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Submitter Information

Name: Peter Crane
Address:
6545 27th Avenue Northwest
Seattle, WA, 98117
Email: kinderhook46@yahoo.com

General Comment

See attached file(s)

Attachments

2019.September20PatientReleaseComments

Comments on NRC Draft Regulatory Guide DG-8057

submitted by

Peter Crane, NRC Counsel for Special Projects (retired)

September 20, 2019

Introduction and Summary

I appreciate the opportunity to submit comments on Draft Regulatory Guide DG-8057, the proposed Revision 1 to Regulatory Guide 8.39, dealing with the release of patients after their treatment with radioactive pharmaceuticals. I wish I could commend it in the same way I **can** praise a related NRC document: a web page, "Information for Patients Administered Radioactive Iodine (I-131)," https://www.nrc.gov/materials/miau/patient-release.html, which was posted to the web about two years ago, I am told. That web page includes a link to a printable brochure for patients, the practical, understandable guidance that the thyroid cancer community has long been waiting for.

When you compare the two documents, DG-8057 and "Information for Patients," the contrast is striking. To begin with, the list of references in DG-8057 includes, at p. 23, citations to two documents that are so flawed as to be valueless. These are NUREG-1492 (1994) and the NRC/ACMUI "Patient Release Report" (2010). The first was written before the Patient Release Rule was put in place, to justify its adoption, and the second much later, to justify keeping it unchanged. Both were advocacy pieces, lacking the factual accuracy and dispassionate analysis that were needed.

At the same time, DG-8057 fails to cite two documents of considerable value: the NRC Regulatory Issue Summaries from 2008 and 2011 (RIS 2008-11 and 2011-1), in which the NRC staff tried to mitigate some of the harm that the Patient Release Rule had caused. Both were, on the other hand, referenced in the staff's "Information for Patients," which is yet a third document that DG-8057 unaccountably omits to mention.

In the discussion of the factual background that follows, it will be seen that one key point is the significance of the "internal dose" delivered to others by thyroid cancer patients who have been made radioactive by high-dose treatment with I-131. Another is the distinction between an "activity-based standard"– meaning that it limits the amount of radioactivity **in** the patient's system at the time of release – and a "dose-based standard," which estimates the amount of radiation that anyone else is likely to receive **from** such a patient.

Prior to 1997, the NRC, in common with the rest of the world, had an "activity-based standard,"which was intended to protect the patient's loved ones and the public at large from **both** external and internal dose. In 1997, however, under pressure from the nuclear medicine

industry and its friends in Congress, the NRC made a fateful mistake, adopting a rule that replaced the activity-based standard with a "dose-based standard" that ignored internal dose. The Commissioners seem to have had no idea at the time of the magnitude of the deregulation that they were approving, much less of its likely consequences.

The NRC's rule change, by abolishing the activity-based standard, opened the door for insurers to stop paying for inpatient treatment across the board. This in turn led providers to make outpatient treatment the norm, often denying inpatient treatment even in cases where it was indisputable that patients and their young children needed to be kept apart until the radioactivity level in the patient had dropped to a safe level.

Medical care of thyroid cancer patients in the United States was thus transformed, with dire results for patients, their loved ones, and the public. Today, Bangladesh offers its children better protection than our country does. The induction times for radiation-caused thyroid cancer are long enough that no patient is likely to be able to prove, if his or her child develops cancer, that the NRC's deregulation was to blame, but that does not mean that it will not happen, or that the train of causation does not start with the leadership of NRC.

For many years, as the evidence has piled up that the current system is broken, the NRC has steadfastly refused to take meaningful action. The Commissioners typically wash their hands of the matter, instead delegating it to the NRC staff, which has been unwilling to do more than offer non-binding guidance to licensees. (It is certainly possible that this is all that the Commissioners have been willing to allow the staff to do.) This guidance has proven to be wholly ineffective, given the financial incentives for providers to ignore it. These are Band-Aids on a gaping wound, and what is more, the Band-Aids have no adhesive to make them stick.

To use a different simile, the NRC's approach of issuing unenforceable guidance is like putting up a scarecrow in a cornfield: once the crows figure out that it is harmless, they will do exactly as they please, and fiddling with the scarecrow – making it a little taller, or putting a new hat on it – will not change anything.

Medicine is probably the sole area of the NRC's responsibilities where the public is actually at risk from agency-licensed activities[1], and yet it has historically received minimal attention from the Commissioners. To the best of my knowledge, the Commission's last

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[1] On August 26, 2019, the NRC staff issued an Information Notice of a medical event in 2018 in which the patient, a 17-year-old being treated with iodine-131 meta-iodobenzylguanidine (I-131 MIBG) for neuroblastoma, received a dose to the skin of 55,000 rads – a staggering amount – owing to human error in disconnecting and then reconnecting a catheter. The staff deserves credit for its promptness in alerting the licensee community to this and an earlier similar event, with a view to preventing more such occurrences.

meeting on the subject of the release of radioactive patients was in 2010. After more than two decades of providing American children with inadequate radiation protection, the Commission needs to face up to the problem, and amend the current Patient Release Rule to bring it up to national and international standards.

Background

A. How it used to be

Thirty years ago, when I was being treated with high doses of I-131 for thyroid cancer, it was universally understood in the U.S., as it still is in most countries of the world, including the Third World, that patients like me needed to be kept in isolation after treatment. That is because we are a danger to others in two ways: from proximity, owing to the radiation we emit ("external dose"), and from the "internal dose" that can result from contact, by inhalation, ingestion, or touch, with the I-131 that we excrete in our breath and bodily fluids. We are what one expert in the field once described in a letter to the NRC as a "leaky source," because I-131 is given by mouth, and is therefore excreted from the body in the days following treatment. **Adults are more at risk from external dose, children from internal dose, and children are more sensitive to the harmful effects of radiation than adults.**

The NRC's rules on patient release of that era, adopted in 1986, therefore required the hospitalization of anyone receiving 30 millicuries or more of I-131. (This was the codification in rule form of decades of practice, which previously had been written into individual licenses.) The NRC rejected the suggestion that patient release could be based simply on how much external radiation another person would receive **from** the patient. In its *Federal Register* notice, it explained that while the equations to be used were straightforward, the much harder problem was to know the underlying facts – who might be exposed to the patient, at what distance, and when – all of which were essential for an accurate estimate of the dose to anyone else. The NRC notice also reiterated that patients were dangerous from both internal and external dose.[2]

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[2] Regarding the risk to the public from I-131 patients, Dr. Dade Moeller, a Harvard professor who later headed the NRC's Advisory Committee on Reactor Safeguards, made the point in a 1978 article in the *American Journal of Public Health* that more I-131 was discharged into the sewers from a hospital treating thyroid patients than from a nuclear plant. He observed that I-131 patients were boarding airplanes with more radioactivity in their systems than would be allowed in baggage in the hold. (And this was before the NRC deregulation of 1997, which increased the danger immeasurably.) It was no exaggeration. In 2006, when the International Commission on Radiological Protection circulated a draft of ICRP 104, "Scope of Radiological Protection," it included the statement that **a single I-131 patient may give off more radiation than a nuclear plant emits in an entire year.** In comments on the draft, the NRC

Virtually everyone in the field, here and abroad, agreed that both external and internal radiation from I-131 patients posed dangers to family members and others. International Basic Safety Standards, adopted by the International Atomic Energy Agency in 1996, declared that for a country's radiation safety program to be considered adequate, it must include a provision calling for inpatient treatment for anyone given more than 30 millicuries of I-131. No other medical isotope was even mentioned.

Moreover, the 30-millicurie limit in the Basic Safety Standards carried an asterisk: it might be too high, by a factor of two or three, to be adequately protective. By 1996, the international community had come to realize, partly because of data from Chernobyl on the extreme radiation sensitivity of children exposed to I-131 in fallout, that this standard needed tightening, and it encouraged countries to amend their regulations accordingly.[3]

The recommendations from the international community came on top of efforts earlier in the decade from the Environmental Protection Agency (EPA) to sharply restrict emissions of I-131 from hospitals. Many institutions, including the National Institutes of Health (NIH), regarded this as a serious threat to their ability to give thyroid cancer patients the treatments they needed.

For all these reasons, there was pushback from the American medical community, intended to prove that the 30-millicurie standard was well grounded in science and needed no tightening. For example, Dr. Pat Zanzonico, Ph.D., a health physicist at Memorial Sloan-Kettering Cancer Center, explained in a 1997 article in *Thyroid*, the journal of the American Thyroid Association, based on calculations, why a 30-millicurie dose of I-131 corresponded to a maximum dose to a family member of 500 millirems (a measure of received dose), which was then the regulatory limit for exposures to the public.[4] Dr. Zanzonico added the caveat that the

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protested the "inappropriate" comparison between people and plants, but did not dispute – it could not have – the accuracy of the statement. The ICRP duly deleted the offending sentence.

[3] An excellent explanation of **why** children are at so much greater risk can be found in a user-friendly document prepared by the Centers for Disease Control (CDC) in 2002: "Radiation Exposure from Iodine 131," https://www.atsdr.cdc.gov/hec/csem/iodine/docs/iodine131.pdf.

[4] It worked in the following way. If, for example, you got an I-131 dose of 150 millicuries, you would be placed in an isolation room with plastic on all the furniture, plastic-coated paper on the floor, and duct tape over the surface of the sink and toilet. You would be encouraged to drink a lot, in order to flush the excess isotope out of your system. Once or twice a day, a radiation safety tech would enter the room, wearing protective gear that covered everything but her eyes, and with a Geiger counter held at a distance of one meter from your neck, measure the amount of radioactivity being emitted by the isotope retained in your thyroid tissue. When the level dropped to six millirems per hour, if I remember correctly, it meant that no more than 30 millicuries of I-131 was left in your body, and you could be sent

30 millicurie limit applied only to **external** dose, from proximity, and explained: "**Of course, the overall hazard is a combination of both the external and internal radiation hazards**." With respect to internal dose, he observed that "**saliva and urine [are] the primary sources of such contamination**." [Emphasis added.] He was entirely correct on both points.

Another expert who fully appreciated the significance of internal dose was Dr. Carol S. Marcus of UCLA. Writing to the NRC in 1992, she declared that with respect to "leaky sources" (that is, patients who are given isotopes orally, and excrete them in bodily fluids and breath):

> It is important to consider situations in which the patient is a "leaky source." In such situations, more conservative considerations need to apply. It is important to consider the patient given NaI-131 in this context.
>
> **I-131 appears in urine, feces, sweat, saliva, lacrimal fluid, nasal fluid, and emitted gases. The radiation absorbed dose to the thyroid in individuals who share households with patients can be much more significant from contaminant I-131 than from the patient as a sealed source. Therefore, the limiting factor in deciding when a patient can go home should be contaminant levels of I-131 that can reasonably be expected to occur.** [Emphasis added.]

B. The NRC changes the rules

In 1997, the NRC, instead of lowering the 30-millicurie limit as some had feared, quite unexpectedly abolished it, making an unexplained 180-degree reversal from its position of 11 years earlier. It did so after heavy lobbying from the nuclear medicine community of the House committees that controlled the agency's budget.

The NRC's rule change came in response to a petition for rulemaking filed, and later amended, by Dr. Carol S. Marcus, the expert quoted earlier. In trying to make sense of what may be the most drastic health and safety deregulation ever enacted by an agency of the U.S. Government, it is worth mentioning that Dr. Marcus once boasted to the NRC that an earlier rule change, also made in response to a petition from her, had been "an 'inside job' from the start."[5] The same could be said of this one.

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home. Once you were at home, you could be confident that no one would receive more than 500 millirems from you, since you and everyone you came in contact with would know of your condition, and be able to keep a safe distance and take other suitable precautions.

[5]The NRC never denied that, nor could it have. The collusion had taken place behind the back of James Taylor, the NRC's Executive Director for Operations (head of the NRC staff), who was incensed, and took immediate steps, including a change in the agency's rules, to try to prevent a repetition of this gross violation of procedural norms.

The NRC's decision to give Dr. Marcus what she asked for needed a scientific rationalization, and it was provided by NUREG-1492, first published in draft form in 1994. On one point after another, the authors deferred to the advice of the NRC's Medical Fellow, Dr. Myron Pollycove (1921-2013), who was a leading crusader for the doctrine of "hormesis," the notion that a little, or even not so little, radiation is good for you. The mainstream scientific community regarded hormesis as poppycock, and still does. The National Academies of Science rebutted Dr. Pollycove's views, mentioning him by name, in BEIR VII, *Health Risks from Exposure to Low Levels of Ionizing Radiation*, published in 2006.

Dr. Pollycove once co-authored an article claiming that if a major nuclear accident occurred, the health effects, if any, would be **beneficial**. Even more to the point, he also believed, notwithstanding the childhood thyroid cancers in Eastern Europe that every responsible authority ascribes to I-131 from Chernobyl, that I-131 did not cause cancer. While personally likable, Dr. Pollycove helped lead the NRC down a path that has left American children with radiation protection inferior to what is considered absolutely basic even in the Third World. As an advisor for that rulemaking, there could hardly have been a worse choice.

If, as Dr. Pollycove believed, I-131 cannot give children cancer, it followed naturally that there was no special need to keep them apart from newly treated patients, who exhale the isotope with every breath, and whose bodily fluids are spreading contamination. Vomiting after administration of I-131 never occurs, said NUREG-1492. It is not only former I-131 patients like me who know better. Kathleen Kaufman, of the Los Angeles Health Department, once described a case in which a newly released I-131 patient vomited on a city bus, and passengers tracked through the radioactive mess all day long.

I could within a few minutes gather from the Facebook group of thyroid cancer survivors fifty or more examples in which patients described vomiting after I-131.[6]

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[6] On August 24, 2019, as I was working on a draft of these comments, a new post arrived, from a woman named Jazmin (to protect her privacy, I won't give her last name), who wrote:

> "RAI [radioactive iodine] was Wed around noon. The first 6 to 48 hours were hell, I literally thought I was dying (nausea, vomiting, diarrhea, swollen salivary glands-I looked like my head grew double its size) ... doc said you will be okay in a few days. Symptoms are not as bad now but the headache has not gone away, the intensity decreased a little but now it is nonstop (taking Tylenol per doc), sore throat is getting worse and now I have an extreme runny nose and it feels like I have fluid in my ears. Did any of yall experience this?"

Those reading this can tell themselves and/or the NRC, if they wish to, that Jazmin and her post are my invention, or that I put her up to it, or that her vomiting, if it occurred, was pure coincidence, having nothing to do with her treatment. Skeptical readers should look into the issue of patient vomiting for themselves. The internet abounds with information on the subject.

On the crucial question of internal dose, NUREG-1492 found it to be insignificant:

> [I]nternal doses from intake of contamination are likely to be much smaller than doses from external radiation and much smaller than the public dose limit. Therefore, **internal exposures will not be considered in this analysis** other than for the breast-feeding infant. [Emphasis added.][At p. 16.]

The NRC had known better in 1986, as noted above, and the underlying science had not changed in the meantime. To be sure, internal exposures are a lesser danger than external exposures **to adults (**other than those who are pregnant or nursing), but to **children**, they are a far greater danger, and it children who are most at risk from the cancer-causing effects of radiation. In the words of the Centers for Disease Control[7]:

> Exposure to I-131, especially in childhood, increases the risk for hypothyroidism, thyroid nodules, and cancer. ... **A child's thyroid dose from ingestion can be up to 20 times that of an adult because the same amount of energy is deposited in a smaller tissue mass. A child's thyroid dose from inhalation can be twice that of an adult, and is 15–20 times higher than the overall dose to the rest of the body.** [At 12-13.][Emphasis added.]

Since external dose was all that mattered, according to Dr. Pollycove and NUREG-1492, it followed that there was no need for the 30-millicurie limit on the level of radioactivity in the patient, or, indeed, for any limit at all. The new rule allowed providers to calculate the likely external dose that any other person would receive **from** the particular patient, and if that number fell within regulatory limits – 500 millirems – the patient could be released, regardless of whether 10 millicuries or 400 millicuries of I-131 were circulating in his or her system. Analytically, this was akin to abolishing all limits on smokestack emissions in favor of calculating how much pollution the nearest resident was likely to inhale. On paper, it might sound plausible, but in the real world, it was far from being adequately protective, for exactly the reasons the NRC had articulated in 1986.

So instead of tightening the regulations as the international community had recommended, and as the medical community had feared, the NRC unexpectedly all but

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[7]I realize that my own views can be brushed off as those of a non-physician, a patient, an advocate with a partisan viewpoint, etc., but it's not so easy to dismiss the Centers for Disease Control. These are the true medical experts, not the NRC, which is headed by political appointees, has not a single physician on the staff, and must depend on consultants whose views may or may not be sound, and often aren't.

abolished them. I am not suggesting that the Commissioners of that era intended any actual harm toward the affected patients and their families, but their intent is completely beside the point.[8] What matters, rather, is the **effect** of their decision, which has been to cause untold harm, which continues to this day.

C. Effects of the new rule

I have described many times, over many years, what happened once the NRC enacted the Patient Release Rule. Insurance companies, as millions of Americans have come to realize, have usurped much of the decision-making power that should be in the hands of patients and providers. In this case, they leaped on the fact that hospitalization for high-dose I-131 treatments was no longer an absolute requirement for every patient. Many insurers stopped covering the cost of inpatient treatment, regardless of whether the patient lived alone or with a houseful of small children in a residence with only one bathroom. Providers in turn learned that if they prescribed the inpatient treatment that the individual living situation required, they might not be reimbursed. The NRC, which should have spoken up to prevent abuses, instead kept silent.

So many providers began, without exception, to "whisk them out the doors as fast as possible," as Dr. Leon Malmud, then Chairman of the Advisory Committee on the Medical Uses of Isotopes, explained with brutal frankness at an October 2007 ACMUI meeting. He gave several reasons, including the fact that hospital staff were afraid of being near radioactive patients, and that the adjoining rooms had to be left vacant, because of the radiation penetrating the walls. (See https://www.nrc.gov/docs/ML0808/ML080850674.pdf, at p. 187.) No one can read that transcript, which can be found on line, and feel confident about the safety of sending radioactive patients home.

Dr. Malmud was describing his own institution, Temple University in Philadelphia, as well as many others. To be sure, on paper the NRC required a finding that no one would receive a radiation dose of more than 500 millirems, but that requirement was often, perhaps usually, ignored. Instead, patients were handed a piece of paper, if they were lucky, telling them the guidelines that they should follow to protect others. Patients who were well-informed and well-off could send their children away, or go elsewhere themselves. Otherwise they all

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[8]Among other things, it seems that relevant information never reached the Commissioners. A number of states had written to the NRC, pointing out the special dangers posed by I-131, but the NRC staff's memoranda to the Commission never mentioned those warnings, and instead told the Commissioners that the proposal enjoyed broad support across the board. This verbal sleight of hand concealed just how radical and controversial a proposal the Commissioners were being asked to approve.

stayed together in the home and hoped for the best.

To give you just one recent example, I recently spent a morning advocating (with her written permission) on behalf of Miranda, a thyroid cancer patient in Bremerton, Washington, who has been told that she will receive I-131 as an outpatient, although she shares a "fifth wheel" trailer with her three children, the youngest of whom is five years old. If you look up "fifth wheel," you will find that it has a maximum area of 430 square feet. The patient had been sent guidance that told her to use a separate bathroom from other family members, and, she told me, "I just had to laugh."

Some patients report on Facebook that they have no trouble obtaining inpatient treatment, like one who posted to the site on September 7. That is great news – but when you ask where they are getting treatment, it turns out to be Brisbane, Australia. Why should the woman in Brisbane get adequate protection when the woman in Bremerton and her family do not? The current leadership of the NRC did not create this situation, but being aware of it, and having done nothing to correct it, they must share in the blame.

It is a measure of the casual and slipshod way in which the NRC Commissioners of 1997 approved the Patient Release Rule is that no one stopped to consider whether high-dose I-131 patients could be released only to their homes or were free to go anywhere, including hotels. The Office of General Counsel later decided, very wrongly in my view, that they could go anywhere – hotels, public transportation, you name it. That meant that the entire rationale for having a 500-millirem (rather than 100-millirem) limit for doses from released patients evaporated, since the possibility now existed for persons with no connection to patients, and no awareness of their situation, to receive doses exceeding the normal 100-millirem limit for members of the public.

Is this a reasonable possibility? On this, the definitive word comes from the NRC staff itself. According to an NRC staff analysis published in 2018 (SECY-18-0015, Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release After Radioisotope Therapy, Jan. 29, 2018), "**all exposure scenarios indicate that transportation scenarios pose a radiation concern for members of the public.**" (Attachment 1, at p. 6.) It found that **a patient with just 100 millicuries of I-131 in his or her system can deliver a radiation dose of 100 millirems to a nearby person in as little as 42 minutes.** If the patient has received more than 100 millicuries, as many do, or the subway or bus ride takes longer than 42 minutes, the dose to the nearby person will inevitably exceed 100 millirems. That nearby person might be pregnant, in which case the unborn baby will also be receiving a dose. If this does not shock the conscience of the NRC, then there is something very wrong with the agency. If you think that I am exaggerating, talk to some nuclear medicine technologists and radiation safety officers, and ask them how they feel, knowing that the patients they have just

treated with high doses of I-131 may be sharing elevators with pregnant women, and afterwards boarding public transportation. The RSO at the hospital where Miranda is to be treated told me, "I see it the same way you do – I have a six-year-old daughter."

The NRC's patient release rule means that the protection for the American public is only as good as the conscience of the individual patient. As one courageous NRC staffer put it in a public meeting, the NRC has "outsourced radiation protection to the patients." It is an insult to the intelligence to pretend, as did the ACMUI's Patient Release Report, that relying on every patient to do the right thing is a fully adequate substitute for binding and enforceable regulations on NRC licensees.[9]

The current 500-millirem limit for exposures applies to **all** persons: family members and members of the general public, including children, babies, pregnant mothers-to-be, and embryos in the womb. This is five times what the National Council on Radiation Protection and the International Commission on Radiological Protection deem appropriate.

Nor is the NRC staff even confident that doses to the public are below the 500-millirem limit. It wanted to inform the Commissioners of this, more than seven years ago. The draft of a staff memorandum, SECY-12-0011, "Data Collection Regarding Patient Release," included the following: **"It is not known whether members of the public are, in fact, receiving doses that are less than 5 mSv [500 millirems] from the released patients."** But the Advisory Committee on the Medical Uses of Isotopes intervened to muzzle the staff, with the extremely dubious argument that the Commission's directive to the staff did not permit the NRC staff to address this issue, and regrettably, the staff yielded. It should instead have stood its ground, for this was information that the Commissioners desperately needed to know: namely, that the NRC staff cannot say that the current rule is actually ensuring adequate protection of public health and safety.

D. An ACMUI report defends the Patient Release Rule (2010)

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[9] Without a shred of evidence or a citation to a journal article, the ACMUI Patient Release Report declared: "Well-informed patients are self-motivated and sensitive to the fact that they are radioactive for a period of time, excreting radioactivity, and will typically do as much as possible to reduce potential exposures to family, caregivers, and other members of the general public." (At p. 17.) This was pure fantasy, plucked out of the air. Surely it is obvious that thyroid cancer patients are no better and no worse than the rest of the population: some are altruistic, willing to endure inconvenience or expense to protect total strangers, and others are not. As a professor at Penn State once told me, "What gets me is when you spend time explaining to patients what they ought to do, and they nod their heads, 'Uh-huh, uh-huh,' and all the time you can see in their eyes that they are going to do exactly as they please." As a long-time thyroid cancer patient, who has talked to many hundreds of fellow patients over the decades, I would love to hear the ACMUI explain its basis, other than wishful thinking, for the quoted statement.

In addition to NUREG-1492, draft Regulatory Guide DG-8057 relies on the 2010 report on the Patient Release Rule by a subcommittee of the Advisory Committee on the Medical Uses of Isotopes. The calculations for the report were made by Dr. Pat Zanzonico, by that point an ACMUI member. The report asserted that the 30-millicurie rule had been wholly without a scientific basis, that its origins were unknown, and that it would be a serious mistake to return to an activity-based limit for patient release. Yet Dr. Zanzonico was the same expert who, as we saw above, had argued the exact opposite in the pages of *Thyroid* in 1997: namely, that the 30-millicurie limit was sound, well-grounded in science, and consistent with the 500-millirem dose maximum to others.

Perhaps the best indicator of the deficiencies of the 2010 ACMUI report is that when it was presented to the Commissioners at an October 2010 meeting, the subcommittee chairman declared that the NRC's Patient Release Rule allowed a dose of 500 millirems to family members and caretakers, and 100 millirems to the general public. An accompanying slide on the screen stated that this was "consistent with national and international recommendations in principle/practice."

Reassuring no doubt, but dead wrong. Just a few minutes later, the NRC staff pointed out, with its own slide on the screen, that the rule in fact allows a dose of 500 millirems to **anyone** – five times what national and international authorities recommend. It was instantly clear to everyone in the room that the members of the ACMUI subcommittee had never read the rule that they were so vigorously defending. They had evidently been looking at the wrong regulation.

E. NRC Staff attempts to mitigate the harm caused by the Patient Release Rule

In 2004, the International Commission on Radiological Protection issued a report, ICRP 94, warning of the danger to children from patients made radioactive by treatment with I-131. It stated, among other things, that one kiss from a radioactive parent could transfer enough I-131 to double a child's risk of developing thyroid cancer.[10] This information, which made clear that the NRC had erred in 1997 in dismissing the hazards of contamination and the resulting internal dose, was not, as far as I know, communicated to the Commissioners.

In 2008, however, the NRC staff felt obliged to deal with ICRP 94, in the context of denying a petition for rulemaking, filed by me in 2005, which asked the Commission to revisit its regulations on patient release, and stressed the hazards of internal dose. In a *Federal Register*

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[10]International Commission on Radiological Protection, "Release of Patients after Therapy with Unsealed Radionuclides," ICRP Publication 94, Annals of the ICRP 34(2), Pergamon Press, Oxford (2004). The reference to the doubled risk of thyroid cancer is found at p. 30.

notice, the staff explained that though it was denying the petition, it intended to "**revise the guidance in NUREG-1556, Volume 9, to include the ICRP Publication 94 recommendations** and issue a Regulatory Issue Summary (RIS) to medical licensees to make them aware of the ICRP recommendations."[11]

This was a major step forward, or so it seemed, and the RIS that followed, RIS-08-11, bore out the expectations that it had raised. The May 16, 2008, press release accompanying that RIS explained that it instructed physicians to "consider hospitalizing patients whose living conditions may result in the contamination of infants and young children." It continued:

> These regulations were based on the assumption that internal doses to family members or others from a patient released following iodine therapy would be small compared to external doses received from being near the patient. **However, concern has increased in recent years that contamination of infants and young children with saliva from a patient in the first few days following treatment may result in significant doses to the child's thyroid.** [Emphasis added.]

But the revision of the NUREG-1556 guidance to include the ICRP 94 recommendations never occurred. It is hard to know for sure, but it appears that there was an internal conflict between reformist elements in the NRC staff, who wanted to bring the agency into conformity with current understanding of radiation safety, and others, including the ACMUI, who were intent on defending NUREG-1492 and preserving the Patient Release Rule without change.

Then in 2009, the International Atomic Energy Agency, assisted by the ICRP, issued Safety Report No. 63, "Release of Patients After Radionuclide Therapy." It reiterated, at p. 7, that treated patients can cause exposure of other persons to radiation in two ways:

> (a) External irradiation of persons close to the patient;
> (b) Internal contamination of persons as a result of excreted or inhaled radionuclides.

IAEA No. 63 also stressed the importance of appropriate measures to control doses to others, stating: "Without precautions, it is possible to envisage doses up to **a number of orders of magnitude higher than the dose limits** or dose constraints." [Emphasis added.] (At p. 8.) It stated:

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[11] 73 FR 29445, 448 (May 21, 2008.)

> Thyroid cancer as a result of radiation exposure is a significant risk for unborn children, infants, and younger persons. **Particular care should be taken to avoid contamination of pregnant women, infants and children.** [Emphasis added.] (At p. 38.)

IAEA No. 63 identified – as the NRC had in 1986, in rejecting the idea of a dose-based standard – the "many methodological issues that can compromise external dose calculations." (At p. 8.) It also explained:

> Wellner et al. [citation to 1998 article in *Nuklearmedizin*] calculated that **the effective dose, from air contamination, for relatives of cancer patients treated on an ambulatory basis could be up to 6.5 mSv** and could, thus, exceed the 1 mSv public dose limit. ... The ICRP concludes that, in general, contamination **of adults** is less important than internal exposure. Notwithstanding this, it is very important to avoid contamination (particularly from saliva) of pregnant women, infants, and young children, owing to the sensitivity of foetal and paediatric thyroids to cancer induction**.** [Emphasis added.] (At p. 10.)

At the risk of repetition, I would note that while contamination of adults, and resulting internal dose, is not a major issue for adults, it is a highly significant issue for children, who are at far greater hazard than adults.

Note also that patients treated with I-131 can, **from exhaled breath alone**, deliver doses to family members of as much as 650 millirems. This is entirely internal dose, and not only does it exceed the internationally accepted dose limit of 100 millirems, it also exceeds the 500 millirems permitted by NRC. Doesn't this seem like something the Commissioners need to know about? But the ACMUI report on patient release, while it cited IAEA No. 63, said not a word about internal dose from exhaled breath.[12]

Let us put this into real-world terms. A young mother is sent home after I-131 treatment and told to keep at a safe distance from her young child. Fine, she thinks, the playpen will be on the other side of the room, and while I keep an eye on the baby, I will stay 15 feet away. Does anyone tell her that she may be delivering a significant radiation dose to her child simply by being in the same room and breathing? Not if the ACMUI subcommittee can help it, it seems.

The ACMUI report criticized the NRC staff's 2008 RIS for having repeated the ICRP's

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[12]There is a great deal of literature, especially in European medical journals, on the subject of the I-131 exhaled by treated patients. See, for example, M. Gründel at al., "^{131}I Exhalation by Patients Undergoing Therapy of Thyroid Diseases," *Rad. Prot. Dosimetry* (2008), Vol. 129, No. 4, pp. 435-438.

warning about the thyroid cancer risk to the children of radioactive patients without also having provided "details regarding the assumptions." (At p. 11.) It "commend[ed] the NRC for adopting the current-risk-based [*sic*] criteria," and declared, at p. 16, **"Change from the 30-mCi rule to the current 10 CFR 35.75 patient release criteria in no way weakened the NRC rules."** [Emphasis added.]

The absurdity of that last assertion was stunning. Thirty years ago, when I was leaving the hospital after an I-131 treatment, and, for all that I or anyone else knew, sharing an elevator with a pregnant woman, the risk to others was limited by the fact that I could have no more than 30 millicuries of the isotope in my system. In 2019, by contrast, people are leaving hospitals every day, and boarding public transportation, with 200 millicuries or more of I-131 in their systems. The Radiation Safety Officers in today's hospitals know that. Just ask them. Commissioners and the EDO should visit some hospitals, preferably unannounced, and talk to RSOs and senior nuclear medicine technologists, explaining that they don't want the party line, they want the truth.

The ACMUI's assurance that the rule change that made this possible **"in no way weakened the NRC rules"** must be weighed against the words of the NRC staff paper, SECY-2018-015, quoted earlier: "**all exposure scenarios indicate that transportation scenarios pose a radiation concern for members of the public.**" This was not a safety concern until the Patient Release Rule went into effect.[13]

I will deal only briefly with RIS 2011-1, in which the NRC staff "strongly discouraged" the sending of radioactive patients to hotels. The NRC staff estimates that five to ten percent of patients go to hotels and motels after treatment. Consider the case of a big cancer center that draws patients from all over the world. Memorial Sloan-Kettering Cancer Center in New York City gives more I-131 treatments than any other facility in the world. More than 99 percent, according to an eminent endocrinologist there, are given on an outpatient basis. Where are patients from abroad or out of state supposed to spend the night, if they are too radioactive to fly home immediately? Realistically, it is a choice between a hotel room and a bench in Central Park.

Several years ago, while visiting a well-known Seattle hospital for another purpose, I dropped by the nuclear medicine department and spoke to a senior technologist there. I asked

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[13] One has to wonder about the point of even having an Advisory Committee if it provides the Commission with misinformation on critical issues, and battles the NRC staff every time it tries to do the right thing. Why is the Commission, which would surely never tolerate such behavior from the Advisory Committee on Reactor Safeguards, so complacent when it comes from the ACMUI, unless it is because it regards medicine, and the patients who receive it, as of less importance than nuclear power plants?

whether they gave I-131 treatments on an inpatient or outpatient basis. He replied that in his ten years there, he knew of a single inpatient treatment. They gave outpatient doses of up to 200 millicuries. I asked whether they ever released patients to hotels. Certainly, he replied, some of our patients come here from Alaska, and they can't fly home right away. I asked whether the hospital was aware of the NRC guidance that "strongly recommended" against sending patients to hotels. "That was taken into account," he said. What about the Washington State guidance to the same effect, I asked. "That was also taken into account," he replied. In other words, it wasn't mandatory, so we blew it off.

Conclusion

The central, continuing problems with the NRC Patient Release Rule go unaddressed and untouched in this Draft Regulatory Guide. These problems include: (1) that patient release is based upon calculated external dose, on the assumption that internal dose is inconsequential; (2) that the NRC allows radiation doses to family members and the public that are five times what national and international standards call for; (3) that non-binding guidance has proved ineffective in correcting the inadequacies in current protection; (4) that the rule has been interpreted to allow newly treated patients to go to hotels, where they contaminate the rooms they stay in and the linens they sleep on; (5) that the NRC has outsourced the protection of the public from licensees, where it belongs, to the conscience of the individual patient, who may or may not be informed and altruistic; and (6) that in practice, the rule allows insurance companies, who look only at the bottom line, to dictate whether patients and their families receive adequate radiation protection.

If the NRC is unwilling to initiate a corrective rulemaking on its own, which seems apparent, the only solution at this point is a petition for rulemaking from members of the thyroid cancer community, who can attest from personal experience to the harm that the current rule has inflicted, and continues to inflict, on them and their families. Persons with no connection to the treatment of thyroid cancer can also join the petition, to make the point that they want neither their children nor themselves to be exposed to radiation while on public transportation or staying in hotels. Not only should such a petition not be necessary, there is no guarantee that the NRC would act on it expeditiously – it has a history of putting petitions that raise awkward issues into cold storage[14] – but I see no other way.

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[14]More than four years ago, Dr. Carol Marcus filed a petition for rulemaking, asking the NRC, in conformity with the principles of "hormesis," to raise the annual permissible dose of radiation to all persons, specifically including infants, embryos, fetuses, and pregnant women, to 10 rems (10,000 millirems) per year, on the grounds that such exposures may not be harmful, and may indeed be hormetic. (This figure is 20 times the amount presently allowed, and 100 times the level recommended by

To sum up, the central issue is whether this country protects children adequately against radiation-caused cancer and birth defects. The Nuclear Regulatory Commission needs to address the root causes of the flaws in the current Patient Release Rule, and recognize that merely tinkering with non-binding guidance, instead of fixing the defects in the rule, means abdicating its responsibilities to America's children.

Finally, I would like to return to the case of Miranda, the patient who lives in the fifth wheel with her three children. (See above at 8-9.) As I was completing these comments on September 20, I phoned her, hoping to hear that the hospital had agreed that she needed to be treated as an inpatient. No such luck. Her consult at the hospital is scheduled for September 24, and she has been told that "insurance companies don't like paying for inpatient treatment, so they will probably send me home." I am about to write her a letter, making clear that the decision is not the insurance company's to make, it is the hospital's, and if the hospital cannot find that the maximum dose to anyone else will be 500 millirems, it cannot legally treat her on an outpatient basis.

Miranda's situation cries out for inpatient treatment. Can anyone doubt it? Why is it so difficult, in this country and nowhere else, to do right by her and people like her? Can there be anyone in authority at the NRC whose heart and conscience are not troubled that cancer patients like her, with so much to worry about already, should have the additional fear that the treatment they receive will one day make cancer patients of their children?

Respectfully submitted,

/s/

Peter Crane, NRC Counsel for Special Projects (retired)

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national and international authorities.) She also asked the NRC to abandon the principle that radiation exposures should be kept "as low as reasonably achievable." The NRC took public comment on the petition, and received the ACMUI's views, years ago. What is it waiting for? I could not disagree more with Dr. Marcus's petition, but she has a right to have it acted on, up or down, and then to take the agency to court if it is rejected.