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(7)

January 6, 2006

Annette Vietti-Cook, Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Re: Comments to Petition for Rulemaking Submitted by Peter G. Crane, Docket No. PRM-35-18

Dear Ms. Vietti-Cook:

The Petition for Rulemaking (PRM) submitted by Mr. Crane (PRM-35-18) requests that the NRC partially revoke 10 CFR 35.75, the "patient release criteria" rule, issued in 1997, to not allow patients to be released from radioactive isolation with more than 30 mCi of I-131 in their bodies. The PRM confines its arguments to orally administered I-131 for the treatment of thyroid cancer. Therefore, orally administered I-131 should be in a class by itself for regulatory purposes and its use should be subjected to a 30 mCi release limit; all other radionuclides and treatments should still be subjected to a dose-based limit. The petitioner believes that the 1997 amendment to 10 CFR 35.75, with respect to orally administered I-131 only, is defective on both legal and policy grounds.

I would like to comment briefly on the legal grounds presented in the PRM. Mr. Crane was an attorney employed by the NRC at the times in question and, importantly, had contemporaneous knowledge of the issues he raises. Mr. Crane apologizes to the thyroid community in his PRM for not dealing with this 8 years ago. He queries in the legal irregularities portion of his PRM, "So long as patients are getting appropriate care and the public is adequately protected, why rake up past controversies now?" But then he responds with, "... the result of this rule change is that patients are *not* getting appropriate care and their family members and the general public are *not* being adequately protected." Therefore, Mr. Crane himself apparently considers the legal issues he raises to be moot, if indeed there were no adverse effects on public health and safety. So it is really only necessary to comment on the policy grounds raised in the petition.

First of all, a return to the "30-mCi rule" would indeed be regressive. There is no credible origin or rationale for this rule as elucidated in the article I published on the topic: Siegel JA. Tracking the origin of the NRC 30-mCi rule. J Nucl Med 41:10N-16N, 2000. For decades, patients administered radioactive materials had to be hospitalized until their content of radioactivity was less than 30 mCi. This release limit was applied to all radionuclide treatments from the 1950s until 1997; importantly there is no evidence demonstrating that 30 mCi would actually present a hazard to the public health and safety. Empirical data obtained by measurement of the dose received by family members of thyroid cancer patients receiving I-131 in the 1970s and more recently (Grigsby et al. JAMA 2000; 283:2272-2274), support and confirm that there is no justification for the 30-mCi limit. Further, a regulatory analysis (NUREG-1492) published in 1996 concluded that the revised patient-release rule is safe according to standard radiation protection principles. Finally, the revised patient-release rule treats patients on an individual basis whereas the 30-mCi rule treats all patients the same regardless of individual circumstances. Simple knowledge of administered activity, without consideration of such things as radionuclide clearance in the body and the patient's lifestyle, would therefore not effectively allow licensees to be in compliance with 10 CFR Part 20. How can you achieve doses to members of the public that are within radiation protection standards and maintain these doses ALARA, when you do not actually know the doses involved? In point of fact, a patient receiving 30 mCi of I-131 for hyperthyroidism can potentially expose individuals to a larger radiation dose than a patient receiving 200 mCi of I-131 for thyroid cancer due to the much longer retention of I-131 in the body in the former case. The "30-mCi rule" has finally been dropped by the NRC and it should not be brought back into regulatory practice.

The NRC believes that a dose-based approach for patient release, rather than the simplistic one-activity-fits-all release limit, better expresses its primary concern for the public's health and safety. This was expressed by NRC when it issued the rule change in 1997. The important radiation safety issue is dose to others, not activity to patients and the revised patient-release rule is consistent with NRC policy. (The NRC is bound by statue to regulate the use of byproduct material, as well as source and special nuclear material, "to protect health and minimize danger to life or property.") Further, in 1997, the Commission directed the staff to revise all of Part 35. One of the purposes for the revision was to develop more risk-informed, performance-based regulations for the medical use of byproduct material. A revised Part 35 was published in the Federal Register in 2002 (67 FR 20298) along with answers to submitted comments. In response to the question, "Should any changes be made to the criteria for release of individuals containing radiopharmaceuticals or implants?" the NRC replied, "The NRC does not believe that any changes are needed..." "We believe that the release criteria provide licensees with needed flexibility in program management." Thus, a full five years after 10 CFR 35.75 was revised, the NRC still did not believe any changes were needed.

During the rewrite of Part 35 and at various workshops given by NRC, I was told repeatedly by NRC staff that to adequately evaluate the new risk-informed, performance-based regulations, including of course the revised patient-release rule, three questions

needed to be asked and their answers carefully evaluated:

1. What could happen?
2. How likely is it?
3. What are the consequences?

Let's keep these questions in mind when determining whether Mr. Crane raises any valid issues in his PRM that would suggest that the revised patient-release rule is contrary to NRC policy and thereby would result in adverse effects on health and safety. The petitioner's justifications for the requested partial revocation of 10 CFR 35.75 for orally administered I-131 include the following points:

1. His knowledge of one woman who had been treated for thyroid cancer with I-131. She took public transportation to her home that she shares with her husband and two children (ages not given) and then became nauseous and vomited.
2. His "question and answer" presentation: "How frequent are such instances of post-treatment vomiting by thyroid cancer patients receiving therapy doses of I-131? I frankly don't know. Does firm data exist? I have no idea."
3. NRC staff in 1994, stated that "Vomiting is seldom an important elimination route for radiopharmaceuticals after the patient has left the medical facility since orally administered radiopharmaceuticals such as Iodine-131 are rapidly absorbed, within a half hour, by the gastrointestinal system. Mr. Crane asserts, "I find it hard to believe that if you vomit up the contents of your stomach 35 minutes after being given a 150 millicurie treatment of I-131, there will be no radioactivity in the vomitus."
4. His belief that the patient release rule creates unwarranted hazards with regard to the radioactive iodine treatment of thyroid patients. "Patients treated for thyroid cancer with radioactive iodine-131 are now being sent home to their families under conditions that guarantee that family members will receive larger and potentially harmful doses of radiation, under uncontrolled conditions."
5. NRC believes that the patient release rule will provide emotional benefits to patients and their families but in Mr. Crane's opinion, a patient, namely him, may experience greater emotional benefit from knowing that by receiving their treatment as an inpatient, they are protecting their families from unnecessary radiation exposure.
6. His perception that a licensee must only perform a calculation showing that no one will receive a dose that exceeds a prescribed limit and that released patients may have trouble comprehending and remembering the instructions they are given to minimize exposure to others, particularly children.

The petitioner has thus identified two things that could happen, namely, increased family member dose and patient vomiting at home, as a result of the revised patient-release rule. But, he has failed to provide any meaningful information regarding their likelihoods or consequences. While it is likely true that family members may receive larger doses, these

doses have been documented to be modest, amounting to a negligible risk. The likelihood of patients vomiting after being administered I-131 for the treatment of thyroid cancer is not known to any reliable certainty but it has never been documented to occur to any significant extent. Some institutions administer antiemetics, but others believe this practice to be counter-productive to totally prevent such a rare occurrence in the first place. If indeed a patient gets nauseous and vomits as a result of the radioiodine, this will not occur for many hours after the administration when the radioactivity in the stomach will be a small fraction of the dosage administered and thus a significant amount of radioactivity in the vomitus is highly unlikely. Lastly, as I will discuss next, some of the petitioner's arguments and concerns (see points #4 and #6 above) have more to do with an incorrect perception of licensee compliance than with the revised patient-release rule itself.

The revised 10 CFR 35.75 requirement states that an individual who has received unsealed byproduct material can be released from licensee control if the TEDE to any other individual from exposure to the released individual "IS NOT LIKELY TO" exceed 5 mSv. A three step approach is necessary to ensure that a treated and released individual is not likely to expose any member of the public to the regulatory dose limit:

1. An evaluation of individual's living and working conditions must be performed to ascertain whether or not the patient can be safely released;
2. A dose calculation should be performed to ensure that no individual will likely be exposed to a dose in excess of 5 mSv. This patient-specific dose calculation should be based on measured patient parameters, such as dose rate and clearance rate (Siegel JA. *Nuclear Regulatory Commission Regulation of Nuclear Medicine: Guide for Diagnostic Nuclear Medicine and Radiopharmaceutical Therapy.* Reston, VA: Society of Nuclear Medicine; 2004); and
3. Written, not just oral, instructions that are simple and clear must be provided so that the patient can limit the radiation dose to others to as low as reasonably achievable. The AU physician must be satisfied that patient compliance with these instructions is highly likely.

Each of these three steps is equally important. For example, it is important to know if infants, young children or pregnant women reside in the released patient's home (or are likely to come in contact with the patient) in order to conclude that the patient should be released and/or in order to provide meaningful instructions to minimize exposure to these individuals, which in the professional opinion of the AU physician will be comprehended by the patient and likely complied with. Any licensee releasing patients "willy-nilly" and not giving due consideration to the three steps above should be considered to be NOT in compliance with 10 CFR 35.75. Clearly, regulations will not prevent all unintended exposures. The underlying premise of NRC regulations is that authorized user physicians will understand radiation safety principles and practices and will make appropriate decisions. Licensees have certain responsibilities and need to implement policies and procedures to ensure adequate and effective radiation safety practices.

In conclusion, NRC should retain the patient-release rule as is and not treat orally administered I-131 as a separate and distinct regulatory entity. The PRM offers insufficient documentation to support the claim that the revised patient-release rule is contrary to NRC policy. No valid arguments to justify the partial revocation of the patient-release rule are presented in the PRM; the petitioner simply presents anecdotal evidence along with his "beliefs." I would strongly urge the NRC to deny this PRM and do so expeditiously.

Sincerely,

Jeffry A. Siegel, Ph.D.
President & CEO

From: <nukephysics@comcast.net>
To: <SECY@nrc.gov>
Date: Fri, Jan 6, 2006 1:25 PM
Subject: Comments on PRM-35-18

Attached please find my comments regarding PRM-35-18. Thank you

Jeff Siegel

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