

UT Health Science Center:	
RSP08 X-Ray Registration, Installation, Repair and Disposal Procedure	
Version 2	Publication Date: 01/13/2025

Objective

This procedure establishes the requirements for registration, tracking, inspection, and disposal of all x-ray emitting medical or veterinary devices on the UTHSC campus.

Scope

This procedure applies to all personnel and students that manage or use x-ray emitting devices for medical or veterinary purposes on campus. Department heads are responsible for ensuring that all x-ray devices owned or under the control of the department and device users comply with this policy.

Roles

Activities mandated in this policy will be conducted by the UTHSC Radiation Safety Officer and the other UTHSC Research Safety Affairs authorized by the Radiation Safety Officer or the Research Safety Affairs Chief Safety Officer.

A responsible person must provide general oversight for an x-ray device or devices for which they have been approved. The responsible person must submit the application to the Campus Radiation Safety Committee to obtain and use a radiation emitting machine. The application must be approved by the campus Radiation Safety Committee.

Definitions

ALARA – As Low As Reasonably Achievable - making every reasonable effort to maintain exposures to ionizing radiation as far below the dose limits as practical, consistent with the purpose for which the licensed activity is undertaken.

Authorized X-ray Inspector – A person registered in accordance with Rules Of The Tennessee Department Of Environment And Conservation, Division Of Radiological Health rule 0400-20-10-.24 to perform inspections for and provide reports to UTHSC

Authorized Installer/Repairer - A person registered in accordance with Rules Of The Tennessee Department Of Environment And Conservation, Division Of

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Radiological Health rule 0400-20-10-.24 to install new x-ray devices on the URHSC campus and repair or modify x-ray devices located on campus

Class I X-ray Device - Dental Radiation Machines: Includes all diagnostic equipment used exclusively for dental diagnostic procedures.

Class II X-ray Device - Medical Radiation Machines: Includes all diagnostic x-ray equipment not in Class III used exclusively for medical or veterinary diagnostic procedures.

Class III X-ray Device - Medical Radiation Machines: Includes all x-ray equipment with energies less than 0.9 MeV used for the purpose of medical or veterinary radiation therapy.

Class IV X-ray Device - Therapy Medical Radiation Machines: Includes all x-ray equipment with energies less than 0.9 MeV used for the purpose of medical or veterinary radiation therapy.

Class V X-ray Device - Industrial and Educational Radiation Machines: Includes closed-beam analytical radiation machines, gauges and industrial radiation machines used in shielded room or cabinet radiography.

Class VI X-ray Device - Industrial and Educational Radiation Machines: Includes all x-ray machines used for industrial radiography and all open-beamed analytical x-ray machines not specifically included in Classes I, II, III, IV, V or VII.

Class VII X-ray Device - Accelerators: Includes equipment designed for and used only for the production of x-rays of 0.9 MeV or greater and equipment capable of discharging nuclear particles into a medium external to the accelerating device.

Mobile x-ray equipment - equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

Portable x-ray equipment - x-ray equipment designed to be hand-carried.

Stationary x-ray equipment - x-ray equipment that is installed in a fixed location.

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Hand-held x-ray equipment - portable X-ray equipment that is specifically designed to operate when held in a person's hand and is approved by the U.S. Food and Drug Administration (FDA).

Responsible Person – a UTHSC employee that provides oversight for the use of an x-ray emitting machine.

Procedure

I. Authorized Use Locations for X-ray equipment

- A. Each installation for x-ray equipment must be equipped with barriers to assure compliance with the following radiation protection standards:
 1. Adult Radiation Workers (personnel trained in the safe use of radiation work and authorized by the Radiation Safety Committee to work with radioactive materials or radiation producing machines)
 - a. Annual total effective dose equivalent of 5 rems, or
 - b. Annual lens-dose equivalent to 15 rems, or
 - c. Annual shallow-dose equivalent of 50 rems
 2. Minors
 - a. Annual total effective dose equivalent of 0.5 rems, or
 - b. Annual lens-dose equivalent to 1.5 rems, or
 - c. Annual shallow-dose equivalent of 5 rems
 3. Embryo/Fetus
 - a. Dose to a declared pregnant woman must not exceed 0.5 during the entire pregnancy
 - b. The dose delivered to the declared pregnant woman must not substantial variation above a uniform monthly exposure rate for the duration of the pregnancy
 4. Individual member of the public (anyone not included in groups 1-3 above)
 - a. The total effective dose equivalent received by any individual member of the public from the licensed or registered operation does not exceed 0.1 rem
- B. Compliance can be demonstrated with shielding calculations that account for the following:
 1. x-ray maximum energy and current the machine can generate.
 2. The machine configuration
 3. The maximum workload the machine will perform.

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4. Demonstration of compliance with applicable radiation exposure limits to the following populations:
 - a. Adult radiation workers
 - b. Minors (individuals under 18 years of age)
 - c. Dose to an embryo/fetus
 - d. Dose to a member of the public (anyone not trained and authorized by the Radiation Safety Committee to work with sources of radiation or radiation emitting machines).
5. The analysis performed in step 4 must be documented in writing and include the following information:
 - a. All assumption on use time, presence of exposure groups listed in item 4.
 - b. Calculations or measurements used to assess the installation.
 - c. Any limitations or use restrictions assumed when performing the evaluation.
 - d. Any required facility modifications (such as shielding requirements) to meet exposure requirements.
 - e. Any PPE, portable shielding, etc. that is required to maintain compliance with the submitted calculations.
 - f. The maximum anticipated exposure to a member of each of the populations in item 4 under as-built conditions and facility standard operating conditions.
6. This document must be submitted to the campus Research Safety Affairs Office 90 days in advance of obtaining the x-ray device(s) for evaluation and presentation to the campus Radiation Safety Committee.
- C. Installation must be completed by a company or person possessing a current installers registration with the TN Division of Radiological Health.

II. Analytical and Veterinary X-ray Machine Possession and user approval

- A. The Responsible Person must complete an IMEDRIS protocol and receive approval from the UTHSC Radiation Safety Committee prior to obtaining and user the device.

III. Registration of x-ray generating equipment

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- A. The Responsible Person for the x-ray emitting machine(s) must submit an application or update an existing application when a new machine is purchased. The new application should be submitted 90 days in advance of the device arriving onto campus. If an application is being amended, the revised application should be submitted 30 days in advance of the device arriving onto campus.
- B. The following information will be needed to complete a new or amended application. Some of this information may need to be requested from the supplier of the x-ray device.
 1. Manufacturer name
 2. Model number
 3. Machine Type (if one of the descriptions in the appendix doesn't properly classify the machine, then contact the UTHSC Radiation Safety Office for guidance.)
 4. Maximum kVp of the tube
 5. Maximum current mA
 6. Equipment Serial Number
 7. X-ray tube Serial Number
 8. Classification of the device I-VII (see definitions for more information; contact Research Safety Services for assistance.)
 9. If the device is a hand-held x-ray device, provide product information including FDA approvals to the Research Safety Affairs Office with the application.
 10. Email a copy of the product user manual to the Research Safety Affairs Office (radsafety@uthsc.edu)
 11. The location on campus the device will be installed.
 12. Is the machine portable, hand-held, or stationary (based on the definitions above).
 13. Name of the company that will be installing the device and their Tennessee Radiological Health installer registration number.
- C. The Research Safety Affairs office must be contacted by the Responsible Person or designee by the end of business on the day the x-ray machine arrives onto campus property.
- D. The Radiation Safety Officer or designee will complete the registration form [RHS 8-4](#) for the device and submit to the following address or submit by email:

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1. xray.registration@tn.gov
 2. Department of Environment and Conservation
Division of Radiological Health
William R. Snodgrass Tennessee Tower
312 Rosa L. Parks Avenue, 15th Floor
Nashville, TN 37243
- E. The registration form must be completed and submitted to the Division of Radiological Health within 10 days of the X-ray device's date of arrival on campus.
- F. A copy of the registration form submitted to the Division of Radiological Health will be maintained by the Radiation Safety Officer or designee.

IV. Relocation of x-ray device, modification of x-ray device, or major repair to the x-ray device

- A. If the x-ray machine is relocated to another building or room within a building or repairs or modifications are performed resulting in a new equipment serial number or a replacement x-ray tube, a new registration form must be submitted within 10 days after the modifications are completed.
- B. Repairs must be done by the manufacturer or a manufacturer authorized service representative appropriately registered with the Tennessee Department of Environment and Conservation, Division of Radiological Health or by an authorized installer/repairer.
- C. The Responsible Person or designee must collect the same information required in section II.B 1-7 and submit it to the Research Safety Affairs Office the day the work has been completed.
- D. If the x-ray device must be returned to the manufacturer or an off-campus repair facility, the Research Safety Affairs Office must be contacted before the device is shipped off campus.
- E. A revised application must be submitted to the Radiation Safety Committee within 10 days of the modification or repair completion.

V. Disposal of an X-Ray Emitting Machine

- A. When a machine is no longer needed, obsolete, or nonfunctional and will not be repaired, the Responsible Person must contact the Research Safety Affairs office to arrange disposal of the device. Disposal options

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include transfer to another Responsible Person on campus, transfer to another facility, or disposal as trash.

- B. Process for transfer to another Responsible Person on campus
 - 1. Contact the Radiation Safety Officer before the actual transfer takes place.
 - 2. The Responsible Person receiving the device must complete an application or amend an existing application.
 - 3. When the application is approved by the Radiation Safety Committee, the Responsible Person must contact the manufacturer or authorized service representative to move a stationary unit. Campus personnel can move portable or hand-held devices. Provide the date of the move to the new location to the Radiation Safety Officer three days in advance of the move.
 - 4. When the move is completed, the Radiation Safety Office or designee will complete an updated registration form and submit it to the Tennessee Department of Environment and Conservation, Division of Radiological Health within 10 days of the move completion.
 - 5. Stationary devices that are moved must be reinspected as soon as practical not to exceed 30 calendar days from the date of the move.
 - 6. The previous Responsible Person must amend their application within 30 days of the transfer and submit to the campus Radiation Safety Committee.
- C. Process for transferring a device off campus to another facility or return to the manufacturer.
 - 1. Contact the Radiation Safety Officer before the actual transfer takes place.
 - 2. Obtain the facility name, facility physical address receiving the x-ray unit, facility mailing address (if different from the facility address), name of a contact person, contact person's email address and phone number.
 - 3. Before shipping the device, obtain the signature of an authorized representative from the receiving facility using the transfer form provided in the appendix of this policy.
 - 4. Send a copy of the signed transfer form and the shipping paper to the Radiation Safety Officer. If the manufacturer of the device is the

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recipient, their standard return acknowledgement for the device can be used in the place of the transfer form.

5. A copy of the shipping paper and transfer form must be provided to the Radiation Safety Officer by the end of business on the day the device was shipped.
 6. The Tennessee Department of Environment and Conservation, Division of Radiological Health will be contacted by the Radiation Safety Officer or designee to cancel the registration since the machine has been transferred to another facility. A copy of the transfer letter and shipping document will be sent with the cancellation request.
- D. Process for disposal of the machine as trash
1. The machine or the portion containing the x-ray tube will be collected by the Radiation Safety Officer or designee.
 2. The device will be rendered electrically safe by a qualified electrician.
 3. The x-ray tube will be broken or otherwise rendered inoperable. Evidence of the destruction will be documented generally by photographing before and after
 4. Any residual equipment of scrape such as oil, lead, or e-waste will be disposed of in accordance with TN waste disposal regulations.
 5. The Tennessee Department of Environment and Conservation, Division of Radiological Health will be contacted by the Radiation Safety Officer or designee to cancel the registration since the machine has been rendered inoperable. Evidence of the tube destruction will be submitted with the cancellation letter.

VI. Inspection of the X-ray Emitting Device

- A. All x-ray machines must be inspected by an inspector currently registered with the Tennessee Department of Environment and Conservation, Division of Radiological Health.
- B. The inspection must be completed no later than the due date from the last inspection performed based on the class of the machine.
- C. The initial inspection must be completed within three months upon arrival on campus.

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- D. All inspection reports for active machines will be maintained by the Radiological Safety Officer or designee.

VII. Documentation

Penalties/Disciplinary Action for Non-Compliance

License violations are subject to civil penalties up to \$5,000 per day per violation. In the event of a threat to public health and safety, the Division has the right to confiscate radiation sources.

References

- I. Tennessee Administrative Code Title 0400 - Environment and Conservation Subtitle 0400-20 - Division of Radiological Health (§§ 0400-20-10-.24 Registration)
- II. Tennessee Administrative Code Title 0400 - Environment and Conservation Subtitle 0400-20 - Division of Radiological Health Chapter 0400-20-06 Use of X-Ray Apparatus
- III. Tennessee Administrative Code Title 0400 - Environment and Conservation Subtitle 0400-20 - Division of Radiological Health (§§ 0400-20-05-.50 Occupational Dose Limits for Adults.)
- IV. Tennessee Administrative Code Title 0400 - Environment and Conservation Subtitle 0400-20 - Division of Radiological Health (§§ 0400-20-05-.55 Occupational Dose Limits for Minors.)
- V. Tennessee Administrative Code Title 0400 - Environment and Conservation Subtitle 0400-20 - Division of Radiological Health (§§ 0400-20-05-.56 Dose to an Embryo/Fetus.)
- VI. Tennessee Administrative Code Title 0400 - Environment and Conservation Subtitle 0400-20 - Division of Radiological Health (§§ 0400-20-05-.60 Dose Limits for Individual Members of the Public.)
- VII. Tennessee Administrative Code Title 0400 - Environment and Conservation Subtitle 0400-20 - Division of Radiological Health (§§ 0400-20-10-.27 Inspections.)

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Responsible Official & Additional Contacts

Subject Matter	Office Name	Telephone Number	Email/Web Address
Policy Clarification and Interpretation	Research Safety Affairs	(901) 448-6114	radsafety@uthsc.edu
Policy Training	Research Safety Affairs	(901) 448-6114	radsafety@uthsc.edu

Related Policies/Guidance Documents

Appendix

Radiation emitting machine standard types

1. Dental Diagnostic – Intraoral
2. Dental Diagnostic – Cephalometric
3. Dental Diagnostic – Panoramic
4. Dental Diagnostic - Hand Held
5. Dental Diagnostic – CBCT
6. Medical Diagnostic - Radiographic – Stationary
7. Med Diagnostic - Radiographic – Mobile
8. Med Diagnostic- Podiatry
9. Med Diagnostic - Bone Densitometer
10. Med Diagnostic – CT
11. Medical Diagnostic – CBCT
12. Medical Fluoroscopic Diagnostic – Undertable
13. Med Fluoroscopic Diagnostic - Mobile C-arm
14. Med Fluoroscopic Diagnostic - Special Units (variable SID, cardiovascular)
15. Med Fluoroscopic Diagnostic - Over Table Units
16. Veterinary - Radiographic – Stationary
17. Veterinary - Radiographic – Portable
18. Veterinary - Fluoroscopic – Therapeutic
19. Medical Therapeutic - Grenz rays (10-15 kVp, SID 2-3 cm)

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- 20. Med Thera - Contact Therapy (15-50 kVp)
- 21. Med Thera - Superficial (50-150 kVp)
- 22. Med Thera - Orthovoltage (150-500 kVp)
- 23. Med Thera - E – Brachytherapy
- 24. Industrial/Educational - Cabinet Unit
- 25. Ind/Edu - Closed Beam Analytical
- 26. Ind/Edu - Closed Beam X-Ray Gauge
- 27. Ind/Edu - Open Beam – Analytical
- 28. Ind/Edu - Open Beam X-Ray Gauge
- 29. Ind/Edu - Open Beam industrial radiography (non-human use)
- 30. Ind/Edu - Open Beam non-hand-held (bomb detection, body scanners)
- 31. Ind/Edu - Open Beam hand-held analytical (non-human use)
- 32. Ind/Edu - Fluoroscopic (non-human use, including hand-held)
- 33. Accelerators - With energies greater than 0.9 MeV - for human use
- 34. Accelerators - With energies greater than 0.9 MeV for veterinary use
- 35. Cyclotrons