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# Congress of the United States

## House of Representatives

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December 9, 2010

The Honorable Greg Jaczko
Chairman
Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

Dear Chairman Jaczko:

It has recently come to my attention that the Nuclear Regulatory Commission's (NRC's) regulations regarding the manner in which patients treated with radioactive materials for thyroid cancer and other disorders are released from the hospital are dramatically less protective than those issued for the release of household pets treated with far smaller amounts of the very same radioactive materials. This bizarre disparity, that provides cats and dogs with greater level of post treatment care and more restrictive guidelines for discharge than for human beings, underscores the need for the Commission to revise its human patient release regulations to make them at least as protective as those that govern the release of cats and dogs.

As you know, the Subcommittee on Energy and Environment recently released the results of a staff investigation[1] that indicated that there is a strong likelihood that members of the public are being unwittingly exposed to radiation from human patients who are discharged after being treated with radioisotopes, and that this has occurred because of weak NRC regulations, ineffective oversight of those who administer these medical treatments, and the absence of clear guidance to patients and to physicians that provide these procedures to ensure that such exposures do not occur.

The regulatory relaxation that led to these unintentional exposures took place in 1997, when the NRC's rules were changed from the prior practice -- still followed in Europe and other countries --which requires the hospitalization of patients emitting high levels of radiation in order to protect children and other members of the public from being irradiated, to one that allows most treatments to be performed on a less expensive outpatient basis. My investigation

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[1] Please see http://markey.house.gov/index.php?option=com_issues&task=view_issue&issue=50&parent=12&Itemid=152 for copies of the investigative results and other relevant correspondence.

also found that around 7 percent of patients treated on an outpatient basis were choosing to recover in hotels rather than risk exposing their family members at home to radiation, which is likely to have resulted in exposures to pregnant women or children who cleaned or occupied these same hotels.

As it turns out, it is not just human patients in Europe that are hospitalized in order to ensure that their families or members of the public are not unintentionally exposed to the radiation they emit; NRC regulations result in a requirement that household pets in the United States be hospitalized for 2-5 days in veterinary facilities following treatment with radioactive materials[2], even though household pets are typically treated with doses of radiation that are 10-50 times lower than human patients (and therefore pets emit much lower doses than human patients).

Specifically, NRC's Appendix H to its NUREG 1556 regulations,[3] which were finalized in 1999 (after the NRC relaxed its rules for human patients), states that animals that are treated with radiopharmaceuticals must not be released until the radiation they emit decays to the point where the total effective dose to an individual member of the public would not exceed 0.1 rem/year. By contrast, NRC's regulations for the release of radioactive human patients from the hospital rely on calculations performed by medical professionals that allow a dose to an individual member of the public to be 0.5 rem – five times as high as the dose released pets are allowed to transmit. Additionally, at a recent meeting of the NRC Advisory Committee on the Medical Uses of Isotopes, members disagreed on whether the NRC's 0.5 rem regulatory dose limit to the public was meant to be a *per exposure incident* limit or *per year* limit. Since many thyroid patients – whether human or animal – often receive more than one radioactive treatment in a year, and therefore could be exposing people in their households multiple times a year, this distinction is important.

Additionally, on July 9, 2002, the NRC staff held a public meeting with Radiocat LLC, a company that provides radioactive iodine treatments to cats, along with several State regulators, a number of private veterinary practitioners and other members of the public[4]. During that meeting, all participants agreed that if cats were kept at veterinary facilities for 72 hours following treatment, exposure to members of the public would be minimized. NRC staff also raised concerns that some pet owners might not follow instructions for what to do following the cat's release and that this might result in overexposure to humans.

Appendix H of NRC's regulations also contains sample instructions for what to tell pet owners when their pet is discharged, even though the pets can only be discharged when they emit much lower amounts of radiation than the typical human patient does upon release. These include:

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[2] See for example, a description of the treatment describing the veterinary facility stays at http://www.radiocat.com/faq.html and http://www.catsvet.com/hyper.html#howl and http://www.catthyroid.com/index.cfm?fuseaction=TreatmentOptions and http://www.felinethyroidclinic.com/

[3] http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v7/sr1556v7.pdf

[4] for a summary of this meeting, see a July 24, 2002 NRC memo entitled "Summary of July 9, 2002 Public Meeting with Radiocat, LLC, Regarding Release Criteria of Cats Treated With I-131"

1. "The animal should be kept inside or in his cage/stall following hospital discharge.
2. The animal should not be permitted to have prolonged contact with children under the age of 12 for days following hospital discharge. Close contact should be limited to less than minutes per day.
3. Pregnant women should avoid ANY contact with the animal or its urine and/or feces for at least days after discharge.
4. Family members should not be permitted to sleep with the animal for days after discharge. They also should limit close contact with the animal (being within 1 meter or 3 feet of the animal) for the next day(s) to no more than minutes a day. Preferably, contact with the animal should be kept to a distance of more than 1 meter or 3 feet for this period."

No equivalently protective directions for human patients released from the hospital following treatment with radioactive materials exists, even though human patients are typically treated with far greater amounts of radioactive materials than animals are, they are almost always immediately released from the hospital after treatment, and are thus much more dangerous to those with whom they come into contact.

At the same time that NRC staff appear to have been very sympathetic to proposals to ensure that pets are kept in veterinary facilities following treatment with radioactive materials and raised concerns that their release, combined with a failure on the part of pet owners to follow post-release directions, could lead to unintentional human exposure, NRC staff evidently completely ignored the much more highly radioactive human patients.

I find the inconsistencies that exist between NRC's regulations governing the safe release of pets and human patients following treatment with radioactive materials to be absurd and unacceptable. Please provide me with a statement regarding the Commission's plans in this area no later than December 15, 2010. If the Commission is unable or unwilling to take action in this area, remedial legislation may be needed to ensure that the regulations that govern human patients being treated with radioactive materials are at least as protective as those currently afforded to their dogs and cats.

Thank you very much for your prompt attention to this important matter. If you have any questions or concerns please have your staff contact Dr. Avenel Joseph of my staff or Dr. Michal Freedhoff of the Energy and Environment Subcommittee Staff at 202-225-2836.

Sincerely,

Edward J. Markey
Chairman
Energy and Environment Subcommittee