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NRC ISSUES QUALITY MANAGEMENT REQUIREMENTS FOR MEDICAL LICENSEES

The Nuclear Regulatory Commission is amending its regulations to require licensees who use radioactive materials for therapeutic procedures and certain procedures involving radioactive iodine to implement a quality management program to ensure that the radioactive material or radiation will be used as prescribed by physicians. This amendment will affect about 6000 NRC and Agreement State licensees.

The Commission is also changing its reporting and recordkeeping requirements related to the quality management program and reportable events and making conforming amendments to its enforcement policy.

An estimated 30,000 therapeutic procedures are performed each year using drugs containing radioactive materials, known as radiopharmaceutical. In these procedures, radioactive drugs are administered to treat hyperactive thyroid conditions and certain forms of cancer.

Sealed radioactive sources that produce high radiation are also used to treat cancer. About 100,000 patients per year receive treatments involving the application of a beam of radiation from cobalt-60 to the part of the patient's body to be treated.

Smaller sealed sources with less radioactivity are designed to be implanted directly into a tumor area or applied on the surface of areas to be treated. This procedure is known as brachytherapy. Licensees perform approximately 5O,OOO brachytherapy treatments annually.

This amendment to the NRC s regulations is intended to enhance patient safety in a cost-effective manner while a}lowing the flexibility necessary to minimize intrusion into medical judgments.

The revisions require affected licensees to implement a written quality management program that includes annual reviews and evaluations to determine whether the quality management program is still effective. The program will have to include written policies and procedures to ensure, for example, that the patient's identity is verified by more than one method prior to administering the radioactive material or radiation.

Currently, medical licensees are required to keep a record of each misadministration of radioactive materials and in certain circumstances to report the mistake to the NRC. The new regulations strengthen the requirements by adding additional types of mistakes to the list of those for which recordkeeping and reporting requirements apply. ~~

The amendments to Parts 2 and 35 of the Commission's regulations will become effective in January, 1992 and affected licensees, by then, must have implemented a quality management program and submitted a copy of the program to the NRC.

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