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NRC VOTES TO OVERRIDE OMB DISAPPROVAL OF INFORMATION COLLECTION REQUIREMENTS FOR MEDICAL USES OF RADIOACTIVE MATERIAL

The Nuclear Regulatory Commission has voted to override the Office of Management and Budget's disapproval of an information collection request associated with the NRC's regulations on the medical uses of radioactive material.

On July 25, 1991, the NRC amended 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 from the material will be used by technologists and other medical personnel as directed by authorized physicians. The amendment affected about 2000 NRC and 4000 Agreement State licensees. It became effective on January 27, 1992, for NRC licensees and remains in effect.

The quality management rule includes requirements that:

- Prior to administration of a radioactive material, a written directive must be prepared (to eliminate confusion resulting from oral directives);
- The patient's identity must be verified by more than one method as the individual named in the written directive;
- Final plans for treatment with certain techniques using radioactive material must be in accordance with the written directive;
- Each administration of radioactive material or radiation from the material must be in agreement with the written directive; and
- Any unintended deviation from the written directive must be identified and evaluated, and appropriate action taken.

At the same time the Commission changed its reporting and recordkeeping requirements related to the quality management program and to misadministrations that are reportable to the NRC and made conforming amendments to its enforcement policy.

On June 26, 1992, OMB notified the NRC that the Information Collection Request submitted to OMB in connection with this amendment had been disapproved.

In overriding OMB's disapproval, the NRC said that it continues to believe that its quality management and misadministration rule has a reasonable likehood of decreasing misadministrations (for example, wrong dose or wrong patient) with a small incremental cost to licensees, and that the rule would be of little value without the recordkeeping and reporting requirements.

The Paperwork Reduction Act authorizes an independent regulatory agency, such as the NRC, to override an OMB disapproval by a majority vote of its Commissioners. Under this law, the override is valid for three years.

In its letter of disapproval, the OBM expressed concern that, based on its discussions with members of the regulated community and the NRC staff, there appears to be significant confusion on exactly what information collection requirements are imposed by the quality management and misadministration rule. The NRC staff intends to clarify any such potential misunderstanding through a public workshop--with details to be announced shortly.

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