X-RAY SAFETY PLAN

THE UNIVERSITY OF TEXAS AT SAN ANTONIO

OFFICE OF RESEARCH INTEGRITY

LABORATORY SAFETY DIVISION
This X-ray Safety Plan for Radiation machines has been reviewed for regulatory compliance and best management practices by the undersigned individuals and is hereby adopted for use and compliance by all employees at The University of Texas at San Antonio.

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<tr>
<th>PRINTED NAME</th>
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<tr>
<td>Amanda Haley, Ph.D</td>
<td>Sr. Director of Laboratory Safety and Compliance</td>
<td>12/4/2020</td>
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<tr>
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This plan was reviewed/revised on 12/4/2020 and replaces the 10/11/19 version which took effect as of October 2019.

Changes to this plan are minor and have been highlighted in “gray” and are summarized below by section:

i. Changed signature page info.

iii. Changed contact phone number.

V.F.4 Special Considerations for Handheld X-ray Device Users

V.I Added UTSA safety training course name and requirement

VI.E.3 Changed contact for X-ray certificate information.
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iii. EMERGENCY TELEPHONE NUMBERS

ROUTINE OFFICE HOURS

Radiation Safety Officer ................................................................. 458-5807
Laboratory Safety Division .............................................................. 458-8515

AFTER-HOURS

UTSA POLICE .................................................................................. 458-4242

LIFE-THREATENING EMERGENCIES

UTSA POLICE (UTSA phone) ......................................................... 911

UTSA POLICE (cell phone) ........................................................... 458-4911

Routine Contact

In case of incidents involving unusual radiation exposure, all personnel are required to notify the Radiation Safety Officer immediately.

After 5:00 pm and on weekends, UTSA Police will assist in contacting Radiation Safety Personnel.
I. OVERVIEW

This plan contains guidelines to assist in complying with the regulation established by the state and federal governments for the possession and use of radiation machines at the University of Texas at San Antonio (UTSA). These regulations are written to provide protection against exposure to ionizing radiation resulting from the use of radiation machines. These regulations refer to X-ray devices, Medical X-ray devices or X-ray producing machines as radiation machines and this terminology will be used throughout this plan.

A person who receives, possesses, uses, owns or acquires radiation machines must ensure the machines are added to UTSA’s certificate of registration and is subject to the requirements of this plan as well as all pertinent Texas Department of State and Health Services (TXDSHS) regulations.

II. SCOPE

This plan applies to persons who receive, possess, use, or transfer radiation machines at UTSA. The dose limits in this plan do not apply to doses due to background radiation, to exposure of patients to radiation for the purpose of medical diagnosis or therapy, or to voluntary participation in medical research programs. However, no radiation may be deliberately applied to human beings except by or under the supervision of an individual authorized by and licensed in accordance with Texas' statutes to engage in the healing arts. Medical research programs must be approved by the Institutional Review Board (IRB) and the Texas Department of State Health Services (TXDSHS) as well as the Radiation and Laser Safety Committee (R&LSC).

IV. X-RAY SUBREGISTRATION APPLICATION

All x-ray machines and ionizing radiation producing devices must be registered with the TXDSHS under UTSA’s x-ray registration.

III. PERIODIC REVIEW

The contents of this plan will be reviewed whenever relevant sections of the Texas Administrative Code on the use of radiation machines are changed and whenever internal policies mandate a review. A review must be completed no less than once every three years.

IV. RESPONSIBILITIES

A. RESPONSIBILITIES OF THE RADIATION SAFETY OFFICER (RSO) INCLUDE:

1. Reviewing all proposals for use of radiation machines; and approving or disapproving them in conjunction with the R&LSC.

2. Inspecting facilities and equipment.

3. Prescribing special conditions and requirements as necessary for safe and proper use of all radiation machines.

4. Acting as a consultant in the design of all new facilities using radiation machines.

5. Supervision of the UTSA training courses on x-ray and radiation safety.

7. Performing radiation surveys and monitoring all facilities in which radiation machines are used or located. Surveys include, but are not limited to radiation level, record checks and interlock tests.

8. Providing personnel monitoring services, including the reviewing and recording of commercially processed dosimeter reports as required by the regulations or deemed advisable by university policy.

9. Ensuring that safety guidelines and requirements are followed in the laboratories utilizing radiation machines.

10. Maintaining proper labeling and signage in areas where radiation machines are operated.

11. Preparing registration applications, amendment applications, and required reports as well as acting as the contact point for all correspondence with State and Federal radiation health agencies.

12. Investigating unusual radiation exposures, incidents, and accidents and reporting corrective action to the principal investigator, supervisory personnel, and R&LSC.

B. RESPONSIBILITIES OF PRINCIPAL INVESTIGATORS AND SUPERVISORY PERSONNEL

Members of the faculty or staff supervising the work of others, either in a teaching capacity, as a principal investigator, or in an administrative supervisory position, are responsible for ensuring that those under their supervision:

1. Verification of the individual responsibilities per section IV.c. of this plan.

2. Receive appropriate orientation and training as to the proper and safe use of the particular radiation machine(s) before operation.

3. Have knowledge of the harmful effects of radiation to which they may be exposed.

4. Are instructed in safe techniques, such as, the application of approved radiation safety practices and the proper use of radiation detection instruments.

5. Have thorough knowledge of this plan.

They are further responsible to ensure that:

1. All radiation machines under their control have been properly approved by the RSO and/or the R&LSC and that all potential hazards are brought to the attention of the Radiation Safety Personnel (RSP).

2. Appropriate radiation surveys are conducted if required such as following transfer or repair.

3. All necessary records are maintained.

4. RSP are notified when new personnel are added or (in advance) when personnel under their supervision terminate or conclude activities that involved radiation machines.

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5. Local laboratory safety procedures are established, with the assistance of RSP if necessary and approved by the R&LSC.

6. Prepare and maintain written laboratory procedures for operating any radiation machine particular to their lab and provide a copy to RSP and/or R&LSC for prior approval.

7. Those directly or indirectly under their supervision are provided equipment and training as required for their specific location and use.

C. RESPONSIBILITIES OF INDIVIDUAL LABORATORY USER

Individuals are responsible for:

1. Following safety procedures and practices in this plan and any additional ones established for the specific laboratory or radiation machine.

2. Keeping exposures to radiation as low as reasonably achievable (ALARA).

3. Wearing appropriate dosimetry as required and strictly following the regular badge change schedule.

4. Immediately reporting to RSP any suspected exposure in excess of permissible limits.

5. Furnishing information to the RSP concerning new activities in their area, particularly alterations of operations that might lead to personnel exposures.

6. Performing appropriate surveys for external radiation if required, and maintaining records of results or requesting assistance from RSP.

7. Contacting the RSO at least ONE WEEK before terminating employment or association with UTSA.

8. Assuring that acquisitions and transfers of radiation machines are made in accordance with the provisions of this plan.

9. Read and be knowledgeable about the lab procedure for operating radiation machines particular to the lab they work in.
V. THE USE OF RADIATION MACHINES

A. REGULATIONS

All radiation machines are regulated by state and federal laws enforced by the Texas Department of State Health Services (TXDSHS) and the Food and Drug Administration (FDA). UTSA will comply with the regulations as listed on the registration from TXDSHS. The listed Texas Administrative Code sections are: §289.203, .204, .205, .226, .227, .228, .231, and .233.

B. REGISTRATION

All radiation machines must be registered with TXDSHS, Radiation Control Program if used, stored or owned by UTSA. All units are to be registered within thirty days of initial use except a mammographic unit must be registered and approved before use. Administration of any radiation to human beings at UTSA for medical research purposes requires approval of the R&LSC, the IRB, and the TXDSHS. Review of a human research protocol may require several months. The RSO should be contacted as much in advance as possible for any research involving patients or human subjects to allow time for all the required approvals/registrations. Administration of radiation to living vertebrate animals requires approval of the Institutional Animal Care and Use Committee (IACUC) as well as the R&LSC and TXDSHS. All other work involving radiation machines requires RSO and/or R&LSC approval.

Contact the RSO when planning to purchase and install a radiation machine. Furthermore, relocating a machine, major repairs or replacement of tube head requires notification of RSP. Registration of the individual units will be done by the RSO. Disposal, transfer or sale of a radiation machine must be pre-approved by the RSO so the unit may be deleted from the registration list and responsibly transferred or disposed. The name of the individual or company receiving radiation machines that are transferred or sold is required when notifying the TXDSHS of the deletion from UTSA’s registration and must be kept on file by the RSO.

Copies of assembler's installation reports are to be sent to the RSO. If possible, arrangements should be made to have RSP present at the time of installation and first generation of x-rays so that any questions about the operation of the machine and any safety issues may be adequately dealt with. Initial surveys are required following installation of a radiation machine.

C. COMPLIANCE FOR TECHNICAL STANDARDS OF RADIATION MACHINES

All radiation machines will comply with the technical standards of Texas regulations unless an exemption has been requested and received from the TXDSHS. Copies of the regulations are located at the EHSRM Office or online at the TXDSHS website.

D. RADIATION SAFETY SURVEYS

Radiation safety surveys will be performed annually by the RSP in accordance with Texas regulations. Surveys should be performed on new equipment before use begins especially to determine the requirements for any shielding in the area of installation. A survey may be required after major repair is performed or a tube head is replaced. Contact RSP when such repairs or replacements are performed upon a unit.

E. PERSONNEL DOSIMETERS

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Any person likely to receive greater than 10% of the annual occupational dose limit (500 mrem for adults) will be required to wear a personnel dosimeter while utilizing radiation machines. The dosimeter may be a monthly, bimonthly, or quarterly badge according to exposure levels. Dosimeters are provided to anyone likely to receive a significant dose above background. Note that special limits and conditions apply to declared pregnant women, minors, and members of the general public.

The dosimeter:

1. shall be worn between the neck and the waist at the unshielded portion of the whole body likely to receive the highest dose.
2. shall be worn at the neck outside of the apron, if a lead apron is worn.
3. shall be worn only by the individual assigned the dosimeter.
4. shall be kept in a safe, low radiation area when not being worn.
5. shall never to be exposed deliberately or willfully damaged.

A fetal/embryo badge will be issued to a woman who has declared her pregnancy in writing to her supervisor and the RSO. This is to be worn at abdomen level under a lead apron if a lead apron is already in use for the activities involving radiation machines.

F. OCCUPATIONAL EXPOSURE LIMITS FOR ADULTS

1. **The Maximum Permissible Dose Limits** as per regulations are specified in the following table:
   
   a. The total effective dose equivalent being equal to: 5 rem/year
   b. A shallow dose equivalent to the skin or to any extremity of: 50 rem/year
   c. An eye (lens) dose equivalent of: 15 rem/year

2. **Additional recommended limits for special situations** include:
   
   a. Fetus during entire pregnancy not to exceed: 0.5 rem
   b. Minors (under 18 years old) are not to exceed 10% of the annual adult dose limits for radiation workers.

3. **Special Considerations for Pregnant Workers**

   A pregnant radiation worker may voluntarily declare her pregnancy, but is not required to do so. The declaration automatically reduces the regulatory limit for the woman to 500 mrem for the entire nine months with a recommended limit of 50 mrem per month. Any “declared” pregnant worker likely to receive greater than 100 mrem in the nine months must use a personal dosimeter. The form “Pregnancy Declaration” may be obtained from the RSO. It is to be completed and returned to the RSO to initiate the necessary actions.

   Should a radiation worker choose not to declare, the regulatory limit for an undeclared worker stays at the same level as any radiation worker: 5 rem (5000 millirem) per year. A radiation worker can rescind a pregnancy notification in writing at any point for any reason without explaining the reason.
4. **Special Considerations for Handheld X-ray Device Users**
   a. Users of any handheld or portable x-ray device will be required to wear a dosimeter for at least one year.
   b. Upon the completion of the first year, the individual dose records will be reviewed. If it is found that no dose is received in excess of 10% of the annual limit then in accordance with Texas Administrative code 289.231, the user will be removed from the dosimetry program.

G. **DOSE LIMITS FOR INDIVIDUAL MEMBERS OF THE PUBLIC**

For consistency with UTSA exposure limits to radioactive material, no member of the general public may be exposed to more than 0.1 rem (100 mrem) in a year and no more than 0.002 rem (2 millirem) in any one hour. Area monitoring may be required to confirm that these limits are being maintained. For medical applications, a special exemption may be requested to allow up to 0.5 rem per year exposure to a member of the general public. This exemption must be approved in advance by the TXDSHS.

H. **PERSONNEL DOSIMETER RECORDS**

The Radiation Safety Office is responsible for the occupational dose records and issuing the individual dosimeters to the various departments. Occupational dose histories are maintained by the RSO.

Any person who has a potential occupational radiation exposure at UTSA who previously or currently has potential occupational exposure through work with another employer should promptly report the other employment to RSP. This will allow the combination of exposure records to ensure annual and lifetime exposure limits are not exceeded.

I. **REQUIREMENTS FOR PERSONNEL**

All personnel working with or in an area with radiation machines must complete training. UTSA Safety course “X-ray Safety” SA 494 is required for all radiation machine users. Any radiation machines used with human subjects require additional training. Contact the RSO for more information.

Radiation machines have specific requirements for operator training and use. In all cases a record of specific training approved by the RSO and/or the R&LSC and a log of users must be kept.

VI. **GUIDELINES FOR PROTECTION**

The fundamental objective of the use of radiation in research is to obtain optimum information or data with minimum exposure of the personnel concerned and the general public.

A. **RESTRICTED AREAS**

All medical radiographic rooms and areas containing control consoles are considered to be "restricted" areas. These are areas into which access is controlled by the registrant for purposes of protection of individuals from exposure of radiation. The restriction must be maintained by the operator of the radiation machine within the area.

B. **PROTECTIVE DEVICES**
If required, protective devices such as leaded aprons, gloves, gonadal shields, thyroid shields, or shin shields are to be visually inspected annually for defects such as holes, tears or cracks. A record of the inspection listing the devices, the results and the name and signature of the individual conducting the inspection shall be maintained. Any device found defective will be removed from service until repaired or discarded. Labels of inspection should be placed on the lead aprons, vests, skirts and gloves. Do not use a lead apron, vest, etc, if a label is not on the device. Remove from service and call Radiation Safety to inspect and label the device. The thickness of the protective device is to be as follows:

1. 0.5 millimeter thickness of lead equivalent material is required for protective devices that will be used to shield for direct beam radiation such as the gonadal shield and when using fluoroscopic units in sterile fields.

2. 0.25 millimeter thickness of lead equivalent material is required for protective devices that will be used to protect for primary (once-scattered) scatter radiation.

C. EXPOSURE OF THE INDIVIDUAL (STAFF)

Reduction of radiation exposure to an individual from external sources of radiation may be achieved by any one or any combination of the following measures:

1. Increasing the distance of the individual from the source.

2. Reducing the duration of exposure.

3. Using protective barriers between the individual and the source.

Shielding and distance are the factors most readily controlled. Protective shielding includes that incorporated into the equipment, mobile or temporary devices, such as moveable screens, or lead impregnated aprons and gloves; or permanent protective barriers and structural shielding, such as walls containing lead or concrete.

The radiation exposure controls for individual radiation machines, such as interlocks will be used unless a waiver has been obtained from the R&LSC. Radiation machines without exposure controls must operated under a protocol which includes radiation control measures that has been approved of by the RSO and/or the R&LSC.

D. EXPOSURE OF THE PATIENT (SUBJECT)

Individuals (patients or subjects) shall not be exposed to the useful beam except for healing arts purposes unless such exposure has been authorized by a licensed practitioner of the healing arts. This provision specifically prohibits deliberate exposure for the following purposes:

1. Exposure of an individual for training, demonstration, or other non-healing arts purposes.

2. Exposure of an individual for the purpose of healing arts screening except as authorized by the TXDSHS to the institution for a specific procedure requested.

3. Exposure of an individual (subject) for medical research except research protocols that have been reviewed and approved by the IRB and the R&LSC.
E. RADIATION EXPOSURE INCIDENTS

Radiation overexposures or possible incidents involving patients are to be reported to your supervisor immediately who will contact the RSO and the Occupational Health & WCI Coordinator.

F. POSTING NOTICES, INSTRUCTIONS, AND REPORTS TO WORKERS; AND POSTING A RADIATION AREA

1. Read the “Notice to Employees” sign posted in the work area.

2. Read this plan on operating and safety procedures and operating procedures specific to your machine.

3. The Certificate of Registration for UTSA and any notices of violations involving radiological working conditions are available from the Lab Safety Office in GSR 2.104V.

4. Your rights and obligations as a radiation worker are found in the regulations. The rooms in which permanent open beam radiation machines are located and operated must have the appropriate signage.