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AUTHOR:	Crane P		
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April 15, 2013

Chairman Allison M. Macfarlane
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Chairman Macfarlane:

I very much appreciated your letter of January 31, 2013, and the invitation to meet with you. I look forward to our meeting.

In advance of it, I thought it might be helpful to outline some of the key issues, including particular legal questions that can only be answered by the General Counsel.

As you know, the NRC's 1997 Patient Release Rule, 10 CFR 35.75, allows patients treated with radiopharmaceuticals to be released if the maximum radiation dose to anyone else will not exceed 500 millirems.[1] This represents an exception to the otherwise applicable regulation, 10 CFR Part 20, which limits to 100 millirems the amount of radiation that a member of the public is allowed to receive annually from NRC-licensed activities.

The present rule, in my view, creates risks to three classes of people when patients are released after receiving high doses of radioactive iodine 131: (a) patients and their families, when patients are sent home; (b) users of public transportation, who may come into contact with newly released patients; and (c) hotel housekeepers and guests, when patients are sent to hotels. I will explain briefly my concerns about each of these groups, but it is the hotel situation that I want to focus on particularly.

(a) Patients and their families when patients are sent home.

First, the treated patient has to **get** home. If a friend or family member does the driving, he or she will receive a radiation dose. Though patients are often advised to sit as far from the driver as possible, there are obvious limits to how much distance is possible. The smaller the car and the longer the drive, the greater will be the radiation exposure. One answer is for patients to drive themselves, but if they are seriously hypothyroid, having been taken off medication in preparation for scanning and treatment, their reflexes will be slowed, and they have no business behind the wheel, since they are a danger to themselves and others.
The greater problem, however, is **after** the patient gets home. It is far easier to tell a young

[1] This 500-millirem maximum applies to everyone: adult males, infants, and pregnant and nursing mothers are all treated alike. It is five times the 100-millirem dose limit recommended by the International Commission on Radiation Protection (ICRP) and the National Conference on Radiation Protection (NCRP). Only if the likely dose to others reaches 100 millirems is the licensee even required to instruct the patient on ways to keep the dose to others as low as reasonably achievable (ALARA).

mother to keep a safe distance from her children than it is for her to explain to toddlers that they need to stay away from her. Children have been known to crawl into a parent's bed at night without the parent noticing. There are also issues of contamination. Not every high-dose patient has a bathroom for his or her exclusive use.

(b) Users of public transportation.

It should be obvious that you do not want someone with 200 millicuries or more of I-131 in his or her system to be spending hours sitting next to a child or a pregnant woman on an airplane, or to be beside them on a crowded subway. If the patient is nauseous, as is not uncommon, you do not want him or her leaving radioactive vomitus on the floor of a bus, for someone else to clean up, and with other passengers walking through the mess before the cleaner arrives. (This occurred in Los Angeles a few years ago, as a senior health department official reported at the time.)

(c) Hotel housekeepers and guests.

(i) Housekeepers.

In some hospitals, a room just vacated by an inpatient treated with I-131 is left closed up for a week before any attempt is made to clean it, in order to let it cool down, radiologically. When at last it is cleaned, it is by someone who is wearing suitable protective gear, including a film badge, and has training in radiation hazards.

By contrast, the hotel housekeeper who cleans a room just vacated by an outpatient is unaware of the radioactivity, unequipped for it, unbadged, and untrained. If she is pregnant or nursing, she can absorb a dose of I-131 to her baby's thyroid. This is radiation exposure in the workplace without informed consent, and as such, a violation of the most basic principle of radiation protection.

From a moral standpoint, it should be obvious to anyone that it is inappropriate to send a radioactive patient to a hotel. And yet it happens, and there are even those willing to argue that there is nothing wrong with it.[2]

[2] In October 2011, at the annual conference of the Thyroid Cancer Survivors' Association, Jim Luehman of the NRC staff described how in a conversation with him, a prominent nuclear medicine doctor had justified a particular decision to send a patient to a hotel. The patient would otherwise have driven for some hours in a car with his wife, who would have received a radiation dose from him. From the standpoint of radiation protection, the doctor said, it was therefore a plus to have sent the man to a hotel. (Commissioner Apostolakis, who was there, would no doubt confirm this.) The fallacy in that doctor's analysis is, of course, that the patient's spouse was being exposed by her own informed consent, and she was also deriving a indirect benefit from the radiation, in that it was curing her husband's cancer. The situation of the hotel housekeeper who cleaned up the patient's contaminated room, with no informed consent and no benefit to herself, could not have been more different.

We now turn to a legal question, or more precisely, an issue in which law and policy are intertwined.

The NRC's rule provides that patients can be released if no one is likely to receive a radiation dose of 500 millirems or more. The ACMUI subcommittee that studied the issue calculated that the hotel worker who handled the patient's contaminated sheets would receive under 100 millirems. But the subcommittee did not deal with an obvious problem: **you cannot assume that the exposed housekeeper will clean only one radioactive room in the course of a year**.

The NRC staff, in an October 2010 meeting, stressed its concern about the cumulative dose to housekeepers working in hotels that receive many patients from cancer centers. But the ACMUI has steadfastly refused to address this question, although it has been raised with it repeatedly. Each time, the issue of cumulative dose from multiple patients has been brushed aside.

I do not believe the issue can be dismissed so lightly, not without creating the impression that hotel housekeepers are viewed as what the Commission, in an earlier era, would have called "Below Regulatory Concern" – in other words, not worth worrying about.

The ACMUI has argued insistently that the NRC meant for the patient release dose limit to apply on a per-incident, rather than an annual, basis. (The NRC staff disagrees.) This would conveniently make the hotel housekeeper issue go away, since the multiple exposures to the housekeeper would not be added up, and the 500 millirem limit would never be reached.

But suppose a housekeeper cleans a radioactively contaminated room once a month, and receives 100 millirem each time. Surely an annual dose of 1200 millirem is a cause of regulatory concern whether it is received in 12 fractions or all at once.

It is true that the NRC, in 1997, deleted a record-keeping requirement from the proposed rule, explaining that there was no common practice that would result in exposures above 500 millirem based upon "multiple administrations in the same year **to the same patient**." [Emphasis added.] 62 FR 4120, 4130. The NRC was under the impression, in other words, that patients' I-131 treatments were sufficiently few and far between that the same patient could not expose others to radiation more than once in a year.

This was factually incorrect[3], as it happens. But even if had been true, its reasoning would have no bearing on the issue of the housekeeper who receives a radiation dose from multiple patients in a year. The NRC Commissioners did not at the time foresee that patients might be

[3] In 1990, I had two treatments of 150 millicuries each, and my case was hardly unique. At the time, my children were five and three. Fortunately, these were the days before the 1997 deregulation, so I was safely in radiological isolation, behind the thick walls of a room in NIH. Today, people like me are sent home.

sent to hotels, or go there on their own, so they did not consider potential doses to hotel housekeepers. Would they have been indifferent, if they had thought about it, to the possibility of multiple doses to a housekeeper?

In a hospital, it goes without saying that cumulative exposures are taken into account. That is why we have film badges and quarterly and annual exposure limits for the workers who clean the contaminated hospital rooms in which I-131 patients have stayed. How then can we ignore cumulative exposure to the workers who clean contaminated rooms in a hotel?

It would be easy to dismiss the whole problem by saying that the released patients will be widely dispersed. But if you are a patient treated and released by Memorial Sloan-Kettering Cancer Center in New York, the odds are extremely high that you will go to one of the eight hotels listed on the Sloan-Kettering website as having preferred rates for its patients. Likewise, patients at the Mayo Clinic have limited choices of hotels.

One legal question is this: is it legally permissible for a hospital to release a patient to a hotel, if it knows that the housekeeper who cleans that patient's room may in a year receive a cumulative dose exceeding 500 millirems? Complicating the situation is that we are unlikely ever to know for certain whether any particular dose, from any particular patient, will leave the housekeeper over the 500-millirem limit. Where is the burden of proof in such a situation, when you cannot say for sure one way or the other?

It may also be asked: what about the NRC's legal obligation? In authorizing hospitals to release patients to hotels, it is implicitly allowing the creation of hazardous work environments for hotel workers, without hotel management or workers being aware of it. Is this consistent with federal law governing occupational safety and health? Should NRC's OGC not consult the legal office of the Occupational Safety and Health Administration?

The Commission has directed that the staff study the issue of patients sent to hotels, and the doses to members of the public that may result. This process may take as much as four years. Let us assume, for purposes of argument, that the staff comes back in several years and reports that based on the number of patients released, the number of hotels to which they go, and the numbers of housekeepers in each hotel, it is statistically unlikely that any one housekeeper will receive a dose in excess of 500 millirem in a given year. That would not, of course, resolve the "informed consent" issue, but it would resolve the question of whether 10 CFR 35.75 was being violated.

But even if the hotel housekeeper issue is somehow made to go away, there remains a separate and to my mind determinative legal issue: the hotel guest sleeping in the next room.

(ii) Guests.

I believe that it is illegal to send I-131 patients to hotels, because the licensee cannot know what

the dose will be to the person in the next room, and therefore can make no judgment as to whether the 500 millirem limit will be exceeded. OGC's contrary conclusion in 2008 was therefore erroneous. To explain in more detail:

1. The NRC did not foresee this problem in 1997. Its final notice of rulemaking makes clear that it was thinking in terms of a binary choice: patients would either go home, if certain criteria were met, or would remain in the hospital. Hotels are never mentioned in the final rulemaking notice.

2. Determining the legality or illegality of sending radioactive patients to hotels therefore requires an analysis of the Commission's rationale in approving the 1997 rule.

3. The NRC's 1997 rule was premised on the licensee's ability to calculate the maximum likely dose to the most exposed person, based on proximity. That assumed a knowledge of the layout of the person's living situation.

4. Since this is impossible in the context of a hotel or motel (perhaps with the exception of a motel made up of separate cabins), releasing a patient to a hotel or motel cannot be legally permissible. If the patient cannot be released to a private residence, where doses to others can be computed, he or she must be kept in the hospital.

5. This problem is real, not imaginary. The distance from the radioactive patient to the person in the next room of a hotel or motel may be less than a meter, if the heads of the beds adjoin a common wall. A child or a pregnant woman who goes to bed at 9 p.m. and gets up at 7 a.m. could have a continuous exposure of ten hours, at short range.

6. The doses involved are substantial. We know, from the published statements of its own doctors, that Sloan-Kettering has been releasing patients directly to hotels with up to 200 millicuries of I-131 in their systems. And if licensees have been relying on the guidance published in 2004 by the Society of Nuclear Medicine, some patients may have been released with as much as 457 millicuries of I-131 in them.[4]

CONCLUSION.

In public forums where these issues are discussed, I always ask these questions: Would you be unconcerned to learn that your own daughter, granddaughter, niece, etc., had cleaned a hotel room just vacated by a highly radioactive patient, without knowing of the contamination? Would you be unconcerned to learn that your own child, grandchild, pregnant daughter, etc.,

[4]Thanks to the recent intervention of the NRC staff, as described in your letter of January 31, 2013, the SNM's advertising no longer makes the claim that its extremely non-conservative guidance has NRC's approval. I hope the NRC staff will move quickly to correct the misapprehension on this point that has been created in the licensee community over the past nine years.

had unwittingly occupied a hotel room adjoining that of a radioactive patient? And would you be unconcerned to learn that your child, grandchild, pregnant daughter, etc., had unwittingly moved into a hotel room vacated hours before by a radioactive patient?

Before answering these questions, consider that one of the reasons given by Dr. Leon Malmud, Chairman of the ACMUI, in describing in October 2007 why his and other hospitals are unwilling to accept I-131 patients as inpatients, is the need to leave adjoining rooms vacant, because of the radiation coming through the walls. What does that tell you about the situation in a hotel, where it can be assumed that the walls on average are thinner than those of a hospital?

So to return to the three questions I posed: if you would not wish these situations on your own loved ones, they should not be happening to anyone's loved ones. And I have yet to hear anyone say that they would be unconcerned if any of this befell their own family members.

The NRC thought in 1997 that it was authorizing licensees to use the methodology set forth by the National Council on Radiation Protection in 1970 in NCRP 37. The authors of that study would ache to see what the deregulation of nuclear medicine, accomplished so to speak in their name, has achieved. To be sure, the authors believed that dose to the recipient, rather than activity in the patient, should be the preferred means of determining patient release. They also recommended greater flexibility than was allowed by the flat 30-millicurie limit in that the NRC then prescribed – but only within very modest limits. They opposed allowing anyone with 50 millicuries of I-131 or more to go to a residence occupied by anyone under the age of 45. If, in highly unusual circumstances, someone was to be sent home with more than 80 millicuries of I-131, the justification needed to be put in writing, **and the local health department notified**.

What a long way we have come since then.

Again, I look forward to our meeting on May 14.

Sincerely,

/s/

Peter Crane