NRC NEWS

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NRC REVISES REGULATIONS ON MEDICAL USES OF RADIOACTIVE MATERIAL

The Nuclear Regulatory Commission has revised its regulations on the medical uses of radioactive material. The regulations also respond to a petition for rulemaking filed by the University of Cincinnati.

The agency currently regulates the use of certain radioactive materials in medical diagnosis and treatment, as well as research, for about eleven million patients a year.

The revisions, designed to be both risk-informed and more performance-based, focus the regulations on the medical procedures that pose higher risks to workers, patients and the public from a radiation safety aspect. The regulations also eliminate some of the previous detailed requirements of those who perform lower risk diagnostic medical procedures such as bone or thyroid scans.

Licensees have six months to implement the new requirements.

Highlights of the revised rule are:

(1) Patient notification/reportable events -- Under the revised regulations, the term "medical event," referring to the administration of radioactive materials in a manner that differs substantially from the physician's direction, replaces the previous term "misadministration." The regulations continue to require that, when a medical event occurs, the licensee must notify the NRC, the referring physician and the affected patient, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. Previously, the licensee was required to provide a written description of the medical event regardless of whether it was requested. Under the revision, the patient must be informed that such a description can be obtained from the licensee. Also, under the revision, if the physician is not the licensee, the licensee must provide a copy of the medical event record to the referring physician.

(2) Radiation Safety Committee -- Under the revised regulations, the Radiation Safety Committee is responsible for broad oversight of the uses of certain radioactive materials. However, the current specific responsibilities of the Radiation Safety Committee have been transferred from the Committee to licensee management. A Committee is still required for certain medical licensees

performing two or more higher risk activities such as those used in the treatment of cancer. The regulations specify radiation safety goals or objectives for the Committee, but allow licensee management flexibility in implementing those goals.

(3) Physician's written directions -- Detailed requirements for a medical licensee to have a quality management program have been deleted. Instead, the revised regulations require that licensees have written procedures for those activities involving higher risk. Licensees must develop and maintain procedures to provide high confidence that the right patient receives the correct dose at the correct treatment site, consistent with the physician's written instructions.

(4) Training and experience -- Some of the training requirements for individuals performing diagnostic procedures using radioactive materials in unsealed form have been reduced, consistent with the lower risk associated with these procedures. However, the revised regulations retain the current training requirements for individuals using sealed sources of radioactive material for therapeutic administrations because of the higher risk associated with using these types of material. The training and experience requirements contained in Subpart J of the current regulation are also being retained for a two-year period from the effective date of the revised rule. Training and experience were the primary concerns expressed by commenters during development of the final rule.

In addition, the revised rule adds a requirement for reporting unintended medical radiation exposure of an embryo, fetus, or nursing child.

The revised rule also addresses a petition for rulemaking filed by the University of Cincinnati. The petition requested a 500-millirem radiation dose limit for certain individuals visiting patients who are required to be confined to the hospital while receiving radiation treatment, where the visitors are determined by the physician to be necessary for the patient's physical or emotional support. The response to the petition, incorporated into the rule, allows physicians the discretion to permit visitors to receive up to 500 millirem from exposure to a hospitalized patient. A millirem is a unit of measurement used to determine the effect of radiation on the body (for instance, a round-trip, cross-country flight is equal to about 5 millirem). The current limit of 100 millirem per year for visitors is the same as for members of the public under other circumstances. The agency believes the emotional benefit to the patient and the visitor outweighs any small increase in radiation risk to the visitor, and, accordingly, physicians should be provided the flexibility to make decisions regarding patients' visitors.

A proposed rule on the medical uses of radioactive material was published in the Federal Register for comment on August 13, 1998. The NRC staff held meetings and workshops since then in San Francisco, Kansas City and Washington, D.C., that included participation by the general public, state regulators, medical professional societies, and medical boards. Also, the Commission was briefed by the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and various stakeholders during public meetings. Issues regarding the rule were also discussed with the ACMUI at public meetings.

Over 600 comments were received during development of the rule, which were considered in development of the final version.

The agency has also revised its medical policy statement on the medical uses of radioactive material. Highlights of the policy statement were announced separately.

This regulation becomes effective six months after publication of a Federal Register Notice on this subject, expected shortly.

Documents related to this rulemaking may be examined at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-1 F23, Rockville, MD 20852. Documents will also be available through the NRC's Agencywide Document Access and Management System (ADAMS). Help in using ADAMS is available by contacting NRC's Public Document Room staff at 1-800-397-4209, 301-415-4737 or by sending an email message to pdr@nrc.gov.

For more information on the final rule, contact Roger W. Broseus at 301-415-7608, or by email at RWB@nrc.gov.

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