

1.16 RADIOACTIVE MATERIALS LICENSE

D Question: Does my company in Maryland possess, manufacture, use or distribute radioactive materials for research, industrial or medical applications?

Why do I need this approval?

Persons who intend to possess or use radioactive materials of certain quantities and types and establish a facility in Maryland must be licensed by the State to ensure that these materials are used properly and safely by qualified persons who have sufficient knowledge and training. Examples of such materials include radioactive isotopes of elements that occur naturally (radium-226), are produced by an accelerator (fluorine-18), or are generated as a by-product of a nuclear reactor (cobalt-60).

Industrial radiographers, hospitals, nuclear pharmacies, medical offices, radioactive source manufacturers, construction companies, laboratories (research and medical) and radiation consultants are among those who may require this license.

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

FEDERAL: Section 274b. of the Atomic Energy Act, which gives Maryland full regulatory authority over radioactive materials users in the State.

STATE: Environment Article, Title 8, Subtitles 1 and 3; COMAR 26.12.01.01

What is the process to get this approval?

- 1) The licensee completes an initial or renewal application. Renewal applications must be received by the Department seven months prior to expiration of existing license.
- 2) All required fees must be paid. The application fee must be submitted upon request by the Department. Renewal requests must continue to maintain a current fee account.
- 3) If the application is complete and satisfactory, and the appropriate fees are paid, an onsite inspection is conducted by the Department to verify applicant data, inspect facilities and security of radioactive material, and review qualifications and training of personnel

Are there any other requirements?

PRE-APPROVAL:

- 1) Training requirements for those who use radioactive materials range from four hours for the use of a well-shielded device containing sealed radioisotopes to a three-year training program for the use of sealed sources in medical therapy on humans.
- 2) Depending upon the specific use and circumstances, there may be a requirement for extensive protective and monitoring equipment.

POST APPROVAL:

Continued license approval is contingent on maintaining up to date fee payment and on operating in accordance with all license requirements and conditions, including requirements relating to occupational exposure, security and control of the material, inspection status reports, inventories, routine surveys, semi-annual leak tests, periodic meter calibration, and other routine equipment checks.

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

Up to 7 months for new and renewal licenses

Up to 45 days for license amendments

There are many different types of radioactive material licenses. Processing times may vary within the 7-month period depending on the complexity of the process or operation covered by the application, the completeness of the initial application, and the quality of any response to deficiencies and staff resources.

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

Seven years

How much will this approval cost?

An annual fee of \$538 to \$17,000 will be assessed, depending on the complexity of the operation. Upon MDE receipt of your application, you will be billed for the appropriate annual fee. Do not send it with the application. This fee must be paid prior to licensing and is credited as the first year's annual fee. Once the annual licensing fees are paid, unlimited license amendments may be made at no further cost. The fee schedule is found in COMAR 26.12.03.

Do I need to know any additional information?

Listing as an authorized user on a Nuclear Regulatory Commission or Agreement State license currently in effect is accepted as proof of adequate training and experience.

Who do I contact with additional questions?

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Related link:

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