

From: [Peter Crane](#)
To: [Holiday, Sophie](#); [CMRMAGWOOD Resource](#); [CMRSVINICKI Resource](#); [CMRAPOSTOLAKIS Resource](#); [CMROstendorf@nrc.gov](#); [Vietti-Cook, Annette](#); [Bradford, Anna](#); [Bupp, Margaret](#); [Luehman, James](#); [Fuller, Michael](#)
Cc: [Avenel, Joseph](#); [Michal Freedhoff](#); [Gene Miskin](#); [Jeff Duncan](#); [matt wald](#); [Steve Sternberg](#); [Daniel Engber](#); [laura weil](#); [Raspa, Rossana](#)
Subject: STATEMENT TO ACMUI MEETING ON DOSES FROM RADIOACTIVE PATIENTS
Date: Monday, September 19, 2011 11:57:34 AM
Attachments: [2011.SeptemberStatementToACMUI.docx](#)

To: Ms. Sophie Holiday

Dear Ms. Holiday,

You are listed in the NRC press release of September 12, 2011, as the contact person for the filing of submissions relating to the ACMUI meeting currently scheduled for September 22 and 23. Attached please find my submission, dated September 19, 2011. Officially, the last date for such submissions was September 16 -- precisely four days after the NRC announced the meeting and the opportunity to file submissions. I trust that the ACMUI will at this point recognize how utterly inadequate that period was, and will accept this for filing. I also wish to take part in the meeting by telephone.

Please circulate this statement to the ACMUI members and the Commissioners as soon as possible, and please confirm for me in writing, by email, that it has been accepted as a valid submission. Thank you.

Peter Crane, Seattle
206-819-2661 (cell)
206-783-8485 (land line)

-

STATEMENT OF PETER CRANE
NRC Counsel for Special Projects (Retired)
to the
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
(Meeting of September 22/23, 2011)
Submitted September 19, 2011

I. Introduction

In a press announcement issued July 13, 2011 (news release No. 11-128), the Commission directed the staff “to examine feasibility and need of study on radiation doses to public from nuclear medicine.” On September 12, 2011, when the NRC issued the news release (No. 11-171) announcing the ACMUI meeting of September 22/23, 2011, the status of the resulting staff paper was one of the agenda items. The same news release announced that any statements from the public must relate to an agenda item and be submitted within four days – that is, by September 16, 2011.

The meeting summary of the ACMUI meeting of April 11/12, 2001, is available online, and it shows that the date for the September meeting was chosen five months ago. The tardy notice inevitably serves to keep away interested persons who might have attended, and a four-day window for comment is utterly inadequate, given the complexity of the subjects that the ACMUI deals with. Why did the ACMUI wait until the last minute to give notice of the meeting, and why did it set a four-day deadline for submissions? There are only two possible explanations, neither flattering to the Committee: either it was deliberately trying to prevent public participation or it was so oblivious to the need to accommodate the public that the inadequacy of these time periods never crossed its mind.

As I emphasized in a brief memo to the Commissioners, emailed on September 18, 2011, what is at stake here is not the merits of the patient release issue or any other substantive matter. Rather, it is a question of process: of the fairness, openness, and integrity of the ACMUI’s consideration of issues. The actions of the ACMUI reflect not only on the Committee itself; they also reflect, for good or ill, on the agency as a whole. In this case, they can only foster skepticism about the genuineness of the NRC’s declared commitment to public involvement.

The Committee should therefore reschedule the meeting to a later date, alter the time for submission of statements, and in the future pay greater attention to the need to accommodate the public meaningfully. In submitting a statement after the September 16 deadline, I do so in the full expectation that it will be accepted as a valid submittal and considered. But how many others are there who will have been foreclosed from making filings by these patently unrealistic deadlines? If the ACMUI does not feel conscience-bound to reconsider its original dates and deadlines, I trust that the Commissioners will intervene and set things right.

I will outline my substantive concerns in a nutshell. The Staff Requirements Memo referred to in the June 13 news release says: “The staff should assume that existing guidance provided to the patients is being followed appropriately, ***including the additional guidance provided recently to the licensees regarding the use of hotels.***” [Emphasis added.] The problem is that this guidance is not being followed appropriately. Irrefutable evidence of this comes from the licensee community itself – most notably, from a March 2011 article in the online publication ASCO Post, a journal for endocrinologists, as I will describe below.

If the Commission has been told otherwise, it has been misinformed, and not for the first time. I think it worth explaining this in some detail, in order to put the Commission on full notice of the risk that exists of being misled in this area.

II. Misinformation about the release of radioactive patients

The subject of the release of radioactive patients seems all too often to produce serious factual errors from sources of whom one would expect better. Let me give three recent examples, the first of which the Commission had an opportunity to witness first-hand. I assure you that this list is not exhaustive, and I can readily produce more such instances, though probably none so glaring as the following.

A. The Advisory Committee on the Medical Uses of Isotopes (ACMUI) Briefs the Commission, October 20, 2010.

The Commission’s October 20, 2010, briefing on medical issues included a presentation by Dr. Susan Langhorst, who chaired a subcommittee that included most of the membership of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Dr. Langhorst assured the Commission, on behalf of the subcommittee, that its regulations on radioactive patients were just fine as is, needing no revision or fine-tuning to deal with radioactive patients in hotels or anything else. They were, she said, consistent with international standards: 500 millirems for adult caregivers, 100 millirems for children and members of the public. (See her slide #11.) The group’s bottom line (see her slide #15) was that “10 CFR 35.75 should not be changed.”

Minutes later, Jim Luehman of the NRC staff took over the microphone, and the Commission learned from him that in fact the NRC does ***not*** follow the 500mr/100mr split standard that the International Commission on Radiation Protection and the National Commission on Radiation Protection recommend. Instead, it has a standard of 500 millirems for everyone, including children and pregnant women. Indeed, the 500/100 split standard was expressly rejected by the NRC in 2008, when the NRC staff denied my petition for rulemaking. (Since the Commission did not involve itself in the matter, leaving it entirely to the staff, the Commissioners may have been unaware of this at the time.) It was apparent to all those watching that this information, which directly contradicted what Dr. Langhorst had told the Commission, took her utterly by surprise.

10 CFR 35.75 is short and crystal clear.¹ (See Appendix B, where it is reproduced in full.) It would have been completely impossible for the subcommittee members to have misunderstood it – *if they had read it*. Plainly, during their five months of effort, handsomely compensated from NRC funds, none had thought to do so.¹ In an ideal world, Dr. Langhorst and her subcommittee would have apologized to the Commission for the inadequacy of their work and returned the money NRC paid them for it.²

B. Article in “Thyroid,” April 2011, by Dr. James Sisson, et al.

The embarrassment suffered by the ACMUI subcommittee was minor, however, compared to that of Dr. James Sisson and fourteen co-authors, whose study of the patient release issue was the lead article in the April 2011 issue of “Thyroid,” the journal of the American Thyroid Association. Whereas Dr. Langhorst and her colleagues spent five months on the ACMUI study, Dr. Sisson and his team spent three *years* studying the issue, and their work product went through extensive review within the ATA. Somehow, however, they did not even become aware of the existence of 10 CFR 35.75 until after they published their results, when they were set straight by Dr. Avenel Joseph of Congressman Markey’s office and me. Until then, they had been under the mistaken impression that 10 CFR Part 20 governed the release of patients.

The June issue of “Thyroid” therefore includes a lengthy correction notice, and the following gracious statement:

The authors deeply regret these errors and oversights, and express their gratitude to Peter Crane, J.D. (retired, Nuclear Regulatory Commission) and Avenel Joseph, M.S., Ph.D. (Office of Edward Markey, U.S. Congress) for bringing our attention to the errors needing correction.

The moral of the story, I believe, is that whether you get reliable information depends less on the degrees and other credentials of those providing it than on their diligence and competence, and on whether their judgment is clouded by a particular agenda. Years ago, Dr. Carol Marcus wrote to the Commission urging that as a non-doctor, I was unfit to comment on matters pertaining to patient release, which should be left entirely to experts in the field. I did not agree then, and after what I have seen from the supposed experts,

¹ Dr. Langhorst incorrectly assured the Commission (see her slide #11) that the current release criteria were “Consistent with national and international recommendations in principle/practice,” with “5 mSv/episode for caregivers/relatives” and “1 mSv/y for child/pregnant woman/public,” and that the criteria “apply to single releases – not annual limit.” Not only are NRC standards much looser, but international standards also make clear that this is an annual limit, not the per-release standard that the ACMUI so passionately advocates.

²The inevitable question is: what or whom were they relying on? Plainly they had not read the staff’s 2008 denial of my petition, nor the petition itself, and if they had consulted Jim Luehman or other knowledgeable staff personnel, they would have been set right immediately. Nor, evidently, had they read ICRP 94, whose authors reported that the NRC standard was 5 mSv for everyone.

I agree even less today. Indeed, I would argue that even a high school student, if conscientious in doing research and open-minded in following it where it leads, may sometimes be a better source of information than doctors and scientists with impressive resumés but also a fixed determination to reach a particular conclusion.

C. The NRC's Brief to the Ninth Circuit Court of Appeals

In March 2011, the Commissioners received a report from the Office of Inspector General on its investigation of the discrepancy between what NRC headquarters told Region I in June 2008, on the permissibility of sending newly treated I-131 patients to hotels, and what the NRC's lawyers told the Ninth Circuit Court of Appeals in November of the same year.

I don't want to rehash this matter at length. Suffice it to say that the Region was told that this practice was permissible under NRC regulations, that it was not uncommon, and that the agency intended to issue safety guidance dealing with the issue. The Court of Appeals, on the other hand, was sent a brief, five months later, that included a section headed, "NRC's rule does not permit or encourage doctors to send treated patients to hotels." Congressman Markey, whose letter to NRC had caused the memo to the Region to become known, asked the Office of Inspector General to investigate the matter.

Charlie Miller, according to the report, told OIG that: "he disagreed with the November 2008 OGC legal brief subtitle, *NRC's rule does not permit or encourage doctors to send treated patients to hotels.*" He said that 10 CFR Part 35.75 does not state that doctors are not permitted to send patients to hotels, and it neither encourages nor discourages doctors from sending patients to a hotel."

Charlie had it right on the money.

The OGC attorney who wrote the brief told OIG in his first interview that the word "permit" should have been replaced with the word "prohibit." He too was absolutely correct. His admission was significant, given that "permit" and "prohibit" are antonyms.³

Strangely, however, the attorney quickly reversed himself 180 degrees. In his subsequent OIG interviews, in the words of the report, he "said he stood by the language in his brief and said that replacing the word 'permit' with 'prohibit' would not have been a correct reflection of his viewpoint." What caused him to recant between his first and later interviews with OIG is not stated in the report. OIG does not seem to have thought to ask.

³When the NRC uses the phrase "does not permit" in giving guidance to licensees, it means that something is forbidden or precluded. See, e.g., Regulatory Guide 1.193, Rev. 3, in October 2010, in which it wrote, "The NRC does not permit the use of rupture disk devices in spent nuclear fuel storage canister designs." Many such examples could be cited, as a simple Google search makes clear. Likewise, when the Ninth Circuit and the Supreme Court use the term in their decisions, there is no doubt that it means "precludes."

Whether or not there was actual wrongdoing involved, something clearly went awry here. In my 21 years in NRC's Office of General Counsel, defending the agency in appellate courts, an absolutely essential part of my job was to work closely with the technical staff to be sure I had my facts straight before making representations on behalf of the NRC and the U.S. Government. For example, when I was defending the Commission's approach to licensing dry cask storage in *Kelley v. Selin*, in the Sixth Circuit – a case I am happy to say that I briefed, argued, and won, and where I believed firmly that we were achieving something valuable for this country – I spent countless hours conferring with Charley Haughney of the NRC's technical staff. We needed to make completely sure that everything I wrote and said was scrupulously accurate. In those days, moreover, it was normal for the relevant staff to attend the moot courts in which lawyers prepared for oral argument, in part to make sure that we had an accurate understanding of the facts. If OGC's standards and practices have changed since then, I am sorry to hear it.

Here, where the issue of whether radioactive patients were going to hotels was centrally important to the case, the NRC staff knew full well that this practice *was* occurring, and that it presented safety issues that needed to be dealt with. A single phone call from the lawyers to a knowledgeable staff official, such as Cindy Flannery, Jim Luehman, or Charlie Miller, would have revealed that fact, and ensured that the NRC gave the Ninth Circuit information that was accurate, complete, and unambiguous. Even under the most charitable view of the lawyers' actions, there was thus a failure to coordinate properly with the staff.

I should make very clear that the lawyers' misinformation to the court did not, as far as we can tell, play any part in the disposition of the case. I lost the case, and the NRC lawyers won it, not on the merits, which the court did not reach, but on "standing" – a threshold jurisdictional question that asks whether the person bringing suit has the right to be in court at all. The NRC argued, and the court agreed, that my own I-131 treatments for thyroid cancer occurred too long ago for me to be sufficiently affected by the present rules to challenge them in court.⁴ Thus the court had no occasion to decide whether patients were going to hotels, or any other substantive issue in the case. The other side of that coin, however, is that the court's decision did not "uphold the NRC's rules on patient release," as some may imagine; rather, it ruled that in a lawsuit brought by me alone, it lacked jurisdiction to hear the case, and therefore had no authority to render judgment pro or con on the NRC's rules.

At a meeting at NRC in 2010, Chris Einberg of the staff explained the delay in acting on the 2008 commitment to issue guidance on radioactive patients in hotels by saying that the staff had been advised – he didn't say by whom – to wait until the lawsuit was resolved. If his recollection was accurate, that is evidence of a shocking failure on someone's part to keep the agency's priorities straight. Protecting the

⁴ What we can never know, of course, is whether the court would necessarily have taken so restrictive a view of standing if the NRC's lawyers, instead of giving the court to understand that the issue of radioactive patients in hotels was my fabrication, had said this: "Yes, radioactive patients are going to hotels in significant numbers; no, nothing in the NRC's rules prohibits this; yes, the petitioner and a number of commenters raised this point; no, we said nothing about it in the denial of the petition; yes, safety issues are raised, which we will eventually address with guidance of some kind; but you, the Court, still have no right to hear this case, because the petitioner's last I-131 treatment occurred in 1991, and what the NRC does and doesn't do with respect to radioactive patients therefore doesn't affect him."

public from harm must always take precedence over perceived advantages in litigation.

As noted above, there would have been no need for an RIS in 2011 if it were true that NRC's rule "does not permit" radioactive patients to be sent to hotels. What seems so regrettable and tragic and inexcusable in all this is that I first raised this issue with NRC in *January 2006*. It took five years for an RIS to be issued – five years in which we have no way of knowing what harm may have been done to hotel staff and guests, and of that harm, how much might have been averted by a timelier warning. If there is just one case of mental retardation or thyroid cancer in a child who was in the womb of a hotel housekeeper when she cleaned a room contaminated with I-131, and if that case could have been prevented by an RIS issued in 2006 or 2008, it will be one case too many.

III. The Commission's July 13 Directive to the Staff

The Commission's July 13 directive tells the staff to proceed on the assumption that its guidance, including that on radioactive patients in hotels, is being followed. In fact, there is irrefutable evidence that licensees are *not* following the NRC's non-binding guidance on the use of hotels. In March 2011, in an article in ASCO Post, an online journal serving endocrinologists, Dr. R. Michael Tuttle of New York City's celebrated Sloan-Kettering Memorial Cancer Center was quoted as saying that "many patients don't have a choice [about staying in a hotel] because they are flying in for their treatments." "We are absolutely comfortable that it is safe for these patients to be in a hotel," he said. (A copy of the full article, converted into Word format, is attached as an appendix.)

It is worth noting that New York City's Department of Health issued a notice in 2009 that included the words, "Do **NOT** advise patients to go to hotels." [Emphasis in the original.] If Sloan-Kettering is not deterred by that directive, it certainly will not be influenced now by NRC's toothless plea for voluntary compliance.⁵

Some explanation may be needed of Dr. Tuttle's statement that "many patients don't have a choice." The problem for patients "flying in" for treatment is that at the same time that the NRC was deregulating I-131, Europe was tightening its restrictions, based on data from Chernobyl on the danger to others. Today, if you are a thyroid cancer patient treated in Europe, you will be hospitalized for an I-131 dose as low as 8 millicuries (in Germany) and no more than 12 to 15 millicuries elsewhere. By contrast, Sloan-Kettering, according to Dr. Tuttle, as quoted in the ASCO Post article, administers up to 200 millicuries to outpatients.

If you are an outpatient who has just been given 200 millicuries of I-131, and you go to JFK airport to board

⁵ What New York City said was this: "To avoid sending iodine therapy patients home, do **NOT** advise patients to go to a hotel. A hotel presents substantial probability of close contact with infants, young children, pregnant women, and of course the general public. In a serious, and not at all implausible case, a patient could have their room or dining area cleaned by a pregnant woman who could come into very close contact with radioiodine-containing-bodily fluids." [Emphasis in the original.] I view this as binding, but I am informed by OIG that it merely constitutes "strong advice." If ever I am stopped for passing in a "Do Not Pass" zone, or for driving where a sign says "Do Not Enter," I doubt I would get far with the argument that these signs merely conveyed "strong advice."

an airplane, you will set off the radiation alarms that are ubiquitous since 9/11. At that point, you will produce a card, given you by the hospital's nuclear medicine department, explaining that you are a patient, not a terrorist. But as Dr. Tuttle explained, "in some other countries, nobody cares if you've got a card saying that you were treated at Memorial Sloan-Kettering."

In other words, the thyroid cancer patients whom doctors in the U.S. now "whisk out the doors as soon as possible," in the unforgettable words of ACMUI Chairman Leon Malmud, are considered a public health menace if they return to their home countries too soon. (Some of them may have come here specifically to take advantage of the NRC's lax regulations – "nuclear tourism," in the words of a 2004 report from the International Commission on Radiation Protection, ICRP 94, at p. 53.) And so these foreign patients while away a few days in a New York hotel room, which is entirely understandable, for once they have been treated as outpatients and discharged, it is probably a choice between that and a park bench.

The corollary is that if you are a patient from out of town in the U.S., from Memphis or Omaha or wherever, there is nothing to keep you from boarding a plane in New York and spending the next several hours elbow to elbow with the next passenger, who may be a small child or a pregnant woman.⁶ And that is the essence of the problem: the protection of the public is only as good as the conscience of the individual patient.

The ACMUI subcommittee report says that "well-informed patients are self-motivated and sensitive to the fact that they are radioactive for a period of time," and they will "typically do as much as possible to reduce potential exposure to others." This is wishful thinking, and as the saying goes, "wishing doesn't make it so." What basis is there for this statement, other than the subcommittee's desire to make a thorny problem disappear?

I would answer the subcommittee's assurances about the character and behavior of I-131 patients in two ways. First, we thyroid cancer patients are no better or worse than other people: some of us are altruistic, some aren't. Generalizations about how considerate we are of others are purely fanciful. Secondly, when patients face a choice between exposing their own families and exposing strangers, they often decide to put their families' well-being first, even if that means contaminating the hotel room that a stranger will clean and other strangers will sleep in.

The same article quoted Dr. Richard Kloos, CEO of the American Thyroid Association, as agreeing that staying in a hotel "can be done safely and reasonably." He suggested, however, that patients pre-register,

⁶ Some patients do this, regrettably, notwithstanding that they will be delivering a substantial radiation dose to those near them on a long flight. Those other passengers will, of course, have no clue that they are being irradiated. Nearly 20 years ago, NIH warned the NRC about this, when the deregulation of I-131 treatments was being proposed, but it was ignored, as was everyone who raised concerns about the plan. The difference between then and now is that then, the most any patient could have in his or her system was 30 millicuries. Today patients are boarding planes with many times that much I-131 in their bodies. I am confident that no Commissioners would want a child or grandchild of theirs to be sitting elbow to elbow with such a patient on a long flight, any more than they would want a child or grandchild to be working in a hotel, cleaning a room and bathroom just contaminated by an I-131 patient. If it is not fit work for your child, it is not fit work for anyone else's child either, given that there is no informed consent involved.

so as to minimize their time in the lobby. For Dr. Kloos, it seems, the only people in the hotel whose radiation exposure matters are the other hotel guests. As for the housekeepers who scrub the contaminated sinks and toilets and handle the contaminated linens, and are at far greater radiation risk than anyone standing in the registration line in the lobby, they don't even enter the equation.

Compounding the problem is the fact that in a hotel near a major cancer center, one housekeeper may clean numerous contaminated rooms in the course of a year, accumulating an ever greater radiation dose each time. Jim Luehman made that point in the Commission meeting of October 20, 2011, but the ACMUI members paid no attention. In the October 21, 2010, ACMUI meeting, at p. 54 of the transcript, we see Dr. Zanzonico saying: "The largest doses we found, which were, predictably, to the housekeeping staff, were less than 100 millirems, so below even the dose limit for 'sensitive' populations."

But what about the pregnant housekeeper who cleans five or ten such rooms, and accumulates a dose from each one? What is happening to her baby's thyroid? Moreover, the subcommittee's analysis was based on someone holding sheets on which an I-131 patient had sweated. Saliva and urine are far hotter than sweat. Did the subcommittee calculate the dose to a housekeeper who, wearing only rubber gloves, cleans a sink in which a radioactive patient has just brushed his or her teeth, and the toilet in which a patient has recently urinated? Were all those added together? The subcommittee seems to have assumed, with no basis whatsoever for that assumption, that housekeepers would clean at most one such room per year. This is fantasy, not reality, and public health standards need to be grounded in the real world, not in make-believe.

Perhaps, however, I am doing the subcommittee an injustice, and it did take in this point. If so, that might explain the ACMUI's fervent insistence that release criteria must be based on a per-release, rather than per year, basis, contrary to what the ICRP and NCRP prescribe. For if you look at doses to affected members of the public on a per-release basis, then a housekeeper could clean a hundred contaminated rooms in a year and NRC's regulatory standards would not be exceeded, since her exposures would not be summed.

If the Commission is really interested in obtaining data pertinent to the hazards posed by released patients, perhaps it should ask permission of the hotels in the vicinity of Sloan-Kettering, the Mayo Clinic, Massachusetts General Hospital, and a few others, to install radiation detectors. In that way, when the monitors signal the arrival of a radioactive patient, inspectors could track the person and measure the actual radioactivity left in the room.

I do not imagine that the NRC or the ACMUI would be eager to set off down that path, which would alert hotels to the contamination that radioactive patients are bringing into their hotels, and their potential liability to those contaminated by them. But if you want meaningful data, you are not going to get it from listening to the ACMUI's assurances of how selfless and thoughtful we I-131 patients are. Are we so selfless and thoughtful that we will bring along our own cleaning equipment and clean our own sinks and toilets? Even if we do, what are we supposed to do with our linens? Patients who are sent home are told to wash their bed linens separately from those of other family members. How is that supposed to happen in

a hotel? We can hardly strip the beds and take the linens with us, explaining to the hotel staff that we intend to launder them at home and then return them.

We saw in the Braidwood Motel incident, in 2007, that the only situation in which a hotel guest is likely to know about contamination from an I-131 patient is if he or she works in a nuclear power plant, in which case he will set off the radiation alarms at work. One patient, checking into that motel to protect her family from radiation, managed to cause alarms to sound in two nuclear plants, Braidwood and La Salle. A Braidwood worker was the next person to occupy her room, and he was found to be contaminated on his skin and clothing. A day later, the LaSalle worker set off the alarms. He had stayed in the same motel, but in a different room. His only contact with contamination came from his sheets, which had been laundered together with those of the patient. The I-131 had been transferred in the washer and dryer.

In the ACMUI meeting of April 12, 2011, at p. 148 of the transcript, we see Chairman Malmud indulging in a bit of sarcasm about the newspaper reports that had contrasted the NRC's regulations on radioactive animals and radioactive people. (A cat given three millicuries of I-131 for feline hyperthyroidism must be hospitalized for a minimum of 72 hours, whereas the cat's owner, given 300 millicuries, can be treated as an outpatient and released.) Dr. Malmud said:

And we are not cats or dogs. We don't generally urinate in the street. So the concern about the effluent of the radiation for animals is different from that for humans. Humans generally use toilet facilities, and the effluent is diluted immediately, so that these are very different issues from the ones that have been highlighted in the newspaper.

The effluent is diluted immediately, of course, only if it lands in the toilet bowl and is flushed away, and as Dr. Malmud surely knows, in his more serious moments, men are frequently careless when they urinate: according to ICRP 94, at p. 27, men leave 75 times as much radioactivity on the toilet rim as women during the first 48 hours after treatment. In a hotel, it is a housekeeper who cleans up the rim of the toilet bowl and any urine that has missed the toilet altogether.

I make no apologies for feeling sympathy for people who are mistreated – and to put someone in danger is to mistreat them, even if they are unaware of it – because they belong to a class that is viewed as somehow expendable, unworthy of the concern and protection that would go without saying for those of us who occupy more privileged positions in life. In this case, my concern is for the hotel housekeepers. They have a hard enough lot in life without being irradiated, and possibly also having their unborn babies permanently harmed by thyroid cancer, retardation, or both, through the tightfistedness of insurance companies and the indifference and/or ignorance of doctors and regulators. (I will explain that statement more fully below, at p. 10-11, in quoting from the transcript of an ACMUI meeting in October 2007.)

I do not mean by this to downplay the risk to thyroid cancer patients' own families. That continues to be a serious issue: patients sent home to households where there are small children, and where keeping a safe distance, and having one's own bathroom to oneself, is not an option. I suggest that the NRC staff should

subscribe to the listserv of the Thyroid Cancer Survivors' Association – I am sure that Gary Bloom, the Executive Director, would give his approval – to get a feel, day by day, for the experiences of the hundreds and thousands of patients who submit their comments and questions. You would read, for example, of the woman in New Jersey who writes that she has been told that there is no point in even asking for inpatient treatment, because even if the insurance company gives its preapproval, it sometimes withdraws that approval after the fact, so that the hospital will not take the financial risk of treating anyone as an inpatient. There are many, many such stories, and though some would dismiss them as “anecdotal,” or suggest that only a doctor's word on such matters can be relied upon, these reports are submitted by people with no motivation to be anything but candid.

Two years ago, Jim Luehman of the NRC staff and I shared a podium at the annual conference of the Thyroid Cancer Survivors' Association, in Danvers, Massachusetts. (His presence there was greatly appreciated by all.) I am sure Jim remembers as well as I the questions and comments from the floor: the young woman who was sent home to her toddlers radioactive, and who commented that it not easy to keep your distance from a one-year-old and a three-year-old, and another woman who was told by the hospital to stay in a hotel for the first night and have her husband pick her up the following day. These people had no reason to fabricate anything, and though they didn't have medical degrees, I am sure that Jim would agree with me that they were unquestionably telling the truth.

IV. Conclusion

I do not doubt that the Commission desires to do the right thing by the American public, including thyroid cancer patients, their families, and the ordinary citizens who go to hotels and ride public transportation also used by radioactive patients. I applaud Commissioner Apostolakis's decision to attend the upcoming conference of the Thyroid Cancer Survivors' Association, to be held in Los Angeles in October. I also commend the Commission for choosing a Patients' Rights Advocate, Laura Weil, who seems splendidly qualified to make that position once again what it was intended to be, a voice for patients' rights and interests.

What I do question, however, is the quality of some of the information the Commission gets. I wonder whether the Commission has been made fully aware that the decisions on who will be hospitalized for I-131 treatments have largely been taken out of the hands of doctors by the insurance companies, which have in the main stopped paying for inpatient treatment, regardless of the patient's home situation. This has made a mockery of the Commission's intent, in 1997, to allow patient care to be tailored to the individual home situation.

The Commission need not take my word for it; it can take Dr. Malmud's. The present reality was described vividly in an ACMUI meeting in October 2007. No one has suggested that the description given in that meeting was inaccurate:

Dr. Eggli: ... We can't get a preceptor to admit most patients to the hospital anymore from

the insurance companies since the release rule went into effect. ... If I am admitting somebody [with] less than 200 millicuries, the chances that I can get an insurance authorization for a hospitalization to isolate them, **even when I have family situations that require it**, it's fighting tooth and nail with the insurance companies....

Dr. Malmud: It is not now possible to treat a patient at our hospital and many hospitals in the Philadelphia area with I-131 in high doses for thyroid cancer because in order to do that a patient has to be isolated in a room which itself is isolated from the rooms next door.

Therefore, **all patients are discharged upon treatment. We whisk them out the doors as fast as possible.** They are given outpatient doses between 100 and 200 millicuries of I-131, depending upon the extent of their thyroid cancer and occasionally, even higher doses. ...

There's also an impossibility of keeping the patient in the hospital since the insurer will not cover it. The insurer will not cover it, will not cover the inpatient stay. It will cover the treatment, but not the inpatient stay. ...

Being in the hospital today in most situations is an absolute impossibility. The nursing staff won't care for the patient. The other personnel in the hospital don't want to be near the patient. The hospital doesn't want the patient in the hospital. More than one room has to be reserved for the patient. It's an impossibility.

... Within the hospital, this patient is an unwelcome guest currently. Uninsured, **their wonderful insurance stops because it's no longer necessary for them to be an inpatient.** [Emphasis added.]⁸

This, unfortunately, is the real world of 21st Century medicine, in which all too often, the insurance companies have the whip hand, and doctors trail along behind, powerless to do what the best interests of their patients demand.

As the ACMUI subcommittee and the ATA journal have demonstrated, you can have impressive credentials and still get your facts wrong. The NRC's 1997 deregulation is testimony to that. It took the NRC staff until 2008 – four years after the issuance of ICRP 94 removed all doubt on the subject – to acknowledge publicly that the 1997 rule had erred in dismissing the risk posed by contamination from I-131 patients. The staff was relying on erroneous advice from Dr. Myron Pollycove, then a Visiting Medical Fellow, whose decidedly non-mainstream views on radiation risk were singled out for criticism by the National Academy of Sciences in BEIR VII, its authoritative report on the biological effects of ionizing radiation. (More recently, in a 2008 article, Dr. Pollycove wrote that if a nuclear accident occurred, “the radiation exposure would not be harmful and might even be beneficial.”) Unfortunately, we find ourselves struggling today with the consequences of that grave mistake.⁹

⁸<http://pbadupws.nrc.gov/docs/ML0808/ML080850674.pdf> See pp. 187-188.

⁹ At the time that the deregulation of I-131 was first proposed, in 1992, Dr. Malmud submitted comments to the NRC in his capacity as President of the Society of Nuclear Medicine. As I wrote to him on November 21, 2010, a review of

In short, rather than telling the staff to proceed on the assumption that the guidance on patients is being followed, the Commission should take a step back, and ask *whether* the guidance is being followed. On that point, it is not good enough to rely on the self-serving statements of doctors' professional associations. It means outreach to the patients, to find out their experiences. If the Commission wants to know whether its regulations are doing an adequate job of protecting the public, it has to go beyond the nominal experts and find out what is happening on the ground: in patients' homes, in hospitals, and in the hotels where too many radioactive patients still go, either because doctors recommend it, or because they have no place else to go, or because they have decided on their own to protect their families from exposure to radiation.

Respectfully submitted,

/s/

Peter Crane
Counsel for Special Projects, USNRC (retired)
September 19, 2011

cc: the Commissioners
Rep. Ed Markey
Rep. Fred Upton
Rep. Jim McDermott
Sen. Barbara Boxer
Sen. Charles Grassley

those comments indicate that what the NRC did in that rule change went radically beyond what Dr. Malmud himself recommended, which was that the NRC should follow NCRP 37. Under NCRP 37, the maximum outpatient dose of I-131 was 80 millicuries, and patients were to wear tags or wristbands identifying them as radiation hazards. NCRP 37 prescribes the precautions appropriate for a person receiving 50 millicuries of I-131 as an outpatient: in the first week, if there is anyone under 45 in the household, no one under 45 is allowed in the same room, or within 9 feet, for more than a few minutes a day. Only after eight weeks is unrestricted contact with others permitted. Where patients lived in multi-family buildings, the proximity of neighbors was to be considered in evaluating the risk to others, and under some circumstances, release of patients required notification of local health departments. We have come a long, long way since then.

APPENDIX A – ASCO POST ARTICLE

How Can Patients Who Receive Radioactive Iodine Treatment for Thyroid Cancer Reduce the Chance of Radiation Risks to Others?

By Charlotte Bath

March 1, 2011, Volume 2, Issue 4

Although patients treated with radioactive iodine (I-131) for thyroid cancer may theoretically expose those in their immediate environment to low levels of radiation for a few days, reports about radioactive patients released from the hospital and endangering those they meet seem to have taken on a half-life of their own. The issue continues to come up in Congress and the media, as it did recently when the Nuclear Regulatory Commission (NRC) met to review its recommendations on the medical use of radioactive materials. The NRC statement issued after the meeting on December 13, 2010,¹ affirmed its previous analysis that patients treated with radioactive iodine can be safely discharged if their radiation dose to others is under 500 millirems (5 millisieverts [mSv]) and that radiation exposure can be effectively managed by following instructions based on NRC recommendations and provided by the treating facility to patients likely to expose others to radiation doses of 100 millirems (1 mSv) or more.

Specific Guidelines

Richard T. Kloos, MD "The framework of this is that the lowest known levels of radiation that cause harm are somewhere between 10,000 to 100,000 millirems (100 to 1,000 mSv) and there is no evidence below 10,000 millirems of any harm," stated Richard T. Kloos, MD, Professor, The Ohio State University, Divisions of Endocrinology and Nuclear Medicine, Co-Director of The Ohio State University Thyroid Cancer Unit, and Secretary/Chief Operating Officer of The American Thyroid Association. "People can go home if they are expected to not give anybody else in the public more than 5 mSv.... Verbal and written instructions are required for patients who might expose others to more than 1 mSv," he added.

"Each hospital has very specific written guidelines that define which patients can be treated as an outpatient and which patients need to be admitted to the hospital for radioactive iodine therapy," explained R. Michael Tuttle, MD, Attending Physician, Endocrinology Service, Memorial Sloan-Kettering Cancer Center, and Professor of Medicine at Weill Medical College of Cornell University. "In some of my thyroid cancer patients, I give 400 or 500 millicuries to treat radioactive iodine-avid metastatic disease, and I would never do that for an outpatient. There is no reliable way to make that safe."

He said that he would also not administer radioactive iodine outpatient treatment to patients who, because of their age, other medical conditions, or cognitive impairment, might not be able to understand or follow precautions to minimize radiation exposure to others. "Those patients are not treated as outpatients," he said. "We wouldn't treat somebody as an outpatient unless we can be comfortable that they will follow the rules" about minimizing risks to others.

Current Standard of Practice

The NRC statement is an update to 1997 modifications of a regulation acknowledging that a facility licensed to provide radiation treatment "is best qualified to assess the suitability of individual patients to release post-treatment and to provide personalized guidance to patients to assure compliance with the applicable release criteria." According

to a joint statement² from the American Thyroid Association, The Endocrine Society, the Society of Nuclear Medicine, and the American Association of Clinical Endocrinologists, "A goal of this rule change was to avoid isolation of a patient in the hospital for prolonged periods if the patient's release to home would be safe for the patient, the patient's family, and the public. This approach enhances patient satisfaction and is the current standard of medical practice."

Most patients with thyroid cancer usually have surgery first. "They go home in a day or two and then usually we give radioactive iodine somewhere between 1 and 2 months after the surgery," Dr. Tuttle said. "So their surgical wound is healed."

Although dependent on the individual, the average I-131 dose for the treatment of thyroid cancer ranges from 30 to 200 mCi. Usually a single dose is all that is needed. "I used to be in the army, so I tell patients it is my heat-seeking missile," Dr. Tuttle said. "They swallow it and it goes everywhere through their body, identifying and destroying thyroid cancer metastases." He estimated that less than 10% of patients get a second dose 6 months or a year later.

Self-motivated Patients

The NRC statement says that "well-informed patients are self-motivated and sensitive to the fact that they are radioactive for a period of time," and they will "typically do as much as possible to reduce potential exposure to others." Dr. Tuttle and Dr. Kloos agreed on this point.

"It is definitely an issue that patients ask about because everybody is afraid that they are going to expose their family or anybody else to radiation," Dr. Tuttle stated. "Most patients are more interested in that than they are about the side effects and how the radioactive iodine might hurt them. Because they are pretty convinced that it is a safe medicine for them."

Many patients knowing they will receive I-131 have researched the treatment and are often "reassured that actually what we ask them to do is much less imposing than what they thought it was going to be and is something they can easily follow," Dr. Kloos said. "It is quite rare that someone is just so frightened or concerned about this that they elect not to receive radioiodine out of concern or fears."

The general advice offered by Dr. Tuttle is "to stay at arm's length from everybody for a day or two." The written instructions patients take with them are more detailed, "because the specifics of how long-whether it is 1, 2, or 3 days-depends on the dose that we give. It also depends on their age, because young people get rid of the radioactive iodine faster than older people."

Dr. Kloos tells patients to "act like you have the flu for the next day or two. Avoid close contact. Avoid swapping bodily fluids. Avoid kissing, sex, and sharing cups or utensils. Avoid food taste testing for others, and for the next day act like you are infectious, keeping time and distance between you and another person," he tells patients. If patients can do this, their risk of exposing others to radiation is low. "If they can't, we talk about admitting them to the hospital." Dr. Kloos reminds patients that they will not actually feel like they have the flu. "Most people feel nothing," he said. "A few will feel a little nausea," which can be treated with antiemetics.

Room at the Inn?

Radiation detectors have become increasingly prevalent and sensitive and "can detect minute amounts of radiation,

way below levels that can cause any kind of harm," Dr. Kloos said.

"My patients will set off airport detectors for a week or 10 days after treatment," Dr. Tuttle reported. "They will set off the detectors on the interstate," he said. While police and transportation workers are generally aware that medical radiation can set off detectors, it can create anxiety among patients and fellow travelers. Patients treated at Memorial Sloan-Kettering Cancer Center receive a card indicating that they were treated with radioactive iodine. Although that may be helpful at U.S. airports, "in some other countries, nobody cares if you've got a card that says you were treated at Memorial Sloan-Kettering," Dr. Tuttle noted. For that reason, staff members often caution international patients to wait a few days after radiation treatment before flying home.

But where do they stay? Some reports have raised concerns about staying in hotels and exposing workers there to radiation risks.

"We tend to discourage people from staying at hotels, although when we look at the data, it seems perfectly fine for them to do so," Dr. Tuttle said. "Many patients don't have a choice because they are flying in for their treatments. If we treat them, they are usually not going to be able to fly for 2 or 3 days," because of precautions to keep at least an arm's distance from others and possibilities about setting off alarms. "We have carefully looked at this because we have lots of people flying in. When we set up these outpatient rules, we asked the question, 'Should we just admit people if they have to stay at a hotel?' Our physicists and nuclear medicine people very carefully went through all the data, and we are absolutely comfortable that it is safe for these patients to be in a hotel," Dr. Tuttle said.

Staying in a hotel "can be done safely and reasonably," Dr. Kloos agreed, but physicians need to discuss with patients some additional risk-reduction strategies. These measures include checking in before treatment so they can go directly to their room afterwards and avoiding interactions in the lobby.

References

1. Nuclear Regulatory Commission Advisory Committee on the Medical Use of Isotopes Patient Release Report, December 13, 2010.
2. Joint Statement on Radioactive Precautions Following Radioactive Iodine Therapy, American Thyroid Association, Endocrine Society, Society of Nuclear Medicine, American Association of Clinical Endocrinologists, October 20, 2010.

<http://www.ascopost.com/articles/march-1-2011/how-can-patients-who-receive-radioactive-iodine-treatment-for-thyroid-cancer-reduce-the-chance-of-radiation-risks-to-others/>

APPENDIX B – 10 CFR 35.75

§ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.

(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).¹

(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include—

(1) Guidance on the interruption or discontinuation of breast-feeding; and

(2) Information on the potential consequences, if any, of failure to follow the guidance.

(c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with § 35.2075(a).

(d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with § 35.2075(b).

[67 FR 20370, Apr. 24, 2002 as amended at 70 FR 16363, Mar. 30, 2005; 72 FR 45151, Aug. 13, 2007]