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September 2, 2005

Ms. Annette Vietti-Cook, Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

**Re: Petition for Partial Revocation of the Patient Release Criteria Rule**

Dear Ms.Vietti-Cook:

**Summary: The NRC's Patient Release Criteria rule, issued in 1997, was defective both on legal and policy grounds. It was purportedly adopted in response to a petition from a member of the public, but the petition, according to its submitter, was in fact drawn up at the request of the NRC staff, with NRC staff assistance, and in accordance with NRC staff specifications. This violated NRC's own rules. The NRC closed its eyes and ears to abundant evidence that the rulemaking was a sham.**

**Worse yet, the rulemaking has had precisely the adverse effects on health and safety that were predicted at the time by States and other commenters, and that were brushed aside by the NRC. Patients treated for thyroid cancer with radioactive iodine-131 are now being sent home to their families under conditions that guarantee that family members will receive larger and potentially harmful doses of radiation, under uncontrolled conditions. The NRC's final rule justified this in part by explaining that though family members would indeed receive more radiation, members of the clergy who visit hospitals frequently would receive less radiation, because the radioactive patients would be at home. This rationale was and is insupportable -- factually, legally, and morally.**

**This petition asks for the revocation of the rule, insofar as it allows patients to be released from radioactive isolation with more than the equivalent of 30 millicuries of I-131 in their systems.**

## I. Introduction

The following are the facts of a real case, personally known to me, which took place this summer. A woman suffering from thyroid cancer received a treatment dose of 150 millicuries of radioactive iodine-131 as an outpatient. She then took public transportation to return to the house that she shares with her husband and two children. Soon after getting home, she became nauseous and vomited. Her husband cleaned up the mess.

This series of facts raises a number of health and safety questions, including:

- How much radiation did the patient's fellow passengers receive from her as she was riding public transportation?
- What level of radiation dose did her husband receive in cleaning up the vomitus?
- What dose if any did her children receive?
- How much of her intended dose did the patient actually receive, and how much was lost when she vomited?
- Did the diminished dose compromise the patient's treatment?

We will probably never know the answers to a single one of these questions. However, there are three related questions which can easily be answered:

- Could these consequences have been foreseen?
- If so, could they have been prevented?
- If they were both foreseeable and preventable, why were they allowed to occur?

The answer to the first of these questions is that these consequences not only *could* have been foreseen, they *were* foreseen. On that point, the documentary record is abundant and irrefutable.

The answer to the second question is that all these consequences could readily have been prevented. How? By the simple expedient of keeping the patient in the hospital in radioactive isolation until the level of radioactivity in her body had dropped to acceptably safe levels. As a patient in radioactive isolation, she would have been under instructions to ring for a nurse at the first sign of nausea, so that an anti-nausea drug

could be administered. In all likelihood, this would have prevented the vomiting. There would then have been no occasion for her husband to have to clean up radioactive vomit, nor would there have been any question that she received her full intended dose of radiation. Her children would almost certainly have received less exposure to radiation, since by the time their mother was back home with them, the level of radioactivity in her body would have dropped significantly. Finally, there would have been no contact with other passengers on public transportation.

The answer to the third question -- why this situation was allowed to occur -- is that in 1997, the NRC made a deliberate decision to abolish the regulation that would have prevented it. Until then, NRC regulations required the hospitalization of patients with the equivalent of 30 millicuries or more of radioactive iodine 131 (I-131) in their systems. (This was consistent with the International Basic Safety Standards on radiation protection, under which one of the criteria for an acceptable radiation protection regime is the hospitalization of patients with more than 30 millicuries of I-131 in their bodies -- a fact that the NRC did not acknowledge in eliminating this requirement.) As a result, many thyroid cancer patients are today being treated with high doses of I-131 as outpatients.

What does that mean in practical terms? It means that patients who are sick, stressed, deeply hypothyroid, potentially nauseous, and highly radioactive are being sent out the door, where they may or may not come into close contact with loved ones and members of the public. To be sure, they are supposed to receive instructions on the precautions they should take in order to minimize exposure to family members and others. But hypothyroid patients may have trouble fully taking in or remembering the guidance they are given, as will be discussed later on in this petition.

As I will describe below, the NRC acknowledged, when it enacted the rule change in 1997, that family members of patients would receive higher doses of radiation. It justified this in part by arguing that members of the clergy who visit hospitals frequently would receive lower doses of radiation, because the cancer patients would be at home instead of in the hospital. As a factual matter, this argument is wholly without foundation, for as I will explain, the radiation burden on members of the clergy is effectively non-existent, whereas the radiation burden on the family members of thyroid cancer patients is all too real. But let us assume momentarily, for purposes of argument,

that it *is* grounded in fact. The following question is then presented: Is it consistent with the Atomic Energy Act and sound policy for the NRC to conduct a balancing of harms and conclude that children, the most radiosensitive segment of the population, should involuntarily receive increased doses of radiation, in their homes, over an extended period, in order that members of the clergy, who are adults, may receive decreased doses of radiation during their voluntary visits to hospitals? The answer is obvious. Whether viewed from the standpoint of law, public policy, common sense, or morality, the notion of shifting radiation exposure from the clergy to children is untenable and indeed repugnant.[1]

In 1999, I happened to meet a veteran professor of health physics from a prominent state university in the East. Without indicating my own thoughts, I asked him what he thought of the NRC's decision. He reddened, and snapped: "The worst decision that agency has made in 40 years."

He didn't know the half of it. For he was simply addressing the *merits* of the decision. In addition, there was ample evidence that this decision, which purported to be the result of a petition for rulemaking submitted by a member of the public, was riddled with impropriety from the outset, and the NRC knew it.

I want there to be no ambiguity: my objection to the Patient Release Criteria rule, as it now stands, is twofold, based both on policy and legal grounds.[2] On policy grounds, it creates unwarranted hazards, where radioactive iodine treatments to thyroid patients are concerned. On legal grounds, the rulemaking by which this rule was adopted was impermissibly tainted by collusion between the nominal petitioner and the NRC staff, as I shall explain.

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[1] I do not doubt that on reading this, the "clergy protection" rationale will quickly be replaced with something more palatable from a public relations standpoint. But the fact remains that this is the reasoning that the NRC offered in the Federal Register in 1997, presumably after all the usual internal reviews. To the best of my knowledge, the argument of reducing radiation doses to the clergy was plucked out of the air; if was ever raised during the rulemaking prior to the issuance of the final rule, I am unaware of it.

[2] I stress the twofold nature of my objections to the rule to ensure that it is understood that in responding to this petition, the NRC is obligated to deal with both points.

## II. Legal Irregularities

I will start with the legal grounds, because the procedural history is helpful to an understanding of the policy issues as well. First, a bit of background may be in order. In the late 1970's, soon after the Nuclear Regulatory Commission took over the regulatory responsibilities of the abolished Atomic Energy Commission, the NRC Commissioners began to take more active interest in the regulation of medical uses of radioactive materials. A few cases of egregious errors at licensed hospitals led the Commissioners, over the strong objections of the NRC technical staff, to introduce a number of new regulations, designed to prevent errors and to ensure that when errors did occur, they were reported to the NRC and to the patient or the patient's family.

These changes did not sit well with some in the regulated community. Some in the medical community thought that they represented regulatory overkill; some thought that the NRC was using its authority over licensed nuclear materials to intrude into areas of medical practice better left to the medical community itself. There is no need to debate those issues here; reasonable people can differ, and in any case, these issues are beside the point. What is beyond debate is that the NRC Commissioners put these changes in place, and the NRC staff made repeated efforts to persuade the Commissioners to retract them. Again and again, the NRC staff's proposals were rejected. Ultimately, the NRC staff came up with a new game plan. Instead of proposing their own rule changes to the Commissioners and being slapped down, they would find a suitable "member of the public" -- in the vernacular, a shill -- to submit their proposals for them. The NRC staff could then go through the motions of reviewing a newly received "petition" -- needless to say, the staff would deem it very meritorious indeed -- and then forward it to the Commissioners as a proposed rule change that responded to the wishes of the regulated community.

The first duty of a shill, of course, is not to give the game away. Unfortunately for the NRC staff, however, the person selected for the role was indiscreet. Rather than hiding her behind-the-scenes collaboration with the NRC staff, she proclaimed it in letter after letter, filing after filing. Her actions led directly to a new rule, codified at 10 CFR 2.802(b) of the Code of Federal Regulations, restricting the assistance that the NRC staff could provide to prospective petitioners. That rule also states that if the NRC *does* provide assistance to a petitioner in preparing a petition for rulemaking, this fact must be

revealed in the final notice of rulemaking.

In the present case, the petitioner who first requested the Patient Release Criteria Rule -- Dr. Carol S. Marcus, M.D., Ph.D. -- has asserted on numerous occasions, in writing, that it was at the request of the NRC staff that she wrote the petition. I pointed out repeatedly, in filings sent to the docket in 1992, 1994, and 1995, that these assertions of Dr. Marcus's raised questions about the integrity of the rulemaking which the NRC needed to address. But the NRC's final notice of rulemaking made no mention of any such involvement between the NRC staff and the petitioner. That can mean one of only two things. Either the NRC staff (1) disregarded the explicit requirements of the regulation by failing to mention its collaboration with the petitioner, or (2) it determined that the regulation did not apply, because, contrary to Dr. Marcus's frequent assertions, no such collaboration had occurred. Which is it?

Years ago, Dr. Marcus and I disagreed on many things; that is ancient history, and there is no need to revisit the particulars today. Suffice it to say that each of us criticized the other's judgment more than once. But the question here is not one of judgment, the question is whether she was making it all up when she described collaborating with the NRC staff on her petition. I believe that she was telling the truth, and that the NRC failed to follow its own rules when it did not disclose the collaboration between the NRC staff and Dr. Marcus. Readers of this petition, in order to draw their own conclusions, should have the opportunity to see what Dr. Marcus said and wrote on this point.

In comments that I filed on the proposed rule on October 31, 1992, I noted that Dr. Marcus, at that time a member of the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), had praised the NRC staff's proposed rule at a recent ACMUI meeting. I wrote:

> It is worth noting that Dr. Marcus, praising the NRC staff's proposed resolution of the outstanding medical issues, speaks of the "40-month gestation," and says that the staff's proposal "is far better than the petition Mr. McElroy help [sic][3] me write." Transcript, p. 363. Given that Mr. McElroy was until recently a member of the NRC staff, could the staff clarify whether in this proposal it is passing judgment on a petition that the staff itself helped to write, or did Dr.

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[3] Needless to say, Dr. Marcus said "helped," not "help." This was a routine transcription error.

Marcus misspeak?

To this, Dr. Marcus responded in a letter to the NRC Secretary, dated November 9, 1992. She wrote:

> My petition was written at the request of Hal Peterson, who was embarrassed at the uncorrected errors in 10 CFR Part 20, and who urged me to "write a petition YESTERDAY." At the time, the new Part 20 was supposed to go into effect 1 Jan 92, and we did not have many months to waste. I argued at the time that I did not want to write another petition (I wonder why?), but he insisted it was the only option open, and that is how I spent Christmas Eve, 1990. It was hastily done, and recommended honoring the methodology of NCRP no. 37, getting rid of the "30 mCi rule" for all radionuclides other than I-131, and retaining the 5 mSv maximum for members of the public from patient sources. ... Much later, after discussing the issues at leisure in more detail with members of the NCRP, ACNP, SNM, and NRC, I wrote an addendum covering the "30 mCi" issue. ...
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> Mr. Crane's naiveté concerning the first Petition I wrote in June, 1989, with Mr. McElroy's help, is surprising. Mr. Cunningham[4] instructed Mr. McElroy to help me write the Petition. I didn't know how to write regulatory language, and it was Mr. McElroy's job to help to do that. NRC had written some very poor quality and dangerous regulations in 1987, and Mr. Cunningham realized that the language had to be fixed, and asked us to do it together. It was an "inside" job from the start. Mr. Cunningham gave us some very tough boundary conditions, but we did the best we could. ... So yes, Mr. Crane, the staff "is passing judgment on a petition that the staff helped to write," and I did not "misspeak."

On January 24, 1995, Dr. Marcus wrote to NRC Chairman Ivan Selin, asking about "the puzzling delay concerning the 'Patient Discharge Rule.'" She wrote:

> Our meeting was held in your office the third week in Sept. 1994, and dealt with the points made in my 18-page letter to NRC pointing out its serious scientific, mathematical, and medical mistakes. You agreed with my points, stated that NRC "had not done its homework," and vowed that it would be repaired. Given the fact that I did all the physics, math, pharmacokinetics, and pathophysiology

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[4] The individuals mentioned (Richard Cunningham, Norman McElroy, and Hal Peterson) were NRC employees at the times in question.

> for NRC, and contributed model calculations, model language and the pertinent references, one would assume that it would require no more than about an hour of NRC time to complete the rule. After all, it was NRC that asked me to write a petition on the subject in the first place, in December of 1990.

This letter, placed on the docket of the rulemaking proceeding, prompted a letter from me, also docketed, addressed to Dr. Selin, and dated February 23, 1995. I wrote that Dr. Marcus's letter "raises questions about the integrity of the current rulemaking, and indeed places it under a cloud which only you are in a position to dispel." Referring to Dr. Marcus's claim that her petition for rulemaking had been filed at the request of the NRC staff, I wrote:

> If this allegation is true, then the NRC is required by its own rules to make this fact known. If it is false, on the other hand, then the NRC owes it to the public and to its own reputation to refute an allegation which could lead the public and a reviewing court to view the NRC rulemaking process as corrupted. If the issue is in doubt, you have an Inspector General to resolve just such questions.

Dr. Selin did not reply to my letter. I am not aware that he ever disputed Dr. Marcus's claim that the request for the petition came from NRC.

It would have been easy and simple for the NRC to dispel the cloud over the rulemaking. All that was necessary was for the NRC to say, in its final notice of rulemaking, that the NRC staff had *not* solicited the filing of the petition, and that the commenter who had doubted the integrity of the proceeding on that score was in error. So why didn't it say just that? I think there is an obvious explanation: namely, that Dr. Marcus's indiscreet comments had placed the agency in a bind. It could not admit the accuracy of her statements without torpedoing its own rulemaking and rubbing egg in its own face; it could not deny their accuracy without prompting an angry and probably quite convincing rebuttal from Dr. Marcus. So it said nothing at all.

At this point, I have to apologize to the thyroid cancer community and to the public as a whole for not having taken the NRC to court then and there. As a commenter, I could have filed a petition for review of the NRC's final rule in the United States Court of Appeals. I did not do so, in part because I was simultaneously pursuing my own petition for rulemaking on the subject of potassium iodide for thyroid protection, and was afraid

of spreading myself too thin.[5] (Whether I would have won such a case is hard to say; though reviewing courts are extremely reluctant to set aside technical judgments by the NRC, the agency may be told to go back and do it right when, as here, agency *procedures* fail to pass the smell test.) All I can say to the thyroid community and the public is that this is a mistake I would not make twice.

If the patient release rule were wise and sensible, my attitude today would be: so what if the rulemaking didn't pass the smell test? So long as patients are getting appropriate care and the public is adequately protected, why rake up past controversies now?

Unfortunately, however, the result of this rule change is that patients are *not* getting appropriate care, and their family members and the general public are *not* being adequately protected, as I shall describe below.

## III. Why the Patient Release Rule is Unwise as Applied to Thyroid Cancer Patients

The central issue in this rulemaking was whether radioactive iodine-131, used in the diagnosis and treatment of thyroid disease, is a special case, because of the potential that the radiation administered to the patient can deliver a dose to others as well. It is highly significant that when Dr. Marcus first submitted a petition on this subject, in 1991, she asked that the 30-millicurie limit for the release of patients be dispensed with for all radiopharmaceuticals *except* I-131. She amended the petition in 1992 to remove this exception, but at least in the beginning, Dr. Marcus herself recognized that I-131 was a special case.

In 1992, when the NRC gave public notice of the receipt of the original and amended petition, it received comments from a number of states, and also from me. Here are some of the individual states that cautioned about I-131:

- **New York.** The New York State Department of Health said of I-131: "At dosages greater than 150 millicuries nausea and the likelihood of vomiting are

[5] At the time, I had been for many years the Counsel for Special Projects in the NRC's Office of General Counsel. In commenting on the Patient Release Criteria, as in filing the petition for rulemaking on potassium iodide, I was acting as a private citizen, working at home, on my own time. The NRC granted my potassium iodide petition and changed its emergency planning rules early in 2001, twelve years after I filed a "Differing Professional Opinion" on the subject, and six years after I filed a petition for rulemaking. I retired from the NRC in 1999.

more likely and present a risk of extensive contamination." New York was willing to consider outpatient treatment above 30 millicuries of I-131, but only to a maximum of 80 millicuries, and then only under special circumstances.

- **Texas**. The Texas Department of Health observed that I-131 is "the most radiotoxic byproduct material used for medical use," warranting especially close controls.
- **Colorado**. The Colorado Department of Health commented that while relaxation of the current 30-millicurie limit might be appropriate for "certain other isotopes," it did "not feel this is justified for patients receiving iodine-131."
- **Alabama**. The Alabama Department of Public Health expressed support for relaxing release criteria for some radiopharmaceuticals, but declared itself "opposed to the petition in that it supports release of patients from hospital (institution) confinement whose body burden of iodine exceeds 30 millicuries, even as high as 400 millicuries."[6]
- **North Carolina**. The state's Department of Environment, Health, and Natural Resources stated that while the "30 millicurie limit is indeed arbitrary in that it has been generically applied to all radiopharmaceuticals," patients dosed with I-131 could cause significant radiation does to "family members, coworkers and other persons they encounter."

The NRC staff, in a meeting with the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI) in October 1992, justified its intention of eliminating the 30-millicurie limit in part by pointing to the "emotional benefit provided the patient when in the direct care of family members." But the NRC staff manager making the presentation was unable to answer a question from one ACMUI member (the patient representative) as to how thyroid patients actually *feel* at the time that they are receiving such treatment.[7] This raised the interesting question of how an agency which exists to protect people from the harmful effects of radiation can presume to offer opinions on patients' *psychological*

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[6] It should be noted that the suggestion that patients could receive 400 millicuries of I-131 as outpatients came not from Dr. Marcus, but from the American College of Nuclear Medicine, which filed its own separate petition for rulemaking on the same subject.

[7] It was an excellent question; someone with knowledge in the area could have described the adverse effects of hypothyroidism on patients' ability to understand and remember instructions that they are given.

state, and propose regulatory changes on that basis, when its experts are wholly ignorant of those patients' *physical* condition.[8]

In any event, the ACMUI was not buying. It recommended that the 30-millicurie limit be retained for *all* radiopharmaceuticals, not just I-131. It is especially revealing that the transcript of the October 1992 ACMUI meeting shows (at p. 512) that the ACMUI Chairman, Dr. Barry Siegel, was anxious about thyroid patients going home with *diagnostic* doses of I-131 in their systems. His concern was that there was a regulatory gap, in that patients were not being given adequate guidance about protection for family members. He was worried, he said, about patients going home with *five* millicuries of I-131 in their systems.

Let me emphasize this point. Here was the NRC, with an existing rule that required thyroid patients to be kept in radiological isolation in the hospital until the level of radioactivity in their bodies had dropped to the equivalent of 30 millicuries or less, so as to protect family members and others. Dr. Siegel, the ACMUI Chairman, was worried that these protections were *insufficient*, since even 5 millicuries of I-131 could pose a danger to family members. The NRC staff, on the other hand, was convinced that these same protections were *excessive*. Brushing aside all advice to the contrary, it continued to move forward toward its goal of allowing patients to be sent home with 150 millicuries or more of I-131 in their systems.

My own comments on the 1992 petitions drew on my then recent experience as a thyroid cancer patient. Between 1988 and 1991, I had been treated as an inpatient five times at the National Institutes of Health, with I-131 doses totaling 700 millicuries, for recurrent cancer. Each time, I was kept one or two nights in radioactive isolation, and then released when the amount of radioactivity in me, as measured a meter from my neck, had dropped below a level equivalent to 30 millicuries of I-131. I wrote:

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[8] The final rule deals with the "emotional benefit" issue in Section VI, as follows: "The individuals exposed to the patient could receive higher doses than if the patient had been hospitalized longer. These higher doses are balanced by shorter hospital stays and thus lower health care costs. In addition, shorter hospital stays may provide emotional benefits to patients and their families. Allowing earlier reunion of families can improve the patient's state of mind, which in itself may improve the outcome of the treatment and lead to the delivery of more effective health care." The NRC's psychologizing did not include any response to my comment, based on my own experience and that of many others, that some thyroid patients may experience greater "emotional benefits" from knowing that by receiving their treatment as in-patients, they are protecting their families from unnecessary radiation exposure.

> Any patient being treated for carcinoma with a therapeutic dose of I-131, whether it is 30 millicuries or 400, is already severely hypothyroid, having been removed from all thyroid medication several weeks in advance of the scan. As a result, the person is physically in a state of extreme exhaustion. ... The patient's reflexes are slowed, making driving more hazardous. Mental processes are also slowed down, and there is a loss of short-term memory. All these factors make it less likely that a patient will remember and follow radiation protection guidance if treated as an outpatient....
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> Speaking from experience, it is not always easy to remember at all times to follow the radiation protection guidance one has been given. Especially in the home, one tends to follow habit, and when a child reaches up to you for a goodnight kiss, one may kiss her without thinking about it. But all my experience involves being at home with an activity level in my body of 30 millicuries or less. Can you imagine how much worse the problems would be, and how much more serious the unintended exposures, if a patient is at home with 300 millicuries of I-131 working its way through his or her system? ...
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> In addition, one of the most common effects of I-131 treatment is nausea. (As one reads the transcript of the October 1992 ACMUI meeting, one finds frequent references to patients vomiting.) As an inpatient, one is instructed to call the nurses' station at the first sign of nausea, so that appropriate medication may be given. Vomiting presents problems for hospital Radiation Safety departments, because they must enter the radiologically contaminated room in order to clean up. Consider, however, how much worse it would be if the patient is at home, vomiting, and unprotected family members, rather than Radiation Safety personnel with rubber gloves and other protective gear, are having to clean up, probably without thinking for a moment, under the stress of the situation, of the radiological implications. ...

That, of course, is precisely the situation I described at the outset, thanks entirely to this ill-considered rule change. How frequent are such instances of post-treatment vomiting by thyroid cancer patients receiving therapy doses of I-131? I frankly don't know. Does firm data exist? I have no idea. It is not clear to me that there is any mechanism by which the situation I described would necessarily have been reported to the NRC or to state health authorities. (The NRC's proposed rule would have required licensees to maintain records on released patients, and on individuals likely to have received radiation doses from them, but this was eliminated from the final rule, as too much of a

burden on licensees.) I hope, therefore, that thyroid cancer patients and treating physicians will contribute their experiences to the record of this rulemaking.

Having heard the adverse comments from the states, the ACMUI, and commenters like me in 1992, the NRC staff proceeded to go ahead and do precisely what it had planned to do in the first place. In 1994, it issued a proposed rule, theoretically responsive to the comments received on the 1992 notice. In reality, though, comments that ran counter to the NRC staff's preferred outcome were largely ignored. In commenting on the proposed rule in 1994, I quoted the 1992 comments of New York and other states, and said:

> But although one commenter after another, as well as the states mentioned above, pointed to the special hazards associated with I-131, the notice of proposed rulemaking never mentioned this, nor did it suggest that one of the key issues in the rulemaking was whether I-131 should be in a class by itself for regulatory purposes. Nor is the issue of patient vomiting ever mentioned.
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> In my earlier comments, I also pointed out that anyone who has been treated with a therapeutic dose of I-131 is already severely hypothyroid (by design), and that this condition may impair the person's ability to follow safety guidelines for the protection of family members and other members of the public. ... This comment also was not dealt with in the notice of proposed rulemaking.
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> Nor was their any response to my suggestion that although the NRC staff was justifying its proposal on grounds of the supposed psychological benefit to patients and their families, it might be more comforting to patients to know that they were minimizing the radiation dose to others by remaining in the hospital in radioactive isolation. Speaking from the experience of five inpatient treatments, radioactive isolation is unpleasant, but worrying that one is putting others at risk may be even less pleasant.

The National Institutes of Health filed comments in 1994 in which it noted that NIH patients from abroad who have received I-131 commonly go directly from the hospital to the airport and board flights to their home countries, despite having been warned to avoid close contact with others. At that time, the maximum amount of radioactivity in such a patient would have been the equivalent of 30 millicuries, and that was bad enough. Today, however, radioactive passengers could potentially deliver much more substantial

doses to their neighbors, thanks to the new release criteria.[9]

Three years later, in 1997, the rulemaking came to an end, and the result, to no one's surprise, was precisely what the NRC staff had first proposed to the Advisory Committee on the Medical Uses of Isotopes in 1992. (41 Federal Register 4120-33, January 29, 1997.) As a result, there is now no hard and fast limit on the amount of I-131 that a patient can be given as an outpatient. All that is necessary is for the licensed facility to perform a calculation that shows that if suitable precautions are taken, no member of the public will receive a dose in excess of a certain prescribed limit. At that point, it is up to the patient -- sick and quite possibly stressed, exhausted, groggy, and mentally fogged -- to remember the guidance and follow it. That patient's memory and conscience, rather than the thick walls of a hospital room set up for radiological isolation, have become the radiological safety net for the American people.

The NRC staff did a better job of responding to the comments in the final rule than it had in 1994. Vomiting was at least mentioned, though it was pooh-poohed: "Vomiting is seldom an important elimination route for radiopharmaceuticals after the patient has left the medical facility since orally administered radiopharmaceuticals such as Iodine-131 are rapidly absorbed, within a half hour, by the gastrointestinal system." I hope that the radiation safety community looks at that statement long and hard. I'm not a physician or a health physicist and don't pretend to be, but I have seen a lot of post-treatment scans in my time, and I find it hard to believe that if you vomit up the contents of your stomach 35 minutes after being given a 150 millicurie treatment of I-131, there will be no radioactivity in the vomitus. But others can speak to this point better than I.

The final notice misrepresented the critical comments from states (quoted earlier, at pp. 9 and 10) on release of patients with I-131 in their systems. Here is how the notice handled the issue:

> *Comment.* One commenter said that the proposed rule did not adequately address the concerns that the Agreement States expressed on the petitions for rulemaking concerning releasing patients with quantities of iodine-131 in excess of 30 millicuries.

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[9] Nowadays, because of radiation monitors placed in airports, subways, etc. to combat terrorism, released thyroid patients typically carry letters from their doctors, explaining why they have caused the alarms to go off.

> *Response*: In commenting on the petitions, a number of States expressed concerns about releasing patients administered 14.8 gigabecquerels (400 millicuries) of iodine-131, which one of the petitioners had requested. However, the States that commented were generally favorable to the proposed rule limiting the dose to the most exposed individual to 5 millisieverts.....

The answer implies that the states were concerned *only* with doses at the 400 millicurie level, when in fact, the comments of New York, Colorado, Alabama, etc. were not limited in that way.[10] This kind of game-playing is unworthy of the NRC. The agency owes it to the states, the public, and its own reputation to be straightforward in dealing with serious, legitimate concerns raised in the comment process. Here, moreover, those concerns had been voiced by knowledgeable State health departments, in the discharge of their responsibilities to safeguard the health and safety of their citizens. A more candidly written notice would have said something like the following: "We are aware that some States raised concerns about doses of I-131 above 30 millicuries, but we disagree with those concerns for the following reasons, etc."

By far the most remarkable aspect of the NRC's final notice, however, is its discussion of what is or should be the central question in this rulemaking: given that sending patients home with treatment doses of I-131 in their systems will inevitably mean larger radiation doses to family members, what benefit does the rule confer that compensates for the additional risk to a patient's children? As I described earlier, the NRC staff has identified such a benefit: removing radioactive patients from the hospital and dispersing them to their homes will reduce the radioactive dose to members of the clergy who visit the hospital regularly.[11]

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[10] The 5-millisievert level was a separate and non-controversial issue; a state's approval of the 5-millisievert standard did not imply agreement or disagreement with the rule's approach to releasing patients with large amounts of I-131 in their systems.

[11] So that no one can accuse me of taking the NRC's statement out of context, let me reproduce below the entire relevant portion of the final rulemaking notice:

"*Comment.* One commenter noted that hospitals now make great efforts to control contamination from patients who are now hospitalized because they contain more than 30 millicuries of iodine-131. This commenter stated that it would not be possible to maintain the same level of contamination control at these patients' homes if these patients were released with more than 30 millicuries of iodine-131.

*Response.* The NRC agrees that, even though released patients are given instructions on how to limit the hazard from contamination, contamination control in a hospital can be more effective than contamination control out of the hospital. However, the two situations are not really comparable. In the case of the released patient at home, therapeutic administrations usually occur no more than once in a year and probably no more than once in a lifetime; but in the case of a hospital, large

What was wrong with the NRC's analysis? Just about everything. Let us go down the list.

- Members of the clergy are no more likely to get exposed to radiation from thyroid cancer patients being treated as inpatients than are pizza deliverymen, florists, ambulance drivers, or hospital employees generally. That's the whole point of radiological isolation: to keep patients shut away behind thick walls, isolated until all but a small amount of the radioactivity administered to them has passed through their system and been flushed down the toilet. The radiation from the patient in isolation isn't getting anywhere near the visitor. A much more plausible way for a member of the clergy to receive a dose of radiation on a visit to a hospital is for him or her to ride in the same elevator as a patient who has just been given a treatment dose of I-131 and told to go home and follow the instructions. Thus even if viewed as a "Clergy Protection Rule," this measure is a failure.

- Exposure of hospital orderlies to radiation (also mentioned by NRC) is a more legitimate issue. When I was at NIH as an inpatient, a hospital orderly would enter the room once a day for a few seconds to collect the trash. But he was wearing protective clothing and a film badge, as were the women from Radiation Safety who came in each day to measure the radioactivity I was giving off. These were adults who had made a conscious decision to work in areas where they might be exposed to radiation; who had appropriate clothing, protective gear, and training; and whose radiation exposure was monitored and limited. If you are given 150 millicuries of I-131 and sent home, no one provides your children with masks, gloves, booties, film badges, and protective clothing. You and they are on your own.

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therapeutic administrations are done repeatedly on many patients. Therefore, areas in hospitals have the potential for contamination from many patients, and people who frequent the hospital (e.g. clergy or a hospital orderly) have the potential to be exposed to contamination from many patients. In addition, the 5-millisievert (0.5-rem) limit that is applied to household members exposed to a patient is a special limit that is appropriate for only occasional use and for use where there is a definite need. This special limit fits the case of doses received by the household members of a released patient, but does not fit the case of people who frequent a hospital on a routine basis. Lastly, in limiting doses, the NRC considers what is reasonably achievable. The mere fact that a home cannot control contamination as well as a hospital does not mean that the contamination control achieved in homes is not adequate. Actual measurements of doses to household members from contamination, as discussed in NUREG-1492, show that the doses from contamination are low, demonstrating that the degree of contamination control that was achieved is adequate."

- Children are more radiation-sensitive than adults and deserve more protection, not less. Nothing in the Atomic Energy Act of 1954 gives the NRC the authority to cut back the real protection of real children for the fictitious benefit of hypothetical adults.

- The assertion that I-131 treatment for thyroid cancer occurs "probably no more than once in a lifetime" is unfortunately unsupported by the facts. (What, one must ask, was the NRC's basis for this statement?) My endocrinologist, an expert in thyroid cancer at the University of Washington Medical Center, estimates that the recurrence rate of thyroid cancer is 30 to 40 percent. My own seven I-131 treatments -- five as an inpatient, two as an outpatient -- are far higher than the norm, to be sure, but many thyroid cancer patients receive multiple doses.

- The implication that no harm is done by exposing family members to the exposure from just one treatment is at odds with the linear no-dose-threshold theory on which all current radiation protection standards continue to be based.

- The implication of the last sentence in the quoted portion of the rulemaking notice is that it is not "reasonably achievable" to keep radiation exposure to family members low by treating patients in radioactive isolation. Given that the NRC had been requiring this for decades, how could it suddenly have ceased to be "reasonably achievable" in 1997?

Procedurally, as I outlined earlier, this rule doesn't pass the smell test. Substantively, it doesn't pass the straight face test, for it is based on the proposition that giving an increased amount of radiation to children just once is better than repeatedly giving an infinitesimal amount of radiation to members of the clergy. Is there anyone at the NRC prepared to defend, in public, so patently loopy an idea? If so, I hope they will speak up.

The Patient Release Criteria rule, like the rulemaking that produced it, is irredeemably flawed. I respectfully request that the NRC institute rulemaking to rescind that portion of the rule that allows patients to be released from radiological isolation with I-131 in their systems in amounts greater than 30 millicuries. I also ask that this be handled

expeditiously. For the issue raised by this petition is not hypothetical. We are not talking about some reactor accident scenario with a one-in-a-million probability of irradiating a member of the public some time in the future. We are talking instead about real people -- cancer patients -- and their families, in the here and now. These family members' chance of exposure to radiation is not one in a million, it is one in one. For decades, mandatory radiological isolation for patients ensured that the inevitable radiation exposure of patients' family members was kept extremely low. The NRC's unwise decision to abolish that requirement, and knowingly allow these exposures to increase, is causing real-world harm to real people, today. It should be reversed without delay.

Respectfully submitted,

Peter G. Crane[12]

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[12] It may be questioned why, as a former NRC employee, I would offer public criticism of an agency with which I was so long associated. Though I don't like to keep quoting myself, I can best answer that by including the last two paragraphs of the letter that I sent to NRC Chairman Selin and the public docket file on February 23, 1995:

"Finally, and perhaps unnecessarily, let me assure you that I am not taking part in this rulemaking for my own entertainment. If there is one thing that all present and former cancer patients share, it is a sense of how precious and irretrievable time is. Using my evenings and weekends to write letters to the NRC docket is not a busman's holiday for me: I have many things that I would rather be doing with my spare time, including working on history projects, woodworking, and enjoying my family's company. But the issue here is of protecting my own family, families like mine, and the public at large from the risks associated with I-131. Patients who come home with 150 or more millicuries of I-131 in their systems will inevitably be delivering a larger radiation dose to their families than when they could not leave radioactive isolation until the level in their bodies dropped below 30 millicuries. Nor is the hazard limited to patients' families. It also affects anyone who travels by airplane [footnote omitted] or public transportation (and, as I pointed out in my 1992 comments, anyone who might go to a supermarket and bring home fruits and vegetables contaminated by the touch of a prematurely released I-131 patient). The conscience of the individual patient is not an adequate substitute for long-standing and sensible regulatory measures, where the hazards of I-131 are concerned.

Protecting the health and safety of the public from radiation risks, including those associated with the use of radiopharmaceuticals in medicine, is the NRC's statutory duty. To yield to the petitioner's demands would be, I respectfully submit, an abdication of that duty. I hope that it will be understood, therefore, that my participation in this rulemaking, and my comments today, are a sign not of disloyalty to the NRC, which I have served since 1975, but rather, on the deepest level, of my loyalty to it."