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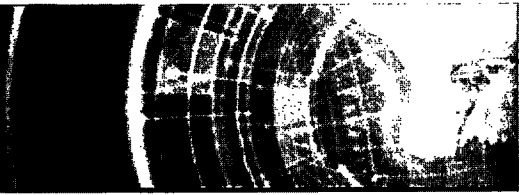
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July 16, 2012

Chairman Allison M. Macfarlane
Commissioner Kristine L. Svinicki
Commissioner George Apostolakis
Commissioner William D. Magwood, IV
Commissioner William C. Ostendorff
U.S. Nuclear Regulatory Commission
Washington D.C., 20555

Dear Chairman Macfarlane and Commissioners:

As an NRC retiree who joined the agency weeks after its founding, I would like, first of all, to offer congratulations to the new Chairman. Her arrival may be an appropriate moment to draw the Commission's renewed attention to some issues pertaining to NRC regulation of nuclear medicine.¹

Probably only a small fraction of the public is even aware that nuclear medicine is part of the NRC's regulatory portfolio. Medicine, however, is where people in this country actually get exposed to radiation from man-made sources. We know from NCRP 160, issued in 2009, that the average American's annual dose of radiation doubled between 1981 and 2006, entirely because of medical procedures. The average dose from medical radiation increased seven-fold, most of it coming from nuclear medicine, which NRC regulates, and CT scans, which are not under NRC jurisdiction.²

This is not the place to describe in detail the problematic history of NRC's regulation of nuclear medicine. The most important single fact in recent times is that in 1997, the NRC Commissioners, giving in to pressure from the licensee community, agreed to a radical deregulation of nuclear medicine.³

¹In the interest of brevity, I will omit most citations, but would be happy to provide them on request.

²The last paragraph of the following journal article, from 1984, estimates a total of 10,000 new cases of thyroid cancer per year. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1424611/> That figure may be slightly low – I recall that in 1983, the American Cancer Society was estimating 12,000 cases – but it is certainly in the ballpark. Today, the American Cancer Society estimates over 56,000 new cases in 2012. The only known environmental cause of thyroid cancer is radiation. Some believe that the increase, higher than for any other kind of cancer in the U.S., is solely attributable to better diagnostic techniques. Others, myself included, think this unlikely.

³For the technical underpinnings, the NRC staff chose to rely on a medical consultant, Dr. Myron Pollycove, a most likable person, but with highly unconventional views on radiation. Singled out for criticism by the National Academy of Sciences in BEIR VII for his views on "hormesis," he is on record as believing that radioactive iodine

Whereas the pre-1997 rule prescribed a flat activity-based standard, with a maximum of 30 millicuries of I-131 in the patient, the new rule allowed use of a dose-based standard. Under it, patients could be released so long as an individualized calculation of their living situation showed that no other person would receive more than 500 millirems of external radiation from them.

The effect of the rule change was that thyroid cancer patients who in the past would have faced mandatory hospitalization for therapy doses of I-131 were now routinely treated as outpatients. Insurance companies seized on the rule change to deny reimbursement for inpatient treatment, without regard to the patient's home situation. At an October 2007 meeting of NRC's Advisory Committee on the Medical Uses of Isotopes, Dr. Leon Malmud, the Committee's chairman, and a former SNM President, described the result memorably: "All patients are discharged upon treatment. We whisk them out the doors as fast as possible."

Dr. Malmud (a strong supporter of the current rule, it should be emphasized) explained that the hospital staff is afraid of the radioactivity in these patients, and that there is also a financial disincentive to treating them as inpatients, since adjoining rooms must be left empty to protect other patients from the radioactivity coming through the walls. How much better, therefore, from the hospitals' point of view, to give patients their I-131 and quickly send them off to their homes or to a hotel, assuring them that all this is perfectly in accordance with NRC safety regulations.

As the Commission (with the probable exception of Chairman Macfarlane) is aware, I filed a petition for rulemaking in 2005, asking the NRC to revisit the 1997 rule change. That petition was denied by the staff in 2008. I then filed a petition for review in the Ninth Circuit Court of Appeals, which dismissed it, at the NRC's urging, on standing grounds: that is, on the theory that my own experience with I-131 treatment was too far in the past for me to be affected by the NRC's rules, and thus qualified to challenge them in court. Since the court had decided that it lacked jurisdiction, it did not address the merits issues, such as whether radioactive patients were going to hotels.

At oral argument, one of the judges suggested that if the case were to be decided against me on standing grounds, a new petition could be submitted by a group that included current patients. This remains a strong possibility. For the present, however, it may be useful to highlight some of the outstanding issues in this area.

I. Divergence between NRC and national and international standards

131 is not carcinogenic, and that any health effects of a major nuclear accident would be beneficial.

Both the ICRP and the NCRP recommend dose limits, to persons exposed to radiation from released patients, of 5 millisieverts (500 millirems) to an adult family member and 1 millisievert (100 millirems) to a child, a pregnant or nursing female in the household, or a member of the public at large. The NRC, by contrast, allows all persons to receive 500 millirems. Only if the dose to another person is likely to exceed 100 millirems does the NRC even require that guidance be provided to the patient on how to minimize doses to others.

In considering my petition for rulemaking in 2008, the staff raised and rejected the idea of making NRC's regulation follow the ICRP and NCRP 500/100 split standard. One might think that this was a significant enough policy issue for the Commission to be advised of it, but the staff disposed of it on its own.

Sooner or later, I submit, the Commission itself will have to deal with the fact that its regulations are so far out of step with national and international standards. That will mean either bringing the NRC into conformity with contemporary expert thinking on radiation safety or else offering a persuasive rationale for maintaining the current standards.

II. Is the NRC's position on patient release being misrepresented?

For some years, the Society for Nuclear Medicine (SNM) has been marketing a book, entitled "Guide for Diagnostic Nuclear Medicine and Radiopharmaceutical Therapy," published in 2004, saying that practitioners can use it in place of the guidance in NUREG-1556, Volume 9. It sells for \$40.⁴ The question I wish to raise is the accuracy of the SNM's representations about the position of NRC on this guidance.

On the relevant page on the SNM website, one finds the following statement about it:

This book may be used by diagnostic nuclear medicine and radiopharmaceutical therapy practitioners in place of NUREG-1556, Volume 9. The NRC views this SNM/ACNP Guide "as providing focused information that may be useful to nuclear medicine professionals in understanding the applicability of NRC requirements to the medical use of byproduct material in diagnostic **and radiopharmaceutical therapy** settings, and as providing measures that practitioners in these settings may use to facilitate implementation of the revised rule." <http://interactive.snm.org/index.cfm?PageID=2712&RPID=1795>: [Emphasis added.]

In addition, Dr. Carol S. Marcus of the SNM has declared explicitly, with reference to this

⁴ At the top of the cover, one finds the words "NUCLEAR REGULATORY COMMISSION REGULATION OF NUCLEAR MEDICINE." Some readers might well mistake this for an official NRC publication.

document: “NRC accepts this as an alternate to its own guidance document.” See:
http://acnm.snm.org/docs/New_Radiation_Guidelines-Carol_Marcus.pdf

But my internet searches have not turned up any document containing the words attributed to the NRC.⁵ What I do find, however, is something quite similar that the NRC **has** said about a different SNM guide, issued two years earlier, and of much more limited scope. This is the “Guide for Diagnostic Nuclear Medicine” published in 2002. Today, the NRC website includes a link to that 2002 guide and describes it as follows:

Guide for Diagnostic Nuclear Medicine - The American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM), in 2002, published a “Guide for Diagnostic Nuclear Medicine.” This guide provides information that was current on October 24, 2002 and maybe [*sic*] useful to nuclear medicine professionals in understanding the applicability of NRC requirements at that time for the medical use of byproduct material in diagnostic settings and provides measures that practitioners may use to facilitate implementation of the October 2002 revised 10 CFR Part 35.
<http://www.nrc.gov/materials/miau/med-use-toolkit.html>

The key difference between the two almost identical quotations is, obviously, the addition of the words “and radiopharmaceutical therapy.”

Did the NRC actually make the statement about the **2004** guide that is attributed to it by the SNM? If so, where and when? Or did the SNM take the NRC’s description of the **2002** guide, adapt it to apply to the 2004 guide, and then use it for advertising purposes?

This is crucially important from the standpoint of public health and safety – how much so can be judged from a December 2007 article by Drs. Jeffry Siegel, Carol Marcus, and Michael Stabin, entitled “Licensee over-reliance on conservatisms in NRC guidance regarding the release of patients treated with 131I,” *Health Phys.* 2007 Dec;93(6):667-77,
<http://www.ncbi.nlm.nih.gov/pubmed/17993847>. Describing compliance with the guidance in NUREG-1556 as “completely optional,” they assert that if their methodology is used, thyroid cancer patients can be released with up to 457 millicuries of I-131 in their systems, as compared with 179 millicuries using the NRC guidance.

The thought of doctors sending patients out the door with 457 millicuries of radioactive iodine 131 in their systems – to their homes, to public transportation, or to hotels – would leave many practitioners and public health officials, both here and abroad, appalled and disbelieving.

⁵ Nor can I find any statement by NRC to confirm Dr. Marcus’s claim that the NRC views the 2004 guide as an acceptable alternative to its own guidance.

Indeed, Dr. Marcus herself once told the NRC that the very idea was “ludicrous.”⁶ (Her thinking has evidently evolved since then.)

If the NRC has really given its blessing to the SNM approach, it will mean that a further radical deregulation has taken place *de facto*, by private arrangement between the SNM and the NRC staff, with no notice to the affected public or opportunity to comment. Did the staff in fact reach such an agreement with the SNM? If so, was it memorialized, and were the Commissioners told of it?

If the SNM advertising of the 2004 guide is accurate, the public has a right to know where and when this relaxation of NRC standards, by a factor of nearly three, occurred. If it is inaccurate, however, then some licensees, purchasers of the guide, have presumably been using it under the misapprehension that the NRC regards it as an acceptable substitute for NUREG-1556. In that case, a great many people may have been exposed to radiation from outpatients who would have been hospitalized if licensees had been following NUREG-1556 instead.

Thus if the SNM has misrepresented the NRC position, corrective action is called for, including an instruction to the SNM to cease and desist, and the issuance of a Regulatory Issue Summary to the licensee community, clarifying the NRC’s expectations with respect to patient release.

III. Lack of timely guidance on measures to protect others

The safety guidance given to patients by hospitals and practitioners varies widely – a point I have been making to the NRC for many years, so far to no effect. In 2007, an article in the *Journal of Nuclear Medicine*, by Luba Katz of Abt Associates and Armin Ansari of the Centers for Disease Control, made the same point. Now there is further confirmation of that point from an expert panel of the American Thyroid Association, headed by Dr. Carol Greenlee, in a February 2011 article in the journal “*Thyroid*,” reporting on a survey of 311 health professionals. It found that “no national guidelines exist to standardize safety instructions related to I-131 administration,” and concluded: “A wide variety of safety recommendations are given to patients who receive I-131.”

What practitioners find, if they look to NUREG-1556, Volume 9, for guidance as to what they should tell their patients, is a recommendation to write to the Society of Nuclear Medicine for a

⁶In a letter to NRC Secretary Samuel Chilk, dated November 9, 1992, and docketed on November 17, 1992, she wrote:

The concept of sending patients home with 400 mCi of NaI-131 was ludicrous. Although I could theoretically concoct a situation where it could possibly be justified, there are not too many patients who would qualify as hermits in isolated areas.

pamphlet it published in 1987. But that pamphlet has been obsolete for 15 years, ever since the current rule went into effect. Isn't it time the NRC published up-to-date guidance of its own?

To be sure, NUREG-1556 acknowledges that the 1987 pamphlet was written in the days of the 30-millicurie rule. But that's not a problem, it says – licensees should simply adjust the guidance to suit the higher dosages being administered. The unanswered question is: “adjust it **how?**”

In the meantime, NCRP Report No. 155, *Management of Radionuclide Therapy Patients*, published by the National Council on Radiation Protection in 2006, includes detailed guidance to be followed by practitioners administering I-131 to hyperthyroid and thyroid cancer patients. That guidance could easily have been incorporated into NUREG-1556 at any time in the last six years. Why hasn't that been done?

What is at stake here, after all, is ensuring that children do not develop cancer or mental retardation through exposure to I-131 from NRC-licensed procedures. Surely that is not so low a priority for the NRC that the patient and practitioner communities should still be waiting, 15 years after the rule went into effect, for appropriate guidance to be issued.⁷

Finally, in this connection, NUREG-1556, Volume 9, Appendix U, includes formulae that licensees can use in determining whether a patient will expose other people to more than 500 millirems of external radiation. The example used, at p. U-21, is of a thyroid cancer patient given 150 millicuries of I-131. Why only 150 millicuries, it may be asked, when we know that much more than that is often administered?

The answer is that originally, in draft guidance published in 1998, the staff used a figure of 200 millicuries, and calculated that this would result in a dose of 453 millirems to others, allowing the patient to be released. However, in comments submitted on November 11, 1998, a Penn State health physicist, Robert Forrest, explained that the NRC had failed to follow its own calculational methods, under which internal dose must be taken into account if it exceeds 10 percent or more of the calculated external dose. The actual dose to others from a 200 millicurie dose of I-131, he showed, was actually 453 millirems of external dose plus 106 millirems of

⁷Also on the subject of waiting for updated guidance: when the NRC denied my rulemaking petition in May 2008, it described in the Federal Register three possible options it had considered for increasing the safety of children and infants. These were: (1) amend the rule to limit the exposure of children and infants to 100 millirems; (2) amend the rule to include special instructions if children or infants were likely to receive more than that amount; or (3) “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.” 73 FR 29445, 448 (May 21, 2008.) The NRC then explained why it had decided in favor of the third option. More than four years later, there is no reference to ICRP 94 that I can find in NUREG-1556, Volume 9. Has that commitment been forgotten, or silently withdrawn, or is the staff just taking its time on a matter considered of slight importance?

internal dose, for a total of 559 millirems, well above the releasable limit.

When the staff responded to Mr. Foster's comment, more than four years later, it said: "We agree with this comment and have revised Example 2 to use 150 millicuries instead of 200 millicuries." See NUREG-1556, Volume 9, Appendix BB, p. 3-33 (2003). It is a pity that instead of revising the **answer**, and explaining that in this example, hospitalization is necessary, the staff revised the hypothetical, thereby ensuring that the result would be the same – no hospitalization.

If patients exceed releasable limits when they have 200 millicuries of I-131 in their systems, one can understand why it is so extremely important to the SNM, as described in the previous section, that the NRC guidance should be ignored in favor of its own. This brings me to the next point, radioactive patients in hotels.

IV. Radioactive Patients in Hotels

As the staff will confirm, the issue of patients in hotels was wholly unforeseen by NRC when it enacted the rule in 1997. Instead, it envisioned that patients would either go home after treatment, if they satisfied the 500 millirem standard for dose to others, or stay in the hospital.

To make my position clear, I believe, as some senior NRC staff members are also on record as believing, that under no circumstances should patients ever be given therapy doses of I-131 as outpatients if they plan to go to hotels after treatment. If patients are not going home, or to a private residence put at their disposal by persons with full knowledge that they are radioactive, they should be hospitalized.

I was unaware of the hotel issue until shortly after filing my petition for rulemaking in September 2005. (My petition dealt with the negative effects of the rule on patients and their families, which were bad enough.) On December 21, 2005, the NRC published notice of the petition in the Federal Register, and announced that comments would be received through March 6, 2006.

The rulemaking was conducted using RuleForum, a brainchild of the late William J. Olmstead, NRC's Associate General Counsel, a pioneer in using computers to enrich the administrative process. It was his idea that rulemaking could be made interactive, with comments posted on line as they were filed, and interested parties responding to one another's filings, defending or supplementing their own positions, trying to find compromise solutions, etc. In that spirit, I filed a supplement on January 30, 2006, responding to some of the comments already filed and also raising the hotel issue, as follows:

In addition, I frequently hear of patients who are scheduled to receive I-131 therapy doses as outpatients and who are advised, when they express concerns to

hospital personnel about the risk to their families, to check into a hotel for a day or two. **If that is true, then the effect of the NRC's 1997 rule has been to transfer part of the radiation dose to the hotel's unsuspecting domestic staff, which collects and washes the contaminated linens and towels and cleans the room, without the protections that would apply in a hospital setting.** I hope that commenters can provide information as to whether these reports are in fact accurate.

That was the crux of the issue then and remains so today.

In 2007, while the petition was pending, an article in *USA Today* reported that a significant fraction of I-131 patients were going to hotels after treatment. Afterwards, NRC's Region I asked NRC headquarters whether this was permissible under the NRC's rules. Yes it was, the Region was told, in a memo in which OGC concurred. The practice was not uncommon, headquarters advised, and the NRC would issue new safety guidance on the subject.⁷

In May 2008, the NRC denied my petition. Its decision said not a word about radioactive patients in hotels. As noted earlier, the resulting lawsuit in the Ninth Circuit was decided on jurisdictional grounds, and the court did not reach the hotel issue or any other merits question, though there were many questions from the judges at oral argument as to whether radioactive patients were going to hotels, and why the NRC had not discussed the issue in the denial.⁸

In 2009, the New York City Department of Health put out an advisory to medical licensees that told them in forceful terms not to send patients to hotels after treatment with I-131. It pointed in particular to the risk to a pregnant or nursing housekeeper. In January 2011, as noted, the NRC issued its RIS discouraging this practice.

⁷The two NRC documents were non-public, however, and I did not learn of them until after the denial had been issued and the lawsuit had been briefed, argued, and decided.

⁸ In court, the essence of the NRC position was that this was not occurring. Responding to a judge who thought it reasonable for a radioactive patient to go to a hotel and order food from room service, NRC counsel replied that "the people you are talking about are being kept in hospitals until they are safe for medical release." Even more specifically, counsel told the court:

There is not a single letter in there [the rulemaking record] where a patient says, "My doctor told me to go to a hotel." Every doctor who commented on the record said that this is not so. They don't do it. And this is simply not true.

I myself have been through all the comments in the record – there are only a few dozen – and cannot find even one in which a doctor discussed whether radioactive patients were being released to hotels. Maybe I missed something.

But the practice of sending radioactive patients to hotels continues, even in New York City, as we know from the March 2011 article in *ASCO Post*. Memorial Sloan-Kettering Cancer Center makes no apology for the fact that it is sending outpatients to hotels with up to 200 millicuries of I-131 in their systems.⁹ Moreover, it can safely be assumed that most of those patients are going to the same few hotels listed on the Sloan-Kettering website as having reduced rates for the hospital's patients. That means that the same housekeepers may be cleaning multiple contaminated rooms in a year, building up cumulative radiation doses. But there is no mechanism in place for the hotel or the housekeeper to know that a patient is radioactive.

Further confirmation that the problem is real is found in the article referred to earlier, by Dr. Carol Greenlee, *et al.*, on the results of an American Thyroid Association of several hundred endocrinologists, surgeons, nuclear medicine radiologists, and allied health professionals. Of the 91 respondents who answered a question on whether they recommended that patients given I-131 go to a hotel as a safety precaution, 4% said that they did so for patients receiving between 7 and 29 millicuries of I-131; 5% for all doses over 30 millicuries; 2% for all doses over 100 millicuries; and 3% for all doses over 200 millicuries. 85% reported that they never recommended that radioactive patients go to hotels. I would submit that if this is typical, these percentages, multiplied by the tens of thousands of Americans who receive I-131 treatments each year, should be deeply troubling to the Commission, the hotel and motel industry, and the hotel-going public.

There are several things to say about the idea of sending patients to hotels with large amounts of I-131 in their systems:

(1) The NRC rule change of 1997 envisioned that there would be a particularized evaluation of patients' living situations, to determine the actual likely dose to others. But if you are sending a patient to a hotel or motel, you have no way of knowing where the nearest person will sleep (unless you know for sure that the patient will be alone in a roadside motel with widely separated cabins, or something on that order). Since you cannot calculate the dose to others, you should not legally be able to release the patient to a hotel. A number of Agreement States already regard this as self-evident. How OGC could find otherwise is beyond me.

(2) If the NRC was correct in its 2003 response to Robert Forrest, the Penn State health physicist, and patients with 200 millicuries of I-131 in their systems will cause a radiation dose to others in excess of 500 millirems, why are they being released at all?

(3) There is no informed consent to the housekeepers exposed to contamination from the I-131 patient who goes to a hotel. In addition to the medical and moral issues presented, there are

⁹I have high regard for the quality of care at Sloan-Kettering, perhaps the pre-eminent cancer center in this country, and deep respect for Dr. Mike Tuttle, the eminent thyroidologist quoted in the *ASCO Post* article. On this question of radiation safety, however, I think they are in error, and I hope they will come to see the matter as I do.

potential liability and OSHA issues.

(4) The ACMUI subcommittee on patient release calculated in 2010 that the maximum probable radiation dose to a hotel worker would be to the person who changed the sheets, and that this would still be within acceptable limits. (The subcommittee did not deal with the point, made both by the staff and me, that one housekeeper could clean a number of contaminated rooms, thereby multiplying the dose.) I made the objection that patients' saliva and urine are far more radioactive than their sweat – in the case of saliva, a thousand times as radioactive. To this, one of the subcommittee members replied (see the ACMUI transcript of April 16, 2012) that I was wrong in saying that the subcommittee had failed to consider urine. The subcommittee **had** considered urine, he said: urine in the patient's **sheets**. It doesn't take a medical degree or a Ph.D. to know that if you really want to know the likely dose to a hotel room cleaner from a patient's radioactive urine, the place to start is the bathroom.

(5) The safety guidance in NCRP 155 says that the sheets of a treated patient are to be laundered separately from those of others. This is plainly impossible if the hotel is unaware that the hotel guest is radioactive. We know from the Braidwood Motel incident that a hotel guest can get radiation contamination significant enough to set off the detectors in a nuclear power plant simply by sleeping on sheets that have been laundered together with those of a released patient.

(6) The argument is sometimes made that foreign patients coming to the U.S. for treatment have "no choice" about going to hotels. (The point is that if patients are given 200 millicuries as outpatients, and then returning to Germany, for example, where hospitalization is mandatory for any dose of I-131 above **eight** millicuries, the airport radiation detectors will find them and they will be sent to a hospital.) I submit that if foreign patients have the money to come to the U.S. for treatment, unreimbursed by insurance, they can also pay for a night or two in the hospital, and should be told in advance to expect this.

(7) I recently read, on line, a posting from a thyroid cancer patient who had been treated as an inpatient. (I am sure I could find it if confirmation were desired.) She was told at the hospital that after she was discharged, the room would be left closed and untouched for a week, to cool down radiologically, before anyone went into the room to clean it. I don't know how prevalent that is, but what does it suggest about the desirability of having a hotel housekeeper cleaning a room an hour after a radioactive patient has left, and a family with children moving into it a few hours after that?

(8) The NRC might explore the possibility that special accommodations could be created for I-131 patients, less elaborate and expensive than hospitals, but nevertheless ensuring the safety of the facility staff and the public.

V. Conclusion

I do not ask the Commissioners or anyone else to take my word for it on these matters. (I hope they **don't**, in fact, since I would prefer that they investigated the issues for themselves.) What I do ask of the Commissioners, however, is the kind of "questioning attitude" that the NRC recommended in its recently issued policy statement on "Safety Culture." That means, the NRC said, identifying discrepancies and avoiding complacency. Here the discrepancies are many.

My primary concern is and will continue to be for the patients, their family members, and the hotel staff and members of the public with whom they come in contact. But as someone who was associated with the NRC for 27 years, I would rather help the agency do the right thing than have to assail it for its failings. It is in that spirit that I have submitted this memorandum. I am available, by telephone or email, to any Commissioner or staff member who wants more information or an opportunity to discuss these issues.

Sincerely,

/s/

Peter Crane

NRC Counsel for Special Projects (retired)