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January 21, 2020

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

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

I write today with sadness and regret. I would always rather be in the position of praising the NRC, which I joined in 1975 when it was ten weeks old, than criticizing it, but today that is not possible. I wear my 20-year service pin with pride. I have many friends still at the NRC whom I hold in high regard both as public servants and as human beings. It gladdens my heart to know that the current Executive Director for Operations is someone who was once described to me, by someone who worked with her for years, when both were assistants to Commissioners, as having – I hope I don't embarrass her by saying this – "a backbone of steel." Moreover, if I did not care about the organization, I surely would not have written to my Senators and Congressman a few years ago, urging that One White Flint North be renamed the Lando Zech Building, in letters that explained why the late Chairman Zech was a model of inspired leadership, particularly in his loyalty and respect toward everyone in the agency, regardless of rank, including the guards at the front desk and the elevator operators in the downtown building where the NRC had its offices. (I never got an answer to those letters. If it were up to me, Two White Flint North would be the Ed McGaffigan Building.)

A few days ago, I learned by merest chance that the NRC will be having a public meeting on medical issues, including the release of radioactive patients, on January 28, 2020. (There is a listserv that is supposed to inform interested persons of matters relevant to NRC medical regulation, and some of us depend on it, but as of this writing, nothing about it had been posted.) It will last for three hours. Of these 180 minutes, all of eight have been allotted to a patient advocate, Mr. Josh Mailman. I mean no criticism of Mr. Mailman, who seems to have done admirable work on behalf of a group of patients suffering from a rare type of cancer. But that cancer is not treated with iodine 131, and I-131 is the elephant in the room: the most radiotoxic of medical isotopes, and the most often prescribed. Mr. Mailman is on record, in comments submitted to the NRC, in support of the SNMMI position on patient release.

One of the staff memoranda up for discussion in the January 28 meeting is SECY-2015-08, dealing with patient release criteria. I can think of three people who know the issues related to the release of I-131 patients inside out. One is Dr. Donna-Beth Howe of the NRC staff. She has been involved with these subjects for nearly thirty years. Her participation in recent years in the annual conferences of the Thyroid Cancer Survivors Association has also given her a high degree of understanding of the patient perspective on I-131. The second is the NRC's Patients' Rights Advocate, Gary Bloom, a thyroid cancer patient for more than 20 years, with many I-131 treatments, who as Executive Director of the Thyroid Cancer Survivors Association (ThyCa), has an unmatched depth on these issues. Nobody is in a better position than he to speak on behalf of patients. Finally, there is me, a long-time thyroid cancer survivor who has been intimately involved in the patient release issue since January 1992. Yet none of the three of us is scheduled to take part. Gary learned of the meeting only from an email from me.

In short, it seems that the Commission is set to conduct a session, scheduled with little or no notice to the interested public, guaranteed to tell them that the status quo is just fine. There will be no dissenting voices. The Commissioners will then be able to rebut the criticism that they have not had a meeting in ten years on the subject of medical regulation, but they should not deceive themselves: the status quo is anything but fine, and there are persons both inside and outside the NRC who know it. It may not have been the NRC's intent, and I hope it wasn't, but the effect, as well as the appearance, is of a stacked deck. If it *was* the intent, however, then cherry-picking your participants to ensure that you hear only what you want to hear is antithetical to the "Principles of Good Regulation" which the NRC professes to follow.

Accordingly, I urge you to postpone the meeting and reschedule it only when a greater diversity of views is represented. In the meantime, I am attaching, as part of these comments, a letter that I wrote to the Commission in 2018, explaining what I saw as the deficiencies in SECY-18-0015.

Finally, I would like to express my thanks to the NRC's splendid Secretary, Annette Vietti-Cook, who wrote me today that I was welcome to submit a written statement.

Respectfully submitted,

/s/

Peter Crane, NRC Counsel for Special Projects (retired)

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September 5, 2018

Chairman Kristine L. Svinicki
Commissioner Jeff Baran
Commissioner Stephen G. Burns
Commissioner Annie Caputo
Commissioner David A. Wright
Margaret Doane, Executive Director for Operations
Marian Zobler, General Counsel

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

On January 28, 2018, the NRC staff sent the Commissioners a policy paper, SECY-18-0015, evaluating the adequacy of the agency's controls on the release of radioactive patients, which is governed by 10 CFR 35.75 of the NRC's regulations, the Patient Release Rule.[1] The staff's analysis reflects six years of work, including a diligent and scrupulously fair public outreach effort, led by Dr. Donna-Beth Howe, and a conscientious analysis of the comments received. Though I am neither a physician nor a scientist, I have been closely involved with the patient release issue since 1992, when I was both the NRC's Counsel for Special Projects and, coincidentally, a thyroid cancer patient undergoing treatment with radioactive iodine 131. Even before that, going back to 1975, when I joined the NRC as a lawyer, I had occasion to see the evolution – it might more properly be called the dismantling – of the agency's program for the regulation of nuclear medicine. Based on that experience, I wish to offer the Commission my views on the staff paper – what it gets right, what it gets wrong, and what it fails to address.

Much in SECY-18-0015 deserves praise, including the following:

- It recognizes that "**the dominant factor in determining both internal and external doses to members of the public is based on the behavior after release**. Patient behavior was a more important factor than the activity, at the time of patient release, of the I-131 that had been administered to the patient." (At p. 3.)
- It acknowledges that in estimating radiation doses from released patients, **"the existing methods could result in underestimating radiation dose in certain situations if patients do not**

[1]STAFF EVALUATION OF THE U.S. NUCLEAR REGULATORY COMMISSION'S PROGRAM REGULATING PATIENT RELEASE AFTER RADIOISOTOPE THERAPY, SECY-18-0015, January 29, 2018. The request had been made by the Commission in January 2012, when Allison Macfarlane was Chairman.

follow the provided instructions." (At p. 4.)

- It reports that calculations performed by Oak Ridge National Laboratories for the NRC staff indicate that in a variety of situations (public transportation and release to hotels and nursing homes), **"the calculations performed by licensees to determine whether the patient meets regulatory release criteria may underestimate doses to members of the public."** It adds that this "highlights the importance of patient discussions and instructions by the licensee to inform the patient on how best to limit the dose to family members, hotel workers, people on buses, people in nursing homes, and others." (At p. 4.)
- It recognizes that **"performing the calculations is not adequate by itself: it does not determine the dose that will actually be received."** (Attachment 1, at p. 4.)
- The paper states that when thyroid cancer patients take public transportation after treatment with I-131, **"all exposure scenarios indicate that transportation situations pose a radiation concern for members of the public."** (Attachment 1, at p. 6.) It calculates that **if a member of the public, including a child or a pregnant woman, is standing in close proximity to a newly released cancer patient with 100 millicuries of I-131 in his or her system, that member of the public could absorb a radiation dose of 100 millirems in as little as 42 minutes.**[2] To put this in context: (a) according to the National Conference on Radiation Protection (NCRP) and the International Commission on Radiation Protection (ICRP), 100 millirems of radiation is the most that any member of the public, regardless of age or sex, should receive in an entire year.

Put these observations together, and the staff paper is telling us that when patients are given therapy doses of I-131 as outpatients, no one has any real idea who will receive a dose of external radiation from a given patient, or in what amount.[3]

Regrettably, however, the staff paper fails to go on to draw the logical conclusion from its findings, which is that the existing rule needs to be amended. Instead, its bottom line is that all the current weaknesses in the NRC's system of controls can be addressed satisfactorily through better guidance, without a rule change.

I respectfully disagree. The faults in the current rule are just too fundamental, beginning with the NRC's egregious error, based on its reliance on a single consultant of eccentric views, in declaring that internal radiation dose, from the ingestion and inhalation of radioactive isotopes, was insignificant. This was, metaphorically speaking, a gaping hole in the hull, below the waterline, from the moment of launching.

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[2]Moreover, many outpatients are released after receiving much more than 100 millicuries of I-131, and thus could deliver 100 millirems to an unsuspecting fellow passenger in a much shorter time.

[3]This is hardly surprising, given that this was the very reason NRC gave in 1986 for rejecting the idea of a dose-based rule. In 1997, when the NRC reversed itself, it was not the science that had changed, it was the NRC, and its willingness to bow to external pressure.

It also represented a reversal, made without any explanation whatever, of what had long been the NRC's position, namely, that **both external and internal dose presented significant hazards.**[4]

A number of state health authorities had done their best to alert the NRC to the special hazards posed by the isotope iodine 131, from both internal and external dose, but their warnings were ignored – if indeed the Commissioners even learned of them, which is far from certain. As a result, the NRC ended up with a rule based on estimating the external dose to others, without reference to internal dose. Later on, thanks largely to an ICRP report published in 2005, which urged a lowering of dose limits for exposure from radioactive patients, the NRC came to realize that **with respect to I-131, internal dose presents a greater risk to children, who are far more radiosensitive than adults, than does external dose.**[5]

The NRC's rule thus addressed only half the problem – the less important half, with respect to children. How could the NRC have made so gross an error? Because the consultant on whom it relied as its ultimate authority on issues in dispute was, whether the NRC Commissioners knew it or not, a leading

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[4]This is not the place for an extended discussion of all that went wrong in the NRC's regulation of nuclear medicine in past decades, especially the 1970's through 1990's, including collusive rulemakings taking place behind the back of the Commissioners and the public, and the occasional hiring of manifestly unsuitable consultants and members of the Advisory Committee on the Medical Uses of Isotopes. In that time, the NRC's technical staff and the Commissioners were often working at cross-purposes, with the staff allied with the licensee community, while the Commissioners, their attention fixed on nuclear power plants, for the most part took an attitude of complacent indifference. There was a telling exchange between Senator John Glenn and then Chairman Ivan Selin in a May 1993 oversight hearing in which Glenn expressed amazement that the NRC tolerated, in the medical area, misconduct that would have produced immediate dismissals if it had occurred on the reactor side. Glenn had hit on the heart of the problem; that the Commissioners neither knew nor cared what was happening in the medical area, notwithstanding that it was there that Americans were actually being harmed by NRC-licensed activities.

[5]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 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."

advocate of the pseudoscientific doctrine of "hormesis."[6] Among other things, he co-authored a journal article claiming that if a major nuclear accident occurred, the health consequences to the public from radiation, if any, would be **beneficial**.[7] He also believed, bizarrely, that radioactive iodine 131 was not carcinogenic. (If you don't think I-131 can cause cancer, there's no reason to be concerned about protecting children and others from ingesting and inhaling it.) Yet some 7,000+ residents of the former Soviet Union, virtually all of whom were small children or in utero at the time that they ingested and inhaled I-131 from Chernobyl, later developed thyroid cancer, and today, only a charlatan or a fool would deny the connection.

The notion underlying the rule was that it would allow the home situation of the I-131 patient to dictate whether inpatient or outpatient treatment was more appropriate. In other words, the patient with small children at home could be hospitalized, while someone who lived alone, and could take care of himself or herself, would be spared the necessity of a hospital stay. But in the words of one prominent health physicist, "We knew that once the door was opened a crack, they would drive a Mack truck through it." Insurance companies began refusing to pay for inpatient treatment under any circumstances, regardless of the home situation, and many providers responded by treating every patient as an outpatient.

The then Chairman of the Advisory Committee on the Medical Uses of Isotopes was brutally frank about this in an October 2007 public meeting. Describing his own hospital, he said: "All patients are discharged upon treatment. We whisk them out the doors as quickly as possible." (So much for the individualized analysis of living situations that the NRC had envisioned.) He explained that there were three reasons

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[6]The most extreme of the hormesis advocates believe, *inter alia*, that nuclear waste should be used to create "radiation spas" where people can go to be irradiated; that nuclear waste should be added to reservoirs, to deliver a dose of radiation in tap water; that survivors of Hiroshima and Nagasaki were benefitted by the radiation they received; that the thousands of cases of post-Chernobyl thyroid cancer in the former Soviet Union were not caused by radiation, because the cancers developed too soon after their exposure to radiation; alternatively, that these post-Chernobyl thyroid cancers were not caused by radiation, because the children in the area received so much radiation that their thyroids would have been ablated, and thus incapable of developing cancer; that the permissible annual radiation dose, even for babies and pregnant women, should be raised to ten rems, 100 times what national and international authorities recommend, on the grounds that radiation in that amount cannot be harmful and may be beneficial; that a conspiracy was hatched in 1946, and perpetuated ever since by scientists and national and international regulatory bodies, the NRC included, to conceal the health benefits of radiation from the world, etc., etc. The followers of hormesis can point to hundreds of published papers supporting their views, but almost all come from the same source, the movement's illuminating house organ, *Dose-Response*.

[7]It sounds like something from the mouth of Montgomery Burns, the nuclear power plant owner on "The Simpsons." In the reactor field, the idea that the NRC would ever rely on a purported expert who held such views is unthinkable. This rulemaking, however, was related to medicine, which was a very different story. All too often it seemed that NRC Commissioners and higher-ups in the NRC staff neither knew nor cared what went on in the medical area, viewing it as peripheral, and of trivial importance. The irony is that this was and still is the only sphere of the agency's responsibilities where members of the public are actually at risk of receiving a significant dose of radiation from an NRC-licensed activity.

for this: first, that hospital staff was afraid of radioactive patients, and did not want to deal with them; second, that the penetration of radiation through hospital walls meant that the rooms adjoining the patient's had to be left vacant; and third, that "their wonderful insurance" would not pay for the hospital stay.

It should be stressed that not all providers and not all institutions take so irresponsible an approach. At Washington Hospital Center, for example, a leader in the field, every patient receiving 30 millicuries or more of I-131 is treated as an inpatient. There, it is as though the 1997 rule had never been enacted. An eminent doctor there recently explained that they do this because "you don't know where the patients will go, and then you don't have to worry about the kids." I will return to this point.

Sadly, Washington Hospital Center is the rare exception. Today, we have a situation in which one of the great cancer centers in New York City, drawing patients from around the country and the world, treats 99 percent of its I-131 patients on an outpatient basis, with doses of up to 250 millicuries.[8] **Even nations as pressed for resources as Bangladesh and South Africa set a maximum of 15 millicuries for outpatient treatment, owing to the risk to others from radioactive patients. The NRC has given Americans protections that fall far below Third World standards, and indeed, don't even come close.**

In addition, a sizeable percentage of patients – five to ten percent, the NRC staff estimates – recover in hotels and motels, leaving contamination behind them. It had never occurred to the NRC that this might happen, which is itself an indication of how cursory and superficial its consideration of the rule was. Its notice of rulemaking was clearly based on the assumption that patients would either be released to their homes or would remain in the hospital. When the agency learned that in fact, many patients were going to hotels, it faced a choice. It could explain that the intention had always been that a patient who could not go home must stay in the hospital; alternatively, it could decide that patients who did not need to be hospitalized could go anywhere, including hotels. It took the latter approach, in defiance of good law and sound health policy. Regrettably, the NRC's Office of General Counsel failed to prevent this.[9]

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[8]In fairness, it must be stressed that patients at this center do not actually leave the hospital with that much I-131 in them; they remain at the facility for several hours, time to eliminate much of the dose by urination. It is also relevant that the center has been a pioneer in using I-131 with restraint and selectivity. Still the fact remains that many patients who leave the facility are dependent on public transportation, and living far away, have little choice but to go to hotels and motels.

[9]Even more regrettable is the fact that a brief submitted by the NRC Solicitor to the Ninth Circuit Court of Appeals in 2008 stated that the NRC's rule "does not permit" sending radioactive patients to hotels; an NRC lawyer assured a panel of the same court that it was "simply not true" that this was taking place. Only months earlier, the Office of General Counsel had approved an internal memorandum which stated that it was legal to send radioactive patients to hotels; that this was a not uncommon occurrence; and that the staff intended to address the health and safety issues this raised.

By the time the NRC learned that the new rule had failed in its purpose, and also that the United States had become an outlier in the international radiation protection community, it was too late. The damage had been done. Many patients were being treated with I-131 in doctors' offices and clinics that had no means of hospitalizing patients, and to crack down on inappropriate outpatient treatment would have cut into their income stream.

The responsible course of action at that point would have been to accept that the 1997 rule was hopelessly defective, and to begin a new rulemaking, with the goal of developing a rule that complied with evolving national and international norms. Alternatively, the NRC could have chosen to admit its limitations in the medical area, and ask Congress for legislation transferring authority over medical isotopes to an agency with a greater understanding of and interest in medical issues. (The NRC itself does not have a single physician on its staff.)

The NRC did neither. Instead, it relied on issuing non-binding notices encouraging its licensees to do the right thing, while making clear that nothing would happen to them if they ignored the advice. This was merely the semblance of regulatory action; making it enforceable might have prompted backlash from the regulated industry and its Congressional allies.[10]

Thus in 2008, the NRC issued a notice stating that the 1997 rule had mistakenly failed to take account of internal dose, and that because of the risk to children from contamination, it was encouraging providers to "consider" hospitalizing patients with small children at home. A few years later, having learned that many I-131 patients were being released to hotels and motels, the NRC issued a second notice, saying that it "strongly discouraged" this practice.[11] There is no indication that these toothless measures actually changed any providers' behavior. I-131 patients continue to be sent home to their children, and to hotels and motels, every day.

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[10]At one point in the 1990's, the nuclear medicine industry's lobbyists prevailed on a House subcommittee to insert a provision into the NRC's appropriations bill that would have prohibited the NRC from spending money to regulate diagnostic uses of radiopharmaceuticals. In reality, isotopes used for diagnostic purposes, with one exception, present minimal risks. (The exception is I-131.) This was a shot across the NRC's bows, making clear to it that to antagonize the nuclear medicine lobby was to risk having its budget cut by Congress. Political appointees, the Commissioners hastily retreated. It is difficult to imagine that there is in any other country in the world where the legislative branch – Parliament, the National Assembly, the Bundestag, etc. – would dream of micromanaging how a health and safety agency regulated medical isotopes.

[11]Only under exceptional circumstances will there be a way of knowing that a patient has contaminated a hotel room. One such instance was in 2007, when a thyroid cancer patient, recently treated with I-131, checked out of the Braidwood Motel, in Braidwood, Illinois, and the next guest to occupy the room happened to be a new hire at the local nuclear power plant. He set off the plant's radiation alarms, and had to be decontaminated. The motel room could not be used for many several months. If ever that happened again, this time not in a mom-and-pop motel in the Midwest, but in an urban hotel bearing the name of the current President, where there may well be radiation detectors for security purposes, what would the NRC say when this became headline news? Whatever else it might say, it cannot be, "But we had no idea."

The staff paper has other deficiencies as well, including the following:

- It does not address the economic reality that is the core of the problem: the fact that insurance companies have taken advantage of the 1997 rule change to deny coverage for inpatient treatment across the board.
- The paper does not deal with the dilemma faced by providers compelled to choose between doing what they know is right – for the patient, the patient's family, and the public – and what they can expect the insurer will reimburse.[12] Currently, providers have no leverage to argue with insurance companies that a particular case requires inpatient treatment, and that the insurance company therefore **must** cover the cost. The NRC has done nothing to help them out in this regard.[13]
- There is no discussion of the gross disparity between standards in the U.S. and other nations, as described in a 2014 staff memorandum to the Commission.
- The staff paper declares that the current 500 millirem dose allowance provides adequate protection for all members of the public, regardless of age and sex. It does not address the fact that both the National Council on Radiation Protection (NCRP) and the International Commission on Radiation Protection (ICRP) set dose limits of 100 millirems annually to members of the public from released patients. If the NRC knows something that the NCRP and ICRP do not know, they should explain what it is. In any event, the 500 millirem standard is addressing only half the problem, external dose.
- NRC's Part 20 establishes a 100 millirem limit for radiation dose from all NRC-regulated activities except radiation from patients, which is governed by Part 35. This means that a baby or a pregnant woman, with no relationship to the I-131 patient being treated, can legally receive a dose of of 500 millirems from that patient, when for every other source of radiation regulated by NRC, the limit, for all ages, is 100 millirems. There is no rational justification for

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[12]In a rare and admirable exception to the norm, Washington Hospital Center, which serves a very high number of thyroid cancer patients, treats **every** patient receiving 30 millicuries or more of I-131 as an inpatient, simply because it is the right thing to do, regardless of the money involved.

[13]The Society of Nuclear Medicine and Molecular Imaging (SNMMI) made this point effectively in comments submitted on May 17, 2017: "We want the NRC to note that many members of the SNMMI already find it exceptionally difficult to admit patients to the hospital for radionuclide therapies. This is true even after writing an appropriate letter outlining the reasons why the radiation safety issues warrant hospital admission. ... **In particular, we would ask that there be a mechanism in place to require insurance companies to cover admissions performed in adherence with NRC regulations**." [Emphasis added.] This excellent suggestion, which if accepted would do much to solve the current problems with patient release, would require a rule change.

this disparity.[14]

- In the real world, the individual patient sometimes has not received any guidance at all; what guidance has been provided may or may not have been accurate; even when accurate, the patient may or may not have understood it; it may have been provided too late for the patient to make suitable arrangements; and in any event, the patient is at liberty to ignore it, without anyone ever knowing the difference. If the patient has expensive tickets to the theater or a sports event, can he or she be counted on to stay home? Whether the public is protected in a given case ultimately depends on the conscience of the individual patient. This is not an adequate basis for ensuring that the health and safety of the public is protected.
- The timing of the safety guidance given to patients is critical. It would be extremely easy to require licensees to provide written guidance at the time that the patient is scheduled for I-131 treatment, to allow arrangements to be made for the protection of others. This would go far to addressing problems with the current rule, but it would require a rule change.
- **Nowhere does the paper address the crucial point that the current rule has outsourced the protection of public safety from the licensee, over whom the NRC has regulatory control, to the individual patient, over whom the NRC has no control whatever.** In relieving licensees of responsibility, the NRC also walked away from its own responsibilities for radiation protection. This is, moreover, the sole area of the agency's duties where Americans are actually in a position to receive a substantial dose of radiation from an NRC-licensed activity.
- The staff paper repeatedly stresses the need for improved guidance as the solution to the current problems with the rule. For many years, the NRC has tried the path of non-binding guidance and it has not worked. What reason is there to believe that the result would be different today? The paper should have dealt frankly with the failure of these efforts, and explained why it expects this approach to succeed where it has repeatedly failed in the past.
- There are deficiencies in the staff paper's description of the comments submitted. For example, it states:

> The responses from medical stakeholders (including licensees, professional organizations, and medical practitioners) indicated that they strongly disagreed with any patient release rulemaking, and that the current regulations are sufficient to protect members of the public from exposure to released patients. **The medical stakeholders further**

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[14] In the pre-1997 era, when only the patient's family had a chance of receiving a significant dose, several factors arguably justified the 500 millirem dose limit: (1) the 30 millicurie activity limit ensured that doses to others would remain relatively low; (2) patients had an obvious interest in protecting their own family members; and (3) family members were indirectly beneficiaries of the treatment received by a loved one. Those arguments for the 500 millirem limit became invalid once it was possible for patients with extremely high doses in their systems to expose total strangers – for example, on a crowded subway car.

> **stated that there is no data from reputable sources that indicate that an exposure of 500 mrem [millirems] causes any statistically significant increase in risk.** [Emphasis added.] (At p. 5.)

The sentence in boldface is directly contradicted by the comments of the American Thyroid Association, which are well worth reading in full.[15] The ATA's letter states, in pertinent part:

> **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.**[16] [Emphasis added.]

- The paper asserts that the same radiation standards must apply to all radiopharmaceuticals across the board, without explaining why this should be so. The NRC declared long ago that I-131 was the most radiotoxic of all medical isotopes, while many other isotopes presented little risk. There is no good reason that different standards cannot apply to medical isotopes that present different levels of hazard. In this regard, it is noteworthy that the petition that resulted in the 1997 rule originally asked that the 30 millicurie limit be retained for I-131 and abolished for all other radiopharmaceuticals. (The petition was later amended.) On the contrary, the NRC's embrace of "risk-informed regulation," several decades ago, argues strongly for putting restrictions where they are needed and relaxing them where they are unnecessary. To use an analogy, if you are a city regulating the keeping of reptiles as pets, there is nothing irrational about differentiating between garter snakes and rattlers.

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[15] They can be found by going to the www.regulations.gov website and searching for "NRC-2017-0094." The ATA comments, submitted by Bobbi Smith, are no. 77.

[16] This last sentence makes an important point, never dealt with in the staff paper, namely, that radiological isolation does not require a conventional hospital room, with all the expense that it entails.

- The paper reports that the board of the Organization of Agreement States and two Agreement States favor a "limited rulemaking to require licensees to conduct radiation safety discussions and provide written instructions in a timely manner before radioisotope treatments," but then blithely dismisses this, on the grounds that it "could impede [*sic*] on the practice of medicine."
- The staff paper asserts that the "consensus" of commenters believes such-and-such. This is a misuse of the term. "Consensus" implies "general agreement." It does not mean "a preponderance" of commenters. Take, for example, p. 9 of the staff paper: "The consensus from the stakeholder engagement indicates that a prescriptive regulatory requirement on when safety instructions must be provided to a radionuclide therapy patient or the patient's guardian is not warranted." This is either incorrect or misleading, as is shown by the point directly preceding this one: the OAS and two Agreement States would not be favoring a rulemaking if in fact there were consensus on this point. All of this argues for Commissioners and their staffs to review the actual comments submitted by stakeholders, rather than merely to rely on the staff paper's characterization of them.[17]
- The paper does not begin to capture the human cost of the current rule, as reflected in many of the comments submitted to the NRC in response to its public notice.[18]

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[17]A saying of Ronald Reagan's applies here: "Trust, but verify." It is also noteworthy that the NRC staff paper does not reveal which commenter made which comment. (I realize that this is standard practice.) Knowing who made what particular point helps the reader determine the weight that it should be accorded.

[18]The following, from a thyroid cancer patient named Heather McNew, is a good example:

In the summer of 2010, I was treated with Radioactive Iodine for papillary thyroid cancer. It was an incredible hardship on my family but not in the way you might think. I have two children who were 6 & 3 at the time. For two whole weeks, I could not be near them. I had no extended family nearby for support and the hospital refused to admit me. Some suggested that I stay at a hotel but my family was struggling financially.

Since there was no one to take care of my children I considered not having the radiation treatment. But, with a 4cm tumor, my doctor was adamant. So, for two weeks, my husband camped out in our small dining room with a 3yr old and 6yr old who didn't really understand why they couldn't go upstairs and see Mumma. The stress was unimaginable. Not only was my husband struggling to care for a spouse with cancer, he had to be on constant guard that our young daughter would be harmed by sneaking up to see me. As emotionally difficult as it was to not touch my little girl for 2 weeks, the thought of her experiencing the very cancer I was fighting was horrific. No parent should have to worry that their child will be harmed by the very treatment meant to save their own life.

As it turns out, it was a very good thing that I was not alone in some hotel. Several days after my dose I experienced a cardiac arrhythmia. Thankfully, my husband was able to rush me to the ER. I had developed a severe electrolyte imbalance from my radiation treatment and it could have killed me. To be clear, there was no need for this to happen. I was 34yrs old, laying in a hospital bed asking an ER doctor if I had just had a heart attack and it was totally preventable. Ha I been admitted for my radiation treatment, this would have been detected much sooner, preventing any cardiac problems.

I would like to see hospitals admit thyroid cancer patients for radiation when young children can not be safeguarded from exposure to that radiation. Without such protection, we are creating a cycle of treatment, exposure and illness that directly violated the Hippocratic oath. Leaving parents in a home with young children risk significant harm to those children. Additionally, I would like to see all patients kept in the hospital for a couple days to evaluate their response to treatment. I firmly believe that assuring that patients are eating and drinking

In sum, the problems with the current rule continue; they are serious; they cannot be remedied without changing the rule; and they are not about to go away. Whatever the Commission may think of the idea of beginning a rulemaking, especially given the present anti-regulatory climate in Washington, the Commissioners should not be under the illusion that just because SECY-18-0015 finds the current rule satisfactory, this is actually the case. It is anything but satisfactory, and it is just a matter of time until this becomes a matter of public knowledge and concern.

It is nothing short of tragic that the Washington Hospital Center must ignore the NRC's rules on patient release, no doubt at financial cost to itself, rather than have to "worry about the kids." This is the only country in the world, rich or poor, where this is true, and it is only because in other nations there are regulators who "worry about the kids," and make the rules accordingly. If the response is that the Commissioners and senior staff **do** care about these issues, let me ask: when did you last have a public meeting on the subject? If the answer is 2010, as I believe is the case, why not hold another one soon, and invite the doctors at Washington Hospital Center, among others, to explain their reasoning?

It would be an easy matter for a group of affected persons to file a petition for rulemaking to bring the protection of Americans, especially children, up to international standards. This may yet happen. On the other hand, it would be an equally easy matter for the NRC to put that petition into cold storage for years without acting on it. For the present, therefore, I would like to appeal to your consciences to do what you surely know is right, no matter whose feathers it may ruffle.

Last year, a former NRC official got in touch with me on behalf of a friend and colleague whose 13-year-old daughter was soon to be treated with I-131 for thyroid cancer. Notwithstanding that the young girl had a 3-year-old brother, and that the family occupied a small apartment with a single bathroom, the mother had been told that treatment would be on an outpatient basis, "because that's the way we do it." She decided that the circumstances called for inpatient treatment, and wrote the hospital a letter to that effect, with just a bit of help from me to make clear that the law was on her side and she knew it. The result was a "firestorm" at the hospital, she later learned, with heated meetings on the subject, but in the end, inpatient treatment was approved, and insurance paid for it. That story had a happy ending, and the girl and her family are doing well. But for every patient in this country who knows to contact a former NRC employee and get appropriate care, there are many hundreds of others who must take what they are offered because they are given no choice. This kind of double standard – good care for the lucky few in the know, sub-Third World care for everyone else – is wrong, in every sense of the word, and you must surely know it.

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normally, is a minimum level of care.

Respectfully submitted,

/s/

Peter Crane
Counsel for Special Projects, USNRC, retired

McCloskey, Bridin

Attachments: 2020.LetterToCommissionOnJanuary28CommissionMeeting.pdf

From: **Peter Crane** <peter46crane@gmail.com>
Date: Tue, Jan 21, 2020, 8:39 PM
Subject: Submission for Commission meeting on medical issues
To: Annette Vietti-Cook <Annette.Vietti-Cook@nrc.gov>

Hi Annette --
Many thanks.
Best to you and all the gang,
Peter