contamination which exceeds one of the levels specified in Table 1 below requires prompt and documented decontamination. Fixed contamination should not exceed 5 times the Table 1 levels. Some screening levels may be significantly higher; final decommissioning gives perspective and the proper view.

Note 1: Unrestricted release and license termination are in view when any level of facility contamination is found. A final site survey will be required to formally certify and release restricted areas utilizing the Multi-agency Radiation Survey and Site Investigation Manual (MARSSIM), Multi-agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME), and complying with the State of Kansas regulations (K.A.R. 28-35-133 through K.A.R. 28-35-505). Kansas Regulations K.A.R. 28-35-205 Termination Without Restriction or here room release or building release:

A site shall be considered acceptable for unrestricted use if both conditions are met:

(1) The residual radioactivity that is distinguishable from background radiation does not exceed 0.25 millisievert or 25 mrem per year.

(2) The residual radioactivity has been reduced to levels that are as low as reasonably achievable.

Note 2: **Table 1 notwithstanding, decontamination shall always be attempted when a "wipe" is measured to exceed an activity of 200 dpm for a surface subject to the "unrestricted" ALARA limit for beta emitters.** Contamination levels above those specified in Table 1 are not allowed unless special permission has been granted by the RSS.

Table 1 - Remedial Levels of Contamination

(Removable contamination)

Type of Radioactive Material*

Type of Surface	Alpha Emitters (dpm/100cm^2)	Beta or X-Ray Emitters (dpm/100cm^2)	Low Risk Beta or X-Ray Emitters (dpm/100cm^2)
1. Unrestricted areas	20	200	1,000
2. Restricted areas	200	2,000	10,000
3. Personal clothing worn outside restricted areas	20	200	200
4. Protective clothing worn only in restricted areas	20	200	200
5. Skin	20	200	200

* Beta or x-ray emitter values are applicable for all beta and x-ray emitters other than those considered low-risk. Low-risk nuclides include C-14, H-3, S-35, Tc-99m, and others whose beta energies are less than 0.2 MeV maximum, whose gamma- or x-ray emission is less than 0.1 R/h at 1 meter per curie, and whose permissible concentration in air (see 10 CFR Part 20, Appendix B, Table 1) is greater than 10^{-6} µCi/ml. (Adapted from Regulatory Guide 8.23, Radiation Safety Surveys at Medical Institutions, and Regulatory Guide 1.86 for removable contamination.)

Note: A **remedial level** of contamination is defined by Regulatory Guide 8.23 for restricted and unrestricted areas, equipment, and/or clothes. When a "remedial level" is discovered, prompt and documented decontamination shall be performed. Table 1 specifies those levels. Note that these levels are defined in terms of removable activity on wipes and not the activity that remains on the surface.

b.) Investigation Level (IL) for Contamination

Any contamination levels that exceed those specified in (I) or (II) below requires an immediate investigation in which causes are determined, corrective actions designed to prevent recurrence are implemented, and reports are submitted to the RSS and the RSC.

Two different IL's are used. These levels are as follows:

I.) For clearly marked and labeled work areas covered with absorbent paper, contamination at more than 25 times the Table 1 "restricted" levels or 5 or more spots at 10 times the

Table 1 levels requires implementation of an Investigation Level.

II.) For unmarked areas, including all floors, contamination at more than 10 times the Table 1 "unrestricted" levels requires implementation of an Investigation Level.

11.3) Control of Radiation Sources and Radiation Producing Devices

11.3.1) Instruments Containing Radioactive Sources (Liquid Scintillation Counters and Gas Chromatographs with radioactive sources) and Radiation Producing Devices

The Authorized Laboratory Supervisor shall:

11.3.1.1) Ensure that the serial number(s) or some other unique identifying number has been registered with the RSS under the permit which governs the use of the instrument and/or radiation producing device.

11.3.1.2) Ensure that the permit specifies where the instrument and/or radiation producing device is located.

11.3.1.3) Ensure that a highly visible label with the following words shall remain attached to such an instrument and/or radiation producing device.

Notice: "Do not move without notifying the Radiation Safety Service."

11.3.1.4) Not transfer responsibility for the instrument and/or radiation producing device unless prior written authorization from RSS and the Committee has been obtained.

Note: These sources are addressed with all other sources of ionizing radiation under standard permit conditions.

11.3.1.5 Promptly notify RSS when the instrument and/or radiation producing device is no longer needed.

Note: Authorized Laboratories, sources of ionizing radiation, and radiation producing devices **shall not be abandoned** by an Authorized Laboratory Supervisor.

11.3.1.6) Not remove such instruments or radiation producing devices from the Equipment Inventory unless prior approval has been obtained from the RSS.

11.3.1.7) Specify the location of storage for instruments, spare radiation producing devices and/or X-ray tubes to be used in instruments in the permit application, and shall not change location without first notifying the RSS.

Authorized Users shall:

11.3.1.8) Use the radiation producing devices and/or sources of ionizing radiation only as specified in the applicable permit. This includes training requirements and procedures

11.3.1.9) **Not move a radiation producing device or source of ionizing radiation to another location without prior approval from RSS.** This is for the purpose of ensuring that the radiation producing device or source of ionizing radiation will never become an "orphan," or that its location becomes unknown to the Radiation Safety Service.

11.3.1.10) Not remove the label specified in Section 11.3.1.3 above and/or "Caution Radioactive Materials" labels. **Only RSS staff members are authorized to remove such labels subject to the restrictions placed upon them by the License.**

11.3.1.11) Maintain the storage of spare radiation producing devices and/or spare X-ray tubes, (etc.) in a secured fashion so that unauthorized access is prevented.

Note: For Authorized Laboratory Supervisors who have only "sources" of the type addressed in this section (11.3.1), the only other applicable sections are 11.4 and 11.8 below.

11.3.2) Outdated Radioactive Sources

The Authorized Laboratory Supervisor shall:

11.3.2.1) **Arrange for approved transfer and/or disposal of all radioactive sources in the inventory of the permit before leaving the university or terminating the permit.**

11.3.2.2) Require an accounting by Authorized Users under their permit of all radioactive sources created by the users **before such users leave the university** (This includes identification and labeling of containers with levels of activity and isotope.)

11.3.2.3) Properly and promptly transfer to RSS for disposal all sources for

which no use is anticipated.

11.3.2.4) Secure all sources and should perform an annual physical inventory of all sources that are listed under the permit in cooperation with the RSS. (Stocks in containers specified in Section 11.3.2.4 above with unbroken seals are inventoried upon identification of the containers.)

Note: The conditions of Section 11.3.2 are agreed upon by the Authorized Laboratory Supervisor when responsibility for a permit and its conditions are accepted by signature of the acceptance letter.

11.4) Control of External Radiation Fields

11.4.1) Restrictions on External Gamma/X-ray Fields and Action Levels

The Authorized Laboratory Supervisor shall:

11.4.1.1) Ensure that the dose rate at the nearest occupiable unrestricted area where radioactive sources are stored or at the surface of the equipment for x-ray producing machines is no greater than 2.0 μGy (0.20 mrem) in any one hour unless analysis by the RSS indicates that achievement of this level is not practical and an exemption is granted explicitly in the permit.

11.4.1.2) Evaluate, plan and perform all activities under the permit with the intent of meeting the ALARA limits on exposure as specified in Section 11.2.

11.4.1.3) Notify the RSS immediately if there is any reason (measurement or calculation) to believe that the exposure of any individual exceeded the Investigation Level listed in 11.2.1 in any one month. Section 11.2.1.1.b establishes this as an Investigation Level, therefore:.

a.) Identify causes for the contamination

b.) Establish Standard Operating Procedures designed to prevent recurrence of the contamination.

c.) Cooperate with RSS in assessing the level of exposure

d.) Submit a report to the RSS and the Committee within two weeks of the incident.

11.4.2) External Beta Fields and Shallow Dose Exposures from Contamination

Authorized Users/Authorized Laboratory Supervisors should:

11.4.2.1) Use clear beta shields whenever high energy beta fields may be present.

11.4.2.2) Perform operations involving microcurie amounts of a high energy beta emitter behind a beta shield.

11.4.2.3) Store beta emitting sources so that betas will not penetrate to accessible areas, if this is readily achievable. The dose rate should not be more than 2.0 μGy (0.20 mrem) in any one hour.

11.4.2.4) Implement decontamination when measurable skin contamination is detected, implement corrective actions if feasible, and document initial and final activities with estimates of the duration of the contamination together with corrective actions.

Note: Measurements are to be made with instruments specified in the Safety Data Sheet for the radioactive source involved and under the conditions specified by the Safety Data Sheet (SDS). Safety Data Sheets provide specific radionuclide data on predicted and measured dose and dose rates, estimates of internal dose, and biological limits. Unless an RSS notation of a more accurate calibration factor is entered into the SDS, the calibration factor or conversion factor suggested in the SDS is to be used. If instruments specified in the general SDS are not available in the laboratory, the Authorized Laboratory Supervisor shall request an RSS calibration for the instruments that are to be used and these shall be noted in the laboratory-specific SDS.

11.4.2.5) Notify RSS immediately if the possibility exists that the exposure could exceed the Investigation Levels.

a.) Identify causes for the contamination

b.) Establish Standard Operating Procedures designed to prevent recurrence of the contamination.

c.) Cooperate with RSS in assessing the level of exposure

d.) Submit a report to the RSS and the Committee within two weeks of the incident.

11.5) Contamination Control

11.5.1) Guidelines and Requirements

Note: In this section, action levels defined in Section 11.2 are used. Section 11.2 should be reviewed as needed.

Authorized Users shall:

11.5.1.1). Plan for and use procedures designed to prevent contamination.

11.5.1.2) Make reasonable attempts to remove any contamination found in unrestricted areas. **The goal is no measurable contamination (less than twice background).**

11.5.1.3) Use judgment in determining when decontamination may be deferred for a limited period of time provided that the contamination levels do not exceed the "Remedial Level".

Note: It always preferable to keep contamination levels in restricted areas at the "not measurable" levels, Areas of contamination are not acceptable.

11.5.1.4) Maintain floors in all areas below "Remedial Levels" for unrestricted areas.

11.5.1.5) Maintain bench tops which are clearly marked and identified as restricted areas below "Remedial Levels" for restricted areas.

Note: Outside surfaces of equipment labeled and exclusively kept in such marked areas shall also be below "Remedial Levels" for restricted areas.

11.5.1.6) Maintain all unrestricted areas and equipment or clothes in such areas below "Remedial Levels" for unrestricted areas and/or equipment.

Note: Every effort should be made to keep levels well below this - preferably nonmeasurable. Destructive decontamination shall be considered, if necessary, with the assistance of Radiation Safety.

11.5.1.7) **Carefully survey laboratory coats and other items to be laundered with appropriate detection methods before release to commercial laundries and/or personal cleaning.** The lab coats shall not be released if there is measurable contamination. Radiation Safety should be notified immediately.

Note: The use of two lab coats is encouraged but not required.

Authorized Users/Authorized Laboratory Supervisors shall:

11.5.1.8) Immediately decontaminate, with the assistance of the RSS, any areas/materials which exceed the Investigation Level of Contamination. (See Section 11.2.2.2.b above)

11.5.1.9) Identify the causes and/or reasons for the contamination.

11.5.1.10) Establish changes in laboratory-specific standard operating procedures designed to prevent recurrence of such incidents, and ensure that all appropriate personnel are trained in those procedures.

11.5.1.11) Maintain written documentation as part of laboratory records.

The Authorized Laboratory Supervisor shall:

11.5.1.12) Report the incident to the RSS as soon as possible.

11.5.1.13) Provide a written report to the RSS and the Committee with review within two weeks of the incident.

11.6) Laboratory Surveys

Note: Laboratory surveys are conducted by the Radiation Safety Service and the Authorized Laboratory. These surveys consist of both smear or wipe and GM instrument, as applicable. Determining removable contamination is significant for evaluating exposure from materials that may be removed from the laboratory. Determining radiation fields is significant for evaluating skin or whole body exposure.

11.6.1) Survey Frequency

Authorized Users should:

11.6.1.1) Perform routine surveys of floors, walls, laboratory furniture, equipment, and/or other areas that may have become contaminated at the end of the day or at the end of the experiment, whichever comes first.

Note: When surveys have been performed at the end of the experiment and no new experiments are performed, surveys do not need to be performed at the end of a day when new experiments were not performed.

11.6.1.2) Survey areas shortly after any high level operation, any stock has been opened, or any operation which is highly vulnerable with respect to

inadvertent contamination (mixing, blending, centrifugation, etc).

Authorized Users shall:

11.6.1.3) Perform surveys as soon as possible whenever there is reason to believe that contamination (spill or handling modification) has occurred.

11.6.1.4) Perform comprehensive documented surveys at the minimum frequency specified in this section as applicable. See Appendix IV-B to determine the level of laboratory.

a.) **In High Level Laboratories**

Comprehensive Surveys are required: 1) immediately following the opening (handling) of a stock; 2) at the end of the day whenever a stock is handled; (3) before a temporary area reserved for work with radioactive materials is returned to unrestricted (unmarked) status.

b.) **In Medium Level Laboratories**

Comprehensive Surveys are required: 1) whenever a stock is handled so that a bioassay must be performed within a day or week; 2) before an area reserved for work with radioactive materials is returned to unrestricted (unmarked) status; 3) at least once a week of selected areas, including the floor, which could become contaminated.

c.) **In Low Level Laboratories**

Comprehensive Surveys are required: 1) before an area reserved for work with radioactive materials is returned to unrestricted (unmarked) status; 2) at least biweekly of selected areas, including the floor, which could become contaminated.

d.) **In Very Low Level Laboratories**

Comprehensive Surveys are required: 1) before an area reserved for work with radioactive materials is returned to unrestricted (unmarked) status; 2) at least monthly on selected areas, including the floor, which could become contaminated.

Note: **The following exception shall apply to all laboratory classes given above:**

During a period of time when radioactive materials are not being used, and

materials are in storage only, area surveys do not need to be performed **if and only if** an extensive "close out" survey has been performed and recorded as such at the time usage was discontinued. Surveys are required during such a period if any accidents occur in the storage areas.

11.7) Actions Prompted by RSS Surveys/Reviews

11.7.1) Actions based upon RSS surveys

The RSS shall

11.7.1.1) Immediately initiate corrective procedures. The RSS will provide the necessary assistance.

The Authorized User/Authorized Laboratory Supervisor shall:

11.7.1.2) Provide the necessary effort to achieve prompt corrective action. See Sections 11.5.1.8 to 11.5.11.

The RSS may:

11.7.1.3) Initiate the procedures described in Section 11.8 if a survey by the RSS finds contamination at Remedial Levels (Section 11.2.2.2.).

Note: Because the actual occurrence of contamination is assumed to be accidental it is not in itself deemed noncompliance. However failure by the users to identify such contamination by appropriate surveying and/or to decontaminate to the extent required by this program could be noncompliance.

Therefore, if surveys performed by RSS were always after the completion of an experiment or after the end of a day's work, the discovery of contamination above the remedial level by them could indicate noncompliance in that laboratory. Because surveys by the RSS are performed during the day and may occur while experiments are still in progress, such findings will not automatically be deemed noncompliance.

However, the frequency with which RSS finds such contamination should be low and the escalating actions specified in Section 11.8 below will be taken. Authorized Laboratory Supervisors should investigate causes for any contamination above remedial levels and should implement additional procedures designed to prevent recurrence if appropriate. High frequency of contamination will most likely result in mandatory changes in the

procedures applicable under the relevant permit.

The RSS shall:

11.7.1.4) Implement the Noncompliance Procedures of Section 11.8 below when levels exceed the Investigation Level (See Section 11.2.2.2.b)

11.7.2) Actions by the RSS when Investigation Levels are Exceeded (whether reported by the laboratory or found with their own surveys)

The Radiation Safety Service shall:

11.7.2.1) Attempt to determine the reason for any exposure in excess of the levels specified in Section 11.2.1.2.b above and to help the laboratory institute procedural changes designed to prevent recurrence of such exposure if feasible under ALARA constraints.

Note: Exposures in excess of these levels are not noncompliance when reported by the laboratory but are action levels for triggering an analysis. They are noncompliance if found by the RSS.

11.7.2.2) Document their findings and include a summary in reports to the Committee.

11.8) Noncompliance Items and Undetected Remedial Level Contamination

A **violation** is a finding by the RSS of noncompliance with State of Kansas and federal regulations, permit conditions, and/or required ALARA procedures and/or conditions. Enforcement actions are based upon the recognition that violations may occur in a variety of activities and have varying levels of significance, and are intended to reflect the significance of the violation and the circumstances involved**.** Actions and conditions have varying degrees of safety, safeguards, or environmental significance.

Level A Noncompliance addresses violations that are **more significant and are of considerable concern.** Violations involving training or lack thereof, personnel protection or lack thereof, required surveys not performed or documented, eating and drinking while at a restricted work bench, leaving radiolabeled sources unsecured, and other procedures that would **greatly affect the health and safety of individuals** are examples of this level. See Section 11.8.1 below. Level A Noncompliance violations are more severe than Level B Noncompliance violations.

Level B Noncompliance addresses violations that are **significant and are of concern.** Examples are not correctly posting and labeling areas and/or equipment, eating or drinking at a personal desk in a posted laboratory, not performing the required surveys and/or inspections, leaving radioactive sources unsecured, working in unrestricted areas, not wearing personnel dosimeters, not preparing or maintaining the required record keeping, placing labeled equipment in unrestricted areas, etc. There may be incidents when these violations would be considered Level A Noncompliance depending upon the level of risk. Some violations are listed as Level A and Level B Noncompliance to show that the severity of these violations depends upon the effects to health and safety. An example of a Level A or Level B Noncompliance would be failure to perform and document surveys.

Sanctioned actions for noncompliance could include

- immediate attention by the Authorized Laboratory,
- written corrections or written responses from the Authorized Supervisor,
- interview with RSO and/or Committee,
- increased RSS inspections,
- additional training requirements,
- increased assessments by the Authorized Users,
- suspended shipments of radioactive materials,
- established restrictions on Authorized User,
- decreased scope of permit,
- confiscated radioactive materials,
- or suspended or permanently terminated permit.

11.8.1) Level A Noncompliance Violations

The Radiation Safety Service shall:

11.8.1.1) Require individuals working with radioactive materials to immediately cease working if training has not been certified at the proper level.

11.8.1.2) Require individuals working with radioactive materials to immediately cease working if gloves and lab coats are not being used in a procedure that requires personnel protection.

11.8.1.3) Require individuals working with radioactive materials to immediately cease working if any Level A Noncompliance violation is identified.

11.8.1.4) Place ordering radioactive materials on a contingent status if the required documentation for surveys has not been completed by the Authorized Laboratory and has a significant impact on health and safety.

Note: Normally this precaution would only be initiated following the action of Section 11.8.2.3. Contingent implies that radioactive materials may be ordered upon completing the required survey.

11.8.1.5) Require individuals working with radioactive materials to immediately cease working if Level B Noncompliance violations have a significant impact on health and safety.

11.8.2) Level B Noncompliance Violations

11.8.2.1) First Violation or Undetected Remedial Level of Contamination

The Radiation Safety Service shall:

a.) Submit a letter to the Authorized Laboratory Supervisor identifying the details of the violation and explaining the required corrective action, and/or condition b. A verbal notice should also be given by the RSS.

b.) Note the violation on the RSS survey sheet in the noncompliance section.

11.8.2.2) Second Violation or Undetected Remedial Level of Contamination

The Radiation Safety Service shall:

a.) Send the Authorized Laboratory Supervisor a notice of violation.

b.) Send a copy to the Chair of the Committee.

11.8.2.3) Third Violation or Undetected Remedial Level of Contamination

The Radiation Safety Service shall:

a.) Send a warning letter to the Authorized Laboratory Supervisor.

b.) Send copies to the Chair of the Department and to the Chair of the Committee.

11.8.2.4) Fourth Violation or Undetected Remedial Level of Contamination

The Radiation Safety Service shall:

a.) Request the Chair of the Committee to arrange for an interview between the Authorized Laboratory Supervisor and the Committee for the purpose of determining steps that need to be taken to prevent recurrence of the noncompliance.

Note 1: In the event of serious, health-threatening violations, the Radiation Safety Service will take appropriate action, including stopping work under a permit, until an interview with the Committee has been completed and it has made recommendations with respect to the safety issues.

Note 2: If the interval between violations is more than eighteen months, the sequence again begins with Section 11.8.1.

The Radiation Safety Committee shall:

11.8.2.5) Take necessary actions to address the problems and monitor the adequacy of those actions.

12) RADIATION SAFETY TRAINING

12.1) Fundamentals and Basics

The **safety of a worker** in the laboratory cannot be accurately evaluated nor addressed **until the nature of the materials of use are understood. These basics or fundamentals are essential tools in properly making an accurate risk assessment.** Trained Health Physicists use classroom and refresher training to teach the nature of the radiochemical and the inherent risks. General standard operating procedure templates and **do's and don'ts** are helpful, but the true assessment of a risk is to **understand the nature of the hazard.**

The experiment's design and a specific protocol is the second step in promoting safe use. The exact experimental design is needed to bring about safe practice. One can't work safely in a laboratory without knowing how the material of risk is used and where the material of risk is located.

12.2) Requirements for Training

All individuals who are likely to receive an occupational dose in excess of 1 mSv (100 mrem) in a year will receive radiation safety training commensurate with their assigned duties and specific to the University of Kansas' Radiation Safety Program before beginning work with or in the vicinity of licensed material. Each individual should also receive periodic refresher training.

K.A.R. 28-35-333 describes the training that must be provided to radiation workers and stipulates that the University of Kansas, in determining which authorized users and occupants are subject to the training requirements, consider assigned activities during both **normal and abnormal** situations involving exposure to radiation and/or radioactive material that can reasonably be expected to occur.

While demonstrating that **it is not likely during a normal situation** for a radiation worker to receive in a year an occupational dose in excess of 1 mSv (100 mrem), these authorized users and occupants could reasonably be expected to receive this level of exposure **during abnormal situations** (e.g., radioactive material left unsecured, a contamination event, or improper disposal of radioactive material in the regular trash) or, by their actions, cause others to receive this level of exposure. Untrained workers represent a potential hazard to themselves, other individuals, and property.

12.2.1) Any Unsupervised Occupant of a Controlled Room or a Controlled Area Shall Have Documented Training.

12.2.1.1) The Authorized Laboratory Supervisor shall ensure that all unsupervised individuals frequenting the Supervisor's Authorized Laboratory, except Facilities Services personnel, have the training required for the category applicable to that individual. The Authorized Laboratory Supervisor shall also ensure that provisions are made for briefing and escorting Members of the Public to the lab.

Note: The Authorized Laboratory Supervisor **shall ensure** that Facilities Services Custodial and Operations personnel are not asked to handle or service any item or device that is restricted, that has not been surveyed, and/or that has a radioactive materials label, nor service any item in an area where ionizing radiation exists.

12.2.1.2) An **Authorized Laboratory** includes the physical facilities and the associated Authorized Users/Occupants, and may consist of several Restricted Areas and/or Controlled Areas.

a.) A **Restricted Area** is an **area or room** to which the access is limited to protect individuals against undue risks from exposure to sources of radiation, and where radioactive materials and/or radiation producing devices are being used or stored. It is included as part of an Authorized Laboratory under a permit.

b.) A **Controlled Area** is an **area** located outside of a "Restricted Area", but inside the site boundary, access to which can be limited, that is **temporarily** established in which radioactive materials are being handled or in which a radiation producing device is being used. The method for establishing the Controlled Area must be specified in an approved permit and a Controlled Area must be under the direct physical supervision of an Authorized User at all times to prevent entry by any unauthorized individuals

c.) An **Unrestricted Area** is an area to which access is neither limited nor controlled.

12.2.2) Categories of Individuals Needing Training

12.2.2.1) Authorized Occupants in Authorized Laboratories

An **Authorized Occupant** is an unsupervised individual who is not working with radioactive materials or radiation producing equipment but who requires access to a Restricted Area or Controlled Area and has completed the documented training.

Note: An unsupervised individual as used in this Part means an individual that is not under the direct and continuous physical surveillance of an Authorized User who has the responsibility of ensuring that the individual will not receive radiation exposures or encounter radioactive contamination.

Authorized Occupants are

a.) **Members of the Public (Visitors)** who require repeated entry (unsupervised) into a Controlled Room.

b.) **Laboratory Personnel** who have responsibilities which make frequent entry into a Controlled Room or regular occupancy of a Controlled Room mandatory but do not use radiation sources.

c.) **Non-laboratory Personnel** performing services in a Controlled Room. Examples are Facilities Services Custodial personnel and Facilities Maintenance personnel.

12.2.2.2) Authorized Users

An **Authorized User** is any individual who handles and/or uses radioactive materials or a radiation producing device who has the requisite documented training and experience and has been certified to have such training and experience by the RSS.

Note: No one at the University of Kansas (Lawrence Campus) may handle or use radioactive materials or radiation producing devices unless they have documented "authorized users" training appropriate to the level of risk. See Section 12.3 below.

12.2.2.3) Authorized Laboratory Supervisor

The **Authorized Laboratory Supervisor** is an individual who has been approved by the Radiation Safety Committee and who is responsible for all operations with sources of ionizing radiation within the Authorized Laboratory subject to Kansas and federal regulations, and University of Kansas and RSS permit requirements.

12.3) Training Requirements for Authorized Laboratory Supervisors

The Radiation Safety Officer with review by the Committee certifies and/or evaluates the training and experience of Authorized Laboratory Supervisors. The Authorized Laboratory

Supervisor must also be an Authorized User.

An Authorized Laboratory Supervisor must be a faculty member and thus must have an advanced degree in the physical or biological sciences or in engineering and, must have at least 40 hours of training and experience in

a) Principles and practices of radiation protection
b) Radioactivity measurements, monitoring techniques, instrument capabilities, standardizations.
c) Mathematics and calculations basic to the use and measurement of radioactivity.
d) Biological effects of radiation including estimates of risk.

which will include training in, (1) the safe handling of radioactive materials, (2) the characteristics of ionizing radiation, (3) units of radiation dose and quantities, (4) radiation detection instrumentation, (5) and biological hazards of exposure to radiation appropriate to the type and forms of byproduct material to be used.

Equivalent training will be evaluated by the Radiation Safety Officer and certification granted based upon both classroom and experience.

A Device Authorized Laboratory Supervisor must be a faculty member and thus have an advanced degree in the physical or biological sciences or in engineering. Formal classroom training and experience with the device will be evaluated by the Radiation Safety Officer. The Radiation Safety Officer will determine the needed training for certification.

12.4) Training Requirements for Authorized Occupants

The Authorized Laboratory Supervisor shall ensure that the training specified in this section is completed before unsupervised visits and/or occupation of Controlled Rooms is permitted.

12.4.1) Training Requirements for Members of the Public (Visitors) of Controlled Rooms not under Direct Supervision (physical presence) of an Authorized User

12.4.1.1) The training shall include general safety training which comprises hazard recognition, hazard exposures, and hazard control measures.

12.4.1.2) The training shall include KU-specific training which comprises hazard assessment and worksite characterizations, hazard identification (labeling, posting, warning signs, and written authorizations), employee exposures and risks and/or cautions, protective measures, and emergency procedures.

12.4.1.3) The training may include more specific information regarding the particular concerns of hazard recognition, hazard exposures, and hazard control measures.

12.4.2) Actions of Unsupervised Members of the Public and the Authorized Laboratory Supervisor

Occasional Unsupervised Members of the Public to Authorized Laboratories shall:

12.4.2.1) Be given a copy of the training, written and presented by the Radiation Safety Officer and the specific appended instructions, if any, for the specific Authorized Laboratory to be visited.

12.4.2.2) Read those instructions.

12.4.2.3) Sign the certified training documentation prior to unsupervised visits to the room.

12.4.2.4) Submit the form to the Authorized Laboratory Supervisor.

Note: With the signature of the certified training documentation, the visitor (member of the public) commits to follow the instructions and procedures of that form.

The Authorized Laboratory Supervisor shall:

12.4.2.5) Submit a copy of the form to the RSS.

12.4.3) Laboratory Personnel Regularly in a Controlled Room but not Using Radiation Sources

Laboratory Personnel shall:

12.4.3.1) Be given a copy of the training and the specific appended instructions, if any, for the specific Authorized Laboratory to be occupied.

12.4.3.2) Read those instructions.

12.4.3.3) Sign the certified training documentation and/or satisfactorily complete an "open material" examination concerning those instructions prior to unsupervised occupation of the room.

Note: The Authorized Occupant commits to following the instructions and procedures with a signature.

The Authorized Laboratory Supervisor shall:

12.4.3.4) Verify that the appropriate form has been signed and/or that the exam has been satisfactorily completed, sign the certified training documentation and submit a copy to the RSS.

Note: Facilities Custodial Services, Facilities Operation and Security personnel are trained by RSS staff. See 12.4.4 below.

12.4.4) Personnel from Facilities Custodial Services, Facilities Operations, and Security with Unsupervised Activities in Controlled Rooms

Personnel from Facilities Services and Security shall:

12.4.4.1) Complete the training provided by RSS before providing services in authorized laboratories if the work involves restricted areas.

Note 1: The instructions given shall be provided to such personnel at the time they are trained by RSS. This training shall be documented.

Note 2: Supervisors of Facilities Services and Security shall not give assignments to personnel which require entry into restricted areas in Authorized Laboratories until the training specified in this section has been completed and documented.

The Radiation Safety Service shall:

12.4.4.2) Provide the training specified in Section 12.4.4.1 above and maintain the documentation for that training.

Authorized Laboratory Supervisors and Authorized Users shall:

12.4.4.3) Not permit Authorized Occupants who are not laboratory personnel to enter a Medium or High Controlled Room until the Authorized Laboratory Supervisor has verified that no contaminated areas/equipment or radiation fields will be encountered by the Authorized Occupants and that they have been thoroughly instructed concerning any areas or items that are not to be approached or handled.

12.5) Training Requirements for Authorized Users

The University of Kansas Graduate School requires that graduate students complete a

Foreign Language or other Research Skill (FLORS) based on the research specialization chosen. Specific research skills requirements vary with graduate degree programs, but all reflect the expectation of a significant research skill component distinct from, but strongly supportive of, the dissertation.

The formal introduction of Biology 702 (Laboratory Practice: Radiation Safety Procedures) and Biology 703 (Radioisotopes and Radiation Safety in Research) into the Graduate Catalog added Radiation Protection and Radiation Instrumentation to the course options for this FLORS requirement. This formal training has served the dual purpose of meeting both the Graduate School Research Skill requirement and the Kansas Regulatory requirement for instruction to radiation workers. Formal certification is granted in lieu of graduate credit; the course may be audited.

Online and web based training opportunities that incorporate state of the art training methods now compliment formal classroom instruction. Aspects of training, listed here as Categories A through F, are available online to help provide self-study aspects of the training. These methods are intended to broaden and to compliment formal classroom instruction, especially where needed to minimize in person contact or accommodate scheduling difficulties.

12.5.1) **All individuals** who handle or use radioactive sources or radiation producing devices shall be trained at the level commensurate with the risk. Appendix IV- C describes the maximum amounts of radioactive materials that a specific category of user may handle. Individuals shall be

12.5.1.1) Informed on the storage, transfer, or use of radioactive materials or radiation producing devices.

12.5.1.2) Instructed in the health protection problems associated with exposure to radioactive materials or radiation producing devices, in precautions or procedures to minimize exposure, and in the purposes and function of protective devices employed.

12.5.1.3) Instructed in, and required to observe to the extent within the Authorized User's control, the applicable provisions of the regulations, license, and permit conditions for the protection of personnel from exposure to radioactive materials and/or radiation producing devices.

12.5.1.4) Instructed of their responsibility to report promptly to the RSS any condition which may lead to or cause a violation of the regulations, license, or permit conditions, or unnecessary exposure to radioactive materials and/or radiation devices.

12.5.1.5) Instructed in the appropriate response to warnings made in the

event of an emergency that may involve exposure to radioactive materials and/or radiation producing devices.

12.5.1.6) Advised as to the radiation exposure reports that Authorized Users may request.

12.5.1.7) Instructed concerning **prenatal radiation exposure and its risks to the embryo/fetus, and of the choice to declare pregnancy for female Authorized Users.**

The Authorized Laboratory Supervisor shall:

12.5.1.8) Ensure that all individuals working within the Authorized Laboratory and who are handling and/or using radioactive sources or radiation producing devices have the documented training appropriate for the levels at which the individuals will be working.

Note: Individuals who have a need to begin working with radioactive materials quickly may qualify as Category F Authorized Users. See Section 12.5.7 below for the restrictions that apply and to Section 12.6 for the additional responsibilities of the Authorized Laboratory Supervisor under whom such individuals are working.

12.5.1.9) **Ensure that a declared pregnant woman, a female Authorized User who has voluntarily informed her Authorized Laboratory Supervisor in writing of her pregnancy and conception date, has been informed of the risks associated with occupational exposures.**

12.5.2) **Category A Training**

12.5.2.1) Required of:

a.) Users who will handle quantities exceeding the Category C and B limits in Appendix IV-C.

12.5.2.2) Requirements for Certification as a Category A Authorized User

Individuals with no prior experience or training shall:

a.) Satisfactorily complete classroom training and a written examination given by the Radiation Safety Service.

b.) Satisfactorily complete a laboratory under the direction of the

Radiation Safety Service staff or a 16 hour supervised on-the-job training session under an Authorized Laboratory Supervisor or an Authorized User approved by Radiation Safety Service staff as qualified to provide the training.

Individuals with training and experience at another institution shall:

c.) Provide written documentation that should include a certificate, syllabus, course schedule, and/or course content of the training to the RSS.

d.) Receive instructions in KU specific procedures by the RSS.

Note: If condition c. does not meet the equivalent training requirements, conditions a. and/or b. shall be met as required by the RSO.

12.5.2.3) Subject matter upon which the written exam will be based.

a.) Part I and II of the text by Dale and Lemon, "Radiation Safety in the Use of Radioactive Materials," or formal class course presentations, or equivalent material.

(Equivalent material is presented in *Radiation Protection: A Guide For Scientists and Physicians* by Jacob Shapiro, etc.)

Note: Completion of Biology 703, including its exam, satisfies the documented training requirement. Prospective users are encouraged either to audit or enroll in Biology 702 and 703 for the purpose of meeting this requirement. Users may choose the "self-study" option.

12.5.3) **Category B Training**

12.5.3.1) Required of:

a.) Users who will handle only **one kind** of radioisotope or specific types of emitter with prescribed conditions in quantities exceeding Appendix IV-C, Category C limits, but less than Category A limits.

b.) Prospective Laboratory Supervisors who have had training and experience, but who do not satisfy the requirements for Category C and/ or Category A certification. Prospective Laboratory Supervisors may be certified to use twice the quantities of Category B users.

12.5.3.2) Requirements for Certification as a Category B Authorized User

Individuals with no prior experience or training shall:

a.) Satisfactorily complete classroom training and a written examination given by the Radiation Safety Service.

b.) Satisfactorily complete a laboratory under the direction of the Radiation Safety Service staff or a 16 hour supervised on-the-job training session under an Authorized Laboratory Supervisor or an Authorized User approved by Radiation Safety Service staff as qualified to provide the training.

Individuals with training and experience at another institutions shall:

c.) Provide written documentation that should include a certificate, syllabus, course schedule and/or course content of the training to the Radiation Safety Service.

d.) Receive instructions in KU specific procedures by the RSS.

Note 1: If condition c. does not meet the equivalent training requirements, conditions a. and/or b. shall be met as required by the RSO.

Note 2: If condition c. is not met by a Prospective Laboratory Supervisor, an 'open material' exam may be completed to satisfy the equivalent training documentation.

12.5.3.3) Subject matter upon which the written exam will be based.

a.) Relevant sections of Part I and II of the text by Dale and Lemon, "Radiation Safety in the Use of Radioactive Materials" or equivalent material. The relevant sections are specified by RSS staff on the basis of the isotope to be used.

(Equivalent material is presented in *Radiation Protection: A Guide For Scientists and Physicians* by Jacob Shapiro, etc.)

Note: Prospective users are encouraged to audit relevant portions of Biology 702 and 703 for the purpose of meeting the documented training requirement and as preparation for the special examination given by RSS. Users may choose the "self-study" option.

12.5.4) **Category C Training**

12.5.4.1) Required of:

a.) Users who will handle no more than the quantities specified in Appendix IV-C, Category C.

Examples are handling no more than 10 mCi H-3, or 0.250 mCi of P-32, or 1.0 mCi C-14.

12.5.4.2) Requirements for Certification as a Category C Authorized User

Individuals with no prior experience or training shall:

a.) Satisfactorily complete classroom training and a written examination given by the Radiation Safety Service.

b.) Satisfactorily complete a laboratory under the direction of the Radiation Safety Service staff or an 8 hour supervised on-the-job training session under an Authorized Laboratory Supervisor or an Authorized User approved by Radiation Safety Service staff as qualified to provide the training.

Individuals with training and experience at another institution shall:

c.) Provide written documentation that should include a certificate, syllabus, course schedule, or course content of the training to the RSS.

d.) Receive instructions in KU specific procedures by the RSO.

Note: If condition c does not meet the equivalent training requirements, conditions a. and/or b. shall be met as required by the RSO.

12.5.4.3) Subject matter upon which the written exam will be based.

a.) Sections of Part I as described in the text by Dale and Lemon, "Radiation Safety in the Use of Radioactive Materials," formal class course presentations, or equivalent material.

(Equivalent material is presented in *Radiation Protection: A Guide For Scientists and Physicians* by Jacob Shapiro, etc.)

Note: Completion of Biology 702, including its exam, satisfies the documented training requirement. Prospective users are encouraged either

to audit or enroll in Biology 702 for the purpose of meeting this requirement, but the "self-study" option may be chosen.

12.5.5) **Category D Training**

12.5.5.1) Required of individuals who will be operating and using radiation producing devices. See Chapter 7 for types of units included in this designation. Examples are x-ray diffraction units, cabinet x-ray units, and diagnostic x-ray units.

12.5.5.2) Requirements for Certification as a Category D Authorized User

Individuals with no prior experience or training shall:

a.) Satisfactorily complete a written examination given by the Radiation Safety Service.

b.) Satisfactorily complete on-the-job training under an Authorized Laboratory Supervisor approved by the Radiation Safety Service staff as qualified to provide the training.

Individuals with training and experience at another institution shall:

c.) Provide written documentation that should include a certificate, syllabus, course schedule, and/or course content of the training to the RSS.

d.) Receive instructions in KU specific procedures by the RSO.

Note: If condition c does not meet the equivalent training requirements, conditions a. and/or b. shall be met as required by the RSO.

12.5.5.3) Subject matter upon which the written exam will be based.

a.) The text by Dale and Lemon, "Radiation Safety in the Use of X-ray Producing Machines," or equivalent material with unit specific material applicable for the types of risk for each unit.

(Equivalent material is presented in *Radiation Protection: A Guide For Scientists and Physicians* by Jacob Shapiro, etc.)

12.5.6) **Category E Training**

12.5.6.1) Required of individuals who will be operating and using moisture and/or density gauges which have radioactive sources in them.

Note: Removed due to no moisture and/or density gauges currently permitted by KU's License of Broad Scope.

12.5.7) **Category F Training (Temporary Certification)**

12.5.7.1) Required of:

a.) Users who will not handle more than 0.1 of the levels specified for Category C Users in Appendix IV-C.

Examples are handling not more than 1.0 mCi H-3, or 0.010 mCi P-32, or 0.100 mCi C-14.

12.5.7.2) Restricted to:

a.) Students in non-research laboratory courses

b.) Laboratory Assistants who need to begin work with radioisotopes very quickly and who are in the process of satisfying one of the other training requirements

c.) Trainees who will be at the University for such a short period of time that completion of one of the permanent certifications is not an option and for whom Category F certification satisfies the training requirements for the levels of activity that will be used.

Note: The Category F certification is **temporary** for a duration of no more than one year and preferably less than that time. Under rare circumstances, Category F certification may be extended beyond one year if adequate justification for such an extension is provided by the Authorized Laboratory Supervisor 30 days before the expiration of the certificate.

12.5.7.3) Requirements for Certification as a Temporary Category F Authorized User

Individuals at Category F level shall:

a.) Satisfactorily complete Blackboard, online, or written training and an examination given by the Radiation Safety Service.

b.) Receive hands-on-instruction in the use of safety practices by the

Authorized Laboratory Supervisor.

12.5.7.4) Subject matter upon which the written exam will be based:

a.) The text, "A Brief Introduction to Radiation Safety," or equivalent material.

12.6) Responsibilities of the Authorized Laboratory Supervisor for Category F Certification

12.6.1) Actions by the Authorized Laboratory Supervisor

The Authorized Laboratory Supervisor shall:

12.6.1.1) Carefully supervise the work of Category F users and shall not give such user independent responsibility for handling radioactive materials.

Note: Although constant surveillance is not required, absence from the room should not be frequent and should be of short duration.

12.6.1.2) Not require such an individual to maintain the records required by this manual.

Note: This does not imply that a Category F worker may not be asked to maintain records as a form of training but they will not be the official records. Official record keeping must be performed by someone with at least Category C training.

12.7) Responsibilities for Contract Services

12.7.1) Actions by the Radiation Safety Service

The Radiation Safety Service shall:

12.7.1.1) Schedule and make available on a timely basis the training required by this chapter.

12.7.1.2) Maintain documentation of the training provided under the specifications of this chapter.

12.8) Responsibilities of the Radiation Safety Service

12.8.1) Actions by the Radiation Safety Service

The Radiation Safety Service shall:

12.8.1.1) Schedule and make available on a timely basis the training required by this chapter.

12.8.1.2) Maintain documentation of the training provided under the specifications of this chapter.

13) Standard Operating Procedures to be Applied in the Use of Sources of Ionizing Radiation

13.1) Classification of Procedures

Standard operating procedures for Authorized Laboratories are procedures designed, developed, and implemented to ensure the safe use of sources of ionizing radiation. These procedures attempt **to encourage planning** and **to promote good habits** for employing techniques that secure the achievement of the goals of ALARA.

These procedures may be universal for all Authorized Laboratories or very specific for particular manipulations and uses of sources of ionizing radiation. Therefore, licensed procedures, Committee approved procedures, procedures adopted by the Laboratory Safety Committee, and laboratory specific procedures could be required in any particular Authorized Laboratory.

Procedures for permit applications, permit renewals, procurement, training, ALARA considerations, exposure control and assessment, and laboratory limits and special design are specifically referenced in this Part. References to additional procedures and general practices are included in Sections 13.3 and 13.4.

13.1.1) **Licensed Procedures** have been approved by the Committee and have been incorporated into the Radioactive Materials License.

13.1.2) **Standard Permit Conditions** have been approved by the Committee and are stipulations that are binding to each permit that is approved by the Committee. These conditions are specific for uses of radioactive materials and/or radiation producing devices, and are automatically part of every permit.

13.1.3) **Guidance Documents** provide Authorized Users with procedures and/or instructions that have the potential to change quickly or that need to be revised routinely. These documents may be Committee approved.

13.1.4) **Laboratory General Procedures** are procedures identified in the Laboratory Safety Plan and that are applicable for a particular Authorized Laboratory.

13.1.5) **Laboratory Specific Procedures** are procedures that have been developed by the RSS and/or Authorized Laboratory Supervisor to address safety and health issues for an Authorized Laboratory.

13.2) Responsibilities Under the Procedures

13.2.1) Authorized Users and Authorized Occupants

Authorized Users and Authorized Occupants shall:

13.2.1.1) Comply with the applicable standard operating procedures identified in this plan and in the approved permit.

13.2.1.2) Inform the Authorized Laboratory Supervisor of procedures that will initiate and/or improve laboratory specific procedures.

13.2.2) Authorized Laboratory Supervisors

Authorized Laboratory Supervisor shall:

13.2.2.1) Ensure that the applicable standard operating procedures are implemented and followed.

13.2.2.2) Develop and implement more specific operating procedures as necessary and/or obtain required permits and implement the requirements and conditions of the permit.

13.2.2.3) Ensure that the facilities and equipment required for compliance with the procedures are available and properly maintained for the Authorized Users.

13.2.3) Responsibilities of the Radiation Safety Service

The Radiation Safety Service shall:

13.2.3.1) Develop and/or recommend to the Committee operating procedures to satisfy the conditions of the license, requirements of the regulations and/or prudent practices.

13.2.3.2) Review the existing operating procedures and recommend, revise, and implement changes as necessary.

13.2.3.3) Provide assistance to Authorized Laboratory Supervisors in implementing specific procedures required under an approved permit.

13.2.3.4) Provide assistance to Authorized Laboratory Supervisors in developing and implementing more specific operating procedures as necessary.

13.3) Descriptions of Procedures

13.3.1) Proposed Facility Use Procedures

13.3.1.1) Specific facility use procedures are described in classroom settings and in documents. These procedures include use as classrooms, cold rooms, instrument rooms, temporary laboratories, authorized laboratories, and field studies.

13.3.1.2) A permit is required for each of these specific uses.

13.3.2) Posting and Labeling Procedures

13.3.2.1) Posting and labeling procedures are described in classroom settings and in documents. Radiation Safety posts all rooms and large equipment. The Authorized Users labels the restricted work areas and the uses in that area. Radiation Safety removes the labels from an authorized laboratory only after the laboratory has been properly decommissioned. These procedures specify the requirements for lab entrance posting, specific hazard warnings, restricted area designations, equipment labeling, etc.

13.3.2.2) Consult the RSS for assistance with the posting and labeling requirements.

13.3.3) Wipe Survey Procedures

The Authorized Users should:

13.3.3.1) Check for removable contamination by performing wipe tests with a smooth, medium, porosity filter paper.

Note: To the extent specified in the Safety Data Sheets, thin window GM pancake probe & meter may be used as a **preliminary** survey for the location of 'fixed' contamination. Such a survey is **not a substitute** for performing wipes to determine the level of "removable" contamination.

13.3.3.2) Record the results of these tests in the survey log book in cpm and/or dpm/100 cm^2 or uCi/100 cm^2, as appropriate.

Note 1: The ALARA limits discussed in Section 11.2.2.2 above shall not be exceeded unless authorization for doing so has been obtained from the RSS and is addressed in the applicable permit. (This would require additional safety precautions.)

Note 2: Areas larger than 100 cm^2 may be tested with a single wipe. However, the actual dpm on any single wipe shall not be averaged over an area greater than 100 cm^2 because it would be possible that all of the activity on the wipe came from one small spot less than 100 cm^2 in area. If the dpm on any wipe exceeds the numerical value given in Section 11.2.2.2., either decontamination shall be initiated or it shall be established by re-wipes that all such areas are below the value. Remember that the goal is to have no measurable removable contamination. Decontamination should be attempted if measurable contamination is encountered.

Note 3: Enough wipes need to be made in places where contamination may have occurred (lab benches, floor in work area, door handles of storage facilities, hood aprons, etc.) to verify the absence of contamination. For beta emitters, the activity may be measured with a Liquid Scintillation Counter (LSC) just as research results are measured. Gamma counters may be used for gamma emitters.

13.3.3.3) Directions for specific types of emitters.

a.) For tritium and similar very low energy beta emitters, the only practical means of monitoring is by wipes or smears counted in the LSC. GM survey meters cannot measure tritium. The LSC efficiency used for research samples may be used in determining the dpm.

b.) For low energy beta emitters like ^{14}C, "thin window" pancake GM survey meters may be used to locate higher levels of contamination. Wipes counted in a LSC shall be used to determine the removable contamination.

c.) For high energy beta emitters like ^{32}P, "thin window" pancake GM survey meters may be used. Removable levels shall be determined with wipes. .

d.) For low energy gamma and x-ray emitters like ^{125}I, normal pancake GM cannot be used. A low energy gamma NaI scintillation detector provides a very sensitive monitoring system and should be used. The NaI scintillation detector may also be used for low energy diffraction x-rays.

e.) For average and high energy gamma or x-ray emitters, a calibrated ion chamber or calibrated micro R meter is the proper instrument for determining the external radiation field because of its energy independence. The ion chamber reads in µR/hr. The instruments as described here are not used to determine dpm, which is needed for the

records. Wipes counted in a gamma counter are required for documenting removable activity.

Note: The GM detector is a pulse counting or count rate instrument. The use of the pancake GM detector for measuring dose rates should not be performed and can only be performed under very limited circumstances. By engineered design, the gamma response is suppressed. The detector was specifically designed to detect particulate beta contamination with minimal gamma interference by reducing the fill gas volume and by the choice and thickness of the wall material. **The GM pancake detector shall not be used for gamma detection.**

13.3.4) Laboratory Design

13.3.4.1) Laboratory design procedures are described in classroom and documents. These procedures include the proper uses for poly-backed absorbent paper, secondary containment, segregation, etc.

13.3.4.2) Consult the RSS for assistance with the laboratory design procedures.

13.3.5) Quality Assurance Procedures

13.3.5.1) Quality assurance procedures are described in classroom and documents. These procedures include the proper uses for survey instruments, liquid scintillation counters, fume hoods, etc.

13.3.5.2) Consult the RSS for assistance with the laboratory quality assurance procedures.

13.3.6) Personnel Dosimetry Procedures

13.3.6.1) Personnel dosimetry procedures and requirements are described in the classroom and in documents. These procedures specify the guidelines for obtaining personnel dosimeters, qualifications that require the monitoring of Authorized Users, and requirements for care and use of personnel dosimeters.

13.3.6.2) Consult the RSS for assistance with the personnel dosimetry requirements.

13.3.7) Waste Management Procedures

13.3.7.1) Specific waste management procedures are described in the classroom, at the generation of waste, and in documents.

13.3.7.2) Records shall be maintained and kept as required by the RSS.

13.3.8) Emergency Response Procedures

13.3.8.1) Emergency response procedures are a part of each permit.

13.3.8.2) The RSS should be notified of any accident or emergency.

13.3.9) Record Keeping Procedures

13.3.9.1) Specific record keeping procedures are described in guidance documents that will be provided by the RSS. Records are required for permit documentation, source use, inventory control, personnel dosimetry reports, laboratory surveys, waste records, training records, etc.

13.3.9.2) Records shall be maintained and kept as required by the RSS.

13.4) General Summary of Safety Practices and Standard Permit Conditions

This list provides standard safety practices that are requirements for working with radioactive materials, and that promote the necessary habits to work safely with radioactive materials.

13.4.1) The University of Kansas is committed to the goal of keeping collective and individual radiation exposures ***as low as reasonably achievable (ALARA).*** This goal serves as the overall controlling aim of radiation safety to plan and to conduct work with radioactive materials so that exposures will be kept as low as reasonably achievable.

13.4.2) The Authorized Laboratory Supervisor is responsible for the safe use of radioactive materials for all those who work in the laboratory. This includes ensuring that all users of radioactive materials have received the applicable training certification and that all laboratory personnel have been appropriately instructed.

13.4.3) All users of radioactive materials shall receive training and instructions and be certified by the Radiation Safety Officer commensurate with the potential radiological health protection problems in the restricted areas. Individuals who have not been trained or approved for radionuclide use shall not handle radiolabeled materials.

13.4.4) All radioactive materials shall be ordered by Radiation Safety, and received on campus by Radiation Safety and delivered to the Authorized Laboratory.

13.4.5) Security will be achieved by either locking the room or by making sure that trained laboratory personnel are present. Posting the room does not provide security.

13.4.6) The transfer of all radioactive sources or samples between laboratories is to be approved and to be performed by the RSS. All off-campus shipments to and from research laboratories or other university laboratories (co-projects) are to be completed by the Radiation Safety Service.

13.4.7) **Gloves and lab coats shall be required for all work with radioactive materials.** General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment. **Personal Protective Equipment is specialized clothing or equipment** worn by an employee for protection against a hazard, and includes lab coats, gloves, eyewear, footwear, and other appropriate personal protection. Open shoes or sandals and shorts are not appropriate lab dress, and should not be worn in a laboratory setting.

13.4.8) Gloves and lab coats worn while handling radioactive materials should be removed and surveyed upon leaving the area. Working areas should be monitored and surveyed for contamination after experimental operations have been carried out. Survey results should be recorded even if the readings are background. Comprehensive surveys are required at a specified frequency. (monthly, biweekly, or weekly).

13.4.9) Personnel exposure monitoring will be recommended by the Radiation Safety Service if appropriate for the particular isotopes that are used. All users of P-32 should obtain personnel dosimeters prior to handling radioactive materials. A TLD ring should be obtained prior to handling more than 5 mCi of P-32 or I-125.

13.4.10) All operations should be planned to limit actual or potential spread of radioactive material. Dry runs and accident evaluations should be made prior to using radioactive tracers in the experiment.

13.4.11) Radioactive material labels on an original shipping container shall be removed or defaced before the container is discarded.

13.4.12) Areas for work should be chosen with respect to ease of decontamination in case of an accident.

13.4.13) Areas of work areas should also be segregated from high traffic areas, and be isolated from other working areas in the laboratory.

13.4.14) All radiolabel work areas should be clearly segregated and defined by absorbent paper and/or trays **and** with ‘caution, radioactive material’ tape. Absorbent paper

should be changed regularly to prevent the likelihood of increasing contamination.

13.4.15) Trash containers for regular trash should not be located near restricted work areas.

13.4.16) Users of radioactive materials should not work alone. Another individual should be within hearing distance to provide assistance in case of an accident.

13.4.17) Radioactive materials labels should identify all work areas, storage areas, labware, and equipment for radioactive materials use. Radiation Safety will post the entrances of all restricted laboratories or rooms where radiolabeled sources have been introduced with a 'Caution, Radioactive Materials' label. The laboratory is responsible for posting the bench area, laboratory equipment (pipettors, water baths, centrifuges), and drawers and cabinets for storage.

13.4.18) Radioactive materials labels shall not be used for labeling areas or items that are not for radioactive materials use.

13.4.19) Hands should be washed upon completing a procedure and/or leaving a work area for radioactive materials.

13.4.20) Solutions shall not be pipetted by mouth in a radioisotope laboratory.

13.4.21) Eating food and drinking beverages are not permitted in designated work areas or restricted laboratories. Food packaging and beverage containers should not be disposed in a restricted laboratory; such practice gives the appearance of food and beverage use in the laboratory.

13.4.22) All radioactive materials and radiolabel equipment shall be appropriately secured against unauthorized use, theft, or tampering.

13.4.23) All radioactive wastes, solid and liquid, which are generated in a laboratory must be collected in approved containers for transfer to the RSS for proper disposal. Only tertiary rinses of glassware may be released to the sanitary sewer in the laboratory. Dilution is not a true means of disposal.

13.4.24) Any accident involving internal or external exposure to radiation or involving uncontrolled release of radioactive materials should be reported immediately to the Radiation Safety Service.

13.4.25) Workers who have worn personnel monitoring devices may request a radiation exposure report at any time from the Radiation Safety Service. Routine reports are issued monthly.

13.4.26) Users of radioactive materials are responsible to report promptly to the Radiation Safety Service any condition which may lead to or cause a violation of the regulations or license conditions or unnecessary exposure to radiation or to radioactive material.

13.4.27) Any significant change in the level of activity, the procedures, or the type of activity utilized requires prior approval by the Radiation Safety Committee.

13.4.28) The user of radiolabeled materials should have the end in the mind when the laboratory or building will be decommissioned and the facility returned to pre-use conditions and no economic or environmental impact achieved.

13.4.29) These procedures and activities are governed by the Kansas Radiation Protection Regulations (K.A.R. 28-35-133 to K.A.R. 28-35-505), Title 10 Code of Federal Regulation Part 20, 10CFR19, the Radiation Safety Plan, and the Radioactive Materials License. These documents are available in the offices of the RSS.

13.4.30) Specific procedures are emphasized and highlighted.

Sources are tracked from receipt to disposal. The three records that track a source from procurement to disposal will be completed – the source card, the inventory, and the waste manifests.

Laboratory surveys will be performed.

> **All materials within a radiolabel work area will be treated as potentially contaminated**, and frequent personal monitoring shall be performed to verify that contamination has not occurred.
>
> **Routine surveys** will be performed by each worker after use. This survey consists of 3 – 5 smears, and will be documented. **Comprehensive surveys** will be performed by the designated safety person at the specified frequency. This survey consists of 15 – 25 smears and will be documented.

Radioactive wastes will be processed as such. **No radioactive materials or waste are disposed to the laboratory sink or sewer.** All restricted laboratory waste (radioactive wastes) will be collected for RSS disposal. Wastes will not be discarded to the sewer, vent, or regular trash. (Dilution is not a true means of disposal.). A waste manifest is used to document the transfer of activity from the laboratory. It details the type of container, the source origin, and the activity.

14) DECOMMISSIONING PLAN

14.1) Introduction

The **Radiation Protection Program** provides requirements to ensure the maximum protection of the public health and the maximum safety to all persons at, or in the vicinity of, the place of use, storage, or disposal of sources of radiation, and specifically addresses making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical consistent with the purposes for which the licensed activity is undertaken. It includes risk assessments for and reducing exposures to chemical, infectious and biological, animal, and other occupational health and safety hazards.

In addition, the Radiation Protection Program addresses environmental sustainability. The **Decommissioning Plan** and **Decommissioning Funding Plan** provide requirements to achieve this view. This view begins with the end in mind, and works towards minimizing the environmental impacts of daily activities and projects, with a goal of having no environmental impact at all.

Although the license application includes the specifics for the required Decommissioning Plan and the financial assurance for decommissioning or the Decommissioning Funding Plan, both plans involve Authorized Laboratory Supervisor and Authorized Users and their use of facility design and procedures for operation to minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. **This, like ALARA, must be addressed in all aspects of their programs from beginning to end. It is not just achieved when an Authorized Supervisor relocates or retires.**

Unrestricted release and license termination are in view for any use of material. A final site survey will be required to formally certify and release restricted areas utilizing the Multi-agency Radiation Survey and Site Investigation Manual (MARSSIM), Multi-agency Radiation Survey and Assessment of Materials and Equipment Manual (MARSAME), and complying with the State of Kansas regulations (K.A.R. 28-35-133 through K.A.R. 28-35-505). Kansas Regulations K.A.R. 28-35-205 Termination Without Restriction or here room release or building release:

A site shall be considered acceptable for unrestricted use if both conditions are met:

(1) The residual radioactivity that is distinguishable from background radiation does not exceed 0.25 millisievert or 25 mrem per year.

(2) The residual radioactivity has been reduced to levels that are as low as reasonably achievable.

14.2) Records Vital to Decommissioning

Radiation Safety and Authorized Supervisors and Authorized Users shall maintain records of information important to the decommissioning of a laboratory or facility until the site, or any area, is released for unrestricted use, so that decommissioning will be carried out with minimum impact on public and occupational health and safety and the environment.

Radiation Safety and the Authorized Supervisor and Authorized User shall maintain decommissioning records, which shall consist of

14.2.1) Records of spills or other unusual occurrences involving the spread of contamination in and around the facility, equipment, or site.

Note: These records may be limited to records of instances in which contamination remains after any cleanup procedures or when there is reasonable likelihood that contaminants could have spread to inaccessible areas. These records shall include any known information identifying the nuclides, quantities, forms, and concentrations involved in the spill or occurrence.

14.2.2) Drawings of the following, both as originally built and, if applicable, as modified:

14.2.2.1) The structures and equipment in restricted areas where radioactive materials are used or stored, or both.

14.2.2.2) The locations of possible inaccessible contamination.

Note: If drawings other than those kept pursuant to this regulation are referenced, the relevant documents need not be indexed individually. If drawings are not available, any available information concerning these areas and locations may be referenced.

14.2.3) A list of the following information, which shall be contained in a single document and updated every two years:

14.2.3.1) All areas designated and formerly designated as restricted areas;

14.2.3.2) All areas outside of restricted areas that require the documentation specified.

14.2.3.3) All areas outside of restricted areas where current and previous wastes have been buried and documented.

14.2.3.4) All areas outside of restricted areas that contain material so that, if the license expired, Radiation Safety would be required either to decontaminate the area to unrestricted release levels or to apply for approval for disposal.

Those areas containing sealed sources only shall not be included in the list if the sources have not leaked, no contamination remains in the area after any leak, or the area contains only radioactive materials having half-lives of less than 65 days;

14.3) Purpose

The Decommissioning Plan and Decommissioning Funding Plan are financial assurance regulations and are designed to provide reasonable assurance that the decommissioning of University of Kansas licensed facilities will be accomplished in a safe and timely manner and that adequate staff and funds will be available to cover all costs associated with decommissioning.

Appendices

Appendix IV-A
Quantities of Radioactive Materials for a Low Level Permit

Appendix IV-B
Radioisotope Laboratory Design and Special Procedures

Appendix IV-C
Limits for Categories A, B, C, and F Certifications

Appendix IV/A

QUANTITIES OF RADIOACTIVE MATERIALS FOR A LOW LEVEL PERMIT

Any radioactive material not listed other than alpha emitting radioactive material 0.1

Radioactive Material	Microcuries
Antimony 122 (Sb 122)	100
Antimony (Sb 124)	10
Antimony 125 (Sb 125)	10
Arsenic 73 (As 73)	100
Arsenic 74 (As 74)	10
Arsenic 76 (As 76)	10
Arsenic 77 (As 77)	100
Barium 131 (Ba 131)	10
Barium 140 (Ba 140)	10
Bismuth 210 (Bi 210)	1
Bromine 82 (Br 82)	10
Cadmium 109 (Cd 109)	10
Cadmium 115m (Cd 115m)	10
Cadmium 115 (Cd 115)	100
Calcium 45 (Ca 45)	100
Calcium 47 (Ca 47)	10
Carbon 14 (C 14)	100
Cerium 141 (Ce 141)	100
Cerium 143 (Ce 143)	100
Cerium 144 (Ce 144)	1
Cesium 131 (Cs 131)	1,000
Cesium 134m (Cs 134m)	100
Cesium 134 (Cs 134)	1
Cesium 135 (Cs 135)	10
Cesium 136 (Cs 136)	10
Cesium 137 (Cs 137)	10
Chlorine 36 (Cl 36)	10
Chlorine 38 (Cl 38)	10
Chromium 51 (Cr 51)	1000
Cobalt 58m (Co 58m)	10
Cobalt 58 (Co 58)	10
Cobalt 60 (Co 60)	1
Copper 64 (Cu 64)	100
Dysprosium 165 (Dy 165)	10
Dysprosium 166 (Dy 166)	100
Erbium 169 (Er 169)	100
Erbium 171 (Er 171)	100
Europium 152 (Eu 152) 13 yr	1
Europium 152 (Eu 152) 9.2 hr	100
Europium 154 (Eu 154)	1
Europium 155 (Eu 155)	10

Radioactive Material	Microcuries
Fluorine 18 (F 18)	1000
Gadolinium 153 (Gd 153)	10
Gadolinium 159 (Gd 159)	100
Gallium 72 (Ga 72)	10
Germanium 71 (Ge 71)	100
Gold 198 (Au 198)	100
Gold 199 (Au 199)	100
Hafnium 181 (Hf 181)	10
Holmium 166 (Ho 166)	100
Hydrogen 3 (H 3)	1000
Indium 113m (In 113m)	100
Indium 114m (In 114m)	10
Indium 115m (In 115m)	100
Indium 115 (In 115)	10
Iodine 125 (I 125)	1
Iodine 126 (I 126)	1
Iodine 129 (I 129)	0.1
Iodine 131 (I 131)	1
Iodine 132 (I 132)	10
Iodine 133 (I 133)	1
Iodine 134 (I 134)	10
Iodine 135 (I 135)	10
Iridium 192 (Ir 192)	10
Iridium 194 (Ir 194)	100
Iron 55 (Fe 55)	100
Iron 59 (Fe 59)	10
Krypton 85 (Kr 85)	100
Krypton 87 (Kr 87)	10
Lanthanum 140 (La 140)	10
Lutetium 177 (Lu 177)	100
Manganese 52 (Mn 52)	10
Manganese 54 (Mn 54)	10
Manganese 56 (Mn 56)	10
Mercury 197m (Hg 197m)	100
Mercury 197 (Hg 197)	100
Mercury 203 (Hg 203)	10
Molybdenum 99 (Mo 99)	100
Neodymium 147 (Nd 147)	100
Neodymium 149 (Nd 149)	100
Nickel 59 (Ni 59)	100
Nickel 63 (Ni 63)	10

(from KAR 28-35-133 Appendix C)

Appendix IV-A (cont.)

QUANTITIES OF RADIOACTIVE MATERIALS FOR A LOW LEVEL PERMIT

Radioactive Material	Microcuries	Radioactive Material	Microcuries
Nickel 65 (Ni 65)	100	Strontium 89 (Sr 89)	1
Niobium 93m (Nb 93m)	10	Strontium 91 (Sr 91)	10
Niobium 95 (Nb 95)	10	Strontium 92 (Sr 92)	10
Niobium 97 (Nb 97)	10	Sulphur 35 (S 35)	100
Osmium 185 (Os 185)	10	Tantalum 182 (Ta 182)	10
Osmium 191m (Os 191m)	100	Technetium 96 (Tc 96)	10
Osmium 191 (Os 191)	100	Technetium 97m (Tc 97m)	100
Osmium 193 (Os 193)	100	Technetium 97 (Tc 97)	100
Palladium 103 (Pd 103)	100	Technetium 99m (Tc 99m)	100
Palladium 109 (Pd 109)	100	Technetium 99 (Tc 99)	10
Phosphorus 32 (P 32)	10	Tellurium 125m (Te 125m)	10
Platinum 191 (Pt 191)	100	Tellurium 127m (Te 127m)	10
Platinum 193m (Pt 193m)	100	Tellurium 127 (Te 127)	100
Platinum 193 (Pt 193)	100	Tellurium 129m (Te 129m)	10
Platinum 197m (Pt 197m)	100	Tellurium 129 (Te 129)	100
Platinum 197 (Pt 197)	100	Tellurium 131m (Te 131m)	10
Polonium 210 (Po 210)	0.1	Tellurium 132 (Te 132)	10
Potassium 42 (K 42)	10	Terbium 160 (Tb 160)	10
Praseodymium 142 (Pr 142)	100	Thallium 200 (Tl 200)	100
Praseodymium 143 (Pr 143)	100	Thallium 201 (Tl 201)	100
Promethium 147 (Pm 147)	10	Thallium 202 (Tl 202)	100
Promethium 149 (Pm 149)	10	Thallium 204 (Tl 204)	10
Rhenium 186 (Re 186)	100	Thulium 170 (Tm 170)	10
Rhenium 188 (Re 188)	100	Thulium 171 (Tm 171)	10
Rhodium 103m (Rh 103m)	100	Tin 113 (Sn 113)	10
Rhodium 105 (Rh 105)	100	Tin 125 (Sn 125)	10
Rubidium 86 (Rb 86)	10	Tungsten 181 (W 181)	10
Rubidium 87 (Rb 87)	10	Tungsten 185 (W 185)	10
Ruthenium 97 (Ru 97)	100	Tungsten 187 (W 187)	100
Ruthenium 103 (Ru 103)	10	Vanadium 48 (V 48)	10
Ruthenium 105 (Ru 105)	10	Xenon 131m (Xe 131m)	1000
Ruthenium 106 (Ru 106)	1	Xenon 133 (Xe 133)	100
Samarium 151 (Sm 151)	10	Xenon 135 (Xe 135)	100
Samarium 153 (Sm 153)	100	Ytterbium 175 (Yb 175)	100
Scandium 46 (Sc 46)	10	Yttrium 90 (Y 90)	10
Scandium 47 (Sc 47)	100	Yttrium 91 (Y 91)	10
Scandium 48 (Sc 48)	10	Yttrium 92 (Y 92)	100
Selenium 75 (Se 75)	10	Yttrium 93 (Y 93)	100
Silicon 31 (Si 31)	100	Zinc 65 (Zn 65)	10
Silver 105 (Ag 105)	10	Zinc 69m (Zn 69m)	100
Silver 110m (Ag 110m)	1	Zinc 69 (Zn 69)	1000
Silver 111 (Ag 111)	100	Zirconium 93 (Zr 93)	10
Sodium 24 (Na 24)	10	Zirconium 95 (Zr 95)	10
Strontium 85 (Sr 85)	10	Zirconium 97 (Zr 97)	10

Appendix IV-B

RADIOISOTOPE LABORATORY DESIGN AND SPECIAL PROCEDURES

All guidelines for the safe handling of unsealed radioactive materials indicate that certain special laboratory design features and special procedures may be necessary. The type of material to be handled, the activity of the material, and the type of operation determine which of these special features and procedures are necessary. The chart on the following page may be used as a general guideline for laboratory design. The list of radioactive materials is intended to be representative rather than comprehensive. For materials not listed, consult the Radiation Safety Service.

When a combination of radioactive materials is involved, the limit for the combination should be derived as follows: Determine for each radioactive isotope in the combination, the ratio between the quantity present in the combination and the limit otherwise established for the specific isotope when not in combination. The sum of such ratios for all of the radioactive isotopes in the combination may not exceed "1" (i.e. unity).

Example: If a Low Level laboratory contains as stock 100 mCi of H^3 and 5 mCi of I^{125}, it may not contain more than 5 mCi of C^{14}. This limit was determined as follows:

$$\frac{100\text{mCi } H^3}{250\text{ mCi}} + \frac{5\text{ mCi } I^{125}}{10\text{ mCi}} + \frac{5\text{ mCi } C^{14}}{50\text{ mCi}} = 1$$

The denominator in each of the ratios listed above was obtained from Column III, Low Level Lab for each radioactive isotope present in the laboratory. The same type of calculation is applicable to the limits for a combination of materials in one experimental vessel (Column I) or to be handled at any one time (Column II).

Appendix IV-B

RADIOISOTOPE LABORATORY DESIGN AND SPECIAL PROCEDURES

	Very Low Level Lab			Low Level Lab			Medium Level Lab		
Isotope	I	II	III	I	II	III	I	II	III
H-3	250 uCi	2.5 mCi	25 mCi	2.5 mCi	25 mCi	250 mCi	250 mCi	2.5 Ci	25 Ci
C-14 S-35 Cr-51	50 uCi	500 uCi	5 mCi	500 uCi	5 mCi	50 mCi	50 mCi	500 mCi	5 Ci
P-32 Ca-45 Fe-59	10 uCi	100 uCi	1 mCi	100 uCi	1 mCi	10 mCi	10 mCi	100 mCi	1 Ci
Na-22 Mn-54 Co-60 I-125 I-131 Cs-137	1 uCi	10 uCi	100 uCi	10 uCi	100 uCi	1 mCi	1 mCi	10 mCi	100 mCi
Sr-90 Po-210 Ra-226	0.1 uCi	1 uCi	10 uCi	1 uCi	10 uCi	100 uCi	100 uCi	1 mCi	10 mCi

I. Maximum activity to be contained in any one experimental vessel.
II. Maximum activity to be handled at any one time (liquid stock container, etc.).
III. Maximum activity present in the laboratory at any one time.

SUMMARY OF SPECIAL DESIGN DETAILS

	Very Low Level	**Low Level**	**Medium Level**
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Floor	-	Non-absorbent	Non-absorbent, no cracks
Walls	-	Painted	Smooth, non-absorbent
Benchtops	-	Non-absorbent or sealed	Non-absorbent
Sink	-	Non-absorbent, not slab	Non-absorbent, not slab
Ventilation	-	No recirculated air to	No recirculated air
Drain lines	-	-	Special drain connection.
Hood (if needed)	Any	80 lfm face velocity	High efficiency design, 80 lfm face velocity. Individual ducting
Other	Closed system for dry, dusty operations.		

Appendix IV-C

LIMITS FOR CATEGORIES A, B, C, and F CERTIFICATIONS

User Category

	C	F	B	A
Isotope	Maximum Stock Amount to be Handled			
H-3	10 mCi	1 mCi	20 mCi	The limits will be specified by the permit.
Cr-51	10 mCi	1 mCi	20 mCi	
C-14	1 mCi	0.1 mCi	2 mCi	
S-35	1 mCi	0.1 mCi	2 mCi	
P-33	1 mCi	0.1 mCi	2 mCi	
Ca-45	1 mCi	0.1 mCi	2 mCi	
P-32	0.250 mCi	0.01 mCi	500 uCi	
Co-60	0.01 mCi	0.001 mCi	0.020 mCi	
I-125	0.01 mCi	0.001 mCi	0.020 mCi	
I-131	0.01 mCi	0.001 mCi	0.020 mCi	

Category C Stock to be Handled (Kansas Radiation Protection Standards Appendix C – times ten)
(smallest P-32 stocks are generally 0.250 mCi)
Category F Stock to be Handled (Kansas Radiation Protection Standards Appendix C values)
Category B Stock to be Handled (Kansas Radiation Protection Standards Appendix C – times twenty)

* The numbers in column C and B above are to be multiplied by the modifying factor. The following factors may be applied after consultation with the Radiation Safety Service for specific permits.

Modifying Factor*	Procedure
x 1	Normal chemical operations
x 0.1	Complex wet operations with risk of spills
x 0.1	Simple dry operations
x 0.01	Dry and dusty operations