ASTRO
American Society for Therapeutic Radiology and Oncology

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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Secretary, U.S. Nuclear Regulatory Commission
Attn: Rulemaking and Adjudications Staff
Washington, DC 20555

RE: PRM-35-18 Peter G. Crane Petition for Rulemaking

The American Society for Therapeutic Radiology and Oncology (ASTRO) appreciates the opportunity to provide comments on the Petition for Rulemaking announced in the Federal Register on December 21, 2005. We strongly oppose the request by the petitioner that the Nuclear Regulatory Commission (NRC) partially revoke the 1997 amendment to 10 CFR 35.75, "Release of Individuals Containing Radiopharmaceuticals or Permanent Implants." We believe instead that this amendment must remain unchanged.

The American Society for Therapeutic Radiology and Oncology (ASTRO) was founded in 1958, and represents the largest radiation society in the world. With more than 8,000 members, ASTRO interacts with the healthcare system at all levels. Radiation therapy is recognized as one of the most effective methods for treating cancer and other nonmalignant diseases, and approximately two thirds of cancer patients are treated with radiation during the course of their disease. ASTRO's mission is to advance the practice of radiation oncology by disseminating the results of scientific research, promoting excellence in patient care, providing opportunities for educational and professional development of its members, developing policies, and representing radiation oncology in a rapidly changing healthcare environment.

Background

This petition for rulemaking requests that the Nuclear Regulatory Commission (NRC) partially revoke the 1997 amendment to the "Medical Use of Byproduct Material" (10 CFR 35), the "Release of Individuals Containing Radiopharmaceuticals or Permanent Implants" (Patient Release Criteria Rule), to specifically prohibit the release of patients from radioactive isolation with more than the equivalent of 30mCi of iodine-131 (I-131) in their systems. This petition represents a request to revert back to the standard for patient release as it originally stood in regulation prior to the amendments in 1997. Specifically, the pre-1997 standard explicitly required hospitalization of patients with the equivalent of 30mCi or more of I-131 in their systems. Clinical and social considerations led the NRC to update the regulations in 1997, permitting the release of patients who had been given unsealed byproduct material if the dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5rem). It also required that the released patients be provided written instructions on how to limit radiation exposure to other individuals if the patients' total effective dose is likely to exceed 1 millisievert (0.1rem) in any one year.[1]

[1] 62 FR 4121

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SECY-02

Clinical and Social Benefits under the Current Rule

The 1997 amendment to 10 CFR 35.75 has several important clinical and social benefits. Allowing patients to be treated on an outpatient basis and to return home sooner has significantly improved both patient comfort and safety. The home environment provides patients with significant emotional benefit, and the risks of nosocomial infection and other adverse effects of hospitalization are well known and documented. Furthermore, patients are instructed carefully in outpatient radiation precautions, and the precautions themselves are easy to understand. Given appropriate written materials or oral education, as required by the current regulation, the vast majority of patients can follow these precautions without difficulty. Those patients who experience difficulty following the precautions or who are unable to follow them may be hospitalized, but compelling the admission of all patients would have a negative effect on both patient safety and emotional well-being. In addition, having the patient at home can be emotionally beneficial for the patient's family.

If all patients were required to be hospitalized, there would be a substantial risk of frequent exposure to radiation for a wide range of hospital staff and employees including physicians, nurses, other health professionals, clergy, food service and janitorial employees. The amount of radiation exposure to a patient's family is minimal, but over time, the small exposure for hospital staff could reach unhealthy levels. Conversely, outpatient therapy with patients who are willing and able to adhere to the required radiation precautions ensures that hospital staff and others will receive very little radiation exposure. The experience of many radiation oncologists providing patients with this treatment indicates that the majority of thyroid cancer patients are young and robust, can readily follow the safe and simple radiation precaution, and have little "trouble comprehending and remembering the guidance they are given," as suggested in the petition.

Public Health and Children's Exposure

The NRC's primary concern is minimizing the public's exposure to radiation, thus maintaining the public's health. The rule in its current form achieves this goal as radiation exposure rates to the public under the current rule are minimal. Specifically, the rule in its current form allows release of patients *only if* the dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5rem). A dose-based limit "provides a single limit that can be used to provide an equivalent level of risks from all radionuclides" which allows exposure to the public to be better measured, controlled and contained. Second, this rule adheres to recommendations of both the International Commission on Radiological Protection (ICRP) and the National Council on Radiation Protection (NCRP) that an individual may be allowed to receive an annual dose of up to 5 millisieverts (0.5rem) in temporary situations when exposure to radiation is not expected to result in annual doses above 1 millisievert.[2]

The petitioner "expressed particular concern regarding how children of released patients will be adequately protected from radiological exposure."[3] The radiation precautions given to every patient explicitly address this issue. In many cases, patients are instructed to arrange to have young children stay with another caregiver for several days while the patient remains at home after I-131 administration. If such arrangements cannot be secured, the physician may choose to hospitalize the patient. Importantly, hospital admissions for radioiodine, even under the rule in its pre-1997 form, are almost

[2] 62 FR 4121
[3] 70 FR 75753

always limited to 1 or 2 days. Radiation precautions for children are required for longer than a 1or 2 day period of time. Therefore, requiring hospitalization of all patients with more than the equivalent of 30mCi of iodine-131 (I-131) in their system would not obviate the need for good patient education and strict compliance with radiation precautions.

Impact on Health Care Costs

Rising health care costs are a major societal concern and are compelling the evaluation of new methods for delivering care in safe and cost-effective ways. It is clear that requiring hospitalization of all patients with more than the equivalent of 30mCi of iodine-131 (I-131) in their systems would be significantly more costly than allowing these same patients to be treated on an outpatient basis. Clearly cost should not be the driving factor in patient care. However, when the patient's course of care and treatment outcomes are not altered (in this case the patient's safety and well-being are enhanced) and where the public's health and safety are maintained, the lower cost option should be utilized. This will allow for the most effective use of limited health care resources.

Conclusion

In summary, the regulation as it stands facilitates good patient care, safety and comfort; maximizes and secures the health of the public, children, and hospital staff; and minimizes health care costs. In addition, it preserves the physician's ability to provide patients with the best possible care, including maximizing quality of life. We strongly recommend that this regulation be left in its current form and not be modified as suggested by the petitioner.

Sincerely,

Laura Thevenot

Laura Thevenot
Chief Executive Officer, ASTRO

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Date: Mon, Mar 6, 2006 4:39 PM
Subject: PRM-35-18 Peter G. Crane Petition; Comments from American Society for Therapeutic Radiology and Oncology

Dear Rulemaking and Adjudication Staff:

Please accept the attached public comments in response to PRM-35-18 on behalf of the American Society for Therapeutic Radiology and Oncology (ASTRO). We appreciate the opportunity to provide comments on this issue.

Please confirm that you are in receipt of this message. Thank you very much.

Sincerely,

Amanda Sarata

Senior Policy Analyst

Department of Government Relations

American Society for Therapeutic Radiology and Oncology

CC: "Laura Thevenot" <Thevenot@astro.org>, "David Diamond" <dagdmail@yahoo.com>, "Lisa Shuger Hublitz" <lisas@astro.org>, <leland@gammawest.com>

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Subject:	PRM-35-18 Peter G. Crane Petition; Comments from American Society for Therapeutic Radiology and Oncology
Creation Date:	Mon, Mar 6, 2006 4:44 PM
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