

X-ray Safety Plan

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I. Introduction, Purpose and Scope

A. Introduction

1. Exposures to high doses of radiation (~ 50 rem), particularly over a short period, are linked to immediate health effects (e.g., erythema and skin burns) and an increased risk of long-term health effects (e.g., cancer and birth defects). However, the effects of low doses of radiation are either nonexistent or too small to observe. The benefits from using X-rays in accordance with this University of Wyoming (UW) X-ray Safety Plan far outweigh any hypothetical health risk.

B. Purpose

1. Compliance with the radiation protection practices in this X-ray Safety Plan is required, in order for X-ray sources to be used without increasing health risks to workers, students or the public.

C. Scope

1. This plan applies to X-ray generating equipment owned and/or operated by University of Wyoming (UW) faculty, staff and students on the Laramie campus, regional campuses, and related facilities and operations.
2. This plan does not apply to radioactive sources that are licensed by the Nuclear Regulatory Commission (NRC). If a work area has both radioactive materials and X-ray equipment, the stricter of the two regulations shall apply. Refer to the UW Radiation Safety Plan.
3. Over and above the requirements specified in this X-ray Safety Plan, the following regulations also apply:
 - a. Wyoming Department of Workforce Services, Wyoming OSHA Commission: Chapter 26, Toxic and Hazardous Substances – Subpart Z. Incorporated by reference 29 CFR §§ 1910.1096 (Ionizing radiation), as it was in effect on June 8, 2016.
 - b. U.S. Food and Drug Administration: 21 CFR Part 1020 (Performance standards for ionizing radiation emitting products)
 - c. Wyoming Board of Radiologic Technologists: Rules & Regulations promulgated by authority under the Radiologic Technologist Examiners Practice Act W. S. 33-37-101

through 33-37-113

- d. University of Wyoming Regulations: UW Regulation 1-2 (Establishment of University Administrative Committees)
 - (1) §§ A. (Animal Care Committee)
 - (2) §§ H.(Institutional Review Board for Projects Involving Human Subjects)
 - (3) §§ J. (Radiation Safety Committee)

II. Radiation Device Acquisition and Maintenance

- A. The University Radiation Safety Committee (RSC) and the Radiation Safety Officer (RSO) must approve all uses of ionizing radiation at the University of Wyoming, including X-rays. See the UW Radiation Safety Plan, Operating Procedures for more details.
 - 1. Approvals for ionizing radiation devices by the Radiation Safety Committee are expressly for the protocols, equipment and personnel specified in the X-ray application. Any unauthorized uses or equipment constitutes a violation of University, State and Federal regulations.
 - 2. UW personnel wishing to acquire an ionizing radiation device shall first obtain a permit from the Radiation Safety Committee. This includes purchases as well as transfers of devices from other labs, departments or institutions.
 - 3. The RSO shall evaluate the health and safety implications of each purchase and ensure operating personnel can operate the equipment in a safe manner when the equipment arrives.
- B. These devices shall not be energized (i.e., produce X-rays) unless the operators have permission from the RSO and the Principal User.
- C. Proper management of ionizing radiation devices and their operators is the responsibility of the authorized Principal User, under whose permit the devices are being used. It is the responsibility of each authorized user to maintain safe use of the devices in their area.
- D. Ionizing radiation devices shall be certified by the manufacturer (as required by the FDA), upon installation, and periodically as recommended by the manufacturer. Service records must be maintained and available for inspection.

III. Radiation Protection Practices (Training, Monitoring and Shielding)

A. Training

1. Users of ionizing radiation devices shall be appropriately trained in radiation safety, equipment operation and applicable Federal and State Regulations prior to beginning work with the device. This training must be provided by or approved by the RSO.
2. All individuals working in or frequenting any portion of a restricted radiation area shall be informed of the existence of radiation sources in the area; and shall be instructed in the risks associated with exposure to such radiation, and in provisions, precautions or devices to minimize exposure.

B. Personnel Exposure Monitoring (Dosimetry)

1. Dosimetry is required for:
 - a. Each adult employee who enters a restricted area who is likely to receive a dose in any calendar quarter in excess of 25 percent of the applicable limits in Table 1;
 - b. Each employee under 18 years of age who enters a restricted area who is likely to receive a dose in any calendar quarter in excess of 5 percent of the applicable adult limits in Table 1; or
 - c. Each employee who enters a high radiation area.
2. Whole body dosimeters, extremity rings or area monitors may be issued to personnel using ionizing radiation devices, as determined by the RSO, in order to demonstrate that exposures to personnel and public are kept as low as reasonably achievable (ALARA).
3. If dosimetry is required, employees shall be advised of reports of radiation exposure, which employees may request pursuant to the regulations.
4. The Radiation Safety Office facilitates the distribution of dosimeters and maintain radiation exposure records.

C. Surveys.

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1. The Radiation Safety Office conducts X-ray equipment inspections and radiation exposure surveys. The Principal User shall coordinate with the RSO to ensure compliance with these inspection requirements.
2. Radiation surveys shall be performed:
 - a. Upon installation of the equipment;
 - b. At least once every 12 months thereafter;
 - c. Following any change in the initial arrangement, number or type of local components in the system;
 - d. Following any maintenance requiring the disassembly or removal of a local component in the system;
 - e. During the performance of maintenance and alignment procedures, if the procedures require the presence of a primary X-ray beam when any local component of the system is disassembled, or removed;
 - f. Any time a visual inspection of the local components in the system reveals an abnormal condition; and
 - g. Whenever personnel monitoring devices show a significant increase over the previous monitoring period, or when the readings approach occupational dose limits.

D. Shielding

1. The ionizing radiation device shall be located or shielded so that no radiation levels exist in any surrounding non-restricted area that could result in a dose to an individual present in excess of 100 millirem per year or 2 millirem in any 1 hour.
2. The Radiation Safety Committee may require the use of other special equipment or devices. This may include special shielding, alarms and warning devices, and other such apparatus.

IV. Occupational Dose Limits

- A. The limits for occupational exposure from ionizing radiation devices at UW are listed in Table 1 below.

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1. Dose limits notwithstanding, it is UW policy to use procedures and engineering controls based upon practical, sound, radiation protection principles to achieve occupational doses and doses to the public that are as low as reasonably achievable (ALARA).
 2. If an employee's dose exceeds the ALARA limits for the month (column 3), they will be requested to review procedures for ways to reduce future exposures.
 3. If occupational doses from radiation devices exceed the monthly average limits (column 2), the RSO will investigate the probable cause of the dose, possible exposure to non-monitored personnel or the public, and methods to reduce future exposures.
 4. The RSO must notify State and Federal authorities of any radiation exposure in excess of quarterly dose limits (column 1).
- B. No radiation-producing device shall emit radiation in such a manner as to create in any non-restricted area:
1. Radiation levels which could result in a dose in excess of 2 millirem (0.002 rem) in any one hour; or
 2. Radiation levels which, if an individual were continuously present in the area, could result in a dose in excess of 100 millirem (0.100 rem) in one year.

Table 1. Occupational Dose Limits (from 29 CFR 1910.1906) and University of Wyoming monthly ALARA limits

<u>Body Part</u>	<u>Col. 1 Calendar Quarter</u>	<u>Col.2 Monthly Average</u>	<u>Col.3 Monthly ALARA</u>
ADULTS:			
Dose to Whole Body: Head and trunk; active blood-forming organs; lens of eyes; or gonads	1.25 rem	0.416 rem	0.010 rem
Dose to Hands and forearms; feet and ankles	18.75 rem	6.25 rem	0.150 rem
Skin of whole body	7.5 rem	2.5 rem	0.060 rem

MINORS (under 18):

No employee under 18 years of age shall receive in any calendar quarter a dose in excess of 10 percent of the adult limits listed above.

DECLARED PREGNANT WOMEN

The exposure to an embryo/fetus during the entire gestation period, due to the occupational exposure of a declared pregnant woman, shall not exceed 0.5 rem. Exposure shall not vary substantially above an average uniform monthly exposure rate so as to satisfy this limit.

V. Signs and Posting

- A. The following signs or labels, carrying the approved radiation symbol, shall be conspicuously posted as indicated.
 - 1. **CAUTION - RADIATION AREA** - for accessible areas in which a major portion of the body could receive a dose in excess of 5 millirem in any 1 hour or in any 5 consecutive days a dose in excess of 100 millirem.
 - 2. **CAUTION - HIGH RADIATION AREA** - for accessible areas in which a major portion of the body could receive a dose in excess of 100 millirem in any 1 hour.
 - 3. **CAUTION - X-RAY EQUIPMENT** - for facilities containing X-ray equipment, but not meeting any of the above dose criteria.
- B. Each authorized user to whom this section applies shall conspicuously post a current copy of this plan and any other applicable operating procedures, or shall keep such documents available for examination by employees upon request.

VI. Security and Storage

- A. Each X-ray user must assure security of ionizing radiation devices. This requires either constant surveillance or locking of storage or facility doors and/or devices.
 - 1. All areas in which radiation devices are used shall have a sign displayed on all entrances as indicated above.
 - 2. Operating keys shall not be kept in the device when the device is not in active use.
 - 3. For portable X-ray equipment, refer to the additional storage requirements in section VIII.D.

VII. Special Rules for Analytical Cabinet X-ray Devices

- A. Analytical X-ray devices utilize x- or gamma radiation to determine the elemental composition or examine the microstructure of materials using diffraction or fluorescence analysis.
- B. Equipment Requirements
 - 1. The design and performance standards in this section are as recommended by the Conference of Radiation Control Program Directors (CRCPD).
 - 2. Each X-ray unit must have a safety device (interlock) that prevents the entry of any portion of an individual's body into the path of the active primary X-ray beam.
 - 3. The X-ray unit must also have a discernible indication of X-ray tube "on-off" status; shutter "open-closed" status; and an easily visible warning light labeled with the words "**X-RAY ON**", or similar words. Equipment should have fail-safe characteristics in the warning devices.
 - 4. Any unused ports shall be secured in the closed position, in a manner that will prevent casual opening.
 - 5. All analytical X-ray equipment shall be labeled near any switch that energizes an X-ray tube with a readily discernible sign bearing the radiation symbol and the words: "**Caution Radiation - This equipment produces radiation when energized.**"
 - 6. X-ray units shall be equipped with a shutter for each port on the radiation source housing that cannot be opened unless a collimator or a coupling has been connected to the port.
 - a. Each source housing shall be equipped with an interlock that shuts off the tube if it is removed from the radiation source housing, or if the housing is disassembled.
 - b. Each radiation source housing or port cover should be constructed so that, with all shutters closed, the radiation dose measured at a distance of 5 cm from its surface is not in excess of 2.5 millirem in one hour.
 - 7. Each X-ray generator shall be supplied with a protective generator cabinet that limits leakage radiation measured at a distance of 5 cm from its surface such that it is not capable of producing a dose in

excess of 0.25 millirem in one hour.

C. Operating Requirements

1. Normal operating procedures shall be written and available to all analytical X-ray equipment workers. No individual shall be permitted to operate analytical X-ray equipment in any manner other than that specified in the procedures unless such individual has obtained the written approval of the RSO.
2. No individual shall bypass a safety device or interlock, unless such individual has obtained the written approval of the RSO. Such approval shall be for a specified period of time. When a safety device or interlock has been bypassed, a readily discernible sign bearing the words "**Safety Device Not Working**", or similar words, shall be placed on the radiation source housing.
3. Except as described in the previous paragraph, no operation involving removal of covers, shielding materials, or tube housings, or modifications to shutters, collimators, or beam stops shall be performed without ascertaining that the tube is off and will remain off until safe conditions have been restored. The main switch, rather than interlocks, shall be used for routine shutdown in preparation for repairs.
4. If the X-ray device contains a radioactive source, replacement, leak testing, or other maintenance or repair procedures shall be conducted only by individuals specifically authorized under the University's NRC Byproduct Materials License.

D. Personnel Requirements

1. Personnel dosimeters (finger or wrist dosimeters) shall be used by:
 - a. Operators of analytical X-ray equipment having an open-beam configuration and not equipped with a safety device; and
 - b. Personnel maintaining analytical X-ray equipment if the maintenance procedures require the presence of a primary X-ray beam when any local component in the analytical X-ray system is disassembled or removed.

VIII. Special Rules for Portable X-ray Equipment Designed to be Held by Hand

A. Equipment requirements

1. The X-ray unit must have a discernible indicator of X-ray “on-off” status. These indicators should have fail-safe characteristics.
2. Handheld X-ray equipment shall be labeled with the radiation symbol and the words: “**Caution Radiation - This equipment produces radiation when energized.**”
3. No individual shall bypass X-ray safety features without the approval of the RSO.
 - a. If a safety feature is disabled, a readily discernible label bearing the words “Safety Device Not Working” shall be attached to the instrument.

B. Operating Requirements

1. All X-ray equipment users shall read and comply with equipment user manuals and/or other operating procedures.
2. Never aim the device at yourself or others.
 - a. Don’t place any part of the body in line with the X-ray beam.
 - (1) Never analyze samples held in a person’s hand.
 - (2) Do not analyze samples on a table if any part of a person’s body is underneath the table.
 - b. Whenever possible, operate the X-ray unit remotely, using stands, tables or other secure mechanical holders.
 - c. Use stands or clips to hold film cassettes or receptors.
3. All unauthorized spectators shall be outside the restricted area (e.g., ten feet in all directions) while the exposure is taken.
 - a. The dose in non-restricted areas shall be less than the limits for the general public, specified in section II.A.5. of this plan.
4. The sample should fully cover the main beam to minimize scatter.
 - a. If a sample is too small to cover the aperture completely,

use a test stand within an enclosure.

5. The RSO will determine if the use of dosimetry or additional shielding (such as lead aprons and gloves) are required.

C. Emergencies and damage to the instrument

1. Notify the RSO immediately about accidental exposures, or if the unit is damaged, lost or stolen.
2. Do not use the equipment if it is damaged or if any of the safety systems are not working.
3. The equipment should only be repaired/maintained by properly trained persons.
4. After it is repaired, the instrument must be checked by the RSO before it is returned to service.

D. Storage and security

1. Secure the instrument when not under direct supervision of authorized users.
 - a. When possible, use at least two sets of durable locks to prevent theft (e.g., locked box and locked room).
 - b. When transporting in a vehicle, secure the instrument in its carrying case and block and brace to prevent shifting.
2. The battery pack shall be separated from the instrument when not in use, in order to render the device inoperable.
3. Use a check-out procedure and log (name of person checking it out, destination, time out, time returned).

IX. Special Rules for Radiation Device Use on Humans

- A. Under University Regulation 1-2, section III.H, research that involves the participation of human subjects requires approval from the University Institutional Review Board (IRB). The Principal User applicant must submit a copy of the IRB approval to the Radiation Safety Committee before human-use radiation devices can be approved.

- B. The Wyoming Board of Radiologic Technologists must first license persons who apply ionizing radiation to human subjects.
 - 1. The use of ionizing radiation on humans shall be under the supervision of a practitioner licensed by the State of Wyoming. The practitioner shall provide a signed authorization only after verifying that only a licensed radiologic technician who is competent in the safe use of the device will operate the radiation device.

- C. Protection for Radiation Study Participants.
 - 1. Participants in research that involves exposure to ionizing radiation must be informed about the risks.
 - a. All participants must sign an informed consent form prior to being exposed to radiation. The operator must confirm that this has been done.
 - b. Applications for authorized use of ionizing radiation involves human subjects must include an example of the informed consent form and questionnaire that will be used.

 - 2. Pregnancy is of special concern and shall be addressed, if the study includes females of childbearing age.
 - a. Pregnant persons shall not be used as participants in studies involving exposure to ionizing radiation. A urine or blood (preferred) pregnancy test must be performed, if the participant is female and within childbearing age.
 - b. The informed consent form shall include information regarding the hazards of radiation exposure to the developing embryo/fetus. The Operator shall document the gender of the participant and, if female, whether or not the subject has been tested for pregnancy.
 - c. If pregnancy cannot be ruled out, the subject shall be

eliminated from the radiation study.

3. A record must be maintained of the name, gender and age of participants, the dates and types of scans, and the estimated participant dose.
 4. Before being used as a participant, it shall be determined whether a person has been exposed to radiation from any other research project in the past twelve months. Study participants shall not receive a radiation dose above background exceeding 100 millirem in 1 calendar year.
 5. Any questionnaires, consent forms and results from radiation tests are by definition medical records and therefore protected under OSHA and/or the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
 6. These participant protection rules apply to all persons exposed for the purposes of the research project, including not only test subjects, but also department employees, authorized users or other volunteers who are used as subjects only for operator training.
- D. The Principal User is responsible for maintaining the ionizing radiation device in the condition that it was installed, and consulting with the RSO on any changes in the device or facility design that may affect radiation exposure to subjects, the operators or other employees working in the area.
- E. No one except the study participant, the responsible physician, the operator or operators-in-training may be present in the radiation device facility during the radiation procedure without prior RSO approval.
- F. Operators are not authorized to hold or support any portion of the research participant's body during a radiation exposure.

X. Special Rules for Radiation Device Use on Animals

- A. Under University Regulation 1-2, Section III.A., research and teaching involving animal subjects requires approval from the Institutional Animal Care and Use Committee (IACUC). If the animal protocol includes ionizing radiation sources, the principle investigator should simultaneously provide a copy of the IACUC forms, as well as the detailed X-ray application, to the Radiation Safety Committee.

- B. As always, radiation doses to personnel and to members of the public shall be kept as low as reasonably achievable (ALARA). Protocols for animal X-rays should consider the following:
 - 1. Unless authorized by the RSO, the X-ray unit shall be operated remotely so that personnel can maintain a safe distance from the X-ray housing and primary beam, as determined by dose calculations and direct measurements.

 - 2. Personnel are forbidden to hold film cassettes or receptors in the path of the primary beam. Stands to hold such film must be utilized.

 - 3. Unless sufficiently justified by research protocol, personnel shall not hold the animals while being X-rayed. Whenever possible, the animal shall be sedated and/or secured by mechanical means.

 - 4. If the operator or animal handlers cannot maintain a safe distance from direct or scattered X-ray radiation, the RSO will determine if the use of dosimetry or additional shielding (such as lead aprons and gloves) are required.

 - 5. All unnecessary personnel shall be outside the restricted area while the exposure is taken. The radiation dose in non-restricted areas shall be less the limits for the general public, specified in section II.A.5. of this plan.

Appendix A. Glossary of X-ray Safety Terms

ALARA (Acronym for "As Low As Reasonably Achievable.")

Making every reasonable effort to maintain exposures to ionizing radiation as far below the dose limits as practical, consistent with the purpose for which the permitted activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations.

background radiation

Radiation from cosmic sources; naturally occurring radioactive materials, including radon (except as a decay product of source or special nuclear material), and global fallout as it exists in the environment from the testing of nuclear explosive devices. It does not include radiation from source, byproduct, or special nuclear materials regulated by the Nuclear Regulatory Commission. The typically quoted average individual exposure from background radiation is 360 millirems per year.

declared pregnant woman

A woman who is also a radiation worker and has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

dose

The quantity of ionizing radiation absorbed, per unit of mass, by the body or by any portion of the body. When the provisions in this document specify a dose during a period of time, the dose is the total quantity of radiation absorbed, per unit of mass, by the body or by any portion of the body during such period of time.

dosimeter

A small portable instrument (such as a film badge, thermoluminescent or pocket dosimeter) for measuring and recording the total accumulated dose of ionizing radiation.

exposure

A general term used loosely to express what a person receives as a result of being exposed to ionizing radiation.

extremities

The hands, forearms, elbows, feet, knees, legs below the knee, and ankles (permissible radiation exposures in these regions are generally greater than in the whole body because they contain less blood-forming organs and have smaller volumes for energy absorption).

high radiation area

Any area with dose rates greater than 100 millirems (1 millisievert) in one hour, 30 centimeters from the source, or from any surface through which the ionizing radiation penetrates. Areas at licensed facilities must be posted as "high radiation areas" and access into these areas is maintained under strict control.

millirem

One thousandth of a rem. (1 mrem = 10^{-3} rem)

radiation area

Any area with radiation levels greater than 5 millirems (0.05 millisievert) in one hour at 30 centimeters from the source or from any surface through which the radiation penetrates.

rem (Roentgen Equivalent Man)

A measure of the dose of any ionizing radiation to body tissue in terms of its estimated biological effect relative to a dose of 1 roentgen (r) of X-rays (1 millirem (mrem) = 0.001 rem). The relation of the rem to other dose units depends upon the biological effect under consideration and upon the conditions for irradiation.

restricted area

Any area access to which is controlled by the employer for purposes of protection of individuals from exposure to radiation or radioactive materials.

risk

In many health fields, risk means the probability of incurring injury, disease, or death. Risk can be expressed as a value that ranges from zero (no injury or harm will occur) to one (harm or injury will definitely occur).

shielding

Any material or obstruction that absorbs radiation and thus tends to protect personnel or materials from the effects of ionizing radiation.

unrestricted area

Any area access to which is not controlled by the employer for purposes of protection of individuals from exposure to radiation or radioactive materials.

X rays

Penetrating electromagnetic radiation having a range of wavelengths (energies) that are similar to those of gamma photons. X rays are usually produced by excitation of the electron field around certain nuclei. Although once formed, there is no difference in x rays and gamma photons; however, there is a difference in their origin. X rays are produced by shifts in the electrons between the rings outside the nucleus of an atom whereas gamma photons are produced by reactions within the nucleus of an atom.