United States Nuclear Regulatory Commission
Office of Public Affairs
Washington, DC 20555
Phone 301-415-8200 Fax 301-415-2234
Internet:opa@nrc.gov

No. 98-138

FOR IMMEDIATE RELEASE
(Friday, August 7, 1998)

NRC PROPOSES TO REISSUE POLICY STATEMENT ON MEDICAL USES OF RADIOACTIVE MATERIALS

The Nuclear Regulatory Commission is proposing to revise its 1979 policy statement on the medical uses of radioactive material. The agency intends to focus regulation on medical procedures that pose the highest risk to workers, patients and the public and to structure its regulations to be risk-informed and more performance-based.

The proposed policy statement stresses the Commission's determination to continue to regulate the use of radioactive materials in medicine, with the goal of protecting the radiation safety of occupational workers, the public and patients, without intruding into medical judgments affecting patients except as necessary to ensure adequate protection. When justified by the risk, the NRC will regulate the radiation safety of patients by ensuring that the physician's directions for administration of the radioactive material or radiation are followed.

The proposed statement and associated proposed revisions to the agency's regulations, which are expected to be published soon for public comment, result from the NRC's detailed examination of issues regarding its medical use program during the last five years. This process started with a 1993 internal senior management review of the medical program. It continued with the NRC-requested 1996 independent external review by the National Academy of Sciences, Institute of Medicine; and culminated in NRC's strategic assessment and rebaselining initiative. In September 1997, the Commission issued its strategic plan, which included the subject of medical oversight and stated that its goal in regulating nuclear materials safety is "to prevent radiation-related deaths or illnesses due to civilian use of...nuclear materials."

In its March 20, 1997, direction to its staff, the Commission stated that it supported continuation of the ongoing medical use regulatory program with improvements, decreased oversight of low-risk activities, and continued emphasis on high-risk activities. The Commission expressed its support for the continued use of its Advisory Committee on the Medical Use of Isotopes (ACMUI), professional medical organizations and societies, and members of the public in the revision of the regulations and the medical policy statement, if necessary.

In developing the proposed policy statement revision, the Commission established a working group and a steering group, made up of members of the NRC staff and state organizations, which held a series of public meetings and workshops in the fall of 1997 and the spring of 1998 to obtain public and stakeholder suggestions. To ensure that a wide cross-section of interests were represented, invited workshop participants included physicians, radiopharmacists, medical physicists, radiation safety officers, educators, patient rights advocates, nurses, medical technologists, hospital administrators, representatives of state and

federal governments, and radiopharmaceutical manufacturers.

The NRC has received comments on the proposed revision of the medical policy (which was posted on the NRC web site), through meetings of the ACMUI, professional medical organization meetings and state regulators. It also has solicited written and electronic comments.

Under the proposed new policy statement:

"(1) NRC will continue to regulate the uses of radionuclides in medicine as necessary to provide for the radiation safety of workers and the general public." This portion restates the first part of the current policy statement, issued in 1979, but substitutes the phrase "uses of radionuclides in medicine" for the phrase "medical uses of radioisotopes." As noted in an August 6, 1997, Federal Register notice requesting public comments on development of revised regulations on medical uses, the Commission "was not persuaded by the National Academy of Sciences, Institute of Medicine report that recommends that the NRC should not be the Federal agency involved in the regulation of ionizing radiation in medicine."

"(2) NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public." This portion is based on the third portion of the current statement. It substitutes the phrase "will not intrude" for the current "will minimize intrusion," as suggested by the ACMUI.

"(3) NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's directions." This portion is based on the second part of the current statement, but makes clear that the focus of this regulation is primarily on ensuring that physician's directions are followed. This part of the statement also reflects the Commission strategy of decreasing oversight of materials that pose the lowest radiological risk to the public and continuing emphasis on high-risk activities.

"(4) NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety." This portion is also based on the second part of the current policy statement, which states that "The NRC will regulate the radiation safety of patients...where voluntary standards, or compliance with these standards, are inadequate." The proposed revision indicates that NRC will consider industry standards in regulating medical uses of nuclear material, as part of its strategy to increase the involvement of licensees and others in its regulatory development process.

The proposed new policy statement will be published in the Federal Register shortly. Interested persons are invited to submit written comments to the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemakings and Adjudications Staff, within 90 days of publication of the Federal Register notice. Comments may also be submitted electronically through the NRC's interactive rulemaking website at http://www.nrc.gov/NRC/rule.html.

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