



University
of Houston
Clear Lake

Environmental,
Health and Safety

X-ray Safety Manual

October 2019

UNIVERSITY OF HOUSTON-CLEAR LAKE
X-Ray Radiation Safety Manual

Contents

X-ray Machines and Other Ionizing Radiation Producing Devices.....	3
Procurement Procedures	3
X-ray Subregistration Application.....	3
Receipt, Setup, Documents, and Use	5
Post Installation Survey	5
X-ray Subregistration Amendment Guidelines.....	6
Basic X-ray Safety Guidelines.....	6
Training.....	7
Definitions.....	7
Operational Procedures.....	9
Personnel Monitoring and Equipment Surveys.....	9
Signage & Postings.....	9
Records.....	9
Analytical X-ray and Other Industrial Radiation Machine Requirements.....	10
Area Requirements.....	11
Personnel Requirements.....	12
Operating Requirements.....	12
Machine Security.....	12
Certified X-ray Systems.....	13
Cabinet X-ray Machine Requirements.....	13
Equipment Requirements.....	13
Radiation limits.....	14
Radiation Safety Requirements for X-ray Machines in the Healing Arts (Medical Research)	14
Training and Certifications.....	14
Exposure and Maintenance.....	15

Appendices

- UHCL X-ray Subregistration Application
- UHCL X-ray Subregistration Amendment
- DXA Operating Procedures & Documentation

UNIVERSITY OF HOUSTON-CLEAR LAKE

X-Ray Radiation Safety Manual

– X-ray Machines and Other Ionizing Radiation Producing Devices –

The guidelines in this manual will ensure that appropriate protective and regulatory actions required of the university in the x-ray certificate of registration and applicable regulations are satisfied. To that extent, all users of x-ray machines and other ionizing radiation producing devices must receive prior authorization from the Radiation Safety Committee (RSC) via the Radiation Safety Officer (RSO) before procurement, installation, testing, use and disposal of x-ray machines and other ionizing radiation producing devices. Please contact the RSO at 281-283-2107 or at coen@uhcl.edu for assistance on guidelines.

– Procurement Procedures –

X-ray machines and other ionizing radiation producing devices must be purchased via the Procurement and Payables Department using a purchase order/requisition. ([See Procurement Policies and Procedures](#)). Requisitions, along with the x-ray subregistration application form and equipment information must be submitted to the EHS department via ehs@uhcl.edu for approval. Transferred equipment and donations must also receive prior approval to ensure it can be installed and operated safely at UHCL in compliance with applicable regulations. The radiation safety office will verify that Principal Investigators (PIs) are authorized for X-ray machine use prior to receipt of all machines.

X-ray safety devices, such as shielding and interlocks (if applicable) must be purchased and installed along with the X-ray machine (for non-certified units). Failure to plan for and install required safety devices will delay final approval to operate the X-ray machine.

Purchase order information must include:

- X-ray machine information: Model#, Serial # (if known), output levels, and other pertinent information
- Brief machine description, copy of technical specification sheet/manual with safety features, emissions test data/dose information
- Name of the PI who will be overseeing X-ray machine operation
- Directions for shipment delivery (X-ray machine should be delivered to proposed installation location)

– X-ray Subregistration Application –

All X-ray machines and other ionizing radiation producing devices must be registered with the Texas Department of State Health Services (TDSHS) under UHCL's certificate of X-ray registration within 30 days of initial installation. Proposed operating procedures for all X-ray machines and other ionizing radiation producing devices must receive authorization from the Radiation Safety Committee (RSC) post-installation, prior to normal operations.

UNIVERSITY OF HOUSTON-CLEAR LAKE

X-Ray Radiation Safety Manual

For registration purposes, covered equipment categories include:

- Minimal threat machines (radiation not emitted in an open beam configuration)
- Other industrial machines (research X-ray for non-human/ not-live animal use)
- Medical radiographic (X-ray for human use) and healing arts screening
- Veterinary X-ray machine (research not-live animal use)
- Dental X-ray machine
- Any other equipment that may produce ionizing radiation

To initiate registration, Principal Investigators (PIs) must complete an [Application for X-ray subregistration](#) and submit to the RSO for review and subsequent approval by the RSC.

Application forms are available at <https://www.uhcl.edu/about/administrative-offices/environmental-health-safety/documents/x-ray-subregistration-application.docx>. To guarantee timely approval from the RSC, the completed application forms must be submitted to the RSO at the same time as or prior to submission to procurement to allow sufficient time for RSC review.

The use of X-ray machines requires specialized safeguards, procedures and associated controls. Investigative procedures also vary widely as do applicable safety measures. The information provided on the use application will enable the RSO and RSC to review the adequacy of safety measures and assist the PI with implementation to ensure operational compliance and public safety.

Information requested with the application form includes:

- A. Contact information, location, purpose of use, and portable monitoring instruments available
- B. A description of the device. Specify the type (s), manufacturer, model number, serial number, beam currents and tube voltage
- C. X-ray control measures. Access control/hazard warning signs & device labels, engineering controls, administrative controls, and safety controls
- D. Operating and safety procedures for the device. Include documentation/procedures for training new staff or students
- E. A brief summary of the pertinent training and experience of the PI and all Authorized Users (AU's).
- F. A sketch of the laboratory facility.
- G. The PI (purchaser) must consult with the RSO concerning the adequacy of the facility shielding where the equipment will be used (if the unit is not self-shielded). Facilities with shielding requirements are required to have a shielding design plan review from a qualified expert or manufacturer-approved installer, prior to installation. A copy of such plan must be submitted along with the application to the RSO and RSC.
- H. Device alignment and maintenance information per manufacturer recommendation

Other than testing as approved by the RSO, the X-ray machine must not be operated until final

UNIVERSITY OF HOUSTON-CLEAR LAKE

X-Ray Radiation Safety Manual

approval is granted by the RSC and communicated in writing by the RSO. Anyone not listed on the subregistration permit may not be allowed to operate the X-ray machine for any reason.

– Receipt, Setup, Documents, and Use –

The RSO must be notified when an X-ray machine arrives. Installation must be performed and documented by a manufacturer representative or a state agency registered service provider. Out of state vendors will be required to present a reciprocity agreement before performing installation (contact RSO for clarification).

Following installation, a certificate of installation is required for certified units. For non-certified units, an equivalent report from the manufacturer's representative or agency registered service provider must be provided to the RSO in lieu of installation reports.

Specific documentation must be maintained by the PI and provided to the RSO as part of the registration application:

- Equipment manuals
- Purchase records
- Receipt/Installation records (Includes transfers or donations)
- Written, stand-alone operational procedures for each X-ray machine including start-up, shut-down, safety device by-pass, alignment, and emergency
- Calibration, maintenance, and modification plans/records
- Safety devices (interlocks, activation warning lights, etc.)
- Other requested information

Copies of these documents must be submitted to the RSO maintained by the PI.

– Post Installation Survey –

Radiation safety personnel will inspect the X-ray machine setup before operation begins (post installation survey) to assure radiation safety prior to X-ray machine use. A post installation survey shall also be conducted following relocation, alteration or modification to the machine. The PI may only turn on the X-ray machine for testing during the initial setup, with the consent of the RSO and/or presence of Radiation Safety staff. All necessary signage and regulatory postings must be posted during post installation reviews.

All safety devices must be installed and verified operational. The X-ray machine must not be operated without the final approval of the RSC. The RSO will communicate final approval for use from the RSC upon full compliance.

It is the responsibility of the PI to promptly notify the RSO if anything changes that warrant an inspection such as repairs or modification to a machine. Please contact Environmental Health and Safety (EHS) at 281-283-2106 if an X-ray signage or posting is missing or defaced.

UNIVERSITY OF HOUSTON-CLEAR LAKE

X-Ray Radiation Safety Manual

– X-ray Subregistration Amendment Guidelines –

Proposed changes to X-ray machine use authorization require a subregistration amendment request, with review and approval prior to the change. These include any changes to the subregistration such as personnel change (addition or deletion), machine relocation, alteration or modification to the machine which could affect shielding or beam quality, machine transfer to another user or disposal, etc. Utilize the X-ray subregistration application form for amendment requests, located at <https://www.uhcl.edu/about/administrative-offices/environmental-health-safety/documents/x-ray-subregistration-application.docx> .

Amendments to X-ray subregistration require RSC review and approval before implementation. To accommodate research objectives, the RSO may grant interim approval to PIs until the next RSC meeting. When the RSO finds reason to grant an interim approval prior to RSC's approval, the authorization will be limited to 90 days, or until ratified at the next RSC meeting, to allow sufficient time for the next RSC meeting. Such interim approvals will be presented for review at the next RSC meeting. The RSC will ratify RSO's approval, disapprove, or stipulate additional conditions to be fulfilled by the PI. Approved PIs will receive an Authorization Permit to work with X-ray machines, which is proof of radiation authorization at UHCL. Once authorized, PIs will remain authorized until either voluntary termination by the PI or revocation by the RSC for noncompliance.

– Basic X-ray Safety Guidelines –

Good Safety Practices

Designated responsible operator - Each laboratory should designate a primary responsible operator for the X-ray machine. This person will be responsible for the interlock bypass keys, performing the alignments, and manufacturer required maintenance on the X-ray machines. This person will also coordinate calibrations, repairs, and modifications of the equipment with the company or manufacturer representative.

Radiation Protection Practices

Time -The shorter the time spent around an X-ray machine, the lower the radiation dose. Authorized Users should minimize their exposures to keep their occupational doses As Low As Reasonably Achievable (ALARA).

Distance -Radiation levels decrease significantly with increase in distance from the source of radiation. The use of distance is one of the easiest and most effective methods for radiation protection.

Shielding -Lead shielding should be used to reduce radiation levels below 2 mR/hr. Most machines have built-in shielding, some will require additional shielding placed around the machine.

UNIVERSITY OF HOUSTON-CLEAR LAKE

X-Ray Radiation Safety Manual

Training

Authorized User Training

The RSC requires all Principal Investigators and users of radioactive material, Class 3b and 4 lasers, X-ray machines, and other ionizing radiation producing devices requiring registration to complete the applicable radiation safety user course. Consistent with the Texas Hazard Communication Act, training on general hazard communication and general laboratory safety shall also be required.

The Radioactive Material, X-ray, and Laser Safety courses are offered to all that intend to work with sources of radiation at UHCL. This includes Principal Investigators and Authorized Users. The courses are provided at least once a year, or upon request. Other interested faculty, staff, and students are welcome to attend.

Note: Completion of a radiation safety course does not automatically qualify someone as an Authorized User (AU). To receive authorization to work with specific radioactive material and/or radiation producing devices, you must be added to a PI's sublicense or subregistration through an amendment application.

Refresher Training

Annual Radiation Safety Refresher Training courses shall be completed by all persons authorized to work with radioactive materials, X-ray machines and Class 3b and 4 Lasers. PIs and AUs may receive notification of required refresher training. Non-completion of the refresher training by not completing or passing the required exam shall lead to suspension from working with any source of radiation.

Exemption from Refresher Training

Inactive PIs and their authorized users shall be exempted from annual refresher training requirements. However, completion of appropriate training shall be required prior to reinstatement from inactivity. The RSO/LSO shall recommend the applicable training when the request is received.

Definitions

Cabinet X-ray System – per 21 CFR 1020.40, an x-ray system with the x-ray tube installed in an enclosure which is intended to contain the material being irradiated, provide radiation attenuation, and exclude personnel from the interior and x-rays generated.

Certified X-ray Systems – Manufacturers of diagnostic x-ray systems subject to 21 CFR 1020.30 through 1020.33 shall certify that each of their products meets all applicable requirements when installed into a diagnostic x-ray system according to instructions. This certification shall be made under the format specified in 1010.2 of this chapter.

UNIVERSITY OF HOUSTON-CLEAR LAKE

X-Ray Radiation Safety Manual

Diagnostic x-ray system – per 21 CFR 1020.30, is an x-ray system designed for irradiation of any part of the human body for the purpose of diagnosis or visualization.

Healing arts – per 25 TAC 289.227(e)(41), any system, treatment, operation, diagnosis, prescription, or practice for the ascertainment, cure, relief, palliation, adjustment, or correction of any human disease, ailment, deformity, injury, or unhealthy or abnormal physical or mental condition.

Healing arts screening – per 25 TAC 289.227(e)(42), the testing of asymptomatic human beings using radiation machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment.

Industrial Radiation Machines – per 25 TAC 289.228, includes educational facility x-ray equipment for non-human or not live animal use, including, but not limited to the following:

- Portable/handheld fluorescence x-ray (open beam)
- Fluoroscopy x-ray
- Industrial accelerator
- Spectrography x-ray
- Flash x-ray
- Diffraction x-ray
- Uncertified cabinet x-ray
- Minimal threat radiation machines

Medical X-ray use – per 289.227(e)(50), medical research includes investigation of various health risks and diseases. In 289.226(f), an application for use of x-rays to humans (for healing arts or therapeutic radiation) requires a medical physician or licensed practitioner.

Medical research – per 25 TAC 289.226(u), any research using radiation machines on humans shall be approved by an Investigational Review Board (IRB) as required by 45 CFR part 46, and include at least one physician to direct any use of radiation in accordance with 25 TAC 289.231(b).

Minimal threat radiation machines – per 25 TAC 289.228 and .231, machines that during operation, radiation is not emitted in an open beam configuration, no deliberate exposure of an individual occurs, and no physical injury has occurred or is known by the state agency. Minimal threat radiation machines include, but are not limited to the following:

- x-ray fluorescence
- x-ray gauges
- particle size analyzer (x-ray)
- electron beam welding
- ion implantation devices
- cathodoluminescence devices
- package x-ray, and
- certified cabinet x-ray (that do not allow a person or body part to be exposed)

UNIVERSITY OF HOUSTON-CLEAR LAKE

X-Ray Radiation Safety Manual

Operational Procedures

Start up, shut down, alignment, and emergency procedures for all X-ray machines (except for minimal threat devices) must be readily available to and acknowledged by all users. The safety and basic operations sections in the manufacturer's manual should include much of the necessary information for the standalone document. X-ray machines classified as minimal threat devices only require knowledge of and availability of the manufacturer's operating manual for compliance.

Personnel Monitoring and Equipment Surveys

Radiation badges (dosimeters) are provided to primary users of X-ray diffraction machines and other such potentially high exposure units. Not all X-ray users will be required to use a dosimeter. Users should keep their dosimeters in an area of low exposure away from the X-ray machine when not in use. If assigned, dosimeters must be worn while working with X-ray machines. Notify Radiation Safety if your dosimeter is lost or damaged. Do not use someone else's. PIs and/or Authorized Users that do not promptly report lost badges or return old badges may be charged for the cost of the badge plus administrative fees. PIs must also immediately report when their Authorized Users terminate and arrange to return their badge promptly to the RSO.

Survey meters are required for potential high exposure units. Survey meters must be kept calibrated and should not be used after the calibration due date has passed. Radiation safety personnel conduct required inspections of all X-ray machines at the initial setup, after modifications, calibrations, and moving. Radiation safety personnel also perform routine inspections and exposure surveys of the X-ray machines.

Signage & Postings

Required X-ray use location door signage and postings will be provided by Radiation Safety personnel to assure standardization and compliance. At a minimum, all X-ray labs must have a "Caution Radiation Area" sign posted at each entrance, a Notice to Employees, and an emergency contact sign. A "Caution Safety Device Not Working" sign must be used whenever the interlocks are bypassed for alignments and equipment changes, as pre-approved by the RSO.

Records

Certain records are required to be maintained by all X-ray PIs and readily available for internal and/or external inspections. All records should be maintained in one central location in the lab. Applicable records are outlined in the "Receipt, Document and Set up" section of this manual. X-ray machines shall also have a use log, to be filled out each time the machine is used. The log shall include, at a minimum, the user's name, date of use, and settings or description of use.

UNIVERSITY OF HOUSTON-CLEAR LAKE

X-Ray Radiation Safety Manual

Engineering Protection Systems

All interlocks, fail safe lighting and shielding must be maintained and inspected at each operation of the X-ray machines with exceptions documented.

X-ray Tube Disposal

Old X-ray tubes are considered hazardous waste and must be disposed of properly. To request disposal of an old X-ray tube, request hazardous waste pickup from EHS at 281-283-2106.

– Analytical X-ray and Other Industrial Radiation Machine Requirements –

The UHCL X-ray Safety Program sets forth controls and safety guidance for research and educational activities involving X-ray machines. The procedures herein are consistent with the regulations in Title 25 of the Texas Administration Code (TAC), Chapter 289, Section 228. This program establishes prudent safety practices to meet the regulatory requirements. If any conflict exists between this program and the state regulations, the latter shall prevail. This section applies to machines including X-ray photoelectron spectroscopy (XPS), X-ray diffraction (XRD), X-ray fluorescence (XRF), and others.

Equipment Safety Practices (Analytical Units)

- Ports - All unused ports must be securely closed to prevent accidental opening.
- Interlocks - All interlocks on the X-ray machine must be functional and in operation for X-ray production. Bypassing should only be performed by the designated responsible operator and only during alignments and equipment changes as required.
- Alignments - should be performed at minimal power settings and only by the designated responsible operator specially trained and designated by the PI to perform alignments.
- Maintenance - should only be performed by trained qualified individuals, at the manufacturer's recommended time intervals.
- Warning Lights - Analytical X-ray machine warning lights must have fail-safe characteristics.
- Beam Stops - The X-ray beam must be terminated within the enclosure at all times and must be pointed away from the door.

Equipment Requirements

Safety Devices: A safety device shall be provided on all open-beam configurations. Exemptions, where necessary, must meet regulatory guidelines in 25 TAC §289.231.

Warning Devices: Open-beam configurations shall be provided with a visible indication of:

- X-ray tube status (ON-OFF) located near the radiation source housing, if the primary

UNIVERSITY OF HOUSTON-CLEAR LAKE

X-Ray Radiation Safety Manual

beam is controlled in this manner; and/or

- Shutter status (OPEN-CLOSED) located near each port on the radiation source housing, if the primary beam is controlled in this manner.

The X-ray control shall provide visual indication whenever X-rays are produced. Warning devices shall be labeled so that their purpose is easily identified and shall have fail-safe characteristics.

Ports: Unused ports on radiation machine source housings shall be secured in the closed position in a manner which will prevent inadvertent opening.

Labeling: Registrant shall ensure that each radiation machine is labeled in a conspicuous manner to caution individuals that radiation is produced when the unit is energized. The label shall be affixed in a clearly visible location on the face of the control unit.

Shutters: On open-beam configurations, each port on the radiation source housing shall be equipped with a shutter that cannot be opened unless a collimator or coupling has been connected to the port.

Radiation source housing: Each X-ray tube 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.

Generator cabinet: Each X-ray generator shall be supplied with a protective cabinet that limits leakage radiation measured at a distance of 5 centimeters from its surface such that it is not capable of producing a dose in excess of 0.5 millirem (5 microsieverts) in any one hour.

Area Requirements

- The local components of an X-ray system shall be located and arranged, and shall include sufficient shielding or access control such that no radiation levels exist in any area surrounding the local component group which could result in a dose to an individual present in the area in excess of the dose limits.
- Radiation surveys of all radiation machines and X-ray systems sufficient to show compliance with area requirements above shall be performed upon installation of the equipment; following any change in the initial arrangement, number, or type of local components in the system; following any maintenance requiring the disassembly or removal of a local component in the system; during the performance of maintenance and alignment procedures, if the procedures require the presence of a primary X-ray beam when any local component in the system is disassembled or removed; any time a visual inspection of the local components in the system reveals an abnormal condition; or whenever personnel monitoring devices show a significant increase over the previous monitoring period or the readings are approaching the radiation dose limits.
- Each area or room containing radiation machines shall be conspicuously posted with a sign or signs bearing the radiation symbol and the words "CAUTION - X-RAY EQUIPMENT," or words having a similar intent.

UNIVERSITY OF HOUSTON-CLEAR LAKE

X-Ray Radiation Safety Manual

Personnel Requirements

- No one shall be permitted to operate the radiation machine unless such person has received instruction in, and demonstrated competence with
 - The operating and safety procedures for the radiation machine;
 - Radiation warning and safety devices incorporated into the equipment and the room;
 - Identification of radiation hazards associated with the use of the equipment;
 - Procedures for reporting an actual or suspected exposure in excess of the dose/exposure limits.
- All Authorized Users including the Principal Investigator must successfully complete the initial UHCL X-ray Safety Training User Course.
- The Principal Investigator must provide and document specific training on the use of the X-ray machine and associated radiation hazards to all Authorized Users prior to being authorized through an amendment to operate the specific device.
- A copy of the current operating and safety procedures shall be maintained near the X-ray machine, and also acknowledged by all authorized users.
- Authorized Users must know how to use a survey meter (if needed in the laboratory).
- In addition to any assigned radiation dosimeters, finger badges shall be provided to and shall be used by personnel maintaining analytical radiation machines if the maintenance procedures require the presence of a primary X-ray beam when any local component in the X-ray system is disassembled or removed.

Operating Requirements

- Operating and safety procedures shall be written and made available to, and acknowledged by all radiation machine authorized users.
- No person shall be permitted to operate radiation machines in any manner other than that specified in the procedures, unless that person has obtained written approval of the RSO.
- No person shall enter the area containing a radiation machine unless they have received awareness information and its authorized user requirement.
- No person shall bypass a safety device unless such person has obtained the written approval of the RSO, and posted a readily discernible sign bearing the words

“SAFETY DEVICE NOT WORKING,”

Or words having a similar intent placed on the radiation source housing.

Machine 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 radiation machines.

UNIVERSITY OF HOUSTON-CLEAR LAKE

X-Ray Radiation Safety Manual

– Certified / Package X-ray Systems –

Certified X-ray systems, including those designed to allow admittance of individuals shall

- Not be modified without prior approval of the RSO.
- Not be operated by any individual without receiving training and instructions in the operating procedures for the unit.
- Be tested for proper operation of interlocks at intervals not to exceed 12 months and documentation maintained for inspection.
- Have an evaluation performed to ensure radiation emitted at 5 cm from the external surface of the unit does not exceed 0.5 millirem (5.0 microsieverts) in any one hour.
- Have associated documentation from above maintained by the registrant for inspection by the state regulatory agency.

– Cabinet X-ray Machine Requirements –

The UHCL X-ray Safety Program sets forth controls and safety guidance for research and educational activities involving X-ray Machines. The procedures herein are adapted from the regulations in Title 25 of the Texas Administration Code (TAC), Chapter 289, Section 228, which refers to Title 21 of the Code of Federal Regulations (CFR), Chapter 1020, Section 40. This program is established to institute prudent safety practices and to meet regulatory requirements. If any conflict exists between this program and the state regulations, the latter shall prevail.

Equipment Requirements

The additional rules in this section apply to certified cabinet X-ray system only:

- I. A key-activated control must be provided to ensure that X-rays will not be generated when the key is removed.
- J. Each door of a cabinet X-ray system must have safety interlocks. Each access panel also must have at least one safety interlock.
- K. A control, other than the safety interlock, must be provided to resume X-ray generation following X-ray interruption by a safety interlock.
- L. Two independent indicators must be provided to indicate when X-rays are being generated. One may be an X-ray tube current indicator; the other indicator must consist of an easily seen warning light labeled "X-RAY ON".
- M. A clearly legible and visible label bearing the statement: "CAUTION: X-RAYS PRODUCED WHEN ENERGIZED" must be posted near the controls that energize the X-ray tube.

UNIVERSITY OF HOUSTON-CLEAR LAKE

X-Ray Radiation Safety Manual

Radiation limits

Radiation emitted from a cabinet X-ray system must not exceed exposure rate of 0.5 mrem/hr at any point 5 cm from the external surface, and at maximum power. A cabinet X-ray system must also contain sufficient shielding and be located so that exposure rates in unrestricted areas do not exceed 2 mrem in any one-hour and 100 mrem/yr.

– Radiation Safety Requirements for X-ray Machines in the Healing Arts – (Medical Research) Screening

The UHCL X-ray Safety Program sets forth controls and safety guidance for research, educational and healing arts activities involving X-ray machines. The procedures herein are adapted from the regulations in Title 25 of the Texas Administration Code (TAC), Chapter 289, Section 227. This program establishes prudent safety practices and to meet the regulatory requirements. If any conflict exists between this program and the state regulations, the latter shall prevail.

- Individuals shall not be exposed to the useful beam except for healing arts purposes and unless such exposure has been authorized by a licensed practitioner of the healing arts or as part of an IRB-approved human-use study. The university utilizes a bone densitometer for research with humans and will comply with applicable requirements in 25 TAC 289.227(g). Among others, PIs must apply for and obtain authorization for healing arts screening from the institutional RSC and IRB before initiating a screening program per 25 TAC 289.226(h).
- Operating and safety procedures must be established in accordance with 25 TAC 289.227(i)(2)
- Operator credentialing shall be maintained in accordance with 25 TAC 289.227(i)(5) as further described in Training and Certifications section below.
- Recordkeeping requirements per 25 TAC 289.227(g)(10) also apply

Other human use applications at UHCL must receive prior approval by the RSC. This manual will be revised to accommodate other applications consistent with regulations and the certificate of registration as need arises.

Training and Certifications

Individuals who operate radiation machines for human use shall meet the appropriate requirements of rules in accordance with the Medical Radiologic Technologist Certification Act, Texas Occupations Code. A copy of the document shall be provided to the RSO and maintained at the location where the individual is working. Required surveys, tests, or evaluations that constitute the practice of medical physics or as determined by the RSO/RSC will require the use of an outside consultant with a license from the Texas Board of Licensure for Medical Physicists in accordance with the Medical Physics Practice Act, Texas Occupations Code. Training for bone densitometers includes 20 hours of initial training, and 4 hours of training recurring every other year by a licensed medical physicist within the State of Texas per 22 CFR 194.15.

UNIVERSITY OF HOUSTON-CLEAR LAKE

X-Ray Radiation Safety Manual

Exposure and Maintenance

No individual other than the patient, operator, and ancillary personnel shall be in the X-ray room or area while exposures are being made unless such individual's assistance is required.

Gonadal shielding of at least 0.5 mm lead equivalent material shall be used on patients in accordance with 25 TAC 289.227(i)(13) when appropriate. This requirement does not apply if the shielding will interfere with the diagnostic procedure.

A radiographic X-ray equipment performance evaluation (EPE) shall be performed by a state licensed Medical Physicist every 2 years or as required in TAC 289.227. Such documentation must be submitted to the RSO.

Mechanical maintenance will be performed by a vendor as required to maintain compliance. Quality assurance tests will be performed by authorized personnel and vendors as required to maintain compliance. In addition, Radiation safety personnel will periodically perform reviews to assure compliance.

University of Houston – Clear Lake Radiation Safety Manual

Application for X-ray Machine Subregistration Registration for X-ray machines

Instructions

X-ray machines must be registered with Radiation Safety. All Principal Investigators (PI) must be approved and sub-registered by the Radiation Safety Committee prior to using x-ray generating machines. Additionally, prior approval for procurement and installation of x-ray machines must be obtained from Environmental Health & Safety (EHS) per MAPP 04.01.01.

The application involves primary items that are required to be completed before the application will be presented for the Radiation Safety Committee's review and approval. Complete this application form and submit to the Radiation Safety Officer (RSO) in the EHS Department. It is very important for the PI to ensure all required items are addressed to avoid delays; approval for use and request to purchase any additional x-ray machines will not be granted until the application is approved by the Radiation Safety Committee.

A Standard Operating Procedure (SOP) is required as part of the application process. A facility evaluation will be performed during the application review process to ensure proposed research can be conducted safely. Engineering controls (if applicable) will also be evaluated post-installation to verify that special safety features for the equipment and facility meet current requirements. Training recommendations required for the PI and all Authorized Users (AU) is part of the application review process and should be completed as early as possible.

Sub-registration Information (to be completed by the Principal Investigator)

1. PI/ Operator/Supervisor: _____
2. Phone: _____ E-mail: _____
3. Lab Emergency Contact: _____ Phone: _____
4. Department: _____
5. Building/ Office #: _____
6. Lab Location: _____
7. Department Chair: _____
8. Purpose or Intended Use*: _____

***For Bone Density or Body composition Scans, see item 15, page 6 for additional requirement.**

University of Houston – Clear Lake Radiation Safety Manual

9. Survey Instrument (Manufacturer/Model/Serial #/Recent Calibration Date):

***Categories of x-ray machine for DSHS registration:** Medical Radiographic (e.g. Bone densitometer), Veterinary, Other Industrial (XRD, XRF, etc.), Minimal Threat (e.g. cabinet x-ray)
(Please consult with the RSO for assistance)

10. X-ray machine description:

Manufacturer	
Model	
Serial #	
Max kV	
Max mA	
Type*	

Manufacturer	
Model	
Serial #	
Max kV	
Max mA	
Type	

Manufacturer	
Model	
Serial #	
Max kV	
Max mA	
Type	

University of Houston – Clear Lake Radiation Safety Manual

11. Proposed X-ray Control Measures

Access Control/Hazard Warning Signs & Device Labels

- | Yes | No | |
|--------------------------|--------------------------|--------------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | Posted entrances |
| <input type="checkbox"/> | <input type="checkbox"/> | Access control/device security |
| <input type="checkbox"/> | <input type="checkbox"/> | Control Area established |
| <input type="checkbox"/> | <input type="checkbox"/> | Warning label |

Engineering Controls

- | Yes | No | |
|--------------------------|--------------------------|-------------------------------|
| <input type="checkbox"/> | <input type="checkbox"/> | Protective (Shielded) housing |
| <input type="checkbox"/> | <input type="checkbox"/> | Protective housing interlock |
| <input type="checkbox"/> | <input type="checkbox"/> | Key/Lock control |
| <input type="checkbox"/> | <input type="checkbox"/> | Activation warning system |

Administrative Controls

- | Yes | No | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | Standard Operating Procedures/Emergency procedures |
| <input type="checkbox"/> | <input type="checkbox"/> | Emergency contacts posted |
| <input type="checkbox"/> | <input type="checkbox"/> | Personnel authorization |
| <input type="checkbox"/> | <input type="checkbox"/> | Designated location of radiation badges (when not in use) indicated |

Safety Controls

- | Yes | No | |
|--------------------------|--------------------------|---|
| <input type="checkbox"/> | <input type="checkbox"/> | X-ray machine is secured from unauthorized move |
| <input type="checkbox"/> | <input type="checkbox"/> | Beam intensity reduced or filtration in place |
| <input type="checkbox"/> | <input type="checkbox"/> | Radiation exposure below 2mR/hr at 30 cm from the machine |
| <input type="checkbox"/> | <input type="checkbox"/> | Limited access to spectators/visitors |

**University of Houston – Clear Lake
Radiation Safety Manual**

12. Provide the following specific information (use additional sheet as required):

- a) Summary of Principal Investigator's training and experience with x-ray machines including institution, courses, machine types, and duration.

- b) Summary of X-ray procedures (experimental protocol)

- c) Procedures for alignment, maintenance, and/or service, including procedures for the bypass of safety interlocks (additional requirements apply for medical radiographic types).

- d) Description of planned equipment modifications or updates to the machine. (Clinical use machines will require Equipment Performance Evaluation documentation).

- e) Outline a method in which the lab and equipment can be shut down by EHS, and users can be denied access in the event of non-compliance. (This will be verified during the application review process).

University of Houston – Clear Lake Radiation Safety Manual

13. Important notes:

- a) Certification of training must be documented for all users to operate or maintain the X-ray machines.

List of Authorized Users*:

Name_____	PSID _____	UHCL Email:_____
Initial____		
Name_____	PSID _____	UHCL Email:_____
Initial____		
Name_____	PSID _____	UHCL Email:_____
Initial____		
Name_____	PSID _____	UHCL Email:_____
Initial____		
Name_____	PSID _____	UHCL Email:_____
Initial____		

* Authorized Users must have read the X-ray Safety Section of the Radiation Safety Manual and must verify by signing their initials.

* Authorized Users must have received specific radiation safety training for the radiation hazards in their labs from their Principal Investigator and must verify by signing their initials.

* Authorized Users must have attended and passed the UH initial X-ray Safety Course and/or refresher course and must verify by signing their initials.

(Other Authorized Users may be added later by amendment after completing these requirements)

- b) This application is strictly for non-human use only except as specifically authorized. X-ray use on humans under the scope of this authorization is prohibited. (Please indicate if clinical/ veterinary use x-ray machine is involved)
- c) Any actual or suspected exposure must be reported to the RSO immediately.
- d) Modifications and repairs to an x-ray machine that could affect the beam quality (excluding routine beam alignment) must be reported to and receive prior approval from the RSO before the device is put back into operation.

**University of Houston – Clear Lake
Radiation Safety Manual**

- e) Notify the RSO prior to the x-ray machine being moved to another location, transferred to another individual, or disposed of.
- f) Notify the RSO when the status of device is changed from “Active” to “Inactive” and vice versa.
- g) Notify the RSO prior to laboratory close-out, relocation, and/or transfer of radiation device or source to another PI(s), including transfer out of the University. PIs leaving the University must follow the [Laboratory and Equipment checkout procedure](#) on the EHS website.
- h) Notify the RSO before the addition of an Authorized User. Privileges of departing Authorized Users should be suspended immediately and communicated to the RSO.
- i) A log should be maintained to document the specific personnel and date/time that the equipment is being used when the machine is used by more than one personnel.

14. Provide a sketch of the room and the proposed location of the X-ray. Identify the X-ray control area. Specify location of radiation badges when not in use. Use additional pages if necessary.

15. LICENSED PHYSICIAN

As a licensed physician, I certify that I am the owner or associated with this applicant, and/or provide supervision to non-practitioners administering radiation to human beings or animals in accordance with Title 25, Texas Administrative Code. I certify that I am qualified and agree to carry out those duties as the Licensed Physician.

Typed or printed name of licensed physician

TX License Board No.

Signature

Date

CERTIFICATION

University of Houston – Clear Lake
Radiation Safety Manual

I certify that the information contained herein and attached hereto is true and correct to the best of my knowledge.

Date: _____ PI Signature: _____

UNIVERSITY OF HOUSTON-CLEAR LAKE

Radiation Safety Manual

	1. PI Responsibilities (Please initial before each responsibility below.)	
	I have provided training to employee using the specified X-ray machine, and model. The training included a discussion of the known and potential hazards and an explanation of the relevant policies, techniques and procedures including the proper use of personal protective equipment (PPE) and accompanying equipment.	
	Employee has been trained initially and will be trained annually thereafter. Their knowledge, competence and practices shall be evaluated and documented.	
	I have implemented a safety program and will include this information in the SOP for that machine.	
	I have limited access to Lab and or equipment to authorized users only.	
	I have implemented practices to minimize the possibility of injury while using the specified machine and or associated equipment.	
	I have developed a Standard Operating Procedures (SOP) for Start-up/Shut-down, and operation of the specified machine. The Standard Operating Procedures (SOP) has a contingency plan in the case of an emergency.	
	I will provide all requested information to the Radiation Safety Officer via email at coen@uhcl.edu or by phone at 281-283-2107.	

PI Name: _____

PI E-Mail: _____

PI Signature: _____

PI PSID #: _____

Date: _____

	2. Future Authorized User Responsibilities (Please initial before each responsibility below.)	
	I have received training and understand the risks of this specific X-ray machine and model. The training included a discussion of the known and potential hazards and an explanation of the relevant policies, techniques and procedures including the proper use of personal protective equipment and accompanying equipment.	
	I have agreed with my PI to be trained initially and annually thereafter. My knowledge, competence and practices have been evaluated and documented.	
	My PI has provided me with a copy or instructed me on how to obtain a copy of the SOP for that machine.	
	I have read, and understand the Standard Operating Procedures (SOP) for Start-up/Shut-down, and operation of the specified machine. I am also aware of the actions required during an emergency.	
	I will use the training I have received from my PI to minimize the possibility of injury while using the machine or associated equipment.	
	I understand that as an authorized user I may have limited access to the lab, or equipment and will not allow anyone that is not authorized to use the equipment or enter the lab.	
	I will report any malfunctions or safety concerns to my PI as they become apparent, and if they cannot be, or are not resolved, I will notify the Radiation Safety Officer via email at coen@uhcl.edu or, by phone at 281-283-2107.	

AU Name: _____

AU E-Mail: _____

AU Signature: _____

AU PSID #: _____

Date: _____