

THE UNIVERSITY OF AKRON

Radiation-Generating Equipment

Quality Assurance Program

INDEX

I.	Design of the Radiation-Generating Equipment Quality Assurance (QA) Program.....	1
A.	Purpose of the QA Safety Manual.....	1
B.	ALARA Goal.....	1
C.	Administrative Line of Authority.....	2
1.	Radiation Safety Officer.....	2
2.	Radiation Safety Committee.....	3
3.	UA Policy Governing Violations of Regulations.....	4
II.	Personnel Involved in the Use of Materials.....	5
A.	Authorized Investigators - Faculty.....	5
B.	Authorized Users - Staff, Students.....	6
C.	Ancillary Personnel.....	6
III.	Policies and Procedures.....	7
A.	Authorization of Radiation-Generating Equipment Locations.....	7
B.	Before Beginning the Use of Radiation-Generating Equipment in an Approved Area.....	8
C.	Use of Radiation-Generating Equipment	9
IV.	Safety Monitoring Program.....	9
A.	Personnel Dosimetry Program.....	10
B.	Pregnant Workers.....	12
C.	Laboratory Audits.....	12
V.	Accidents or Incidents Involving Radiation-Generating Equipment.	12
VI.	Forms.....	13
A.	Radiation-Generating Equipment Training Document.....	14
B.	Analytical Radiation-Generating Equipment Maintenance, Repair, and Alignment Report.....	15
C.	Temporary Alteration of Safety Devices Request Form.....	16
D.	Request for a Personal Dosimeter.....	17
E.	Radiation-Generating Equipment Biannual Safety Survey...	18

THE UNIVERSITY OF AKRON
RADIATION SAFETY PROGRAM

I. Design and Purpose of the Radiation-Generating Equipment Quality Assurance (QA) Program

A. Purpose of the QA Manual

This manual is designed to provide information to personnel and the general public regarding the structure of The University of Akron=s (UA) Radiation-Generating Equipment Quality Assurance Program. It presents those procedures adopted by the Ohio Department of Health (ODH) and the University as safe, reasonable, and enforceable. It is designed to conform to the applicable requirements set forth in Chapters 3701:1-38, 3701:1-66 and 3701:1-68 of the Ohio Administrative Code. These regulations can be accessed in draft, pending and final form via the internet at www.odh.state.oh.us. Additionally, copies of these regulations are on file in the Radiation Safety Office.

B. The ALARA Goal

The chief goal of the Radiation-Generating Equipment QA Program is to minimize the exposure to radioactive materials and their radiations to a level AS LOW AS IS REASONABLY ACHIEVABLE (ALARA). There are three objectives to an effective ALARA program.

1. To reduce occupational radiation exposure to levels reasonably achievable by means of good radiation protection, planning and practice.
2. To reduce radiation exposures to the general public to levels as low as is reasonably achievable.
3. Commitment of management to encourage good radiation safety planning, to establish and enforce radiation safety practice, and to remain vigilant to the goal of improving the Radiation Safety Program.

C. Administrative Line of Authority

1. Radiation Safety Officer (RSO)

The Radiation Safety Officer is vested with the responsibility and authority to administer and enforce the regulations of the Ohio Department of Health. The RSO has the full authority to immediately halt any activity judged to be a threat to health, safety, the environment, or a violation of ODH regulations, or the conditions of the radiation safety program. The RSO shall have free access to all areas on campus where radiation-generating equipment is located, used, or stored, and where radiation is produced. The RSO reports to the Vice President of Capital Planning and Facilities Management and performs the following duties:

- a. General surveillance of all health physics activities, including both personal and environmental monitoring.
- b. Furnishing consulting services to personnel at all levels of responsibility on all aspects of radiation protection.
- c. Reviewing and approving the credentials of all individuals who desire to use radiation-generating equipment.
- d. Reviewing and approving all procedures for the use of radiation-generating equipment to determine if the proposed work can be safely accomplished and in conducted in accordance with regulatory requirements.
- e. Controlling the receipt, delivery, transfer, and shipping of all radiation-generating equipment coming to or leaving the campus.
- f. Monitoring of all radiation-generating equipment capable of producing ionizing radiations.
- g. Instructing personnel in proper radiation safety procedures for the use of radiation-generating equipment.

- h. Approving all radiation-generating equipment acquisitions.
- i. Approving all internal transfers of radiation-generating equipment between authorized investigators.
- j. Maintaining an inventory of radiation detection equipment in proper working order and recalibrated on an annual basis.
- k. Maintaining a current inventory of radiation-generating equipment on campus.
- l. Maintaining permanent records of personnel occupational exposures
- m. Maintaining records of radiation-generating equipment surveys
- n. Performing annual audits of radiation-generating equipment facilities.
- o. Promoting the ALARA concept in all aspects of the Radiation Safety Program.

In case of a temporary absence from campus, the RSO shall empower the Assistant RSO, the Chairman of the Radiation Safety Committee, or another member of the committee with his duties and authority.

2. Radiation Safety Committee (RSC)

The Radiation Safety Committee shall be appointed by the Vice President for Capital Planning and Facilities Management. The Radiation Safety Officer (RSO) and the Vice President for Capital Planning and Facilities Management (or his designee) shall be non-voting members of the committee. At least three (3) faculty members, appointed from the faculties of the academic units which use radioactive materials or radiation-generating equipment, shall be voting members of the committee.

The Vice President for Capital Planning and Facilities Management may appoint other University personnel to the committee as non-voting observers.

The committee has the responsibility for overall administration of the Radiation Safety Program, and performs the following specific functions:

- a. Provides advice to the Vice President for Capital Planning and Facilities Management and RSO on policies and technical matters regarding radiation safety.
- b. Reviews periodic reports from the RSO on items such as monitoring, contamination, personal exposure, and regulatory changes.
- c. Conducts annual audits of the Radiation Safety Program to determine that all necessary functions are being performed at their required intervals, and all required records are intact.
- d. Reviews actions taken by the RSO against individuals committing significant violations of radiation safety regulations.
- e. Promotes the implementation of good ALARA practices in all aspects of the Radiation Safety Program.

The Chairman of the committee is designated backup for the RSO during any absence from campus. The Chairman has the authority to approve purchase requisitions, receive radioactive packages, and may be called upon to provide emergency response support.

3. University Policy Governing Violations of Regulations

Violations of safety regulations can range from incidental to life threatening. The RSO has the right to fully investigate a possible violation at any time. The RSO has the right to immediately terminate any activity found to be a threat to

health, safety, the environment, or a violation of the ODH regulations, or the conditions of the license

The RSO has the authority to make the final institutional decisions regarding violations of ODH or University of Akron regulations. The RSO will determine the severity of the violation and the appropriate prompt action to be taken. Those individuals committing serious violations or frequently violating safety standards will have their privilege to use radioactive materials revoked.

If necessary, individuals may appeal a decision to the Radiation Safety Committee or Vice President for Capital Planning and Facilities Management. In the event of a disagreement between the Committee or Vice President for Capital Planning and Facilities Management and the RSO, representatives of the ODH will be contacted to review the situation.

II. Personnel Involved in the Use of Radiation-Generating Equipment

This section discusses the requirements for participation in the Radiation Safety Program, and outlines the training and responsibilities of each person in the program.

A. Authorized Investigator - Faculty

All investigators who desire to use radiation-generating equipment or other forms of ionizing radiation, must provide to the RSO a summary of their past training and experience in the use of radiation-generating equipment. The RSO will either accept the credentials as sufficient or require them to complete a training program and pass a written examination.

Authorized investigators are responsible for the health and safety of all personnel in their laboratory. They must ensure that procedures used to accomplish the intended research goals are as safe as possible. They are responsible for:

1. Determining that all individuals working in their laboratory have completed the necessary training programs before beginning to use radiation-generating equipment.

2. Assuring that all personnel working in their laboratory are included in the personnel monitoring program if necessary.
3. Assuring that all postings, warning signs, and labels are appropriately displayed and kept current and accurate.
4. Notifying the RSO of any changes in the standard operating procedures for any and all the radiation-generating equipment
5. Notifying the RSO of any radiation safety related incidents or accidental exposures arising from the use of radiation-generating equipment.

The authorized investigator will explain the ALARA concept and the need to maintain exposures ALARA to all personnel under their supervision. The authorized investigator will review each planned use of radiation-generating equipment to ensure that doses will be kept ALARA. The investigator must also ensure that all personnel under their supervision, subject to occupational exposures, are trained and educated in good health physics practices and in maintaining their exposures ALARA.

B. Authorized Users - Visiting Faculty, Postdoctoral Fellows, Technical Staff, and Students.

All individuals who desire to use radiation-generating equipment or other forms of ionizing radiation must provide to the RSO a summary of their past training and experience in the use of radiation-generating equipment (see form on p . The RSO will either accept the credentials as sufficient or require them to complete a training program and pass a written examination.

Authorized users must work under the supervision of an authorized investigator. Authorized users will be responsible for setting up and completing their experiments in as safe a manner as possible. They shall report all unsafe or non-ALARA conditions to the authorized investigator responsible for that area or the RSO.

C. Ancillary Personnel

All ancillary personnel (e.g., safety, security, cleaning, maintenance, etc.) who enter laboratories containing radiation-generating

equipment will be trained on current policies and procedures at the beginning of their employment, and periodically updated thereafter. Ancillary personnel will be instructed in the ALARA philosophy and informed that the University is committed to its implementation

III. Policies and Procedures

A. Authorization of Radiation-Generating Equipment Locations

All rooms in which radiation-generating equipment is used or stored must be specifically approved for that purpose by the RSO. Approval will consider the type of equipment to be used and whether the preparation of a shielding design by a radiation expert is required.

All rooms approved for use of radiation-generating equipment must also be under the direct control and supervision of an authorized investigator. The investigator must accept full responsibility for the continual safe conditions in that laboratory.

Definitions: The ODH defines **areas** as follows:

1. Unrestricted Area – “any area, access to which is neither restricted nor controlled by the licensee or registrant.”
2. Restricted Area – “any area, access to which is limited by the licensee or registrant for the purpose of protecting individuals against undue risks from exposure to sources of radiation. Restricted area does not include areas used as residential quarters, but separate rooms in a residential building may be set apart as a restricted area.”
3. Controlled Area – “any area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee or registrant for any reason.”
4. Radiation Area – “any area accessible to individuals in which radiation levels could result in an individual receiving a dose equivalent in excess of 0.05 millisievert (0.005 rem) in one (1) hour at thirty (30) centimeters from the source of radiation or from any surface that the radiation penetrates.”

5. High Radiation Area – “any area accessible to individuals in which radiation levels could result in an individual receiving a dose equivalent in excess of one (1) millisievert or 0.1 rem in one (1) hour at thirty (30) centimeters from the radiation source or thirty (30) centimeters from any surface that the radiation penetrates.”
6. Very High Radiation Area – “any area accessible to individuals in which radiation levels could result in an individual receiving an absorbed dose in excess of five (5) Gy, or five hundred (500) rad, in one (1) hour at one (1) meter from a source of radiation or from any surface that the radiation penetrates. At very high doses received at high dose rates, units of absorbed dose, gray and rad, are appropriate, rather than units of dose equivalent, sievert or rem.”

B. Before Beginning the Use of Radiation Generating-Equipment an Approved Area

Before working with radiation-generating equipment, all personnel must be authorized as outlined in Section 2. The authorized investigator must contact the RSO and arrange for personnel radiation exposure monitoring, including bioassay, if necessary. The authorized investigator supervising the research project is responsible for the health and safety of all personnel on the project. The investigator must be certain that all requirements and preparations have been met before assigning someone to work with any radiation-generating equipment. All personnel must also know how to contact the RSO in the event of an emergency.

The RSO must approve all procedures and applications using radiation-generating equipment. The authorized investigator must establish standard operating procedure(s) for each and every application for which the radiation-generating equipment is used. Most equipment will be operated in accordance with the standard operating procedures of the equipment's manufacturer; however, any modifications to said procedures must be put into writing and disseminated to all authorized users. A copy of the standard operating procedure shall be maintained at the location of each radiation-generating instrument. The RSO will review the procedures to determine if they can be safely performed in accordance with the ALARA concept.

The RSO, or authorized designee, will perform a meter survey of all radiation-generating equipment at the time of installation or relocation. Additionally, radiation safety personnel will conduct an annual meter survey of all operational

radiation-generating equipment to ensure that they are functioning properly and that radiation exposure is maintained ALARA.

C. Use of Radiation-Generating Equipment

1. All radiation-generating equipment must be used and stored in designated areas approved by the RSO.
2. The use of radiation-generating equipment must be conducted in compliance with the standard operating procedure(s) established for each instrument.
3. Dosimeters (rings, film badges or both - as deemed necessary) must be worn while performing any functions for which they are required.
4. No authorized investigator or user may utilize radiation-generating equipment in an open-beam configuration unless he/she has been specifically trained to perform approved procedures - including maintenance, repair, calibration or alignment work - and when equipped with required survey meter(s), dosimeter(s) and any other designated personal protection equipment.
5. Each laboratory or area utilizing equipment capable of being operated in open-beam configuration for the purpose of conducting repair, maintenance, calibration or alignment work shall be equipped with a portable survey meter. The Radiation Safety Office will make available an appropriate survey meter to laboratories requiring same. All other laboratories may request a survey meter, which will be provided based on availability. Additionally, authorized investigators may request the services of the Radiation Safety Office to perform meter surveys of equipment as needed or desired.
6. Authorized investigators will conduct and document safety checks of radiation-generating equipment in accordance with the requirements set forth in ORC 3701:1-68 and 3701:1-66.

IV. Safety Monitoring Program

The goals of the monitoring program are to assure the safe working conditions for all personnel in restricted and unrestricted areas. Monitoring of laboratories and personnel helps to assure that individuals will not exceed their maximum permissible exposure limits, and that radiation levels remain as low as reasonably achievable (ALARA).

The RSO will maintain all required records of personnel occupational exposure histories and laboratory working conditions.

A. Personnel Dosimetry Program

UA contracts with accredited firms for a monthly radiation dosimetry program. The type of dosimeter selected – whole body badge; ring or wrist extremity device; or both – will be determined based on the potential area(s) of exposure and in accordance with the pertinent rules established of ORC 3701:1-38, 3701: 1-66 and 3701: 1-68.

The maximum permissible exposures for personnel are as follows:

MAXIMUM PERMISSIBLE DOSE LIMITS (Dose in Rem)

<u>Occupational Radiation Workers</u>	<u>Yearly</u>
Total Effective Dose	5.0
Deep Dose Equivalent or Committee Dose Equivalent to:	
Eye	15
Other organ	50
Shallow Dose Equivalent to:	
Skin	50
Each of Extremities	50
Pregnant Women	0.5
Members of the General Public	0.1

The annual occupational dose limits for minors are 10 percent of the annual dose limits specified for adults.

Prior to beginning work in which personal dosimetry is required, the RSO will determine whether the individual requesting the dosimeter has previously been employed at an institution where occupational radiation exposure was monitored. If so, the RSO will have the

individual complete a request form authorizing the previous employer(s) to release information regarding the individual's prior accumulated occupational dose.

The RSO will perform monthly reviews of occupational radiation exposures with particular attention to instances in which the investigational levels in the following table are exceeded:

Exposure Investigational Levels (mrem/month)

	<u>Level I</u>	<u>Level II</u>
Deep Dose Equivalent	20	200
Lens Dose Equivalent	60	600
Shallow Dose Equivalent	1,000	2,000

All reported exposures in excess of Level I will be conveyed to the individual as soon as they are detected. The RSO will attempt to determine the cause of the exposure and try to eliminate it. All reported exposures in excess of Level II will be immediately conveyed to the individual, the authorized investigator, and the Chairman of the RSC as soon as they are detected. If deemed necessary, a special meeting of the Radiation Safety Committee will be scheduled. All concerned will attempt to determine the cause of the exposure and take corrective measures. Corrective measures may include revision of standard operating procedures, construction of additional shields, implementation of additional ALARA measures, and/or suspension of the use of radiation-generating equipment by the individual.

Any exposures to radiation in excess of the limits established in ORC 3701:1-38-12 (A) (1) ((a -b) and (A) (2) (a-b) will result in the immediate cessation of all ionizing radiation activities conducted by the affected individual(s). An investigation into the cause(s) and circumstances resulting in an overexposure will be initiated immediately.

Notification of the State will be made in accordance with the requirements established in ORC 3701:1-38-21 (B) and (C).

All individuals have the right to examine their exposure reports at any reasonable time in the Radiation Safety Office. Future employers of the individual have the right to obtain a copy of their exposure history.

B. Pregnant Workers

A declared pregnant woman means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception. To ensure the health and safety of a developing fetus, the following steps shall be taken in the protection of declared pregnant workers.

1. Regulatory Guide 8.13 contains information which shall be presented, both orally and in writing, to the pregnant worker.
2. Reduced embryo/fetus dose limits outlined in 3701:1-38-12 will be implemented until the declared pregnant woman withdraws the declaration, in writing, or is no longer pregnant.

C. Laboratory Audits

The RSO and the RSC shall conduct an annual audit of all laboratories for the purpose of evaluating compliance with all requirements.

Copies of the RSC audit report will be provided to all RSC members. The RSC will review the findings following each audit and recommend appropriate ways to address any noted problems or deficiencies. The findings of the RSO audit will also be shared with the RSC.

V. Accidents or Incidents Involving Radiation-Generating Equipment

We are all human and occasionally make mistakes. There is no shame in reporting an accident or incident involving radiation-generating equipment. It is imperative that any suspected accidental radiation exposure(s) be reported immediately to the Radiation Safety Office. There is considerable hazard in NOT REPORTING an accident involving exposure to ionizing radiation.

Additionally, any and all incidents – mechanical or electrical problems, component failure, fires, etc. - involving radiation-generating equipment must be immediately reported to the authorized investigator responsible for the affected instrument(s). The authorized investigator is responsible for notifying the Radiation Safety Office of any issues involving the safety of the radiation-generating equipment. The RSO may de-authorize any individual failing to promptly report any emergencies involving radiation-generating equipment.

IV. Forms

- A. Radiation-Generating Equipment Training Document**
- B. Analytical Radiation-Generating Equipment Maintenance, Repair, and Alignment Report**
- C. Temporary Alteration of Safety Devices Request Form**
- D. Request for a Personal Dosimeter**
- E. Radiation-Generating Equipment Biannual Safety Survey**

Radiation-Generating Equipment Training Document

Part I. Radiation Hazards and Safety Training

I, the undersigned, received radiation safety training related to the proper operation of radiation-generating equipment on _____. The training included information on radiation hazards; equipment warning, safety, and interlock devices, or other needed precautions; exposure symptoms; and, incident reporting procedures. A copy of the materials covered and my competency test (required of all users as of 10/1/01) is available at the university=s radiation safety office.

(Trainee=s Name- Printed)

(Trainee=s Signature)

(Instructor=s Name-Printed)

(Instructor=s Signature)

Part II. Standard Operating Procedure

I, the undersigned, received training in the safe operating procedures for the equipment and applications specified hereafter. The training was provided on _____. A copy of the standard operating procedures for each piece of equipment and the associated application(s) is available at the site of the equipment. The instructor in signing this document verifies my competency in operating the equipment.

Equipment: _____.

- Application(s):
1. _____
 2. _____
 3. _____

(Trainee=s Name- Printed)

(Trainee=s Signature)

(Instructor=s Name -Printed)

(Instructor=s Signature)

**Analytical Radiation-Generating Equipment
Maintenance, Repair, and Alignment Report**

Date: _____

Instrument: _____

Application: _____

Procedure performed: Maintenance Repair Alignment

Description of Activity: _____

Radiation Source Off: Yes No

Safety Devices Altered: Yes No (If marked Yes, prior approval of the RSO, or acting designate, must be obtained before performing any procedure(s) where an external radiation beam is present. The temporary alteration approval form, available from the radiation safety office, must provide a description of the safety alteration(s) that are needed to perform the work and the length of time that the instrument will be operated in an open beam configuration. Once the signed approval form is obtained from the RSO, or designate, it must be posted near the instrument during the time the work is conducted, attached to this form after completion, and retained per the records retention requirements.

Date(s) that instrument was inoperable or out of service: _____

Person(s) Performing Procedure: _____

Radiation Survey Performed (see 3701-66-13, (C)(2)): Yes No

Person(s) Performing Survey: _____

Survey Results: _____

Survey Instrument(s):

<u>Model</u>	<u>Serial No.</u>	<u>Calibration Date</u>	<u>Background</u>
_____	_____	_____	_____
_____	_____	_____	_____

Temporary Alteration of Safety Devices Request Form

This form is required to be submitted to the RSO, or acting designate, and approved prior to the initiation of any maintenance, repair, and alignment procedure(s) on radiation-generating equipment that will be operated in an open-beam configuration with an external beam present. It must be posted near the instrument while the work is being performed, attached to the Maintenance, Repair and Alignment Report Form after completion of the work, and retained per the records retention requirements.

Date: _____

Instrument: _____

Application: _____

Procedure performed: Maintenance Repair Alignment

Safety Devices Altered: Interlocks disabled Shielding removed

Description of Alteration: _____

Date(s) and length of time that the instrument is to be operated in an open-beam configuration:

Person(s) Performing Procedure(s): _____

Approval of RSO (or acting designate): _____

Printed Name

Signature

Date

The University of Akron
Radiation Safety Office
32 S. College St. Bldg.
Akron, OH 44325-0607
Contact: Jason McNicholas, RSO
330-972-5712 (Tel.)
330-972-5711 (Fax)
jbm@uakron.edu (E-mail)

Request for Personal Dosimeter(s)

Date: _____

Name: _____
(Please print; not to exceed 16 characters including spaces)

SSN: _____ - _____ - _____

DOB (MM/dd/yy): ____/____/____

Type: Whole Body _____

Ring _____ Hand: Left _____ Size: S _____

Right _____ M _____

L _____

XL _____

Fetal _____

RADIATION-GENERATING EQUIPMENT BIENNIAL SAFETY SURVEY

Date: _____

Location: _____ Investigator: _____

Instrument Type: _____

Instrument Manufacturer: _____

Instrument Model No: _____ Instrument Serial No: _____

Instrument Application(s): _____

Instrument Status: Operational ____ In-operable ____

Safety Devices:

I. Lights (indicating power, x-ray generation, shutter, and interlock status as applicable):

Operational ____ In-operable ____ Corrective actions taken to address problem(s):

II. Labels (indicating radiation-generating capability of instrument):

Present ____ Missing ____ Corrective actions taken to address problem(s):

III. Interlocks:

Operational ____ In-operable ____ Corrective actions taken to address problem(s):

Qualified Individual Performing Safety Check: _____

(Name Printed)

(Signature)

(Date)