



DEPARTMENT OF
**ENVIRONMENTAL SAFETY,
SUSTAINABILITY & RISK**

**Supplement
to
Radiation Safety
Plan**

For Radiation Producing Equipment

Revised 1996

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COMAR 26.12.01.01

(Maryland - Department of the Environment Regulations for Control of Ionizing Radiation)

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Introduction

This supplement to the University of Maryland's Radiation Safety Manual is provided to users of Radiation Producing Devices/Machines utilized in the performance of research, education, and diagnostic medical requirements, and veterinary medicine applications at UMD Campus and Satellite facilities.

Maryland Regulations require two separate actions regarding radiation producing devices - Registration and Certification. **Registration** involves a request to the State to register a device and gives specifics about the equipment, location, and the responsible person for the equipment. **Certification** is a function of inspection by the State certified inspector that a registered piece of equipment has been inspected, has been described adequately, and is considered safe to operate as requested by the applicant. A registration fee is imposed on all new requests. A yearly certification fee is required on accelerators (Group 1 machines); a bi-yearly certification fee is required on diagnostic equipment (Group 4 machines); and a tri-year certification fee is required on industrial/research types of equipment (Group 5 machines). In addition to the State fees, the inspection functions are not a State action, but rather a State certified inspector who is contracted by the University to perform these functions and charges an inspection fees for each device. These fees may vary with the contract at each of the intervals of certification inspection activities.

The frequencies of certification/inspections are established by these regulations.

This supplemental manual is provided for use only by those persons having responsibility for the safe operation, training of operators, and utilization of diagnostic X-Ray, research X-Ray and Accelerator equipment. This manual gives the requirements for registration, inspection and certification.

Definitions

Device/Machine - Any assemblage of components of a radiation machine that includes:

1. not more than one control panel;
2. the necessary supporting structures; and
3. any additional components or auxiliary equipment that functions with the assemblage to produce the results desired by the using machine.

Inspect - The process of observing the use and operation of a radiation machine for the purpose of judging whether its use may violate a provision of the Maryland Radiation Act or any regulations issued under the act.

Inspector - A person who has a valid or current license issued by the Agency pursuant to Regulations 26.12.01.02 to inspect radiation machines.

Major Component - A part of a radiation machine that if improperly installed, maintained, or operated could result in a higher radiation dose to humans than would occur if the component were properly installed, maintained or operated.

Radiation -

1. Ionizing radiation, including gamma rays, X-rays, alpha particles, beta particles, neutrons, high speed electrons, high speed protons, and any other atomic or nuclear particles or rays.
2. All electromagnetic radiation that can be generated during the operation of a manufactured device that has an electronic circuit.
3. All sonic, ultrasonic or infrasonic waves that are emitted as a result of the operation, in a manufactured device, of an electronic circuit that can generate a physical field of radiation.

Radiation Machine - A device that is capable of producing radiation.

State Certification - A declaration by the Agency that the use of a radiation machine complies with the Maryland Radiation Act and all regulations adopted under the Act.

Reference Inspection Procedure -

1. Used by the Agency to determine compliance of a radiation machine with a provision of the Maryland Radiation Act or any regulation issued under the Act; and
2. Has been described in the "Maryland State Catalog of Reference Inspection Procedures for Inspecting Radiation Machines" (April 15, 1986) which is incorporated by reference.

State Certification of Radiation Machines

Applicability - This regulation does not apply to persons using the following radiation machines:

1. Those used for dental diagnosis or treatment;
2. Radiation machines exempted from the requirements of Section B.3 of the Maryland State Department the Environment Regulations for Control of Ionizing Radiation (1995) which is incorporated by reference in Regulation 26.12.01.01; and
3. Radiation machines that are licensed by the Agency as provided by Section C. of the incorporated document in Regulation 26.12.01.01.

Classification of Radiation Machines - Radiation machines are classified according to the following system:

1. Group 1 - Radiation machine that can generate radiation levels of 500 rems in one hour at one meter from the source of radiation and are used to irradiate materials. These are the radiation machines subject to Section D.203(c)(6) of the incorporated document in Regulation 26.12.01.01.
2. Group 2 - Radiation machines that are used for human medical therapy. These are the radiation machines subject to Section F.8 and F.9 of the incorporated documents in Regulation 26.12.01.01.
3. Group 3 - Radiation machines other than those in Group 2 that are used for healing arts purposes in hospitals certified by the Joint Commission on Accreditation of Hospitals.
4. Group 4 - Radiation machines that are not included in Group 3 or Group 5, but their use is prescribed by a physician, chiropractor, or podiatrist.
5. Group 5 - Radiation machines that are not included above, but are used:
 - a. for research purposes;
 - b. in health care facilities operated by a local government;
 - c. solely for educational purposes.

State Certification Required for Radiation Machines -

1. Exemptions from other regulations not implied. A person is not exempted from complying with an applicable provision of the incorporated document in Regulation 26.12.01.01 because of compliance with this regulation.
2. General State Certification -- Other than during inspections for compliance with these regulations, a person may not cause or permit the use of any radiation machine after the State Certification due date specified for that machine (per the following table) if it has not been State Certified by the Agency.
3. Recertification after Replacement or Rebuilding of Major Components -- Except for routine X-ray tube replacement, a person may not cause or permit the use of any radiation machine that has had major components replaced or substantially rebuilt until the major component that has been effected has been re-inspected and the radiation machine has again been State Certified.
4. Interim State Certification -- A radiation machine shall be considered State Certified by the Agency until the first State Certification due date scheduled (per the following table) provided that the machine has been registered by the Agency under Section B. and F. of the Maryland State Department of The Environment Regulations for Control of Ionizing radiation (1995) which is incorporated by reference in Regulation 26.12.01.01 and provided that the person responsible for the use of the machine has not been notified by the Agency that the machine does not meet a provision of this chapter.

Application for State Certification -

1. Each person responsible for the use of a radiation machine shall apply for State Certification of the machine at least 45 days, but not more than 180 days, before the scheduled date shown (per the following table) and again after that according to the repeat cycle shown.
2. The application shall be made on a form issued by the Agency and shall contain:
 - a. All information indicated on the form;
 - b. A Departmental inspection report form that has been completed and signed by an inspector licensed under Regulation 26.12.01.03.
3. Except for applications for recertification following replacement or rebuilding of a major component, each person submitting an application shall remit a State Certification Fee with the application based on the following fee schedule:
 - a. Group 1 and Group 2 machine - \$250.00
 - b. Group 4 and Group 5 machine - \$100.00

Denial of Certification -

1. The Agency shall deny State Certification of a radiation machine if it determines that the use of the machine will result in a violation of either the Maryland Radiation Act, or any regulation promulgated under the Act.
2. A determination made by the Agency under 1) above may be made based on information contained on the inspection report form from an independent inspection made by the Agency, or any other pertinent information known by the Agency.

Note:

The Radiation Safety Office at UMD Campus will be responsible for ensuring compliance with these regulations and all submittal for registration and certification will be completed by this Office.

**Table 1
Certification Due Date**

Certification Due Date	Group 1	Group 4	Group 5
July 1, 1995	All	Even	
December 31, 1995			Odd
July 1, 1996	All	Odd	
December 31, 1996			Even
July 1, 1997	All	Even	
December 31, 1997			
July 1, 1998	All	Odd	
December 31, 1998			Odd
July 1, 1999	All	Even	
December 31, 1999			Even

Note: Odd and Even means those facilities with registration numbers ending in an odd or even number.

All refers to facilities of that group regardless of registration number.