



NRC NEWS

U.S. NUCLEAR REGULATORY COMMISSION

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No. 00-115

July 26, 2000

NRC REVISES POLICY STATEMENT ON MEDICAL USES OF CERTAIN RADIOACTIVE MATERIALS

The Nuclear Regulatory Commission has revised its 1979 policy statement on the medical uses of NRC-regulated radioactive material to put greater emphasis on higher risk procedures, and correspondingly less emphasis on procedures posing lower risk to the patient, workers and the public.

The policy statement affirms the Commission's determination to continue its role in regulating the use of certain radioactive material in medicine with the goal of providing adequate radiation protection for workers, the public, and patients. The policy statement focuses the Commission's direction on radiation safety issues and furthers the objective of utilizing industry and professional standards that define acceptable levels of radiation safety.

The policy statement and amended regulations on the medical use of certain radioactive material, which will be announced separately, result from the NRC's detailed examination of its medical use program during the last several years.

One purpose of NRC regulation of the medical use of certain radioactive material is to reduce unnecessary radiation exposure to patients, workers, and the public. The focus of NRC regulation to protect the patient's health and safety is primarily to ensure that the physician's directions are followed as they pertain to the administration of radiation or of NRC-regulated radioactive material, rather than to non-radiation aspects of the administration. Although the Commission recognizes that physicians have primary responsibility for the protection of their patients, NRC also has a necessary role in the radiation safety of patients. NRC regulations are based on the assumption that properly trained and adequately informed physicians will make decisions that are in the best interest of their patients.

NRC established a working group of agency staff and state organization representatives to develop the revised policy statement. The group held a series of workshops and meetings over a two-year period. To ensure that a wide variety of interests were represented, invited workshop participants included physicians, radiopharmacists, medical physicists, radiation safety officers, educators, patients rights advocates, nurses, medical technologists, hospital administrators, representatives of state and federal governments, and radiopharmaceutical manufacturers. The revised policy statement takes into account written comments on the statement as proposed in the Federal Register, and those obtained during the workshops and meetings.

The revised medical policy contains the following statements:

“(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.” Retention of this portion of the previous policy statement affirms the Commission determination that it will continue its role of regulating the use of certain radioactive material in medicine, with the goal of providing radiation safety for workers, the public, and patients.

“(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 sentence is based on the third statement of the previous medical policy statement. It substitutes the phrase “will not intrude” for the previous “will minimize intrusion.”

“(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 statement makes clear that the focus of NRC regulation is primarily on ensuring that physician’s directions, as they pertain to the administration of radiation or of NRC-regulated radioactive material, are followed. It also reflects the Commission’s strategy of decreasing oversight of those uses of certain nuclear materials that pose the lowest radiological risks and strengthens emphasis on those posing higher risks.

“(4) NRC, in developing a specific regulatory approach, will consider industry and professional standards that define acceptable approaches of achieving radiation safety.” The revision incorporates NRC’s intention to consider industry and professional standards in developing regulations and guidance for the medical use program.

The policy statement will be published shortly in the Federal Register, and will be available at the agency’s Public Document Room in Washington, D.C., telephone 202-634-3273.

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