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From: "Stephen Gerard" <skgnuc@earthlink.net> (70FR 75752) December 27, 2005 (10:00am)
To: <SECY@nrc.gov>
Date: Thu, Dec 22, 2005 5:58 PM
Subject: Comment on PRM-35-18 Proposed Rule Change

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

December 22, 2005

Dear NRC:

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I am deeply concerned about the above-captioned rule change proposed by a retired attorney, who apparently has not had much experience in patient care. I am a Nuclear Medicine practitioner with 17 years' experience in the treatment and management of patients with thyroid cancer, including the administration of radioactive I-131, and I take serious issue with the proposal to "turn the clock back" on this option of outpatient I-131 treatment of patients with thyroid cancer.

Please note the following advantages of outpatient I-131 dosing of thyroid cancer patients: 1) decreased COST of treatment, averting the expense of a hospital stay; 2) decreased exposure to other ancillary hospital staff and nearby patients; even though efforts are required to keep exposures below the specified thresholds, these exposures are still cumulative for occupational workers at the time of release and monitoring, when repeated routinely for multiple such patients admitted to the hospital; 3) IMPROVED patient comfort and convenience of being at home, rather than confinement in the hospital environment, particularly when recovering from the symptoms of severe hypothyroidism. The aesthetics of this aspect to the patient should not be underestimated.

The petitioner is concerned that patients are "sent out the door" where they are risk of exposure to others. We do not blithely send post I-131 treatment patients "out the door", but rather, we carefully explain to them that they exit rapidly for their escort vehicle driven typically by a close family member. We do not permit them to drive themselves. We explain to them that they must sit "catycorner," i.e. at the opposite far corner of the passenger seat from the driver's seat, and we even make sure that this drive is not of an excessive duration, out of ALARA consideration to the driver.

The petitioner is concerned about the risks of vomiting of the I-131 dose and exposure to others. We educate our patients to bring with them for the trip home a very sturdy plastic lined bag, the size of a large shopping bag, in which to contain any vomitus on the way home. We inform them that they should take efforts to avoid vomiting of the dose if at all possible, and we prescribe for them anti-nausea medication if there is any question in this regard. We also inform them that this is a rare complication, so that they do not obsess excessively on this possibility, which helps to decrease the likelihood of post-dose vomiting. We inform them to call our department if they do vomit the dose, to give them further instructions on disposing of the vomitus, should they develop nausea and vomiting. However, as noted, this has been an extremely rare complication in our experience.

The petitioner has apparently failed to consider that those of us who are responsible for treatment of patients with high doses of I-131, such as those used for treatment of thyroid cancer, are not just technicians blindly following a standard protocol without regard for the ability of the patient to maintain safety in regards to bystanders in the household and in the proximate environment. On the contrary, we routinely and carefully interview our patients and their family members accompanying them to assess their ability to understand and comply with the requirements of minimizing exposure to other household inhabitants and bystanders. It is a responsibility we all take very seriously. We are well aware of the patients' hypothyroid status, which may well compromise their ability to follow instructions. Insofar as small children are concerned, we would typically not authorize placement of a post-thyroid-cancer-treatment patient at his or her home unless those small children could be placed elsewhere during the initial week. We educate our patients as to all such guidelines, with clear written instructions, as required. When we deem that the patient is unable and/or unwilling to comply, then in-patient dosing is always available as an alternative in such circumstances. As nuclear medicine practitioners, we are well trained and schooled in how to make such assessments as part of our clinical expertise.

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The change in the NRC rules in 1997 to allow outpatient administration of high-dose I-131 for treatment of thyroid cancer was a good idea. It has improved patient comfort and convenience and reduced the costs of treatment. This change does not violate the ALARA principle. In fact, the argument could be made that the exposures of cleanup are vastly decreased for those radiation safety technicians and/or health care workers who would otherwise deal with such tasks recurrently in the hospital setting, versus the very limited frequency of such clean ups in the individual patient's household.

It would be a mistake to go backwards in this regard. Please do not change the existing rules allowing outpatient I-131 treatment of patients with thyroid cancer. Thank you for your attention to my comments.

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