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June 10, 2019

Chairman Kristine L. Svinicki  
Commissioner Jeff Baran  
Commissioner Annie Caputo  
Commissioner David A. Wright  
Ms. Margaret Doane, Executive Director for Operations  
Ms. Marian Zobler, General Counsel  
Ms. Sophie Holiday, ACMUI

Dear Chairman Svinicki, Commissioners, Ms. Doane, Ms. Zobler, and Ms. Holiday:

This afternoon, June 10, 2019, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) will hold a teleconference on the subject of patient release: the draft regulatory guide prepared by the NRC staff, and the comments on it by an ACMUI subcommittee. Unfortunately, the emailed notification of the meeting went into my spam folder, and I only found it yesterday.

For the past 27 years, I have closely followed the issue of the release of patients made radioactive by treatment with the isotope iodine 131 (I-131). My interest in the subject originated with my having been treated with that isotope, numerous times, for thyroid cancer. I was at the time a lawyer with the NRC.

I will just briefly review the background. The NRC's 1997 deregulation of I-131 treatments was once described to me by a Penn State nuclear medicine doctor as "the worst decision made by that agency in 35 years." That was 20 years ago. Everything I have seen since confirms the soundness of his comment.

Technical advice for that rulemaking came from an elderly nuclear medicine doctor who was a prominent advocate of "hormesis," the theory, considered crackpot by mainstream science, that radiation, even in what most experts would consider substantial doses, is good for you. This particular doctor, whose name I do not mention because he is deceased, was on record as believing that iodine 131 was not carcinogenic, and that if a serious nuclear accident occurred, the resulting radiation exposure could not be harmful to health and might be beneficial. He also believed, crucially, that the danger posed by released I-131 patients was exclusively from external dose. He dismissed internal dose – from ingestion, inhalation, and skin contact with I-131 – as insignificant.

Only a decade earlier, in a 1986 rulemaking, the NRC had correctly declared that I-131 presented hazards both from external and internal dose. Now, in 1997, it decided that internal

dose did not matter, as it enacted what may be the most drastic deregulation ever by a federal agency created to protect public health and safety. Whereas previously, release had been based on the activity level in the patient, in order to protect loved ones and others from both external and internal dose, the new rule was based on the likely external radiation dose to others.

The effect has been to make the United States, formerly a leader in the world radiation protection community, into an extreme outlier. The United States now has radiation protections far inferior to those of Bangladesh, South Africa, the Philippines, Indonesia, and many other nations. In those countries, no one leaves the hospital with more than 15 millicuries of I-131 in his or her system. In Europe, the limit is even lower than that. In the U.S., by contrast, people are being sent home to their families every day with up to 200 millicuries of I-131 in their systems, and sometimes even more.

These patients also have to get home. That often means traveling by public transportation. According to an NRC staff analysis published last year (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 (the most that a member of the public should receive from a licensed activity in a year, according to the National Council on Radiation Protection and the International Commission) to a nearby person in as little as 42 minutes. And yet the NRC staff concluded, with one courageous staff member listed as non-concurring in the paper, that no rule change is needed.

Sadly, no one who reviews the history of this issue objectively can avoid the conclusion that regulatory authorities in other countries put a higher priority on protecting children from cancer and other radiation-caused illnesses than do those in the United States. To the extent that the NRC tells itself that America's children are just as well protected by the current rule as children in other countries, it is kidding itself. The thyroid cancer patient community certainly knows better, and if ever the NRC Commissioners would schedule a public meeting on the subject of patient release, they could hear from some patients and doctors directly.

The NRC staff deserves credit for some modest steps it has taken over the years to try to rectify, to some extent, the harm done in 1997. Thus for example, when the staff's attention was drawn to the fact that the International Commission on Radiation Protection (ICRP) had issued a report on the risk posed to others by radioactive patients,<sup>1</sup> including the special risk to

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<sup>1</sup> ICRP Publication 94: Release of patients after therapy with unsealed radionuclides. International Commission on Radiological Protection (2005). The abstract, which explains that the ICRP is recommending a tightening of controls on exposures to young children and infants, begins as follows: "After some therapeutic nuclear medicine procedures with unsealed radionuclides, precautions may be needed to limit doses to other

children from contamination, such as that transmitted by a parent's kiss, the NRC put out a Regulatory Information Summary (RIS) encouraging doctors to "consider" hospitalizing patients with young children at home. This was non-binding, and though it changed nothing as a practical matter, it at least acknowledged the problem, and was frank in stating that the 1997 rule had paid insufficient attention to the risk, especially to children, from internal contamination.

A few years later, another RIS addressed the problem of radioactive patients going to hotels, saying that this practice was "strongly discouraged." Again, this was non-binding, and with little or no practical effect, but at least it recognized the impropriety of discharging patients to hotels, where a pregnant or nursing mother may unwittingly absorb I-131 while cleaning the room and bathroom.

This does not mean that the NRC staff could not and should not have gone further than it has. The fact that the rule was premised on a fundamental scientific error should have led the NRC to advocate a rulemaking long ago to correct this error. After more than 20 years in which guidance to licensees has failed to solve the problems with the current rule, the staff continues to put its faith in more and better guidance, rather than a rule change, when only a rule change, imposing mandatory and enforceable requirements, can achieve any meaningful reform. If non-binding admonitions were the answer, they would have worked by now.

The draft report of the Advisory Committee on the Uses of Medical Isotopes subcommittee is problematic in several respects. The ACMUI has for years been a vigorous proponent of the view that no change is needed in the current rule. Consistent with that approach, it has consistently downplayed the risks of internal exposure, the special risks to children, and the undesirability of sending radioactive patients to hotels. (All of these, it will be noted, are areas in which the NRC staff has taken positive, if limited, steps.) The essence of the problem can be seen on the last page of the ACMUI subcommittee's report, under "Other Recommendations." The first one reads as follows: "In the Patient Precautions and Instructions Sections, it should be emphasized that the major source of radiation dose to other individuals will be from external exposure from the patient (Ref. 1)." The "Ref. 1" referred to is ICRP 94,

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people, but this is rarely the case after diagnostic procedures. Iodine-131 results in the largest dose to medical staff, the public, caregivers, and relatives. Other radionuclides used in therapy are usually simple beta emitters (e.g. phosphorus-32, strontium-89, and yttrium-90) that pose much less risk. Dose limits apply to exposure of the public and medical staff from patients. Previously, the ICRP has recommended that a source-related dose constraint for optimisation of a few mSv/episode applies to relatives, visitors, and caregivers at home, rather than a dose limit. The present report recommends that young children and infants, as well as visitors not engaged in direct care or comforting, should be treated as members of the public (i.e. be subject to the public dose limit). **The modes of exposure to other people are: external exposure; internal exposure due to contamination; and environmental pathways. Dose to adults from patients is mainly due to external exposure. Contamination of infants and children with saliva from a patient could result in significant doses to the child's thyroid. It is important to avoid contamination of children and pregnant women.** [Emphasis added.]

quoted above.

Now let us compare that with the way that the American Thyroid Association characterized the views of the ICRP, in comments to the NRC last year:

The International Commission on Radiological Protection (ICRP) has estimated the risk for all cancers in children is 0.1-0.2% from an effective I-131 dose of 1 mSv [1 millisievert, or 100 millirems]. **Risks to children include those from external radiation exposures as well as potential ingestion of contamination from excreted or secreted I-131 from treated patients.** The ATA currently recommends that “having a treated parent staying in the home with children is often problematic due to children’s needs and desires to be near the treated parent. **Special arrangements should be made for children to stay with relatives or friends; alternatively, the treated parent may stay with relatives or friends where children and pregnant women are absent.” In circumstances where this is not possible, inpatient isolation is an appropriate alternative.** Development of lower acuity isolation facilities would help reduce the cost of inpatient isolation.  
[Emphasis added.]

Why cannot the ACMUI state plainly what everyone knows to be the case: that children are far more radiosensitive to I-131 than adults, and that to children, internal exposure is a major hazard? Why does the NRC pay for stockpiles of the drug potassium iodide (KI) around nuclear power plants, if not because internal exposure to I-131 can cause cancer and other harm, especially in small children?

It is worth noting that whereas the ICRP and its domestic counterpart, the NCRP, recommend a maximum radiation dose of 100 millirems to members of the public, the NRC allows five times as much, 500 millirems, to everyone, including babies, infants, pregnant women, and babies in the womb. If the ICRP and the American Thyroid Association are correct, that means that a dose of 500 millirems to a child from I-131 creates a cancer risk of half a percent to one percent.

What benefit does the present rule confer that would compensate for a one percent cancer increase in children? Sadly, I know from experience that this is the kind of question that never gets answered, simply because there is no palatable answer. It is easier to pass over it in silence.

**Kissing.** It is noteworthy that neither the draft Regulatory Guide nor the ACMUI comments say anything about the risks presented when a radioactive patient kisses a child, although that was a major point made in ICRP 94. Nor does either one make the point that if a

radioactive patient is being transported after treatment, there should be no children in the car.

**Hotels.** On page 11 of the ACMUI comments, the following appears: "Pg 13, Section 2.3.1, i: Add 'hotel' to the list of examples of post treatment lodging the patient may use." This is troubling, in part because the word "may" has two distinct meanings. In this context, it could mean either: "It is possible that a patient will go to a hotel," or "Patients are permitted to go to hotels." Unless the NRC has changed its mind, and no longer thinks that it is "strongly discouraged" for patients to go to hotels, this ambiguous comment should not be accepted. On the contrary, the Regulatory Guide should reiterate the admonition made in the RIS.

**Additional Points.**

One of the issues most stressed by commenters was the need for licensees to communicate guidance to patients in a timely and comprehensible way. To do so properly would require a rule change. The NRC staff rejected this, regrettably. The discussion in the draft Regulatory Guide, includes the following, at Section 2.3.4: "Prior to release of the patient, the patient should acknowledge receipt of instructions and the licensee should acknowledge the patient understands the instructions as communicated. These acknowledgments **could** be obtained by using a form signed by both parties." [Emphasis added.] I stress the word "could" just to make the point that the guidance here is so feeble. The NRC will not even go so far as to say, in guidance that it stresses is non-binding, that this is something that licensees **should** do, unless there are issues, such as illiteracy, that stand in the way.

Under 10 CFR 35.75, if a licensee cannot find that a patient's exposure of others will be under 500 millirems, it cannot release the patient – no ifs, ands, or buts. The draft Regulatory Guide makes this point, under Section 2.3.2., "Patient Precautions," but because the entire Guide is declared to be non-binding (e.g., "compliance with RGs is not required," at page 2), the reader may not realize that this is a requirement of the regulations, and thus has the force of law. Clarification may be helpful.

I appreciate the opportunity to submit these comments.

Respectfully,

Peter Crane

Counsel for Special Projects, USNRC (retired)

**McCloskey, Bridin**

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**From:** Peter Crane <peter46crane@gmail.com>  
**Sent:** Monday, June 10, 2019 1:34 PM  
**To:** Vietti-Cook, Annette; Howe, Donna-Beth; Zobler, Marian; Holiday, Sophie; Doane, Margaret; Gary Bloom; Leo Slaggie; laura weil  
**Subject:** [External\_Sender] Letter to Commission re June 10, 2019 ACMUI Teleconference  
**Attachments:** 2019.June10.ACMUIMeeting.LetterToCommissioners.pdf

Dear Ms. Vietti-Cook:

Would you be so kind as to circulate the attached to the Commissioners? It concerns the ACMUI meeting to begin shortly. Unfortunately, I only learned of the meeting yesterday, so there hasn't been time to circulate it to the ACMUI members as I would have wished. Thank you for your consideration.

Regards,  
Peter Crane