

1.14 RADIATION MACHINE FACILITY REGISTRATION

Question: Do I own or operate (or want to own or operate) a radiation machine (X-ray machine)?

Why do I need this approval?

This registration ensures that each x-ray tube and the facility in which it is used are registered with the State. Registration is required before operating any radiation machine or modifying any facility in which an x-ray machine is to be used for dental and medical diagnosis and therapy, industrial, scientific or veterinary purposes. It is also required when changing the location or ownership of a machine. This registration must be updated each time an x-ray machine (tube) is added to or removed from the facility inventory.

What laws or regulations give MDE the legal authority to issue this approval?

STATE: Environment Article, Title 8, Subtitle 3; COMAR 26.12.01 and 26.12.03.

What is the process to get this approval?

- 1) An applicant submits a completed registration packet to the Department. When required, the applicant must also forward a plan review that has been prepared by a service provider registered by the State, and, if applicable, a State certification inspection by a State licensed private inspector--see 1.15 "Certification of Machines Emitting Radiation."
- 2) The Department sends the applicant an approval of the facility plans and shielding, if submitted.
- 3) The Department issues the applicant a registration number and Certificate of Registration.

Is this approval directly related or contingent on other approvals?

A State form, MDE RX 24 "Report of Assembly, Reassembly, or Removal of Radiation Machine," must be sent to the Department by the registered service provider who assembles/installs the radiation machine.

Are there any other requirements?

PRE-APPROVAL: Registration is contingent upon completion of the registration packet which must contain the Radiation Machine Registration Form, the fee payment transmittal form, remittance of all appropriate fees, and a federal machine installation report (FDA 2579). If applicable, a facility must submit construction or modification plans to ensure proper shielding. All radiation machine facilities must be registered before the radiation (x-ray) machine is operated. Radiation machine facilities with cardiac catheterization labs, computed tomography (CT) scanner(s), or linear accelerator(s) must provide a copy of the current license issued by the Maryland Department of Health and Mental Hygiene Office of Health Care Quality.

POST-APPROVAL: A registrant must submit a Form MDE RX-24 and FDA Form 2579 if a tube is installed, removed, or permanently disabled. Any change in location of a radiation machine, even a move from one room to another, is subject to re-registration, and a plan review and state certification inspection, if applicable, and must be reported to the RHP. Radiation machines must undergo preventive maintenance according to manufacturer schedule and specifications to ensure optimum operating level. The registrant is responsible for ensuring that the preventive maintenance reports generated by the registered service provider are submitted to the Department.

How long should I expect it to take to get this approval once I submit a complete application?

Up to 90 days for dental and veterinary machines
Up to 6 months for all other machines

Once I get this approval, how long will it last?

Each facility must apply for registration renewal every two years. Facilities must notify the Department in writing when they no longer own the x-ray unit and provide documentation from a registered service company that the radiation machine has been rendered inoperable, removed, or sold. Also, all fees must be paid before the Department will cancel the registration. The facility must also notify the Department in writing when the number of tubes increases or decreases.

How much will this approval cost?

Type of Facility	Annual Fee per Machine*
Dentists	\$80
Veterinarians	\$220
Mammography Facilities	\$220

*Effective January 1, 2016

A late registration fee amount from \$80 to \$4,364 per tube/facility/year may be assessed to facilities which do not register properly or on time as required.

Do I need to know any additional information?

Fees are based on the number of operational tubes at a facility and must be paid before the registration process is complete. A payment transmittal form will be provided. All machines except those used in dental, veterinary, or mammography practices must also be periodically certified (see 1.15 "Certification of Machines Emitting Radiation.").

Who do I contact with additional questions?

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Related link:

http://mde.maryland.gov/programs/Air/RadiologicalHealth/XRayApplicationFormsandGuidance/Pages/Programs/AirPrograms/radiological_health/xray_applications/index.aspx