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

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NRC PROPOSES EXTENSIVE REVISIONS TO REGULATIONS ON MEDICAL USES OF RADIOACTIVE MATERIAL

The Nuclear Regulatory Commission is proposing extensive revisions to its regulations on medical uses of radioactive material. The revisions, designed to be risk-informed and more performance-based, focus regulation on the medical procedures that pose the highest risk to workers, patients and the public from a radiation safety aspect.

The NRC regulates the use of byproduct material and radiation from byproduct material in medical diagnosis and treatment, as well as research, for about eleven million patients a year.

In developing the proposed changes to the regulations, the NRC provided extensive opportunities for public input beyond the normal rulemaking process. Publicly announced meetings and workshops were held last year and this year where rulemaking alternatives for significant “cross-cutting issues” were discussed. The alternatives for the cross-cutting issues were discussed with the NRC’s Advisory Committee on the Medical Uses of Isotopes, as well as with state regulators, medical professional societies, and the public at meetings in Philadelphia and Chicago. In addition, the rulemaking alternatives and an early “strawman” version of the NRC staff’s proposed revisions to the regulations were made available for comment on the Internet and in the NRC’s Public Document Room in Washington, DC, as early as January of this year.

In general, the proposed changes to the regulations reflect an overall change in regulatory philosophy to make the regulations more performance based and to delete some of the more detailed requirements. An applicant for an NRC medical-use license would have to develop and implement procedures, but would no longer be required to submit those procedures as part of the license application. Further, licensees would have maximum flexibility in developing their procedures, because most of the requirements in the proposed changes to the regulations are stated in terms of the objectives to be achieved, rather than stated with a list of prescriptive details.

The significant cross-cutting issues that were identified, and their resolutions in the proposed revisions to the regulations, are:

(1) Patient notification/reportable events -- The requirements in the current regulations for notifying individuals following a misadministration would remain unchanged, with the exception of substituting the term “medical event’ for “misadministration.” The term, defined in detail in the proposed revisions to the regulations, generally refers to the administration of radioactive materials or radiation in a manner that differs substantially from the physician’s direction. Using “medical event” responds to objections that the term “misadministration” has possible connotations of carelessness and harm, which is not always the case. In addition, “medical event” is consistent with terms used to characterize events in non-medical activities regulated by the NRC. The proposed regulations would continue to require that, when a medical event occurs, licensees must notify the NRC, the referring physician and the affected patient -- unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgment, telling the individual would be harmful. If the patient is a minor, or is unconscious and incapable of comprehending the information, it is expected that the licensee would report to the patient’s responsible relative or guardian rather than to the patient.

(2) Radiation safety committee -- The proposed revisions to the regulations delete the requirement for a medical institution licensee to have a radiation safety committee, with specified membership and duties, to oversee the use of radioactive material. The key functions of the committee would be transferred to licensee management. The proposed regulations specify the responsibilities for and functions to be accomplished by the radiation safety program, including some of the functions previously listed as those of the radiation safety committee.

(3) Quality management program -- Provisions in this area have been revised to focus more on patient safety. Detailed requirements for a medical licensee to have a quality management program have been deleted. Instead, the proposed revisions to the regulations require licensees to have written directives for procedures involving greater risk. Licensees would also have to develop, implement and maintain procedures to provide high confidence that the right patient receives the correct dose at the correct treatment site, consistent with the physician’s written directive. This proposed revision not only eliminates unnecessary details, but is more consistent with a proposed revision to the agency’s NRC’s medical policy statement, which states that “NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides in accordance with the physician’s directions.”

(4) Training and experience -- Requirements in both the current regulations and the proposed revisions differ for diagnostic versus therapeutic uses of nuclear material. The proposed regulations basically retain the current training requirements for therapeutic uses of sealed sources of radioactive material because of the high risk associated with the types of material in such uses. However, the proposed revisions would reduce some of the training requirements for diagnostic procedures using radioactive materials in unsealed form, because of the lower risk associated with these procedures. Training and experience were the primary concerns expressed by the

public comments during development of the proposed changes to the regulations. Most of the commenters thought the current requirements should be retained. Under the proposed revisions, the current training requirements would stay in effect for two years to allow licensees time to implement the new requirements. During the intervening period, licensees would have the option of meeting either the current or the revised requirements.

(5) Precursor events -- The Commission considered, but is not proposing, changes that would have required licensees to notify the NRC after identifying certain types of defects in equipment, radioactive material or procedures supplied by a manufacturer or vendor. Instead, the agency will issue an information notice to alert licensees to existing requirements and will reinforce the need for compliance with these requirements in its inspection and enforcement activities.

The proposed changes to the regulations also address a petition for rulemaking filed by the University of Cincinnati. The petition requests a 500-millirem radiation dose limit for certain individuals visiting patients who are required to be confined to the hospital while receiving radiation treatment, where the visitors are determined by the physician to be necessary for the patient's emotional or physical support. The current limit of 100 millirem for visitors is the same as for members of the public under other circumstances. The proposed regulations would respond to this petition by allowing licensees the discretion to permit visitors to receive up to 500 millirem from exposure to a patient who could not be released under Section 35.75 of the Commission's regulations.

In addition, the proposed changes add a requirement for reporting unintended radiation exposure of an embryo, fetus, or nursing child, and add specific requirements for medical uses of radiation by a licensee at temporary job sites and for specific technologies that are not currently addressed in the regulations. They also add a section to allow easier licensing of new medical procedures that use radioactive material or radiation.

Details of these and other aspects of the proposed changes to the regulations are contained in a Federal Register notice to be published shortly. Interested persons are invited to submit comments within 90 days of publication of the Federal Register notice to the Secretary, U.S. Nuclear Regulatory Commission, Attention: Rulemakings and Adjudications Staff.

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