

X-ray Registration – Frequently Asked Questions (FAQ)

General Information

What is a radiation machine?

Under Rule 0400-20-04-.04, a radiation machine is defined as any device capable of producing radiation, except for devices that generate radiation through the use of radioactive material. Equipment that produces radiation from radioactive materials is regulated separately under the Divisions licensing program. If you are unsure whether your device falls under registration or licensing requirements, you should contact the Division for guidance.

Who is required to register a radiation machine?

Pursuant to Rule 0400-20-10-.24, any individual or entity that owns or possesses a radiation machine or accelerator must register that equipment with the Division within ten (10) days of acquisition, unless the equipment qualifies for an exemption under Rule 0400-20-10-.07. This requirement applies regardless of whether the machine is actively in use, as long as it is capable of being energized.

Registration Process

How do I register my radiation machine?

Radiation machines must be registered using Form RHS 8-4, which is available on the Division's website. Registrants should carefully review all instructions included with the form, particularly those on the final page, to ensure the correct form type is submitted. Submission of incorrect or incomplete documentation may delay processing. In addition, prior to registration approval, the Division may require submission of the FDA 510(k) clearance number specific to the device, when applicable.

For accelerators, Rule 0400-20-10-.24 requires that the owner or possessor submit an application for certified registration in accordance with Chapter 0400-20-09 within ten (10)

days of acquisition. Accelerators may not be energized until the Division has completed the registration process and issued approval.

What happens after I submit my registration?

Once a registration request is submitted via email, a confirmation email acknowledging receipt will be sent. The Division will then review the submission for completeness and accuracy. If additional information or clarification is needed, staff will contact the registrant using the contact information provided. After the registration is approved, the Division will issue a registration number, which is tied to a single physical address, along with individual control numbers assigned to each radiation machine. Registrants should retain this information and include the registration number in all future correspondence with the Division.

How long is an x-ray registration valid?

X-ray registrations do not expire. Once issued, registration remains valid indefinitely unless the registrant notifies the Division of changes such as ownership transfer, disposal, or relocation of equipment in accordance with Rule 0400-20-10-.24.

When can I begin using my x-ray machine?

X-ray machines may generally be used upon installation, provided all applicable provisions of the Tennessee Code Annotated and the State Regulations for Protection Against Radiation (SRPAR) are met. However, there are important exceptions. Facilities intending to perform mammography must first comply with all applicable FDA requirements. Accelerators may not be used until authorization is granted by the Division under Chapter 0400-20-09. Additionally, local, county, or federal regulations may impose further requirements that must be satisfied prior to operation.

Tennessee regulations require radiation machines to be registered within 10 days of acquisition. While registration does not, by itself, ensure that all compliance requirements have been met, it provides a level of regulatory review and approval. To promote compliance and avoid potential enforcement concerns, equipment should not be placed into service until registration has been submitted and applicable regulatory requirements have been verified.

Changes and Updates

Do I need to report changes to my registration?

Yes. Rule 0400-20-10-.24 requires registrants to notify the Division within ten (10) days of any changes to previously submitted registration information. This includes changes in address, ownership, possession, or location of use. Updates must be submitted using Form RHS 8-4, selecting the “Update Registration” option.

How should I report a change in Radiation Safety Officer (RSO) or responsible individual?

A change in the individual responsible for supervising radiation machines may be submitted in the same manner as other registration changes, using Form RHS 8-4 within ten (10) days.

What should I do if my facility changes ownership?

In accordance with Rule 0400-20-10-.24(6), a registrant who permanently discontinues use of radiation machines or transfers ownership must notify the Division in writing within sixty (60) days. The notification must include the name and contact information of the transferee.

The new owner is required to submit registration documentation within ten (10) days of acquisition.

Ownership changes are evaluated on a case-by-case basis to determine whether an update to the existing registration is sufficient or if a new registration and control numbers are required.

What should I do if my business moves or my x-ray equipment is relocated?

If your business changes location or your x-ray equipment is moved, you are required to notify the Division by completing **Form CN-2850 (X-Ray Equipment Transfer and Moved Location Form)**. This form is used to document both facility relocations and equipment transfers under the same ownership.

It is important to understand that this form must be completed for each individual x-ray machine. If your facility has multiple machines, a separate form must be submitted for each unit to ensure accurate tracking and compliance.

When completing the form, you will need to indicate the type of action being taken. A “Moved Location” (relocation) applies when your facility has physically moved to a new address. An “X-Ray Equipment Transfer” applies when equipment is moved to a different site but remains under the same ownership.

After completing the form, it should be submitted to the Division by email at **xray.registration@tn.gov**. Carefully reviewing the instructions on the form before submission will help avoid delays in processing.

Failure to report a change in location or equipment placement may result in incorrect registration records and could lead to compliance issues, including continued billing or enforcement action.

Fees and Billing

When are registration fees due?

Annual registration fees are assessed in accordance with Rule 0400-20-10-.24(3). Invoices are issued on May 1 of each year, and payment is due by June 15. Registrants must submit payment within forty-five (45) days of the invoice date. Failure to pay on time may result in penalties, interest, and enforcement actions. Invoices are mailed, and delinquency notice of non-compliances specific to fees may be sent electronically in the following calendar year.

Will I be billed for newly acquired equipment?

Yes. If equipment was acquired in a previous calendar year but not yet billed, a manual invoice will be issued. For equipment acquired in the current year, billing follows the Division’s fee schedule, with invoices typically issued in September or January depending on the acquisition date.

Do I have to pay fees for machines that are not in use?

Yes. As long as a radiation machine is capable of being energized, it is subject to registration requirements and associated fees. To discontinue fees, the machine must either be removed from the registrant’s possession or rendered permanently inoperable. This must be documented and reported to the Division using the Deletion Form (CN-2848).

Special Situations

How are mobile or multi-location machines registered?

Machines that are not used at a single fixed location should be registered to the primary address where they are most frequently used or stored. If a machine is located at a single site for more than thirty (30) days, that location must be registered.

What are the requirements for leased, rented, or shared machines?

Radiation machines must be registered by the entity that possesses and uses the equipment. In cases where equipment is shared among multiple entities, each entity must maintain its own registration in accordance with Rule 0400-20-10-.24.

Do loaned or replacement machines require registration?

Temporary loaned machines of the same type, use, and classification may not require registration if used for less than three (3) months; however, records must be maintained, and the Division may require registration at its discretion. Machines of a different type or classification must be registered. Replacement machines provided due to defect within ninety (90) days may retain the original control number if they are equivalent in type and use.

Out-of-State Registrants

Do I need to register my x-ray machine if my business is located out of state?

Yes. Any radiation machine that is brought into Tennessee must comply with Tennessee registration requirements, regardless of where the business is headquartered.

What if my company temporarily brings equipment into Tennessee?

If radiation machines are brought into Tennessee for temporary use, such as mobile operations, contract work, or short-term projects, they are still subject to registration requirements prior to entry.

How should out-of-state companies register their equipment?

Out-of-state registrants must follow the same registration process as in-state facilities. This includes completing **Form RHS 8-4** and submitting it to the Division prior to entry with all required information, including the FDA 510(k) number where applicable.

Are there additional requirements for out-of-state registrants?

Out-of-state registrants must comply with all applicable Tennessee State Regulations for Protection Against Radiation (SRPAR) while operating within the state. This includes registration, fee payment, inspection requirements, and operational compliance.

In addition, out-of-state registrants must comply with Rule 0400-20-10-.25(2), which establishes specific requirements for each out-of-state person who brings radiation machines into the state for any temporary use:

Under this rule, each out-of-state person who brings radiation machines into Tennessee for temporary use must complete the following:

- Provide **written notification to the Division at least three (3) days prior** to use. This notification must include the location, duration, and type of use within the state. If meeting the three-day requirement would create an undue hardship, the registrant may request approval from the Division to proceed sooner.
- Register the radiation machine(s) with the Division using Form RHS 8-4 **prior to entering the state.**
- Comply with all applicable state regulations, including proper operation, inspection requirements, and payment of applicable fees based on the machine classification.

These requirements apply unless the equipment qualifies for a specific exemption under Rule 0400-20-10-.07.

Do out-of-state registrants need to pay Tennessee registration fees?

Yes. Any radiation machine subject to registration in Tennessee is also subject to applicable fees. Fees apply as long as the registration remains active, regardless of whether the equipment is actively being used within the state.

If the radiation machine is no longer located in Tennessee, the registrant must submit a request to close the account using Deletion Form (CN-2848) and indicate account closure to prevent continued billing and maintain accurate registration records. Until the account is officially closed by the Division, fees will continue to accrue.

Out-of-state registrants who anticipate performing multiple or future jobs within Tennessee may choose to keep their registration active for convenience. However, it is important to understand that maintaining an active registration will result in continued billing, even during periods when the equipment is not in use within the state.

What if my equipment is only passing through Tennessee?

Radiation machines that are strictly **in transit** through Tennessee and not used, installed, or stored within the state are generally not subject to registration requirements.

Disposal and Removal

How do I remove a machine from registration?

To remove a radiation machine from registration, the registrant must submit a completed Deletion Form (CN-2848). In accordance with Rule 0400-20-10-.24, the machine must either be no longer in the registrant's possession or rendered permanently inoperable. Failure to report disposal, transfer, or disablement may result in continued billing and potential compliance actions.

What is the process to remove a machine from registration?

To officially remove a machine, complete the Deletion Form (CN-2848), sign it, and email it to xray.registration@tn.gov. Once submitted, the Division will review the request and send a confirmation email after the deletion has been processed.

When completing the form, you will select the reason for removal:

- **Sold or Donated:**
If the machine has been transferred to another owner, you must provide the new owner's contact information (name, phone number, and email). This ensures the equipment can be properly registered under the new owner.
- **Salvaged (Inoperable):**
If the machine is being kept for parts or otherwise retained, it must be made permanently non-functional. Once a machine is rendered inoperable, it is no longer subject to registration or fees.
Important: If a machine reported as salvaged is later returned to operational status,

fees and penalties may be applied retroactively from the date it was declared inoperable.

- **Disposed:**

If the machine is being discarded, you may either arrange disposal yourself or hire a qualified service provider. The Division does not maintain a dedicated disposal vendor list; however, many companies listed on the Service (Installer) Provider List may offer disposal services.

Does the Division provide disposal services?

No. The Division does not provide disposal or disassembly services. Registrants are responsible for ensuring proper disposal. You may contact manufacturer, vendor, service provider, or local waste authorities for guidance and assistance.

For additional support, the Special Waste Application managed by the Division of Solid Waste Management may serve as a resource to determine appropriate disposal methods and locations: <https://www.tn.gov/environment/permit-permits/waste-permits1/special-waste-approval.html>

Technical Information

How can I obtain technical information about my machine?

Technical specifications such as maximum energy output or tube configuration should be obtained from the manufacturer's documentation or by contacting the manufacturer or vendor directly.

Are MRI machines required to be registered?

No. MRI machines do not produce ionizing radiation and are therefore not subject to registration under Tennessee's radiation machine registration program administered by the Division of Radiological Health.

However, registrants should be aware that the Tennessee Health Facilities Commission may require registration or oversight of certain medical equipment, including MRI

machines, under separate healthcare facility regulations. These requirements are independent of SRPAR and may apply.

Are lasers required to be registered?

No. Lasers emit non-ionizing radiation and are not regulated under the State's radiation machine registration program. Instead, they fall under the regulatory authority of the U.S. Food and Drug Administration (FDA).

Are mobile, portable, or hand-held x-ray units allowed in clinical settings?

Tennessee does allow certain mobile and portable x-ray units in clinical settings; however, newer technologies may not always align with current State regulations. Because equipment designs can vary, registrants are encouraged to submit product information (such as a brochure or specifications) for review **before taking possession**. This allows the Division to determine applicable regulatory requirements and identify whether additional components, such as manufacturer-designed stands or supports, are needed for compliant use.

Under Rule 0400-20-06-.05, medical x-ray equipment must be used in a manner that ensures stability and operator safety. The tube housing assembly must be mechanically supported and maintained in a stable position during exposures. The regulation also prohibits holding the tube housing assembly or position-indicating device by hand during an exposure. These requirements apply to stationary, mobile, and portable systems used in medical settings. Additionally, operators are required to stand at least 2 meters away from the patient, primary beam, and tube head during exposure.

For clarification, equipment types are defined as follows:

- **Mobile equipment:** Mounted on a wheeled base for movement within a facility
- **Portable equipment:** Designed to be carried
- **Hand-held equipment:** Portable units designed to be operated while held in the hand and approved by the U.S. Food and Drug Administration (FDA)

If you are considering purchasing or using this type of equipment, you are encouraged to contact the Division for review and guidance prior to use

Inspections and Compliance

Are inspections required?

Yes. The Division conducts inspections in accordance with Rule 0400-20-10-.27.

Inspection frequency depends on the classification of the radiation machine, ranging from annually to every four years. Registrants must comply with all applicable provisions of the State Regulations for Protection Against Radiation.

The Division has the right to inspect the registrants as follows:

- Class I - once every four years
- Classes II and V - once every two years
- Classes III, IV, VI, and VII - once every year

Do I need to schedule an inspection?

If the Division conducts the inspection, no scheduling is required. Alternatively, registrants may participate in the Registered Inspector program, which allows for inspections by approved third-party inspectors under a reduced-fee structure. For more information regarding this program please reach out to the division or refer to the RI section of our website.

Shielding

Are shielding plans required?

While SRPAR does not prescribe specific shielding design requirements, it establishes dose limits under Chapter 0400-20-05, including Rules .50, .55, .56, and .60. Registrants are responsible for ensuring that radiation exposure to workers and the public remains within these limits. Consultation with qualified experts is recommended when designing shielding.

X-ray installers and service provider list is located on our website and may help in finding a qualified expert.

Exemptions

What equipment is exempt from registration?

Certain machines and equipment are exempt from registration under Rule 0400-20-10-.07; however, these exemptions are limited and apply only under specific conditions.

Common exemptions include:

- Household televisions and similar devices, as long as radiation levels remain very low (specifically, less than 0.5 milliroentgen per hour measured at 5 centimeters from the surface).
- Equipment that produces radiation incidentally, such as certain electrical devices not designed to produce radiation, provided radiation exposure remains extremely low (not exceeding 0.5 rem per year to an individual under worst-case conditions).
- Radiation machines in transit
- Machines that are permanently inoperable and used only for parts (salvage).

It is important to understand that these exemptions are conditional. Even if a machine falls into one of the categories above, it is **not exempt** if it is used or handled in a way that could expose an individual to radiation levels above the limits established in the State Regulations for Protection Against Radiation.

For non-federal entities working under contract with a federal agency, exemption from State registration requirements **does not apply**.

If you are unsure whether your equipment qualifies for an exemption, it is recommended that you contact the Division before assuming exemption, as improper classification may result in compliance issues.

Need Additional Assistance?

For questions or assistance, please contact:

xray.registration@tn.gov

Phone: 615-532-0364