SOUTHWESTERN UNIVERSITY

Radiation-Producing Equipment Policy

Introduction

The purpose of this policy is to ensure that Southwestern University research personnel and study participants work safely with machines that produce ionizing radiation and comply with all Federal and State regulations.

Radiation producing equipment can include:

- Bone Densitometry or dual-energy x-ray absorptiometry (DEXA or DXA)
- X-ray diffraction (XRD), x-ray fluorescence (XRF), x-ray photo spectroscopy (XPS) or any other applications with x-ray tubes
- Radiographic imaging for human and non-human use

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

The goal of this policy is to assist all individuals in complying with Texas Department of State Health Services (DSHS) radiation regulations . This policy sets forth controls and safety guidance for research and educational activities involving X-ray machines and other radiation producing machines. The procedures herein are consistent with the Texas DSHS regulations in the Texas Administrative Code (Title 25 Part 1 Chapter 289). Where existing or future federal, state, local regulations or SU policies are found to be different from the requirements contained in this manual, those legally accepted regulations shall supersede this document.

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).

Radiation Safety Officer (RSO)

Texas DSHS regulations require a Radiation Safety Officer for the institution. The RSO must be willing to fulfill the duties and accept the responsibilities of a RSO as required in 25 (TAC) 289.226, 232, or 233 as applicable. SU's RSO must be approved by the DSHS (Form RC42-3).

The SU RSO (Dr. Ed Merritt, Dept. of Kinesiology, merritte@southwestern.edu) is responsible for ensuring that all radiation-producing devices in use are currently registered and compliant with the DSHS (Form RC204).

X-ray Use Application

All X-ray machines and other ionizing radiation producing devices must be registered with Texas DSHS. The RSO handles this process and manages all X-ray machines and radiation producing devices on the campus.

A new Authorized User (AU) must obtain and submit to the RSO a "Registration Application for designated primary responsible operators of Radiation Machines" (RC 226-2) from the Texas DSHS. The application must be filled out completely and the standard operating procedures (SOP) for the equipment must accompany the application when it is submitted to the RSO. Anyone not listed on the application must not be allowed to manage x-ray machine usage. The RSO will review the application and the SOP and submit to the DSHS. After DSHS approval, a post-installation survey must be conducted by the RSO and a licensed radiological physicist prior to normal operations. AUs must notify the RSO of the X-ray installation date.

Our Certificate of X-Ray registration number for the DEXA X-Ray machine located in Kinesiology Lab - Fondren-Jones Science Building is: R45881 with a start date of September 30, 2019 and expiration of September 30, 2027. DSHS (Form 289.204). Renewal fee of $200 is due every two years to maintain radiation license (certificate). Schedule of current fees can be found at DSHS (Form RC 204). Renewal due by September 30, 2021.

Receipt, Installation, and Records

X-ray Receipt

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 and a computerized automatic log if available

Post-Installation Survey

State certified, third party radiation safety personnel will inspect the X-ray machine setup in addition to the manufacturer's installation records before operation begins to assure radiation safety prior to X-ray machine use. All safety devices must be installed and verified to be operational. The X-ray machine must not be operated without the final approval of the RSO. A post-installation survey must also be conducted following relocation, machine modification, other changes made to the machine, or if the machine's quality control or calibration fails. The AU may only turn on the X-ray machine for testing during the initial setup, and must notify the RSO when it is ready be operated. Within 30 days of installation, as per the state's requirements, a licensed radiological physicist must inspect the machine. The physicist will measure the radiation levels from the machine and in the surrounding area including adjacent rooms. His report must be sent to the state prior to the DSHS granting a license for use. All necessary signage and regulatory postings must be posted during or after the post-installation survey.

Installation of the DEXA X-Ray machine in the Kinesiology Lab, Fondren-Jones Science and DSHS inspection was completed on August 22, 2019.

Location

The location of the equipment will depend on the type of machine, but all locations must be approved by the RSO and Safety and Risk Management prior to installation. Equipment should not be located in a room occupied by faculty, staff, or students during operation. Radiation levels in adjoining rooms/offices must be measured while the machine is in use. This measurement will be accomplished at SU by using thermoluminescent dosimeter badges. An X-ray system must be located away from heavy traffic areas and must provide sufficient shielding such that no radiation levels exist in any area outside the X-ray use area, restricted area, above 2 mrem in any one hour or 50 mrem in a year above the background (to be determined by control dosimeter in lab at six month or one year intervals). For reference, the average natural background radiation dose (non-medical exposure) is approximately 310 mREM per year. An AU or designated primary responsible operator should monitor routinely for stray or scattered radiation in the immediate vicinity of the X-ray machine with an appropriate survey meter if applicable (SU does not monitor with real time meter for the DEXA machine since it produces such a low dose - area dosimetry badges will be utilized to measure for stray or scattered radiation at pre-determined locations - see floor plan for specific locations).

Each area or room containing X-ray machines or ionizing radiation producing devices shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words “CAUTION - X-RAY” or words having a similar intent.

If the DEXA X-Ray machine is to be relocated from its current position, a new DSHS inspection by a Radiological Physicist must be conducted and approved. This will be overseen by the RSO.

Security

Radiation machines shall be secured from unauthorized removal or use. Security devices and/or administrative procedures shall be used to prevent unauthorized use of X-ray machines or radiation producing machines.

Record of Use

Unless the X-ray machine is solely used by the AU or a computerized automatic log is available, designated primary responsible operators must record every time the X-ray is used. This record includes at least the date, and time, name, and purpose. Designated primary responsible operators and any other AUs in the room must wear dosimeter badges anytime the machine is in use.

X-ray Procurement Procedures

X-ray machines and other ionizing radiation producing devices must be ordered through the SU Business Office and the purchase requisitions must be submitted to the RSO for approval prior to submitting to the Business Office. Transferred and donated machines must also receive prior approval by the RSO in compliance with applicable regulations to ensure they can be installed and operated safely at SU. During this process, the RSO verifies that AUs are authorized for X-ray machine use at SU, the current registration information for the X-ray machine, current user/organization information, etc.

X-ray safety devices, such as shielding and interlocks (if applicable) should be purchased and installed along with the X-ray machine if they do not come with the unit. Without installing required safety devices, X-ray machines will not be approved for use on the campus.

Purchase order information must include:

- X-ray machine information such as type, Model and Serial number, power, etc.
- Brief machine description or copy of technical specification sheet/manual
- Name of the AU who will be responsible for the X-ray machine operation
- Address for shipment delivery (X-ray machine must be delivered to proposed installation location directly)

Basic X-ray Safety Guidelines

General Safety 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.

X-ray User Training to obtain "Designated Primary Responsible Operator" Status
All designated primary responsible operators are required to complete SU X-ray radiation safety training and annual refresher trainings thereafter. Individuals will complete training and demonstrate competence with the items in §289.228(g)(1) and 289.229(f)(4). The initial training by the RSO will provide basic radiation physics, and information on X-ray types, hazards, regulations and policies. After the initial X-ray safety training, all designated primary responsible operators must receive training from the AU for the specific X-ray machine that includes the SOP for the X-ray machine, system failures or other unusual conditions recognition. It is the AUs responsibility to keep training records for all designated primary responsible operators.

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 designated primary responsible operators. 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. No one is permitted to operate X-ray machines or radiation producing machines in any manner other than that specified in the procedures, unless that person has obtained written approval of the RSO. No one is allowed to bypass a safety device except an AU and/or designated primary responsible operator for alignment, maintenance, and other permitted activity approved by the RSO. When a safety device has been bypassed, a readily discernible sign bearing the words "SAFETY DEVICE NOT WORKING," or words having a similar intent must be placed on the radiation source housing or radiation producing machines. All designated operators should minimize their exposures to keep their occupational doses As Low As Reasonably Achievable (ALARA). As recommended by the Occupational Safety and Health Administration, no individual, AU or otherwise, should be exposed to more than 50 mSv/year or 5,000 mREM per year. Certified and closed unit X-ray machines should have enough shielding to reduce radiation level below 2 millirem (mrem) per hour or 0.02

milliSieverts (mSV) per hour during operation. Our method to measure and determine radiation exposure levels is to conduct both area and personal dosimetry badge monitoring and calculate per hour dose based on scans conducted and total scan time. X-Ray (DEXA) operator will wear a personal dosimetry badge each time a scan is conducted. In addition, an area badge will be fixed to the DEXA table to simulate research subjects' exposure and to calculate the average radiation dose per scan to compare to the manufacturers claim of < 6 uSV/scan or 0.6 mREM/scan. The total dose will be divided by the total number of scans to yield a per scan dose. If the shielding is not sufficient to maintain the radiation level below the 2 mREM per hour from the surface where any person can have access, the AU must contact the RSO and Safety & Risk Management 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. The RSO will consult with and review all dosimetry results (upon receipt) with the Safety & Risk Management Office.

Personnel Requirements

No one is permitted to operate the radiation machine unless they have received X-ray safety training, specific X-ray training, and demonstrated competence with the operating and safety procedures for the X-ray machine. After receiving training, these "designated operators" must be able to recognize radiation warning signs and safety devices incorporated into the equipment and the room, recognize radiation hazards, and acknowledge X-ray safety manual and the SOP for the machine.

The AU/RSO must provide and document specific training on the use of the X-ray machine to all X-ray designated primary responsible operators prior to being authorized to operate the specific device. A current SOP must be maintained near the X-ray machine and also acknowledged by all designated primary responsible operators.

Personnel Monitoring and Equipment Survey Program

Radiation badges are needed for primary designated operators of X-ray diffraction machines and other such potentially high exposure units. In addition, AU can request dosimeters for his/her designated operators if necessary even if they are not primary designated operators and no potential exposure above 10 percent of the regulatory limits of 5,000 mREM per year (500 mREM/year). Dosimeters used will be thermoluminescent badges. The vendor selected to provide and analyze dosimeter badges is: Radiation Detection Company (Radetco), 3527 Snead Dr. Georgetown, TX 78626, (512) 831-7000. Radetco is NVLAP accredited and certified to ISO 90001.

Dosimeters will be placed in selected locations to determine exposure dose - see attached floor plan. Dosimeters are exchanged annually unless an AU, RSO or Safety & Risk Management Office suggests that more frequent exchange is needed. Upon initial startup of the X-Ray machine (DEXA), SU will send out for analysis on a six month basis. Survey meters are required for potential high exposure units. State certified, third party radiation safety personnel conduct required inspections of all X-ray machines at the initial setup, after modifications, calibrations, and moving. Third party radiation safety personnel also perform annual routine inspections and exposure surveys of the X-ray machines. The RSO has the responsibility to oversee personnel monitoring (dosimetry), equipment survey, and inspections.

Signage & Postings

Required "Notice to Employees" signs will be posted in locations as required by DSHS (RC203-1). Postings must be visible at all times. A "Caution Safety Device Not Working" sign must be used whenever the interlocks are bypassed such as during or after alignments, maintenance, and equipment changes, and all designated primary responsible operators of the X-ray must be notified. When the X-ray is back to normal operating condition, an AU or a designated primary responsible operator must verify all safety devices are operational including interlock and warning lights. If discovered that the safety devices are not working, designated primary responsible operators must notify the AU or designated primary responsible operator and the RSO immediately.

Engineering Protection Systems

All interlocks and fail safe lighting must be maintained and inspected at each operation of the X-ray machines and must be documented on the log book.

High Voltage Hazards

The high voltage power supply of X-ray machines can be particularly hazardous. Personnel must never tamper with high voltage equipment. Only properly trained personnel are permitted to install, repair, or modify high voltage equipment.

Research Participants

Study participants examined using any radiation producing device must be at least 18 years old. All research study procedures must be approved by the SU Institutional Review Board (IRB).

Records

Certain records are required to be maintained by all X-ray AUs and readily available for Texas DSHS inspections. All records should be maintained in one central location in the lab. The RSO is responsible for insuring record keeping requirements are met by each AU. 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

Additionally, AUs and the RSO will notify the IRB, Safety and Risk Management Office (CC: Dean of Faculty and VP Finance and Administration) for the following:

- Radiation safety license/equipment registration status and updates
- Dosimetry survey reports and assessments
- Complaints or concerns raised

Emergency Response

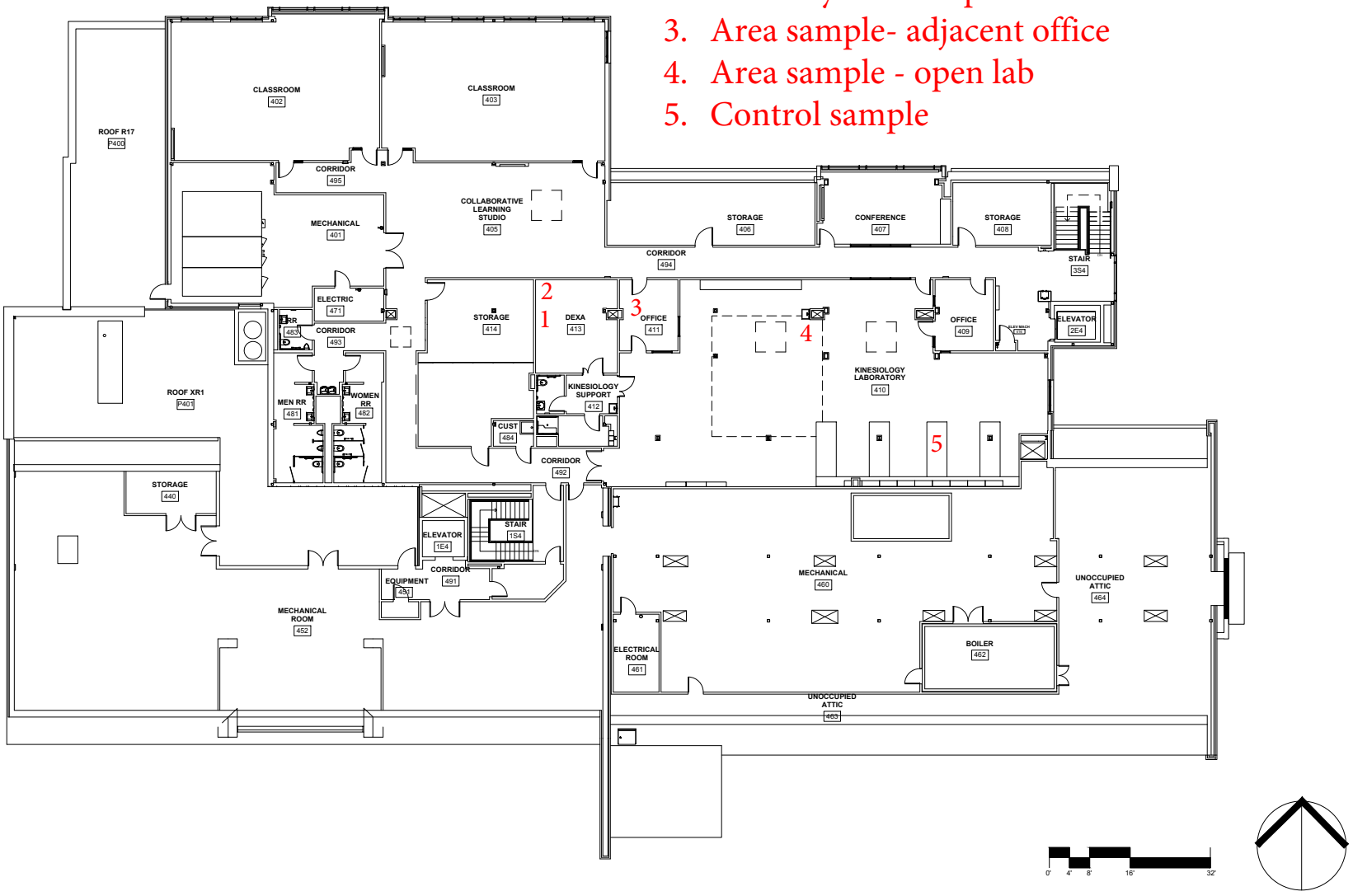
Radiation exposure by X-ray incidents may require medical attention and reporting to the DSHS. All events may raise exposure with potentially increased dose to the X-ray designated primary responsible operators and members of the public. Each incident must be carefully evaluated before proceeding and approached properly to prevent additional exposure.

General Procedures

- Immediately shut off the machine.
- Notify all personnel in the room.
- Notify the AU, the RSO and Safety & Risk Management Office
- If suspected exposure is high, seek medical attention immediately

Dosimeter

1. Fixed to the DEXA table
2. Worn by DEXA operator
3. Area sample- adjacent office
4. Area sample - open lab
5. Control sample



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