January 21, 2011

The Honorable Edward J. Markey
United States House of Representatives
Washington, D.C. 20515

Dear Congressman Markey:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am responding to your letters of October 20 and December 9, 2010. In your October 20th letter, you provided the results from a recent Subcommittee investigation regarding the release of patients treated with radioactive materials from hospitals and offered a set of recommendations for our consideration. In your December 9th letter, you expressed concern that the release requirements for such patients are less protective than those for household pets treated with radioactive materials. After discussion with your staff, we are providing this consolidated response to both of your letters. Enclosed with this letter are our responses to your four specific recommendations from the October 20th letter.

We appreciate receiving the results from the subcommittee's investigation on the topic of patient release from hospitals, as discussed in your October 20th letter, and would like to draw to your attention a recent survey with a similar focus entitled, "Use of a Patient Survey to Evaluate Compliance with and Quality of Instructions Given to Patients Treated with Radioiodine." That study of 1,800 patients treated for thyroid cancer was presented at the 55th Annual Meeting of the Health Physics Society in July 2010. The results indicate that implementation of the requirements for patient release instructions is working reasonably well, although instructions to patients could be improved. Specifically, 97 percent of respondents indicated that they followed oral and written instructions completely or almost completely, and most patients considered those instructions clear, concise, and easy to understand. This study provides an additional perspective regarding the adequacy of patient release regulations and guidance and their implementation by licensees and Agreement States. A copy of the study abstract is enclosed for your information.

I also have enclosed a copy of a new report from the Patient Release Subcommittee of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). ACMUI is an official NRC advisory body consisting of health care professionals from various disciplines that counsels the NRC on policy and technical issues arising in the regulation of the medical uses of radioactive material in diagnosis and therapy. The conclusion of this ACMUI-endorsed final report is that the current 10 CFR 35.75 release criteria appropriately balance public safety with patient access to efficacious and cost-effective medical treatment. The report also included several recommendations for improvements in the NRC's program for patient release. The NRC will be reviewing these recommendations to determine what actions may be needed.

In light of the original basis for the patient release rule, the Health Physics Society study, the ACMUI report, and ongoing efforts to enhance program guidance, the NRC believes the patient release program continues to provide adequate protection of public health and safety. While this analytical information indicates that our current requirements are protective, little empirical data exists to demonstrate actual doses to members of the public as a result of the release of patients following medical isotope treatment. The Commission expects to explore the utility of collecting additional data on public doses as a result of patient release.

Our views on the topic of patient release are not altered when we compare current program requirements with those applicable to animals receiving similar treatment, as discussed in your December 9th letter. Veterinary use of byproduct material is regulated under the specific license provisions of 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." Animals treated with radioactive iodine (I-131) are released under the provisions of 10 CFR Part 20, "Standards for Protection against Radiation," which establishes a public dose limit of 100 millirem.

When the criteria for the release of human patients in our regulations were revised to incorporate a dose-based, rather than an activity-based standard for release, the NRC also amended our regulation for standards for protection against radiation to emphasize that these were separate standards. Both standards were based, in part, upon recommendations of the International Commission of Radiological Protection (ICRP) and National Council on Radiation Protection (NCRP).

It is important to note that human patients, unlike an animal, have the ability to understand and follow precautions for maintaining distances from other individuals and distinguishing between time and distance differences for closeness to adults or children. A physician also can screen a patient's ability to follow instructions and understand the need for precautions to reduce radiation exposure to others. Additionally, the regulations for animal release take into account other factors, such as the management of radioactive waste not controlled by a sanitary sewer system, as is generally the case with human waste.

These distinctions, together with factors such as the potential benefits of allowing patients to return to their families, the Commission's policy of not interfering in the practice of medicine, not placing an unacceptable burden on the medical community and other supporting information discussed above and in the enclosure, lead us to conclude that the current release limit for human patients is appropriate and protective of public health and safety. As stated above, we do plan to consider the utility of collecting data on the doses from release of patients treated with medical isotopes.

If you have additional questions, please contact me or Ms. Rebecca Schmidt, Director of the Office of Congressional Affairs, at 301-415-1776.

Sincerely,

/RA/

Gregory B. Jaczko

Enclosures:
1. Responses to Recommendations
2. Abstract from July 2010 Supplement to *Health Physics: The Radiation Safety Journal,* Vol. 99, No. 1
3. December 13, 2010 Advisory Committee on the Medical Uses of Isotopes (ACMUI) Patient Release Report