

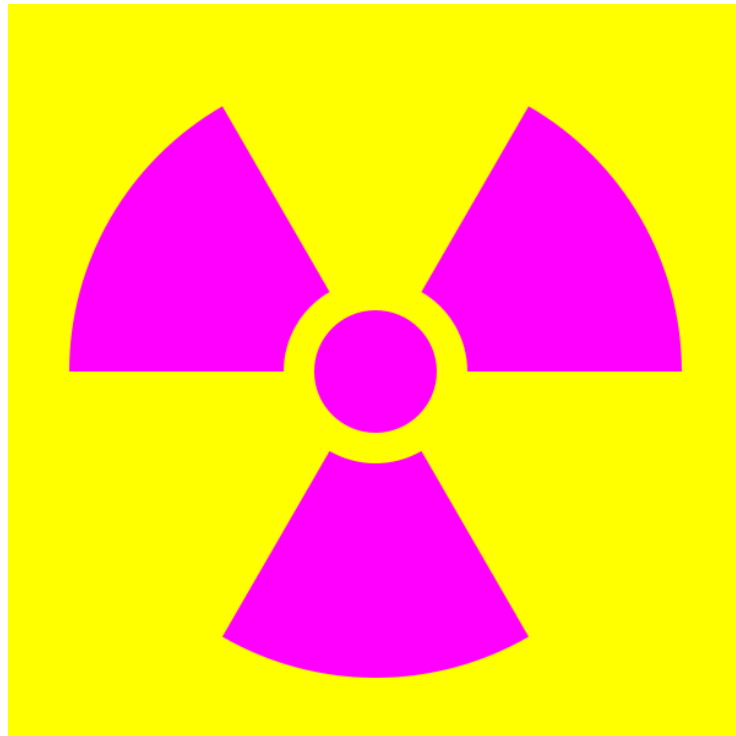
RADFORD UNIVERSITY

ENVIRONMENTAL HEALTH & SAFETY

Radiation Producing Machines

Safety Manual

X-Ray and Analytical Equipment



Environmental Health and Safety

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Definitions

Exposure – term used to describe the amount of ionization produced in air from a radiation source. The unit used for this measurement is Roentgen (R) or milliroentgen (mR). Most portable survey instruments measure exposure. Exposure rate measurements can be used to calculate dose or dose equivalent.

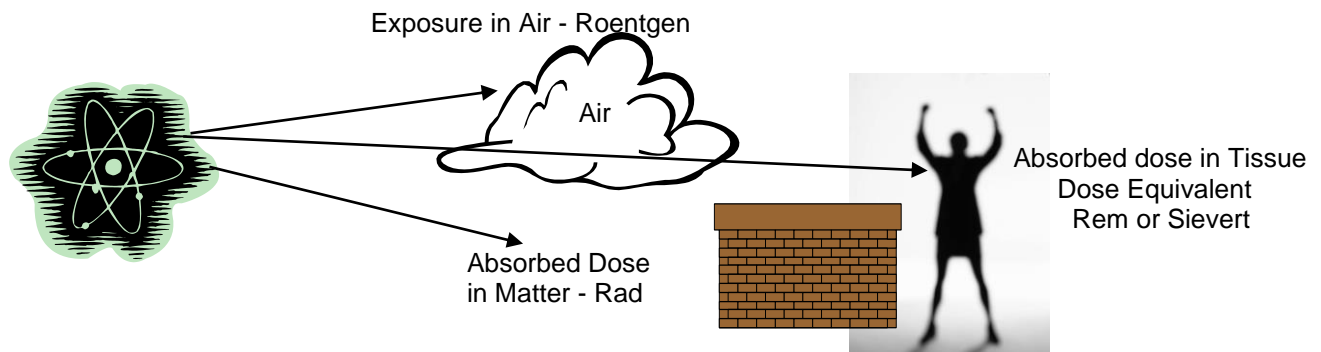
Absorbed Dose – means the energy imparted by ionizing radiation per unit mass of irradiated material. The units of absorbed dose are the rad and the Gray (Gy).

Rad – is the special unit of absorbed dose. One rad is equal to an absorbed dose of 100 ergs/gram.

Gray – is the SI unit of absorbed dose. One gray is equal to an absorbed dose of 1 Joule/kilogram (100 rads)

Rem – is the special unit of any of the quantities expressed as dose equivalent. The dose equivalent in rems is equal to the absorbed dose in rads multiplied by the quality factor (1 rem = 0.01 sievert (Sv))

Sievert – is the SI unit of any of the quantities expressed as dose equivalent. The dose equivalent in sieverts is equal to the absorbed dose in grays multiplied by the quality factor (1 Sv = 100 rems)



Dose Equivalent – is a measure of how much energy is absorbed by the body from radiation. Dose equivalent means the product of the absorbed dose in tissue, quality factor, and all other necessary modifying factors at the location of interest. The units of dose equivalent are the rem and sievert (Sv). 100 rem = 1 Sv. These are also the units reported on your dosimetry report and quantify how much dose you have received.

Deep Dose Equivalent (DDE) – which applies to external whole-body exposure, is the dose equivalent at a tissue depth of 1 cm.

Lens Dose Equivalent (LDE) – applies to the external exposure of the lens of the eye and is taken as the dose equivalent at a tissue depth of 0.3 centimeter.

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Shallow Dose Equivalent (SDE) – applies to the external exposure of the skin of the whole body or the skin of an extremity, is taken as the dose equivalent at a tissue depth of 0.007 centimeter.

Effective Dose Equivalent (EDE) – is the sum of the products of the dose equivalent to the organ or tissue and the weighting factors applicable to each of the body organs or tissues that are irradiated.

Total Effective Dose Equivalent (TEDE) – means the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

MeV – Mega electron volt (1 million electron volts). Unit of measurement which quantifies the amount of energy carried by particulate or electromagnetic radiation, e.g. Cs-137 emits a 0.662 Mev gamma ray and P-32 emits a 1.7 MeV Beta particle.

Activity – when talking about radioactive material, the units of Curie or Becquerel (SI unit) or number of nuclear disintegrations per minute (dpm) are used to describe the quantity of material that is present.

1.0 Introduction

Radiation Safety is the responsibility of all individuals at Radford University including faculty, staff, students, researchers, and visitors. The use of X-ray machines or radiation producing devices at Radford University makes strict compliance to federal and state regulations, and university policies important for the safety and protection of all individuals at the University.

1.1 Purpose

The use of machines which produce ionizing radiation are necessary to carry out the research and teaching responsibilities of Radford University. The guidelines contained in the Radiation Producing Machines Safety Manual have been established by the Radiation Safety Officer for the following purposes:

- To provide for the protection of the University population and the general public against radiation hazards associated with its use of machines and equipment that emit ionizing radiation.
- To provide for the University's compliance with applicable State and Federal regulations.

The intent of the Radiation Safety Officer and the Environmental Health and Safety (EHS) office is to ensure that all employees and students are provided a safe working/learning environment, and an environment that employees and students feel free to raise safety concerns to University Administration, Environmental Health and Safety, or the Radiation Safety Officer without fear of retaliation. Formal complaints should be in writing delivered to the Radiation Safety Officer.

1.2 Scope

This manual details Virginia's Department of Health (VDH), Division of Radiological Health and Radford University requirements for equipment procurement and validation, procedure developments, and education of personnel. This manual is not intended to be a fully comprehensive reference. Further advice concerning hazards associated with specific X-ray or radiation producing devices and/or the development of new and unfamiliar procedures should be obtained through consultation with the Radiation Safety Officer (RSO).

1.3 Importance of Radiation Safety

The improper or unsafe use of radiation producing sources or equipment has the potential to create a health hazard for not only the user but the general public in the environment surrounding the area of use. The licenses that are issued to Radford University by the Virginia Department of Health (Radiological Health Division) specify what equipment may be used and how it must be handled. If you work with radiation producing devices you must abide by safe work practices and follow the requirements of this manual.

Radiation safety is the responsibility of all users. Radiation safety policies are established for everyone's benefit and require everyone's support. All personnel using radiation sources are

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expected to become familiar with this manual and to conduct their operations accordingly. Failure to adhere to the requirements in this manual and/or state regulations could jeopardize the University's ability to use radiation producing devices.

2.0 Virginia X-ray Regulations

The following link is to the applicable regulations regarding radiation producing machines [12VAC5-481](#). The regulations are viewable by clicking on the previous link (this will launch your default web browser) or by visiting the following web address: <http://www.vdh.virginia.gov/radiological-health/radiological-health/x-ray-machine-program/regulations/>. These regulations are the basis of this Radiation Producing Machines Safety Manual. Not all requirements specified in the regulations are restated in this manual. The manual is meant to summarize the requirements and indicate additional requirements determined by the Radiation Safety Officer and EHS. Please contact the Radiation Safety Officer at 540-831-7790 if you have any questions.

3.0 Abbreviations

For the purposes of this Radiation Producing Machines Safety Manaul:

- AU – Authorized User ; *see also PI*
- ALARA – As Low As Reasonably Acheivable
- DDE – Deep Dose Equivalent
- EHS – Environmental Health and Safety
- LDE – Lens Dose Equivalent
- NVLAP – National Voluntary Laboratory Accreditation Program
- NRC or USNRC – United States Nuclear Regulatory Commission
- PI – Principal Investigator ; *see also AU*
- PPE – Personal Protective Equipment
- RSC – Radiation Safety Committee
- RSO – Radiation Safety Officer
- RUP – Radiation Producing Machines Use Permit
- SDE – Shallow Dose Equivalent
- SPD – Signed Pregnancy Declaration
- SU – Supervised User
- XRD – X-ray Diffraction
- XRF – X-ray Fluorescence

4.0 Administrative Organization

4.1 Radiation Safety Committee

The Radford University Radiation Safety Committee (RSC) has not currently been formalized at the time of this publication. When the committee has been formally implemented it will have the authority and responsibility for developing and maintaining a Radiation Safety Program for the University to ensure the safe handling of ionizing radiation in the University's instructional, research, and operation programs. It will be the first duty of the committee to ensure the safe use of any source of ionizing radiation

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employed within the jurisdiction of the University. It will be the second duty to facilitate the use of ionizing radiation and to provide advices and council as recommended. In absence of the RSC, the University Radiation Safety Officer (RSO) is charged with the duties as would normally be assigned the RSC.

The RSO will assume duties of the RSC including recommend University policy with respect to radiation safety; establish standards and regulations for radiation safety at all University-controlled facilities; review and record safety evaluations of all activities involving ionizing radiation at University-controlled facilities and authorize those found to be acceptable; and review annually the operations and procedures of Radiation Safety.

4.2 Radiation Safety Officer

General RSO Responsibilities for Radiation Producing Machines

- Be qualified by training and experience to assume the responsibilities of apprising him/herself of all hazards and precautions involved in handling the radiation machine(s) for which he/she is responsible.
- Give instructions concerning hazards and safety practices to persons who may be occupationally exposed to radiation.

RSO Responsibilities for Analytical X-ray Equipment

- Establishing and maintaining operation procedures so that the radiation exposure of each worker is kept as far below the maximum permissible dose as is practical.
- Instructing personnel who work with or near radiation machines in safety practices.
- Maintaining a system of personnel monitoring.
- Arranging for establishment of radiation control areas, including placement of appropriate radiation signs and devices.
- Providing for radiation safety inspection of radiation machines on a routine basis.
- Reviewing modifications to x-ray apparatus, including x-ray tube housing, cameras, diffractometers, shielding, and safety interlocks.
- Investigating and reporting to proper authorities any cases of excessive exposure to personnel and taking remedial action.
- Being familiar with applicable regulations for control of ionizing radiation.

RSO Authority

To meet these responsibilities, the RSO has been given the following authority:

- To review and approve proposed uses of radiation producing machines.
- To grant, deny, or suspend authorization to use radiation producing machines by University personnel while on University property. Such action by the RSO follows a review of information relative to the authorization in question.
- To apply restrictions on the amount of occupational radiation exposure that any individual University personnel may receive during his/her University association.
- To terminate any activity employing radiation which is a threat to health or property after notification of person in charge.

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- To recommend or order remedial action to correct safety or regulatory deficiencies.
- To delegate, as necessary, tasks and responsibilities to the Assistant RSO that are normally under the purview of the RSO.

4.3 Authorized Users

Receives authority from the RSO to possess and use radiation producing machines. Only Radford University Faculty/Staff may qualify as an AU.

An Authorized User has been approved to use a given radiation-producing device by the Radiation Safety Officer.

Responsibilities

- To help all personnel maintain doses ALARA.
- To submit a Radiation Producing Machines Use Permit (RUP) to the RSO, requesting permission to possess and use a radiation producing machine.
- To maintain an up-to-date listing with the RSO of all Supervised Users (SU).
- To ensure that students and staff using radiation producing devices under his/her supervision are trained in safe laboratory practices, are familiar with terms of the RUP, and are complying with University polices and applicable regulations. The RSO offers training sessions upon request to assist the AU in this regard.
- To inform the RSO of any proposed changes to operations as defined in the approved RUP.
- To provide supervision for all Supervised Users under their authority.
- To provide training on the operation of the equipment to al SU under their authority.
- To ensure that laboratory personnel wear the assigned dosimetry (badge).
- To ensure that laboratory personnel are properly instructed in the guidelines involving radiation producing machines.
- To notify the RSO immediately of overexposure or suspected overexposure.
- To establish appropriate guidelines to ensure compliance with posting and labeling requirements.
- Informing the RSO if they or any of their SU have declared pregnancies (i.e. as defined by 10 CFR 20.1003, so stated in the U.S. NRC Regulatory Guide 8.13 attached as Appendix D).

AU Authority

- To restrict laboratory activities involving radiation to those defined in the approved proposal (RUP).
- To allow only authorized people to use radiation producing machines and allowing only authorized people to enter rooms that are specified as restricted areas.

4.4 Supervised Users – Radford University Personnel

Are appointed by the Authorized User who accepts responsibility for the SU.

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Responsibilities

- To use radiation producing machines in a manner which complies with the guidelines and precautions outlined in this document and with those established in the proposal (RUP) of the AU under whom he/she works.
- To control the radiation exposure to the lowest practical level.
- To be knowledgeable of emergency guidelines.
- To notify the AU immediately of any accident involving radiation.
- To notify your AU if you (female users) wish to declare pregnancy.

4.5 Supervised Users – Non-Radford University Personnel

Are appointed by the Authorized User who accepts responsibility for the SU.

Responsibilities – See *Supervised Users – Radford University Personnel*

Additional Requirements

- Prior dose history must be submitted to the RSO.
- May use dosimetry provided by non-Radford University employer provided dosimetry is appropriate for the type of radiation expected and employer copies dosimetry results to Radford University RSO at the end of each monitoring period (i.e. monthly, quarterly).
- Dosimetry will be issued by RSO if no dosimetry currently possessed by individual.
- Must complete Radford University Radiation Safety Training as provided by the RSO.

4.6 Visitors

Non-Radford University individuals may need to be in areas operating radiation producing machines. In such cases, the visitor must have the proper dosimetry (if needed), and be under direct physical supervision by the AU.

5.0 Dose Limits and Assessment

5.1 Maximum Permissible Dose Limits

Exposure to ionizing radiation, both internal and external, shall be kept As Low As Reasonably Achievable (ALARA). The external and internal exposure from sources of radiation shall be controlled in such a way as to provide reasonable assurance that no individual shall receive an absorbed dose in excess of the permissible value.

Radiation Workers

Maximum permissible dose limits for adult radiation workers (listed in Fig. 1) apply to any combination of dose received from external or internal exposure. These limits do not apply to doses received from background radiation or from medical procedures or exams. An adult radiation worker is defined as an individual 18 years of age or older that works with or around sources of radiation. Child labor laws prohibit individuals under the age of 18 from working with certain types of radioactive materials or in certain areas where

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occupational radiation exposures may occur. It is the policy of EHS that minors are not normally permitted to work with sources of ionizing radiation at Radford University. For more information regarding this policy, contact the Radiation Safety Officer at 540-831-7790.

Annual Maximum Permissible Dose Limits		
5,000 mrem (5 rem)	50 mSv (0.05 Sv)	Whole Body Deep Dose Equivalent <i>(Head, trunk (including male gonads), arms above the elbow, legs above the knee)</i>
50,000 mrem (50 rem)	500 mSv (0.5 Sv)	Whole Body Shallow Dose Equivalent <i>(Skin of the whole body)</i>
15,000 mrem (15 rem)	150 mSv (0.15 Sv)	Lens of Eye Dose Equivalent <i>(Eye)</i>
50,000 mrem (50 rem)	500 mSv (0.5 Sv)	Extremities <i>(Hands, forearms, elbows, knees, leg below the knees, and feet)</i>

Fig. 1 – Annual Maximum Permissible Dose Limits

Declared Pregnant Radiation Worker

Under state and federal law, the whole body dose limit of a pregnant radiation worker remains at 5,000 mrem (50 mSv) per year until she specifically declares her pregnancy in a written and signed statement directed to the RSO. The declaration is voluntary. Following the RSO's receipt of a signed pregnancy declaration (SPD), the dose limit to the worker's embryo/fetus is limited to 500 mrem (5 mSv) for the duration of the pregnancy. Upon the receipt of an SPD, the RSO will provide monitoring for potential internal and/or external exposure to the embryo/fetus as appropriate. A copy of the pregnancy declaration form is available in Appendix D of this manual.

The RSO recommends that a pregnant radiation worker declare her pregnancy so that her occupational radiation exposure potential can be evaluated to ensure that the dose to the unborn child does not exceed 500 mrem (5 mSv) over the duration of the pregnancy.

General Public

The limit to members of the general public (including employees not involved in working with sources of ionizing radiation) is 100 mrem (1 mSv) per year from licensed or registered activities at this institution. The dose rate limit is 2 mrem in any one hour.

5.2 Determination of Exposure

Dosimeters

Personal dosimeters used to record occupational radiation exposures are supplied and processed through an NVLAP (National Voluntary Laboratory Accreditation Program)-approved commercial dosimeter service. The administration and management of the personnel monitoring program is provided by RSO.

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Dosimetry is required for adults likely to annually receive external dose in excess of 10% of the annual permissible dose limits found in Fig. 1. Dosimetry is also required for individuals that enter a high or very high radiation area. Personal dosimeters are also available upon request.

Personal dosimeters are normally exchanged on a semi-annual basis. Copies of dosimetry reports are available from and are maintained on file by the RSO. Contact 540-831-7790 if you have questions concerning dosimeters or dosimeter reporting.

Documented completion of RSO radiation safety training applicable to job function is required as a prerequisite to obtaining a personal dosimeter. Contact the RSO at 540-831-7790 for more information regarding applicable training for your job function. Dosimetry can be requested using the Appendix C Radiation Safety Training and Dosimetry Request Form.

Types of Dosimeters

Whole Body and Collar Dosimeters provide measurement of penetrating and non-penetrating radiation exposure. Penetrating radiation is designated on reports as “DDE” for deep dose equivalent and includes exposure to the whole body (head, trunk, active blood-forming organs, and reproductive organs). Non-penetrating radiation is designated as “SDE” for shallow dose equivalent, and includes exposure to the skin and extremities. Lens of the eye dose equivalent is designated as “LDE.” Whole body dosimeters are to be worn on the torso in the region likely to receive the highest radiation exposure. If a protective lead apron is worn, wear the whole body dosimeter underneath your lead apron. Collar dosimeters are to be worn at the collar and external to a thyroid shield or lead apron.

Ring dosimeters provide measurement of radiation exposure to the extremities (hands and forearms). The ring dosimeter is to be worn under any gloves and on the hand most likely to receive the highest radiation dose.

5.3 Accidental Exposure Assessment

Anyone suspecting that they have received an overexposure due to radiation emitted from a radiation producing machine must call the RSO immediately (540-831-7790).

6.0 ALARA Program

The maximum permissible occupational dose limits established by regulation are based on limiting individual radiation dose to what is considered to be an acceptable level of occupational risk. Although there is no documented evidence linking any health effect with exposures less than 10,000 mrem (100 mSv) delivered at a high dose rate, it is assumed that any radiation exposure may carry some risk. Therefore, regulation requires that the University provide a program designed to reduce exposures As Low As Reasonably Achievable (ALARA) to the extent practical, utilizing procedural and engineering controls.

The University’s ALARA Program provides a process for the RSO to review the radiation safety program annually, review all proposals for radiation producing machine

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usage, review all occupational radiation exposure reports, and investigate any occurrences where occupational exposures exceed established program action levels.

6.1 Action Levels

The University has established investigational levels for occupational exposure to radiation.

Operational Action Level

The RSO contacts individuals and their supervisor/department head if their semi-annual exposure exceeds any of the action levels listed in the following table.

Action Level I

In addition to “Operational Action Level” notifications, the RSO requires the completion of a questionnaire for “Action Level I” exposures.

Action Level II

In addition to operational and Level I actions the RSO requires a meeting with the staff member and supervisor regarding exposures in this category.

Action Levels (per semi-annual basis)			
	Operational	Level I	Level II
Whole Body Deep Dose Equivalent (Head, trunk (including male gonads), arms above the elbow, legs above the knee)	125 mrem (1.25 mSv)	375 mrem (3.75 mSv)	625 mrem (6.25 mSv)
Whole Body Shallow Dose Equivalent (Skin of the whole body)	1,250 mrem (12.5 mSv)	3,750 mrem (37.5 mSv)	6,250 mrem (62.5 mSv)
Lens of Eye Dose Equivalent (Eye)	375 mrem (3.75 mSv)	1,125 mrem (11.25 mSv)	1,875 mrem (18.75 mSv)
Extremities (Hands, forearms, elbows, knees, leg below the knees, and feet)	1,250 mrem (12.5 mSv)	3,750 mrem (37.5 mSv)	6,250 mrem (62.5 mSv)

Figure 2 – Semi-Annual Action Levels

7.0 Acquisition of a Radiation Producing Machine

7.1 Pre-Registration

Prior to obtaining a radiation producing machine, the Authorized User must:

- Pre-register with the Radiation Safety Officer by providing the following information on the Radiation Producing Machine Pre-Registration Form, Appendix A.
 - Name and address of the person having administrative control and responsibility for the proposed facility.
 - Location where the device(s) is to be stored or used.
 - A designation of the general category of proposed use (analytical, dental, medical, industrial, veterinary, or other).

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- Plans and specifications (shielding, etc.) for the proposed facility.
- Other information as requested
- After the Authorized User has obtained the RSO's signature on the Radiation Producing Machine Pre-Registration Form, the AU is authorized to receive shipment of the machine.

7.2 Radiation Producing Machine Use Permit (RUP)

In conjunction with or shortly after Pre-Registration, the AU needs to submit a Radiation Producing Machines Use Permit to the Radiation Safety Officer. The permit form can be found in Appendix C. The AU shall not install or operate the machine until the Radiation Safety Officer has approved the Radiation Producing Machine Use Permit. Additionally, all users must have received radiation training prior to operating the machine in such a way to produce radiation.

7.3 Registration of a Radiation Producing Machine

All machines capable of producing ionizing radiation must be registered with the Virginia Department of Health (VDH), Division of Radiological Health, within 10 days of the receipt of the machine.

The Radiation Safety Officer will register the machine with the VDH based on information provided by the Authorized User in the Radiation Producing Machines Use Permit (Appendix B). The RSO will not request the VDH to add a machine to the registration within 10 days if, on the Pre-Registration form, it was indicated the machine, upon receipt, will be put into storage for future use. In this case, the RSO will communicate this fact in the pre-registration letter to the VDH and indicate registration will be requested at a later date.

The following machine types must be registered:

- Academic x-ray (x-ray diffraction/fluorescence units)
- Dental x-ray units (intra-oral, panoramic, etc.)
- Diagnostic x-ray (radiographic, fluoroscopic and other diagnostic or therapeutic units)
- Particle accelerators
- Neutron generators (only neutron generators not also containing radioactive material)
- Any other equipment that may produce ionizing radiation.

Registrants using radiation producing machines shall provide the Radiation Safety Officer with documentation of the type, make, model, serial number, and maximum radiation output of the device before installation. The registrant shall also provide the date of initial operation (or the approximate intended date) of the radiation producing machine.

A copy of the radiation survey performed at the installation and acceptance testing shall be maintained for inspection, including exposure rates in all adjacent rooms. Radiation surveys shall be repeated after major maintenance, modification or relocation of the device.

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An initial radiation safety survey of the equipment and all adjacent rooms shall be conducted and a copy maintained. Similar radiation surveys shall be repeated after major maintenance, modification or relocation.

The Radiation Safety Officer must be notified prior to any device installation, maintenance, modification or relocation, discontinuation or transfer of a radiation-producing device. Reports of transfer (surplus, sale, gift, etc.) must include the name and address of the transferee.

The RSO must be notified when an X-ray machine arrives and of the scheduled installation date. Installation must be performed and documented by a manufacturer representative or a state agency registered service provider. Following installation, a certificate of installation is required of certified units. For non-certified units, an equivalent report from the manufacturer representative or agency registered service provider must be provided to the RSO. At a minimum, the below listed documents must be provided to the RSO after installation within 30 days.

- Purchase records
- Receipt/Installation records (Includes transfers or donations)
- SOP for each X-ray machine including start-up, shut-down, safety device by-pass, alignment, and emergency
- Calibration, maintenance, and modification records

In addition to the documents listed above, AUs must maintain the below documents.

- Equipment manuals
- Safety devices (interlocks, activation warning lights, etc.) information
- Other requested information by the RSO, regulations, or the University policies
- X-ray log book unless the X-ray machine is solely used by the AU or a computerized automatic log available

8.0 Safeguarding Radiation Producing Devices

State regulations require that **all radiation producing devices must be secured from unauthorized use or access**. It is essential that everyone take responsibility for ensuring that all radiation producing equipment is either under direct observation by authorized personnel, or when unattended, be secured at all times.

The test for compliance with this security requirement is straightforward: Can someone remove or use the device in your area without you or another authorized person in your area knowing it? If the answer is “yes,” then the security in your area of use is not satisfactory. That is the test that the RSO will use in evaluating individual laboratory security plans.

9.0 Basic X-ray Safety Guidelines

9.1 General Guidelines

The X-ray AU should designate a primary responsible operator for the X-ray machine if the AU cannot be in the X-ray use area or on the campus during operation all the time. The primary responsible operator's responsibility will be the same as the AU when AU is not present on the campus including interlock bypass keys, perform the alignments, and manufacturer required changes/maintenance on the X-ray machines. The primary responsible operator can also coordinate calibrations, repairs, and modifications of the equipment with the company or manufacturer representative. X-rays can only be operated when the AU or the designated primary responsible operator is present in the X-ray lab or in the campus. The AU or the designated primary responsible operator must know who uses the machine when the machine is in use. When neither of them are available to supervise the X-ray operation, the X-ray must be turned off and the key must be removed from the machine to secure it from unauthorized operation.

9.2 Operational Procedures

An SOP including start up, shut down, alignment, and emergency procedures for all X-ray machines must be written and readily available to and acknowledged by all users. The safety and basic operations sections in the manufacturer's manual can be used but a standalone specific X-ray manual is strongly recommended. The X-ray operation must follow basic radiation safety practices. All users should minimize their exposures to keep their occupational doses As Low As Reasonably Achievable (ALARA). Certified and closed unit X-ray machines should have enough shielding to reduce radiation level below 2 millirem (mrem) per hour or 2 milliRoentgen (mR) per hour during operation. If the shielding is not sufficient to maintain the radiation level below the 2 mR per hour from the surface where any person can have access, the AU must contact the Radiation Safety Office to consult to have additional access controls added for using the X-ray machine, such as key card access, or an X-ray in use indicator at the entrance.

9.3 Records

Certain records are required to be maintained by all X-ray AUs and readily available for the radiation safety annual audit and VDH inspections. All records should be maintained in one central location in the lab. Minimum required records are

- Equipment manuals
- Purchasing/Receipt/Installation records (Includes transfers or donations) – AU can keep these records in his/her office
- SOP for each X-ray machine
- Calibration, maintenance, and modification records
- Use log book

10.0 Radiation Safety Training

All individuals using radiation-producing machines shall receive radiation safety training offered by the Radiation Safety Officer or a source approved by the Radiation Safety Officer. Training must be completed prior to using a radiation-producing device. In addition, individuals shall be trained on the operation of the particular radiation producing device he/she will be using and actions to take in the event of an emergency.

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This use training shall be provided by the Authorized User or other person approved by the Radiation Safety Officer.

All individuals who wish to operate diagnostic, analytical, or cabinet X-ray systems shall receive instruction in and demonstrate ability in:

- General properties of ionizing radiation.
- Principles of radiation detection.
- Radiation hazards associated with the use of the equipment.
- Biological effects of ionizing radiation.
- Procedures to minimize exposure.
- Radford University's Radiation Safety requirements.
- Emergency procedures.

Ability shall be demonstrated by passing a written examination administered by the Radiation Safety Officer. Machine specific hands-on training must be provided by experienced personnel.

In some cases, the Authorized User will give the safety training, with the course content approved by the Radiation Safety Officer.

Exceptions to radiation safety training requirements may be granted because of pervious training, experience, or education at the sole discretion of the RSO.

Radiation Safety Training can be requested using the Appendix C Radiation Safety Training and Dosimetry Request Form.

10.1 Refresher Radiation Safety Training

In addition to the initial training requirements, there is a retraining requirement. Anyone who uses radioactive equipment while working at the University, must complete annual retraining. The RSO will send out a notice to all Authorized Users reminding them of the need to ensure that he/she and all personnel working under their authorization must complete the retraining. If a user fails to complete the required retraining, they may lose the authorization to work with radioactive equipment. Reauthorization can only be obtained by completing retraining. Retraining courses normally include training on the Chemical Hygiene Plan and HAZCOM as well. Retraining is normally provided online through the D2L platform.

Live lecture retraining can be provided if a request is made to the RSO.

11.0 Vendor Radiation Safety

All vendors, who sell or service radiation-producing equipment at Radford University, must have a radiation safety program that includes at least the following:

- Education about risks and hazards
- Appropriate use of PPE
- Radiation monitoring (personnel) program and record keeping

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The vendors must provide program documentation to the University upon request.

Vendor representatives who are in the room during radiation-producing procedures must wear monitoring devices, appropriate aprons and other shielding, and other PPE appropriate to the situation.

The company must provide the monitoring devices. The University will provide aprons, shields, and other PPE for use by the vendor representatives.

If the vendor does not need to be in the procedure room, he/she should use the observation window.

12.0 X-rays – General

The following items apply to x-ray producing machines in general. These, therefore, apply to diagnostic x-ray, dental x-ray, x-ray diffraction, x-ray fluorescence instruments, etc. Please contact the RSO if you have any questions.

- Individuals operating x-ray systems shall be adequately instructed in safe operating procedures and shall be competent in the safe use of the system.
- Written safety procedures and rules for the particular x-ray system shall be posted in a conspicuous place beside each x-ray system's control panel and a copy of these administrative regulations shall be made available in each general work area.
- Records of surveys, calibrations, maintenance and modifications performed on the x-ray system along with the names of persons who performed the service shall be kept.
- If protective clothing is worn on portions of the body and a monitoring device(s) is(are) required, at least one (1) monitoring device shall be utilized as follows:
 - If an apron is worn, the monitoring device shall be worn at the neck area outside of the apron; and
 - If more than one (1) device is used and a record is made of the data, each dose shall be identified with the area where the device was worn on the body.

13.0 Analytical X-ray

This section applies to instruments that employ methods like x-ray diffraction and x-ray fluorescence. Specifically, enclosed beam configurations are addressed. Contact the RSO with any questions.

X-ray diffraction and spectrographic devices generate in-beam radiation dose rates of 30 to 7000 rads/sec. Severe tissue damage can be inflicted by very brief exposures to these high dose rates. Surgical treatment or amputation may be required when small body parts, such as fingers, receive greater than 1000 rads.

It is imperative that stringent safety precautions be applied when using these devices. Safety precautions include mechanical and electrical interlocks as well as proper training and instruction. The following safety procedures have been established to help prevent accidents. Adherence to these rules is mandatory.

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- Normal operating procedures shall be written and available to analytical x-ray equipment workers. No individual shall be permitted to operate analytical x-ray equipment in a manner other than specified in the procedures unless the individual has obtained written approval of the Radiation Safety Officer.
- Safety interlocks shall be tested monthly. Record the results of the test, the date, and the name of the person conducting the test.
- A label bearing the words, "**Caution - Radiation - This Equipment Produces Radiation When Energized**" shall be placed near the switch that energizes the tube.
- A sign bearing the words, "**High Intensity X-ray Beam**" shall be in place adjacent to each tube housing.
- Unused ports on radiation source housings shall be secured in the closed position.
- Under no circumstances shall shutter mechanisms or interlocks be defeated or in any way modified, except as approved in writing by the Radiation Safety Officer.
- If it is necessary to temporarily, intentionally alter safety devices (e.g., bypassing interlocks or removing shielding) this action shall be:
 - Specified in writing and posted near the x-ray tube housing so that other persons know the existing status of the machine; and
 - Terminated as soon as possible.
 - When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent, shall be placed on the radiation source housing.
- **Be alert to the beam status.** Stay constantly aware of the on/off status of the X-ray beam by repeatedly checking the status indicators.
- **Avoid the beam path.** Stay out of the beam path, even when the beam is OFF.
- **Only experienced, skilled workers should perform beam alignments.** Concentrate fully on the job when doing alignments. Wear the finger and body radiation monitor badges.
- No person shall be permitted to operate academic X-ray machines until they have:
 - received instructions in relevant radiation hazards and safety
 - received instructions in the theory and proper use of the machine
 - demonstrated competence, under direct supervision, to safely use the machine
- Operators must wear extremity (finger) and whole body radiation badges, as applicable, while using the equipment. The RSO will assist in determining applicability based on the individual's involvement with the machine (e.g., operation, maintenance and repair, beam alignment, etc.)
- Operators shall remain in constant attendance while the X-ray beam is on, or the device shall be secured against access by unauthorized persons.
- Any changes in the status or location of a device shall be referred to the Radiation Safety Officer for prior approval.
- Periodically monitor for scatter radiation. Sheet lead, lead foil, lead tape or leaded acrylic are all useful for auxiliary shielding.
- **Be aware of non-radiation hazards.** Cryogenic liquids and gases, high voltage and heavy metals are some examples of other lab hazards that require precautions.

13.1 Annual Inspections

Analytical X-ray facilities shall be inspected annually by the Radiation Safety Officer or a qualified private inspector.

13.2 Emergency Procedures

The following X-ray emergency procedure and general safety guidelines must be posted at each analytical X-ray device:

13.3 Analytical X-ray Machines Radiation Emergency Procedures

If you are exposed to the direct x-ray beam or suspect an exposure, IMMEDIATELY follow these steps:

- ❖ Shut off the x-ray beam.
- ❖ Remain calm.
- ❖ Call the Radiation Safety Officer.
- ❖ If there is a medical emergency in addition to the exposure, call the Radford University Police.
- ❖ Arrange for a medical examination. Important: Notify the examining physician that exposure to low energy x-rays may have occurred.

Radiation Safety Officer 540-831-7790

Radford University Police 540-831-5500

13.4 General Safety Guidelines

X-Ray diffraction and spectrographic devices generate in-beam radiation dose rates of 30 to 7000 rads/sec. Severe tissue damage can be inflicted by very brief exposures to these high dose rates. Surgical treatment or amputation may be required when small body parts, such as fingers, receive greater than 1000 rads.

It is imperative that stringent safety precautions be applied when using these devices. Safety precautions include mechanical and electrical guards as well as proper training and instruction. The following safety procedures have been established to help prevent accidents. Adherence to these rules is mandatory.

1. No person shall be permitted to operate analytical x-ray machines until they have:
 - a. Received instructions in relevant radiation hazards and safety.
 - b. Received instructions in the theory and proper use of the machine.
 - c. Demonstrated competence, under direct supervision, to safely use the machine.
2. Radiation exposure to the operator and others shall be kept ALARA (As Low As Reasonably Achievable).
3. Operators shall wear monthly exchanged finger-ring and body radiation badges (if applicable). The RSO will assist in determining applicability based on the individual's involvement with the machine (e.g., operation, maintenance and repair, beam alignment, etc.)

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4. Operators shall remain in constant attendance while the x-ray beam is on, or the device shall be secured against access by unauthorized persons, unless an interlock device is provided to prevent accidental entry into the primary beam.
5. Safety interlocks shall be tested monthly.
6. ANY changes in the status or location of a device shall be referred to the Radiation Safety Officer for prior approval.

14.0 Diagnostic X-ray Units

14.1 Warning Label

The control panel containing the main power switch shall bear the following warning statement or an equivalent statement, legible and accessible to view: "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

14.2 Other Signs

- X-ray room doors shall be closed during x-ray procedures. These doors shall be labeled "CLOSE DOOR DURING X-RAY PROCEDURES".
- A sign indicating "Caution: X-rays" shall be posted on doors leading into the x-ray room.

14.3 Technique Chart

In the vicinity of each x-ray system's control panel a chart shall be provided which specifies for examinations which are performed by that system a list of information for each projection within that examination. The chart shall include but not be limited to the following:

- The patient's anatomical size versus technique factors to be utilized;
- The type and size of the film or film-screen combination to be used;
- The type and focal distance of the grid to be used, if used;
- The source to image receptor distance to be used; and
- The type and location of gonadal shielding to be used, if used.

14.4 Personnel in X-ray Room

Except for patients who cannot be moved out of the room, only staff and ancillary personnel required for the medical procedure or training shall be in the room during the radiographic exposure. The patients and personnel shall be protected as follows:

- Other than the patient being examined, individuals in the x-ray room shall be positioned so that no part of the body not protected by five-tenths (0.5) mm lead equivalent, is struck by the useful beam.
- Staff and ancillary personnel shall be protected from direct scatter radiation by protective aprons or whole body protective barriers of not less than 0.25 mm lead equivalent;
- Patients who cannot be removed from the room shall be protected from the direct scatter radiation by whole body protective barriers of not less than 0.25 mm lead

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equivalent or shall be so positioned that the nearest portion of the body is at least two (2) meters from both the tube head and the nearest edge of the image receptor; and

- If a portion of the body of staff or ancillary personnel is potentially subjected to stray radiation which results in that individual receiving one-quarter (1/4) of the maximum permissible dose as defined in these administrative regulations, additional protective devices may be required by the cabinet.
- If a patient or film is provided with auxiliary support during a radiation exposure, the registrant shall:
 - Provide mechanical holding devices to be used if the technique permits;
 - Provide written safety procedures, as required by this administrative regulation, which shall indicate the requirements for selecting a person to hold a patient or film and the procedure which the holder shall follow;
 - Provide the human holder with protection from radiation exposure as required by these administrative regulations; and
 - Ensure that no person is used routinely to hold film or patients.

14.5 Annual Inspections

Medical diagnostic facilities shall be inspected annually.

14.6 Typical Exposure

The primary beam exposure at a distance of 32” has been measured to be up to ~240 mR.

15.0 Other Radiation Producing Machines (D-D Neutron Generators, etc.)

Radiation producing machines that are not discussed in detail in this manual will be addressed on a case by case basis. The RSO will provide direction to help make sure that the appropriate regulations are applied to the given radiation producing machine.

16.0 Research Involving the Use of Animals

The University requires that, before any investigator purchases/obtains and begins research involving vertebrate species of animal, an animal research protocol must be submitted for review and approval by the Institutional Animal Care and Use Committee (IACUC).

For additional information please contact EHS at 540-831-7790.

17.0 X-ray Machine Out-of-State-Use, Transfer, Donation, and Disposal

17.1 Out-of-State-Use

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Any user planning to use an X-ray unit out of state (for ex. Portable) must contact the Radiation Safety Office at least two weeks prior to use for purpose of notifying appropriate state agencies, or other counties if applicable.

17.2 Transfer or Donation

An X-ray unit can be transferred or donated to another organization as long as the organization has appropriate registration. AUs must contact the URI property office and the Radiation Safety office before processing the transfer or donation.

17.3 Disposal

Most newer X-ray units don't contain hazardous materials except beryllium and lead.

Generally beryllium is contained within the X-ray tube and must be removed from the system and disposed of as chemical waste. You must verify the manufacture's information about the X-ray tube. Most of the time, it is indicated on the tube. Before the disposal process, the AU must remove the head, being careful not to break the X-ray tube. The tube is under vacuum and, if broken, could splinter and cause injuries and exposure to beryllium. Some X-ray systems have beryllium windows and a "poison" sign on the window unit that warns users that the window unit contains a very toxic chemical and must be disposed of properly. If you need assistance, please contact the Radiation Safety Office.

For disposal of X-ray units, contact the URI property office. Contact the Radiation Safety office to assist in disposing of the unit.

PCBs - X-ray machines made before July 1979 may contain a toxic chemical called polychlorinated biphenyls or PCBs, in the transformer oil. If your machine is older than 1979 or around that time frame, oil must be tested before the process of disposal. If the test results show that the oil contains PCBs, you need to contact the URI Environmental Health Safety (EH&S) to remove the oil and disposed of as chemical waste.

Hazardous Metals - Older equipment may contain hazardous metals. Before taking a machine out of service you need to be aware of what's in the machine and what needs to be done to dispose of it properly. How you go about this could either save or cost you a lot of money. Contact the Radiation Safety Office and the EH&S if you need assistance. The Radiation Safety office and the EH&S can help you to determine if your old machine contains a hazardous waste metal regulated by the U.S. Environmental Protection Agency and assist you to properly dispose of it.

18.0 Exemptions

- No person shall be required to register due to the ownership or possession of the following:
 - Electronic equipment that produces radiation incidental to its operation for other purposes provided the dose equivalent rate averaged over an area of ten (10) square centimeters does not exceed five-tenths (0.5) mrem per hour at five (5) cm from an accessible surface of the equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

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- Radiation producing machines while in transit or storage incident thereto.
- Domestic television receivers are exempt from the regulations.

18.1 Electron Microscopes

Electron microscopes are exempt from registration provided the dose equivalent rate averaged over an area of ten (10) square centimeters does not exceed five-tenths (0.5) mrem per hour at five (5) cm from an accessible surface of the equipment. As such, a radiation survey of electron microscopes shall be conducted on an annual basis. A survey shall also be conducted after modification, maintenance, or repair of the electron microscope. Contact the Radiation Safety Officer at 540-831-7790 to schedule a survey.

The user orientation for the electron microscope shall include a brief radiation safety discussion indicating potential radiation issues for these instruments.

Appendix A

Radiation-Producing Machine Pre-Registration Form

I. Authorized User Information		
Name:	Professional Title:	
Department:	Building:	
Room Number:	Phone Number:	
II. Radiation-Producing Equipment Information		
Supplier/Manufacturer, Make, Model, S/N:		
Location where device will be used or stored:		
General category of proposed use:	<input type="checkbox"/> Human Use: Diagnostic <input type="checkbox"/> Research <input type="checkbox"/> Storage for future use (please provide detail in Comments) <input type="checkbox"/> Other (specify):	
Specific type of equipment:	<input type="checkbox"/> Radiographic <input type="checkbox"/> Dental <input type="checkbox"/> XRF <input type="checkbox"/> XRD <input type="checkbox"/> Neutron Generator <input type="checkbox"/> Accelerator <input type="checkbox"/> Other (specify): _____	
<i>Plans and specifications for proposed facility (as evaluated by a qualified expert) attached?</i> <i>Note: If the device is designed to be self-shielding, please include a copy of the manufacturer-provided user's guide describing the shielding. If shielding cannot be determined until after receipt, submit the shielding plan with the Radiation Use Permit.</i>		<input type="checkbox"/> Yes <input type="checkbox"/> No
Radiation Producing Machines Use Permit Attached? <i>Note: The use permit may be submitted after pre-registration and receipt of the machine provided it is not installed or operated upon receipt. Installation and operation shall not be done until approval has been received by the RSO.</i>		<input type="checkbox"/> Yes <input type="checkbox"/> No
Expected Equipment Delivery Date:		
Comments:		
III. Activity Type		
<input type="checkbox"/>	New Purchase: By University Funds <input type="checkbox"/> or Grant Funds <input type="checkbox"/> Index #:	
<input type="checkbox"/>	Donation/Gift	
<input type="checkbox"/>	Temporary Loan	
IV. Signatures		
I certify that this radiation producing machine will be ordered and received in accordance with 12VAC5-481 and the Radford University Radiation Producing Machines Safety Manual.		
Requestor Signature:		Date:
I have reviewed the above information, and confirm that the applicant is authorized to receive this radiation producing machine, and that acquiring this machine will not violate 12VAC5-981 or the policies set forth in the Radford University Radiation Producing Machines Safety Manual.		
Radiation Safety Officer		Date

Appendix B

Radiation Producing Machines Use Permit

If an Authorized User (AU) wishes to use a radiation producing machine, then he/she must have an approved Radiation Producing Machine Use Permit (RUP).

The RUP, and its supporting documents (found in this Appendix) shall be completed by the Primary Authorized User and submitted to the RSO for review. If the RUP is approved by the RSO, then the AU shall be allowed to use the radiation producing machine under the conditions of the RUP, the University Radiation Producing Machines Safety Manual, and 12VAC5-481.

If the AU needs to make a change to the RUP after it has been approved, then the AU must submit an amendment request, or an entirely new RUP (depending on the amount of change required), the amended RUP will undergo the same process as described in the previous paragraph.

The RSO and RSC reserve the right to request updated information from an AU regarding their work with radiation producing machines as they deem appropriate.

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ENVIRONMENTAL HEALTH & SAFETY

Radiation Producing Machines Use Permit

This form is to be completed and approved prior to any work performed with the radiation producing machine.

Primary Authorized User Information

Name: _____	Telephone: _____
Department: _____	Fax: _____
Building: _____	E-mail: _____
Room: _____	

Additional Authorized Users

Name	Department	Telephone	E-mail

Radiation Producing Machine Information

Vendor: _____
Control Panel Manufacturer, Model & Serial No.: _____
Tube Housing Manufacturer, Model & Serial No.: _____
Proposed Use: <input type="checkbox"/> Research <input type="checkbox"/> Industrial <input type="checkbox"/> Human Use: Diagnostic <input type="checkbox"/> Other (specify): _____
Type of Machine: <input type="checkbox"/> Radiographic <input type="checkbox"/> Dental <input type="checkbox"/> XRF <input type="checkbox"/> XRD <input type="checkbox"/> Neutron Generator <input type="checkbox"/> Accelerator <input type="checkbox"/> Other (specify): _____
Additional Description of Machine: _____
Maximum kVP (if applicable): _____
Maximum mA (if applicable): _____
Maximum MeV (if applicable): _____
<input type="checkbox"/> Fixed <input type="checkbox"/> Mobile <input type="checkbox"/> Portable
Proposed Use Location Facility Name, Street Address, Building, Room # (Attach a copy of a scale building floor plan indicating the location and adjacent areas):
Date of Proposed Initial Operation: _____

Please answer the following questions (use attachments, where requested, and if additional space is required).

General Information

1. Explain briefly the intended use of the radiation producing machine.
2. Will this machine be used by Supervised Users? Yes No
If yes, please list their names and indicate how you intend to ensure that they receive adequate supervision. Any time a person is added to or removed from this list, submit the change in writing to the RSO (e-mail notification is sufficient).

3. Are you familiar with the provisions and regulations of the following:

X-Ray Regulations, 12VAC5-481? Yes No
RU Radiation Producing Machines Safety Manual? Yes No

If you answered “No” to either question, contact the RSO to discuss these items.

4. If there is (or shall be) possession of survey and monitoring equipment, complete the Survey and Monitoring Equipment Form. Itemize specific items owned and/or those which you plan to obtain if this application is approved.

There is (or shall be) survey/monitoring equipment; information concerning the survey equipment is listed below. Include any additional information that is important regarding survey/monitoring equipment.

Survey/monitoring equipment is not required.

5. Describe arrangements that have been made with the Radiation Safety Officer with respect to personnel monitoring requirements.

There is (or shall be) personnel monitoring; information concerning the personnel monitoring is listed below. Include any additional information that is important regarding personnel monitoring.

Personnel monitoring is not needed (state why).

Radiation Producing Machines – General

6. Attach plans and specifications (shielding, etc.) for the proposed facility.

Attached? Yes No

7. Describe the training that has been or will be provided with regards to radiation safety and operation of the machine.

General X-ray (Dental, Diagnostic, Analytical)

8. Attach a copy of written safety procedures and rules for the particular x-ray system. These shall be posted in a conspicuous place beside each x-ray system's control panel.
Attached? Yes No
9. Describe any protective clothing (e.g., lead aprons) that will be used. If protective clothing is not needed, state this.

Analytical X-ray Equipment (XRD, XRF, etc.)

10. Attach a copy of the normal operating procedures that will be made available to analytical x-ray equipment workers.
Attached? Yes No
11. Is there a label reading "CAUTION - RADIATION - THIS EQUIPMENT PRODUCES RADIATION WHEN ENERGIZED" near the tube power switch? Yes No
12. Is there a sign stating "CAUTION - HIGH INTENSITY X-RAY BEAM" adjacent to the tube housing? Yes No
13. Attach a copy of your beam alignment procedures. Attached? Yes No
Specify the individual(s) below that will perform beam alignments.
14. Describe how you will prevent access to the beam by unauthorized individuals.
15. List any non-radiation hazards that need to be addressed (e.g. high voltage, chemicals, cryogenic liquids, gases)?

Dental X-ray

16. Attach a copy of the technique chart that will be used and posted at the dental x-ray control panel.
Attached? Yes No
17. Is the source to skin distance (SSD) ≥ 18 cm when the unit is operated >50 kVP?
 Yes No
18. Is the source to skin distance (SSD) ≥ 10 cm when the unit is operated <50 kVP?
 Yes No
19. Describe radiation safety training provided faculty, staff, and/or students prior to their use of Radford University dental x-ray equipment.

Diagnostic X-ray

20. Does the control panel have the following or equivalent statement near the power switch?
"WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."
 Yes No

21. Attach a copy of the technique chart that will be used and posted at the control panel.
Attached? Yes No

22. What are the procedures for selecting a person to hold a patient or film and the procedures the holder will follow? What protection will the human holder be provided?

23. Please provide any other information that might be helpful to the Radiation Safety Officer and/or the Radiation Safety Committee.

CERTIFICATION: I certify that the work performed with the radiation producing machine(s) requested in this application will be done in accordance with the rules and regulations contained in 12VAC5-481, Radford University's Radiation Producing Machines Safety Manual, and in accordance with procedures specified in this application.

Primary Authorized
User Signature _____

Date _____

Approved by _____
(Radiation Safety Officer)

Date _____

Appendix C

Radiation Safety Training and Dosimetry Request Form

Radiation Worker Information

Full Name: _____ Today's Date: _____
RU ID#: _____ Date of Birth: _____ Sex: M F
Department: _____
Position Title: _____ RU Employment Status:
Telephone: _____ Faculty Staff Student
E-mail: _____ Adjunct Faculty Adjunct Staff
Supervisor Name: _____ Non-RU, Employer Name: _____

Radiation Safety Training Request

Type of Equipment to be Used (Select all that apply):

XRF XRD
Other (specify), _____

Dosimetry Request and Prior Dose History

Type of Dosimeter Requested (Select all that apply):

Whole Body
Radiation Type(s) Beta Gamma X-ray Neutron
Ring
Right Finger Left Finger, Small Medium Large
Radiation Type(s) Beta Gamma X-ray

Have you ever worn a radiation dosimeter other than at Radford? Yes No

If yes, provide the complete name and address of the employer and the time period employed.

Previous Employer Name: _____

Address: _____

Address 2: _____

City: _____

State: _____ ZIP: _____

Country: _____

Employment Dates From _____ to _____

I hereby authorize my previous employer to release my prior radiation exposure history to Radford University Department of Environmental Health & Safety.

Signature: _____ Date: _____

(RSO USE ONLY)

Date Radiation Safety Training Conducted: _____

Date Dosimetry Ordered: _____

Prior Dose History Received? _____

Appendix D

Declaration of Pregnancy

Please find in the following pages a copy of the USNRC Regulatory Guide concerning prenatal radiation exposure. Contact the Radiation Safety Officer if you have any questions.

NRC Regulatory Guide 8.13 Instruction Concerning Prenatal Radiation Exposure

A. INTRODUCTION

The Code of Federal Regulations in 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," in Section 19.12, "Instructions to Workers," requires instruction in "the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed." The instructions must be "commensurate with potential radiological health protection problems present in the work place."

The Nuclear Regulatory Commission's (NRC's) regulations on radiation protection are specified in 10 CFR Part 20, "Standards for Protection Against Radiation"; and Section 20.1208, "Dose to an Embryo/Fetus," requires licensees to "ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv)." Section 20.1208 also requires licensees to "make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman." A declared pregnant woman is defined in 10 CFR 20.1003 as a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

This regulatory guide is intended to provide information to pregnant women, and other personnel, to help them make decisions regarding radiation exposure during pregnancy. This Regulatory Guide 8.13 supplements Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure" (Ref. 1), which contains a broad discussion of the risks from exposure to ionizing radiation.

Other sections of the NRC's regulations also specify requirements for monitoring external and internal occupational dose to a declared pregnant woman. In 10 CFR 20.1502, "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," licensees are required to monitor the occupational dose to a declared pregnant woman, using an individual monitoring device, if it is likely that the declared pregnant woman will receive, from external sources, a deep dose equivalent in excess of 0.1 rem (1 mSv). According to Paragraph (e) of 10 CFR 20.2106, "Records of Individual Monitoring Results," the licensee must maintain records of dose to an embryo/fetus if monitoring was required, and the records of dose to the embryo/fetus must be kept with the records of dose to the declared pregnant woman. The declaration of pregnancy must be kept on file, but may be maintained separately from the dose records. The licensee must retain the required form or record until the Commission terminates each pertinent license requiring the record.

The information collections in this regulatory guide are covered by the requirements of 10 CFR Parts 19 or 20, which were approved by the Office of Management and Budget, approval numbers 3150-0044 and 3150-0014, respectively. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

B. DISCUSSION

As discussed in Regulatory Guide 8.29 (Ref. 1), exposure to any level of radiation is assumed to carry with it a certain amount of risk. In the absence of scientific certainty regarding the relationship between low dose exposure and health effects, and as a conservative assumption for radiation protection purposes, the scientific community generally assumes that any exposure to ionizing radiation may cause undesirable biological effects and that the likelihood of these effects increases as the dose increases. At the occupational dose limit for the whole body of 5 rem (50 mSv) per year, the risk is believed to be very low.

The magnitude of risk of childhood cancer following in utero exposure is uncertain in that both negative and positive studies have been reported. The data from these studies "are consistent with a lifetime cancer risk resulting from exposure during gestation which is two to three times that for the adult" (NCRP Report No. 116, Ref. 2). The NRC has reviewed the available scientific literature and has concluded that the 0.5 rem (5 mSv) limit specified in 10 CFR 20.1208 provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total lifetime risk of leukemia and other cancers associated with radiation exposure during pregnancy.

In order for a pregnant worker to take advantage of the lower exposure limit and dose monitoring provisions specified in 10 CFR Part 20, the woman must declare her pregnancy in writing to the licensee. A form letter for declaring pregnancy is provided in this guide or the licensee may use its own form letter for declaring pregnancy. A separate written declaration should be submitted for each pregnancy.

C. REGULATORY POSITION

1. Who Should Receive Instruction

Female workers who require training under 10 CFR 19.12 should be provided with the information contained in this guide. In addition to the information contained in Regulatory Guide 8.29 (Ref. 1), this information may be included as part of the training required under 10 CFR 19.12.

2. Providing Instruction

The occupational worker may be given a copy of this guide with its Appendix, an explanation of the contents of the guide, and an opportunity to ask questions and request additional information. The information in this guide and Appendix should also be provided to any worker or supervisor who may be affected by a declaration of pregnancy or who may have to take some action in response to such a declaration.

Classroom instruction may supplement the written information. If the licensee provides classroom instruction, the instructor should have some knowledge of the biological effects of radiation to be able to answer questions that may go beyond the information provided in this guide. Videotaped presentations may be used for classroom instruction. Regardless of whether the licensee provides classroom training, the licensee should give workers the opportunity to ask questions about information contained in this Regulatory Guide 8.13. The licensee may take credit for instruction that the worker has received within the past year at other licensed facilities or in other courses or training.

3. Licensee's Policy on Declared Pregnant Women

The instruction provided should describe the licensee's specific policy on declared pregnant women, including how those policies may affect a woman's work situation. In particular, the instruction should include a description of the licensee's policies, if any, that may affect the declared pregnant woman's work situation after she has filed a written declaration of pregnancy consistent with 10 CFR 20.1208.

The instruction should also identify who to contact for additional information as well as identify

who should receive the written declaration of pregnancy. The recipient of the woman's declaration may be identified by name (e.g., John Smith), position (e.g., immediate supervisor, the radiation safety officer), or department (e.g., the personnel department).

4. Duration of Lower Dose Limits for the Embryo/Fetus

The lower dose limit for the embryo/fetus should remain in effect until the woman withdraws the declaration in writing or the woman is no longer pregnant. If a declaration of pregnancy is withdrawn, the dose limit for the embryo/fetus would apply only to the time from the estimated date of conception until the time the declaration is withdrawn. If the declaration is not withdrawn, the written declaration may be considered expired one year after submission.

5. Substantial Variations Above a Uniform Monthly Dose Rate

According to 10 CFR 20.1208(b), "The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (a) of this section," that is, 0.5 rem (5 mSv) to the embryo/fetus. The National Council on Radiation Protection and Measurements (NCRP) recommends a monthly equivalent dose limit of 0.05 rem (0.5 mSv) to the embryo/fetus once the pregnancy is known (Ref. 2). In view of the NCRP recommendation, any monthly dose of less than 0.1 rem (1 mSv) may be considered as not a substantial variation above a uniform monthly dose rate and as such will not require licensee justification. However, a monthly dose greater than 0.1 rem (1 mSv) should be justified by the licensee.

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees and applicants regarding the NRC staff's plans for using this regulatory guide.

Unless a licensee or an applicant proposes an acceptable alternative method for complying with the specified portions of the NRC's regulations, the methods described in this guide will be used by the NRC staff in the evaluation of instructions to workers on the radiation exposure of pregnant women.

REFERENCES

1. USNRC, "Instruction Concerning Risks from Occupational Radiation Exposure," Regulatory Guide 8.29, Revision 1, February 1996.
2. National Council on Radiation Protection and Measurements, Limitation of Exposure to Ionizing Radiation, NCRP Report No. 116, Bethesda, MD, 1993.

APPENDIX: QUESTIONS AND ANSWERS CONCERNING PRENATAL RADIATION EXPOSURE

1. Why am I receiving this information?

The NRC's regulations (in 10 CFR 19.12, "Instructions to Workers") require that licensees instruct individuals working with licensed radioactive materials in radiation protection as appropriate for the situation. The instruction below describes information that occupational workers and their supervisors should know about the radiation exposure of the embryo/fetus of pregnant women.

The regulations allow a pregnant woman to decide whether she wants to formally declare her pregnancy to take advantage of lower dose limits for the embryo/fetus. This instruction provides information to help women make an informed decision whether to declare a pregnancy.

2. If I become pregnant, am I required to declare my pregnancy?

No. The choice whether to declare your pregnancy is completely voluntary. If you choose to declare your pregnancy, you must do so in writing and a lower radiation dose limit will apply to your embryo/fetus. If you choose not to declare your pregnancy, you and your embryo/fetus will continue to be subject to the same radiation dose limits that apply to other occupational workers.

3. If I declare my pregnancy in writing, what happens?

If you choose to declare your pregnancy in writing, the licensee must take measures to limit the dose to your embryo/fetus to 0.5 rem (5 millisievert) during the entire pregnancy. This is one-tenth of the dose that an occupational worker may receive in a year. If you have already received a dose exceeding 0.5 rem (5 mSv) in the period between conception and the declaration of your pregnancy, an additional dose of 0.05 rem (0.5 mSv) is allowed during the remainder of the pregnancy. In addition, 10 CFR 20.1208, "Dose to an Embryo/Fetus," requires licensees to make efforts to avoid substantial variation above a uniform monthly dose rate so that all the 0.5 rem (5 mSv) allowed dose does not occur in a short period during the pregnancy.

This may mean that, if you declare your pregnancy, the licensee may not permit you to do some of your normal job functions if those functions would have allowed you to receive more than 0.5 rem, and you may not be able to have some emergency response responsibilities.

4. Why do the regulations have a lower dose limit for the embryo/fetus of a declared pregnant woman than for a pregnant worker who has not declared?

A lower dose limit for the embryo/fetus of a declared pregnant woman is based on a consideration of greater sensitivity to radiation of the embryo/fetus and the involuntary nature of the exposure. Several scientific advisory groups have recommended (References 1 and 2) that the dose to the embryo/fetus be limited to a fraction of the occupational dose limit.

5. What are the potentially harmful effects of radiation exposure to my embryo/fetus?

The occurrence and severity of health effects caused by ionizing radiation are dependent upon the type and total dose of radiation received, as well as the time period over which the exposure was received. See Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Exposure" (Ref. 3), for more information. The main concern is embryo/fetal susceptibility to the harmful effects of radiation such as cancer.

6. Are there any risks of genetic defects?

Although radiation injury has been induced experimentally in rodents and insects, and in the experiments was transmitted and became manifest as hereditary disorders in their offspring, radiation has not been identified as a cause of such effect in humans. Therefore, the risk of genetic effects attributable to radiation exposure is speculative. For example, no genetic effects have been documented in any of the Japanese atomic bomb survivors, their children, or their grandchildren.

7. What if I decide that I do not want any radiation exposure at all during my pregnancy?

You may ask your employer for a job that does not involve any exposure at all to occupational radiation dose, but your employer is not obligated to provide you with a job involving no radiation exposure. Even if you receive no occupational exposure at all, your embryo/fetus will receive some radiation dose (on average 75 mrem (0.75 mSv)) during your pregnancy from natural background radiation.

The NRC has reviewed the available scientific literature and concluded that the 0.5 rem (5 mSv) limit provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total lifetime risk of leukemia and other cancers. If this dose limit is

exceeded, the total lifetime risk of cancer to the embryo/fetus may increase incrementally. However, the decision on what level of risk to accept is yours. More detailed information on potential risk to the embryo/fetus from radiation exposure can be found in References 2-10.

8. What effect will formally declaring my pregnancy have on my job status?

Only the licensee can tell you what effect a written declaration of pregnancy will have on your job status. As part of your radiation safety training, the licensee should tell you the company's policies with respect to the job status of declared pregnant women. In addition, before you declare your pregnancy, you may want to talk to your supervisor or your radiation safety officer and ask what a declaration of pregnancy would mean specifically for you and your job status.

In many cases you can continue in your present job with no change and still meet the dose limit for the embryo/fetus. For example, most commercial power reactor workers (approximately 93%) receive, in 12 months, occupational radiation doses that are less than 0.5 rem (5 mSv) (Ref. 11). The licensee may also consider the likelihood of increased radiation exposures from accidents and abnormal events before making a decision to allow you to continue in your present job.

If your current work might cause the dose to your embryo/fetus to exceed 0.5 rem (5 mSv), the licensee has various options. It is possible that the licensee can and will make a reasonable accommodation that will allow you to continue performing your current job, for example, by having another qualified employee do a small part of the job that accounts for some of your radiation exposure.

9. What information must I provide in my written declaration of pregnancy?

You should provide, in writing, your name, a declaration that you are pregnant, the estimated date of conception (only the month and year need be given), and the date that you give the letter to the licensee. A form letter that you can use is included at the end of these questions and answers. You may use that letter, use a form letter the licensee has provided to you, or write your own letter.

10. To declare my pregnancy, do I have to have documented medical proof that I am pregnant?

NRC regulations do not require that you provide medical proof of your pregnancy. However, NRC regulations do not preclude the licensee from requesting medical documentation of your pregnancy, especially if a change in your duties is necessary in order to comply with the 0.5 rem (5 mSv) dose limit.

11. Can I tell the licensee orally rather than in writing that I am pregnant?

No. The regulations require that the declaration must be in writing.

12. If I have not declared my pregnancy in writing, but the licensee suspects that I am pregnant, do the lower dose limits apply?

No. The lower dose limits for pregnant women apply only if you have declared your pregnancy in writing. The United States Supreme Court has ruled (in *United Automobile Workers International Union v. Johnson Controls, Inc.*, 1991) that "Decisions about the welfare of future children must be left to the parents who conceive, bear, support, and raise them rather than to the employers who hire those parents" (Reference 7). The Supreme Court also ruled that your employer may not restrict you from a specific job "because of concerns about the next generation." Thus, the lower limits apply only if you choose to declare your pregnancy in writing.

13. If I am planning to become pregnant but am not yet pregnant and I inform the licensee of that in writing, do the lower dose limits apply?

No. The requirement for lower limits applies only if you declare in writing that you are already

pregnant.

14. What if I have a miscarriage or find out that I am not pregnant?

If you have declared your pregnancy in writing, you should promptly inform the licensee in writing that you are no longer pregnant. However, if you have not formally declared your pregnancy in writing, you need not inform the licensee of your non-pregnant status.

15. How long is the lower dose limit in effect?

The dose to the embryo/fetus must be limited until you withdraw your declaration in writing or you inform the licensee in writing that you are no longer pregnant. If the declaration is not withdrawn, the written declaration may be considered expired one year after submission.

16. If I have declared my pregnancy in writing, can I revoke my declaration of pregnancy even if I am still pregnant?

3Yes, you may. The choice is entirely yours. If you revoke your declaration of pregnancy, the lower dose limit for the embryo/fetus no longer applies.

17. What if I work under contract at a licensed facility?

The regulations state that you should formally declare your pregnancy to the licensee in writing. The licensee has the responsibility to limit the dose to the embryo/fetus.

18. Where can I get additional information?

The references to this Appendix contain helpful information, especially Reference 3, NRC's Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure," for general information on radiation risks. The licensee should be able to give this document to you.

For information on legal aspects, see Reference 7, "The Rock and the Hard Place: Employer Liability to Fertile or Pregnant Employees and Their Unborn Children--What Can the Employer Do?" which is an article in the journal Radiation Protection Management.

You may telephone the NRC Headquarters at (301) 415-7000. Legal questions should be directed to the Office of the General Counsel, and technical questions should be directed to the Division of Industrial and Medical Nuclear Safety.

You may also telephone the NRC Regional Offices at the following numbers: Region I, (610) 337-5000; Region II, (404) 562-4400; Region III, (630) 829-9500; and Region IV, (817) 860-8100. Legal questions should be directed to the Regional Counsel, and technical questions should be directed to the Division of Nuclear Materials Safety.

REFERENCES FOR APPENDIX

1. National Council on Radiation Protection and Measurements, Limitation of Exposure to Ionizing Radiation, NCRP Report No. 116, Bethesda, MD, 1993.
2. International Commission on Radiological Protection, 1990 Recommendations of the International Commission on Radiological Protection, ICRP Publication 60, Ann. ICRP 21: No. 1-3, Pergamon Press, Oxford, UK, 1991.
3. USNRC, "Instruction Concerning Risks from Occupational Radiation Exposure," Regulatory Guide 8.29, Revision 1, February 1996.¹⁽¹⁾ (Electronically available at www.nrc.gov/NRC/RG/index.html)
4. Committee on the Biological Effects of Ionizing Radiations, National Research Council, Health Effects of Exposure to Low Levels of Ionizing Radiation (BEIR V), National Academy Press, Washington, DC, 1990.

5. United Nations Scientific Committee on the Effects of Atomic Radiation, Sources and Effects of Ionizing Radiation, United Nations, New York, 1993.
6. R. Doll and R. Wakeford, "Risk of Childhood Cancer from Fetal Irradiation," *The British Journal of Radiology*, 70, 130-139, 1997.
7. David Wiedis, Donald E. Jose, and Timm O. Phoebe, "The Rock and the Hard Place: Employer Liability to Fertile or Pregnant Employees and Their Unborn Children--What Can the Employer Do?" *Radiation Protection Management*, 11, 41-49, January/February 1994.
8. National Council on Radiation Protection and Measurements, Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus, or Nursing Child, NCRP Commentary No. 9, Bethesda, MD, 1994.
9. National Council on Radiation Protection and Measurements, Risk Estimates for Radiation Protection, NCRP Report No. 115, Bethesda, MD, 1993.
10. National Radiological Protection Board, Advice on Exposure to Ionising Radiation During Pregnancy, National Radiological Protection Board, Chilton, Didcot, UK, 1998.
11. M.L. Thomas and D. Hagemeyer, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1996," *Twenty-Ninth Annual Report, NUREG-0713, Vol. 18, USNRC*, 1998.⁽²⁾

REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this regulatory guide. A regulatory analysis prepared for 10 CFR Part 20, "Standards for Protection Against Radiation" (56 FR 23360), provides the regulatory basis for this guide and examines the costs and benefits of the rule as implemented by the guide. A copy of the "Regulatory Analysis for the Revision of 10 CFR Part 20" (PNL-6712, November 1988) is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW, Washington, DC, as an enclosure to Part 20 (56 FR 23360).

1. Single copies of regulatory guides, both active and draft, and draft NUREG documents may be obtained free of charge by writing the Reproduction and Distribution Services Section, OCIO, USNRC, Washington, DC 20555-0001, or by fax to (301)415-2289, or by email to <DISTRIBUTION@NRC.GOV>. Active guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5285 Port Royal Road, Springfield, VA 22161. Copies of active and draft guides are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

2. Copies are available at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-1800); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343

Radford University Form Letter for Declaring Pregnancy

This form letter is provided for your convenience. To make your written declaration of pregnancy, you may fill in the blanks in this form letter or you may write your own letter.

Declaration of Pregnancy

To: _____, Radiation Safety Officer

In accordance with Virginia's regulations at

12VAC5-481-710 Dose to an embryo/fetus,

I am declaring that I am pregnant. I believe I became pregnant in _____ (only the month and year need be provided).

I understand the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 500 millirem (5 millisievert), unless that dose has already been exceeded between the time of conception and submitting this letter. I also understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy.

(Your Signature)

(Your Name Printed)

(Date)

RSO Use Only

Date Declaration Received: _____

Date Fetal Dosimeter Ordered: _____

Date Fetal Dosimeter Delivered: _____