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# NRC CHANGES REGULATIONS TO INCREASE FLEXIBILITY IN MEDICAL USES OF NUCLEAR MATERIAL

The Nuclear Regulatory Commission is changing its regulations for the medical use of nuclear material to provide greater flexibility for authorized physicians and qualified pharmacists.

The changes are responsive to a petition for rulemaking submitted to the NRC by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The revisions will:

(1) Include the concept of an "authorized nuclear pharmacist," so that pharmacists who meet specified training and experience requirements would be authorized to prepare radioactive drugs from scratch. Currently, these pharmacists are restricted to preparing radioactive drugs using special kits and certain devices, known as "generators," that produce needed short-lived radioactive materials from other--more stable and long-lived--radioactive materials.

(2) Allow the use of radioactive materials in research involving human beings, provided that the licensee obtains informed consent and approval of the research project by an institutional review board, as described in the Federal Policy for the Protection of Human Subjects. Currently NRC licensees must get special permission to use radioactive materials in research involving human beings. The proposed rule would allow the practice on a more routine basis.

(3) Allow the use of radiolabeled biologics (such as antibodies to which radioactive material has been affixed). The biologics could be used for purposes such as to (a) detect the presence of tumors that may not be detected by other means and (b) treat the tumors by directing highly radioactive antibodies to these sites. Current NRC regulations do not specifically permit licensees to use radiolabeled biologics, although research uses have been permitted by special permission for certain licensees.

(4) Continue the flexibility provided in an NRC interim rule published on August 23, 1990. The interim rule allowed physicians more discretion in using radioactive drugs, since it deleted the requirement in the previous regulations that physicians must follow (a) Food and Drug Administration approved package insert instructions regarding indications and method of administration of radioactive drugs to treat patients and (b) manufacturers' instructions for preparing radioactive drugs from kits and "generators." FDA generally does not require physicians to follow these instructions.

The changes also include miscellaneous revisions to clarify, update and simplify the current regulations, such as accepting certification in nuclear medicine by the Royal College of Physicians and Surgeons of Canada.

The Commission does not believe that these changes will result in any significant increase in radiation exposure to the public or the environment beyond the exposures currently resulting from medical uses of nuclear material.

A proposed rule on this subject was published in the Federal Register for public comment on June 17, 1993. Minor changes made as a result of the comments received are discussed in a Federal Register notice issued on November 30. The amendments will be effective on January 1.

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