

1.15 CERTIFICATION OF MACHINES EMITTING RADIATION

Question: Do I own (or want to own) a non-dental, non-veterinary, or non-mammography electronic radiation producing machine?

Why do I need this approval?

All radiation machines in Maryland except mammography, dental and veterinary practices must be certified as meeting State performance standards to ensure minimal health risk and optimal safety of anyone exposed to its radiation. Affected facilities include hospitals, clinics, industries, government facilities and academic institutions that house operable x-ray machines.

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

FEDERAL: 21 Code of Federal Regulations, Chapter I, Subchapter J.
STATE: Environment Article, Title 8, Subtitle 3;
COMAR 26.12.02

What is the process to get this approval?

- 1) Owners of radiation machine facilities other than dental, veterinary, and mammography facilities must have a State licensed private inspector inspect the machine(s). For a listing of State licensed private inspectors, see http://mde.maryland.gov/programs/Air/RadiologicalHealth/Documents/www.mde.state.md.us/assets/document/air/xray_inspectors.pdf.
- 2) The inspector certifies to the Department that the machine functions properly and that necessary repairs have been made if violations have been cited.
- 3) The Department issues a certification approval letter. A state sticker with a unique machine number plus suffix, which must be affixed to the machine, will be issued to machines not previously identified.

Are there any other requirements?

PRE-APPROVAL: All applicants except dental, veterinary, and mammographic practices must hire a state licensed private inspector to examine the radiation machine and the facility, and produce certification data within the six months prior to the certification due date. If the machine is not in compliance, it must be repaired and then reevaluated by a state licensed inspector. An application must be submitted at least 45 days before the certification due date.

POST-APPROVAL: Radiation machines must undergo preventive maintenance according to manufacturer specifications including frequency of maintenance 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.

Any change in location of a radiation machine, even a move from one room to another, requires a State certification inspection by a State licensed private inspector.

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

Up to 6 months

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

Must be renewed every one, two or three years depending on the type of machines.

How much will this approval cost?

There is no charge for certification approval, however, there is a fee for registration of your radiation machine facility. Please see document 1.14 Radiation Machine Facility Registration at <http://mde.maryland.gov/programs/air/radiologicalhealth/documents/www.mde.state.md.us/assets/document/air/1.14.pdf>. Annual registration fees are based on the number of tubes at a facility and must be paid before the initial registration process is complete. A payment transmittal form will be provided. Once registered, your facility will receive an annual invoice.

Who do I contact with additional questions?

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Related link:

<http://mde.maryland.gov/programs/Air/RadiologicalHealth/Pages/XRayApplicationFormsandGuidance.aspx>