VMS Summary
Vermont Department of Health Radiological Health Rule

Full proposed rule text found at:
https://www.healthvermont.gov/sites/default/files/documents/pdf/Radiological%20Health%20Rule.December%2013%202022.DRAFT_.annotated.pdf

This updated rule provides requirements for the safe handling, use, monitoring, notifications, record keeping, and reporting associated with radiation-producing (x-ray) machines in Vermont. These regulations primarily address diagnostic machines, but also establish requirements for radiation-producing machines used for therapeutics, as well as non-medical applications such as for security (e.g. body scanners) and industrial purposes.

Almost the entirety of Part A of the rule is new and was developed to be similar to the regulations of other states, including Colorado and New Hampshire. It also includes references to regulations and guidance from other agencies and organizations, including the Food & Drug Administration, American Academy of Physicists in Medicine, and the National Institute for Standards & Technology.

Sections 8 and 9 include the bulk of the new requirements, and physician practices that use radiation-producing machines in Vermont should review these sections to ensure they are consistent with current and/or best practices. **If your practice uses x-ray or other radiation-producing machines, please review the draft rule and contact Jessa Barnard at VMS at jbarnard@vtmd.org with questions or concerns by Friday, February 3rd.** The rule is open for public comment through February 14th.

Below is a brief summary of key sections:

- Section 5.0 – Registration – This section expands on Vermont's current registration requirements for ionizing radiation machine facilities and persons providing radiation machine installation, servicing and/or services, to encompass service providers and identifies the qualifications of these providers. It also adds a requirement that most facilities submit their shielding plans for Department review and approval. These plans may be developed at the request of the architect, installer, or the facility. This section also introduces reciprocal recognition of out-of-state machines.

- Section 7.0 - Radiation Protection – This section provides standards for radiation protection, including dose limits, record maintenance, notification and reporting requirements. Each registrant shall also develop, document, and implement a radiation protection program and post certain notices to workers. This section is consistent with Part B (related to radioactive materials, and which has not been updated), allowing facilities that are subject to both Parts to have one consistent program across their departments.

- Section 8.0 - X-Ray Imaging in the Healing Arts and Veterinary Medicine - This section describes requirements specific to the healing arts and veterinary medicine, including requiring written administrative controls, technique information, safety procedures and quality assurance programs. It requires that the floor plan and equipment configuration of each radiation machine facility be provided to a Qualified Expert who designs or evaluates shielding, and that the plan be submitted to the Department. It also addresses design requirements; radiation exposure control; reports of radiation medical events; and special requirements for certain equipment, such as fluoroscopy, handheld diagnostic equipment, CT, mammography and bone density. It updates the use of gonadal and fetal shielding consistent with new AAPM guidance.

- Section 9.0 - This section describes additional requirements specific to radiation therapy machines, including high-energy linear accelerators, used in the healing arts. It outlines required administrative controls, qualifications for operators, safety procedures, quality management programs, shielding and safety design requirements, recordkeeping and reporting requirements. There are requirements specific to Radiation Machines of Less than 500 kV; systems above 500 kV/keV; Radiation Therapy Simulation Systems, Electronic Brachytherapy, and other Electronically Produced Radiation

- Section 10.0 – This section addresses machines that are used in industrial and other non-healing arts applications.

- Section 11.0 – This section describes requirements for industrial radiographic machines.

- Section 12.0 – This section addresses particle accelerators not used in the healing arts and emphasizes radiation safety and monitoring.

- Section 13.0 – This section addresses the general requirements for records required to be maintained by other sections of the rule – such as legibility and electronic storage.

- Section 14.0 – This section addresses corrective action and enforcement. The Department may first issue a notice of non-compliance and may also issue notices of violation.

The economic impacts estimated by the Department of Health associated with this rulemaking are anticipated to be limited: Licensees may need to employ a Qualified Medical Physicist (QMP) or Qualified Expert to develop or review shielding plans, facility designs, configurations, preparations and/or dosimetry. In some cases, the QMP will be an existing employee of a facility, whereas other facilities may need to hire a QMP to provide these services. There may be economic costs for initial and refresher training requirements established for users of particle accelerators and therapeutic radiation machines used in the Healing Arts. There are new registration requirements for service providers for radiation-producing machines, which will have a negligible impact associated with the time it takes to complete that registration form.