**Radiation Safety Program**

**X-Ray Safety Plan**

**Table of Contents**

1. **Rules, Regulations and Responsibilities**
2. **Occupational Dose Limits**
3. **Radiation Device Acquisition (Purchase or Transfer)**
4. **Radiation Protection Practices (Training, Monitoring and Shielding)**
5. **Signs and Posting**
6. **Security and Storage**
7. **Special Rules for Analytical Cabinet x-ray Devices**
8. **Special Rules for Portable x-rays and x-rays on Animals**
9. **Special Rules for Medical (Human Use) Radiation Devices**

**Rules, Regulations and Responsibilities**

A. All uses of ionizing radiation at Montana State University whether from radioactive materials or radiation devices, must be approved by the University Radiation Safety Committee (RSC) and the Radiation Safety Officer (RSO).

B. 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 constitute a violation of University, State and Federal regulations.

C. In Montana, the Department of Labor Occupational Health & Safety Division, determines safe practices for sources of ionizing radiation that are not licensed by the Nuclear Regulatory Commission (NRC). This includes electron microscopes as well as analytical and medical x-ray devices.

* Montana has adopted the federal regulations on ionizing radiation as published by the Occupational Safety and Health Administration (OSHA) in 29 CFR 1910.1096.
* These regulations are similar, but not identical to those published by the NRC in CFR Title 10. If a work area has both radioactive materials and radiation producing devices, the stricter of the two regulations shall apply
1. Use of ionizing radiation on human subjects must be licensed by the State of Montana Board of Radiologic Technologists.
* Procedures involving ionizing radiation on humans shall be under the direction of a practitioner licensed by the State of Montana.
* Projects that involve the participation of human subjects require approval or exemption from the University Institutional Review Board (IRB).
* Projects that involve the participation of animal subjects require approval or exemption from the Institutional Animal Care and Use Committee (IACUC).

E. The Food and Drug Administration (FDA), Department of Health and Human Services, regulates the design and performance standards for ionizing radiation emitting products, including diagnostic and cabinet x-ray devices. Specifications are codified in 21 CFR Part 1020.

F. Proper management of ionizing radiation devices and their operators is the responsibility of the authorized Principal User, under whose permit the device is being used. It is the responsibility of each member of the laboratory to maintain safe use of the device(s) in their area.

G. Ionizing radiation devices shall be certified initially and periodically (as recommended by the manufacturer) thereafter by a qualified expert. Service records must be maintained and available for inspection. Additionally, radiation exposure surveys and surveys following repairs or changes are to be coordinated through the RSO. The Principal User shall register all ionizing radiation devices with the RSO to ensure compliance with these inspection requirements.

H. All machines and devices designed to produce x-rays or which produce x-rays incidentally shall be registered with the State of Montana Department of Public Health and Human Services every two years.

**Occupational Dose Limits**

1. The limits for occupational exposure from ionizing radiation devices at MSU are listed in Table 1 below.
* Dose limits notwithstanding, it is MSU 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).
* 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.
* If occupational doses from radiation devices exceed the monthly average limits (column 2), the Radiation Safety Officer will conduct an investigation into the probable cause of the dose, possible exposure to non-monitored personnel or the public, and methods to reduce future exposures.
* The RSO must notify State and Federal authorities of any radiation exposure in excess of quarterly dose limits (column 1).
* No radiation producing device shall produce radiation in such a manner as to create in any non-controlled area:

a. Radiation levels which could result in a dose in excess of 2 millirem (0.002 rem) in any one hour; or

b. 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.

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| **TABLE 1: Occupational Dose Limits (from 29 CFR 1910.1906) and Montana State University quarterly ALARA limits** |
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| **Body Part** | **Column 1 Calendar Quarter (29 CFR 1910.1906)** | **Column 2 Monthly Average (29 CFR 1910.1906)** | **Column 3 Monthly Average (ALARA)** |
| **Adults:** |
| *Dose to Whole Body* | 1.25 rem | 0.416 rem | 0.010 rem |
| *Dose to Hands, 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**: 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 (approximately .05 rem/month)  |

**Radiation Protection Practices (Training, Monitoring and Shielding)**

A. Training.

* Users of ionizing radiation devices shall be appropriately trained in radiation safety and 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.
* All individuals working in or frequenting any portion of a controlled radiation area shall be informed of the occurrence of radiation in the area; and shall be instructed in the safety problems associated with exposure to such radiation and in provisions, precautions or devices to minimize exposure.
* Montana State University ionizing radiation use training plan requires training for x-ray machine usage every three years.

B. Personnel Monitoring (Dosimetry).

* Dosimetry is required for:

a. Each adult employee who enters a controlled 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 controlled 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; and

c. Each employee who enters a high radiation area.

* 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.
* If dosimetry is required, employees shall be advised of reports of radiation exposure, which employees may request pursuant to the regulations.
1. Surveys.
* Unless specifically exempted by the RSC and RSO, each Principal User using radiation-producing devices shall have access to a functioning and calibrated survey instrument appropriate to the type and level of ionizing radiation used. Radiation surveys shall be performed:
1. Upon installation of the equipment;
2. At least once every 12 months thereafter;
3. Following any change in the initial arrangement, number or type of local components in the system;
4. Following any maintenance requiring the disassembly or removal of a local component in the system;
5. 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;
6. Any time a visual inspection of the local components in the system reveals an abnormal condition; and
7. Whenever personnel monitoring devices show a significant increase over the previous monitoring period, or when the readings approach occupational dose limits.

D. Shielding.

* The ionizing radiation device shall be located or shielded so that no radiation levels exist in any surrounding non-controlled area that could result in a dose to an individual present in excess of 100 mrem per year or 2 mrem in any 1 hour.
* 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.

E. Usage Log

* A log of usage logs including Max kVp, Max mA, date and duration of beam energization will be kept by AUs and the PI, with the ultimate responsibility of this document falling on the PI.

**Signs and Posting**

1. The following signs or labels, carrying the approved radiation symbol, shall be conspicuously posted as indicated:
* **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.
* **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.
* **CAUTION - X-RAY EQUIPMENT** - for facilities containing x-ray equipment, but not meeting any of the above dose criteria.

B. Radiation Safety shall also provide Emergency Notification placards that include telephone numbers for the Principal User, RSO and/or other emergency contact designee.

C. Each authorized user to whom this section applies shall conspicuously post a current copy of this manual and any other applicable operating procedures, or shall keep such documents available for examination by employees upon request.

**Security and Storage**

A. Each laboratory must assure security of ionizing radiation devices. This requires either constant surveillance or locking of laboratory doors and/or devices. All laboratory areas in which radiation devices are used shall have a sign displayed on all entrances as indicated above. Operating keys shall not be kept in the device when the device is not in active use.

**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

* The design and performance standards in this section are as recommended by the Conference of Radiation Control Program Directors (CRCPD).
* 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.
* 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.
* Any unused ports shall be secured in the closed position, in a manner that will prevent casual opening.
* 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**.**”**
* 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.
* 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. 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 mrem in one hour.
* 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 mrem in one hour.

C. Operating Requirements

* Normal operation 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.
* 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.
* 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.
* 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

* 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.

**Special Rules for Medical (Human Use) Radiation Devices**

A. 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 and before the ionizing radiation device(s) can be purchased.

B. The Montana Board of Radiologic Technologists must first license persons who apply ionizing radiation to human subjects. Contact the RSO if you require assistance with licensing radiologic technologists or technicians.

C. The use of ionizing radiation on humans shall be under the supervision of a practitioner licensed by the State of Montana. 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.

1. Protection for Radiation Study Participants. Participants in research that involves exposure to ionizing radiation must be informed about the risks. All participants must sign an informed consent form prior to being exposed to radiation. The operator must confirm that this has been done.
* 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.
* 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.

* A record must be maintained of the name, gender and age of participants, the dates and types of scans, and the estimated participant dose.
* 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 mrem in 1 calendar year.
* 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).
* 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.
1. 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.

F. 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.

G. Operators are not authorized to hold or support any portion of the research participant’s body during a radiation exposure.

**Special Rules for Portable X-rays and X-rays on Animals**

1. Under University regulations 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. This is so that approval from both committees can occur before veterinary radiation devices are acquired.
2. 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:
* 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.
* “Portable” x-ray equipment shall not be held by operators while the unit is energized. Stands, tables or other secure mechanical holders shall be used. The useful beam shall be collimated to avoid unnecessary scatter.
* Personnel are forbidden to hold film cassettes or receptors in the path of the primary beam. Stands to hold such film must be utilized.
* 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. Declared pregnant personnel and individuals under the age of 18 should not be used to support or hold animals during x-ray exposure.
* 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.
* All unnecessary personnel shall be outside the room during the exposure. The radiation dose in non-controlled areas shall be less the limits for the general public, specified in table I of this manual.