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

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF



Re: Petition for Rulemaking, Docket # PRM-35-18 (Patient Release Criteria)

Dear Ms. Vietti-Cook:

Since filing the above-referenced petition for rulemaking, involving the criteria for release of patients treated with radioactive iodine-131, additional information relevant to this issue has come to my attention, and some of the comments filed in this rulemaking, and posted on the NRC's website via "RuleForum," warrant a response from me.

My petition raised two sets of issues: safety-related and legal. I will deal with the comments on the safety issues first.

1. The Grigsby study of doses to family members

Dr. Perry Grigsby, of the Washington University School of Medicine at Washington University Medical Center, has pointed to his 2000 article in the *Journal of the American Medical Association* in support of his view that experience with the 1997 patient release rule shows that exposures to patients' family members are minimal. Other commenters have also cited his study.

Dr. Grigsby's study is unquestionably a valuable data point, but it also has its limitations, as indicated by the press release issued on May 3, 2000, by the Office of Medical Public Affairs of the Washington University School of Medicine. It included the following:

The Nuclear Regulatory Commission (NRC) ruled in May 1997 that patients could be sent home after being treated with an I-131 drink if other individuals, including household members, were not likely to be exposed to more than 500 millirem of radiation. However, exposure estimates have been based on computer models, making many doctors reluctant to try early discharge. Women with young children and other patients expressed concern about exposing family members, Grigsby says.

To address such concerns, the Washington University researchers treated 30 patients with an average dose of I-131 and sent them home half an hour later. The patients were told to minimize time spent with household members and to stay far away from them

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for two days. In addition, they were advised to drink lots of fluids and **take several showers a day** to help purge their bodies of excess iodine. [Emphasis added.]

The central question, in evaluating an experiment like this, is whether the conditions accurately reproduce what the experiment is intended to test. Dr. Grigsby, with his very modestly sized sample of 30 patients and 65 family members, found that with the precautionary measures he required patients to follow, doses to family members were low. If those precautionary measures were typical of the guidance that thyroid cancer patients receive, then the study may be valid evidence of the radiation doses to family members when treatment is given on an outpatient basis. If however, those precautionary measures are far more stringent than the norm, then Dr. Grigsby's study surely underestimates actual doses to family members. (In that case, its value would seem to be limited to showing that extraordinary precautionary measures *can* reduce radiation exposures to family members and pets.)

Just how typical were the precautionary measures employed by Dr. Grigsby? A search of the Internet is helpful in answering that question. A website maintained by the Health Physics Society says this, in answer to the question, "What precautions need to be taken when a family member or I have radioiodine therapy that uses ^{131}I (iodine-131) and go home?":

General guidelines given to patients who are going home may include the following items:

- * Arrange to have sole use of a bathroom for two days following treatment.
- * Avoid public transportation for the first day following treatment.
- * Limit personal automobile travel with others to **only a few hours per day for the first two days** following treatment. Keep as much distance as possible between you and other passengers.
- * Sleep in a separate room for the first two nights following treatment.
- * Arrange for any pregnant individuals or children less than two years old currently living at your residence to stay at a separate residence for three days following treatment.
- * **Avoid close contact with others by maintaining a distance of 1 meter (approximate three feet) for up to three days following treatment.**
- * Avoid going shopping, to the movies, to restaurants, etc., for the first two days following treatment.¹ [Emphasis added.]

The New York Thyroid Center's website has a list of "Precautions After RAI Scanning or

¹ The Health Physics Society website precedes these guidelines with this advice: "The total radiation dose to anyone else, **even with close, continuous contact, will not cause harmful effects. There is no need for concern about effects on your family, pets, etc.,** but it is prudent to avoid close, prolonged contact for the first week. ..." [Emphasis added.]

Treatment.” (After three days, it says, “the radiation exposure to other people is negligible and you do not need to follow any additional precautions.”) It recommends washing hands with soap and water after using the bathroom, using a towel that others in the household do not use; flushing two or three times; washing the bathroom sink, shower, etc. after each use; washing bed linens and towels separately from those used by other family members; and other, similarly conservative protective measures. Then it says, however:

“Avoid prolonged intimate physical contact with babies, children, and pregnant women. **You may perform all essential duties such as changing diapers, if no one else is available to help you. Wash your hands before and after these tasks.**”

It does not appear that Dr. Grigsby’s 30 patients were spending up to several hours a day traveling in automobiles with others during their first two days after treatment, nor were they, in a pinch, changing babies’ diapers. Nor do the Health Physics Society and New York Thyroid Center websites say anything about frequent showering. All this suggests is that additional studies -- studies that are more realistic in tracking actual conditions for patients and their families -- are badly needed.

In the meantime, more data on this point would certainly be helpful. This is the moment for thyroid cancer patients and health care personnel around the country to be heard from.

In addition, I frequently hear of patients who are scheduled to receive I-131 therapy doses as outpatient 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.

2. Is the 30-millicurie standard “arbitrary”?

Dr. Robert Reiman of the Duke University Medical Center, one of the commenters, asserts that the 30-millicurie rule is “arbitrary,” and makes the point that in only 38.3% of the cases where his hospital gave I-131 therapy doses on an outpatient basis were there children in the home. (My own view is that 38.3% is a high percentage, not a low one, where exposure to children is concerned.) Although in her original rulemaking petition of December 26, 1990, Dr. Carol S. Marcus wrote, “I propose to retain the 1110 Mbq [= 30 millicurie] limit for I-131,” she subsequently amended that petition, and since then, she has frequently described the 30-

millicurie standard as “arbitrary.”²

The 30-millicurie standard for the hospitalization of I-131 patients was applied for some decades before the NRC abolished it. It continues to be part of the International Basic Safety Standards, which the U.S. Government strongly supports. (I raised this issue at the time of the earlier rulemaking, and was surprised and disappointed that the NRC did not even discuss these long-established international standards, and the agency’s reasons for disregarding them.³)

For those readers who are new to the debates over radiation protection, I should explain that the NRC’s radiation standards, like the International Basic Safety Standards, are premised on the “Linear No-Dose Threshold” (LNT) theory. This means that radiation is assumed to be harmful to the human body, and that the greater the dose, the greater the harm. Just last summer, the National Research Council issued its authoritative report, the seventh in a series, on the Biological Effects of Ionizing Radiation. BEIR VII reaffirmed the LNT theory, and it went out of its way to reject as unfounded the theory of “hormesis,” a minority view, but passionately espoused by some of its adherents, that holds that radiation in low doses is not only unharmed, but beneficial.⁴

If you start from the premise that the LNT theory is wrong, and that low-dose radiation is actually good for you, then it is only to be expected that you would consider LNT-based limitations arbitrary. I have no reason to believe that Dr. Reiman is a believer in hormesis, but the same cannot be said for Dr. Marcus. In a January 5, 2005, letter to the Food and Drug Administration, she criticized the FDA for relying, in a particular document, on references that were “all from organizations intractably committed to the ‘Linear, Non-Threshold Hypothesis’, or LNT.” She continued: “FDA did not seek to use references from ... any of several thousand papers on radiation hormesis at low dose, that is, the *beneficial* effects of low dose radiation.”⁵

²See, e.g., her posting, “Re: NRC’s Patient Release Rule,” on the RADSAFE bulletin board, dated October 28, 1999, describing the 30-millicurie standard as a “completely arbitrary and capricious standard with no scientific basis at all.”

³I am incorporating by reference all my docketed filings in the previous rulemaking.

⁴BEIR VII also explained the fallacy in the theory that because places such as Denver have high background radiation levels, exposure to radiation below those levels is therefore harmless. Readers who want to know more can find the report on the Internet. In a memorandum to the NRC Commissioners dated October 29, 2005, Executive Director for Operations Luis A. Reyes summarized the BEIR VII report as follows: “The major conclusion is that current scientific evidence is consistent with the hypothesis that there is a linear, no-threshold dose response relationship between exposure to ionizing radiation and the development of cancer in humans. This conclusion is consistent with the system of radiological protection that the NRC uses to develop its regulations.”

⁵This ideological approach to radiation can have some curious and tortured results. There is widespread scientific consensus that the approximately 4000 cases of thyroid cancer in Belarus, Russia, and Ukraine were caused by radioactive iodine released from Chernobyl. (See, for example, the report of the National Research Council of

Jeffrey A. Siegel, Ph.D., argues against the 30-millicurie standard, and makes the point that “a patient receiving 30 mCi of I-131 for hyperthyroidism can potentially expose individuals to a larger radiation dose than a person receiving 200 mCi of I-131 for thyroid cancer due to the much longer retention of I-131 in the body in the former case.” (This is because the hyperthyroid patient is likely to have an intact thyroid, whereas the cancer patient will normally have had a thyroidectomy, complete or partial, before receiving I-131, and thus will have less thyroid tissue in the body.) This is true enough. But the point of the 30-millicurie standard was that it sought to ensure that all patients, regardless of the dose they received and the condition for which they received it, were below the same level of radioactivity, as actually measured at a distance of one meter from the patient, before their release could be authorized.

I would grant that a hyperthyroid patient with 30 millicuries in an intact thyroid is more likely to be a hazard to others than is a thyroid cancer patient with the same amount of I-131 in his or her system, because the latter patient is likely to eliminate the radioactive material more quickly, mostly through urination.⁶ But does that mean that the 30-millicurie standard is therefore arbitrary?

The 30-millicurie rule is arbitrary, I would suggest, only in the sense that 55-mph or 65-mph speed limits are also arbitrary. In setting the limit at 55 mph, the state is not declaring that at that speed, there will be no accidents at all, nor is it implying that driving faster than that will necessarily have deadly consequences. Rather, the state is saying that it knows that there is a correlation between greater speed and greater harm, and that it is therefore drawing the line at a point where it believes that the harm can be kept acceptably low. That sort of line-drawing goes on in regulatory agencies every day, and there is nothing inherently arbitrary about it. The fact that in real-world terms, the same road may be more hazardous when driven at 50 mph on a rainy night than at 70 mph on a sunny day does not prove that enforcing a 55-mph limit is therefore improper or unwise.

the National Academies of Science, *Distribution and Administration of Potassium Iodide in the Event of a Nuclear Incident* (2004)). But Dr. Marcus, writing to RADS SAFE on September 16, 1999, had a different view: “We don’t know why young children near Chernobyl developed thyroid cancer, but we have not seen this in other children who received NaI-131 for medical reasons. We do know that babies and young children near Chernobyl received massive doses of SSKI [super-saturated potassium iodide], and it is conceivable that SSKI-induced thyroiditis led to thyroid cancer.” In reality, of course, the problem in Belarus, Ukraine, and Russia (in contrast to Poland) was that children did *not* receive potassium iodide, by which the upsurge of thyroid cancer in those three countries could have been prevented. The notion that these childhood cancers were caused not by radioiodines, but by medicine to prevent the uptake of radioiodines, does not command wide acceptance, to put it mildly.

⁶See, for example, the 2002 misadministration, reported belatedly in the NRC’s 2005 Abnormal Occurrence Report to Congress, in which a patient being treated as an outpatient for hyperthyroidism was mistakenly given 128 millicuries of I-131 instead of the intended dose of 32 millicuries. That patient was undoubtedly a source of potential radiation doses to family members for a much longer time than would have been a thyroid cancer patient who had been given 200 millicuries of I-131, but who had only tiny amounts of iodine tissue capable of retaining radioiodine.

3. Does the petition allege that medical providers are indifferent to patients' well-being?

Dr. Stephen Gerard, of the Seton Medical Center in Daly City, California, apparently understood my petition to be disparaging medical practitioners' sense of responsibility to their patients. I meant no such imputation. I do not doubt for a moment that Dr. Gerard cares about his patients, their well-being, physical and emotional, and the safety of their family members. Nor do I doubt that he is conscientious in discharging his duties to them. My concern, rather, is for the economic pressures that the 1997 rule change has created.⁷

The comment filed by Mr. Palmer Steward, PhD, a medical physicist in Davenport, Iowa, lends support to my concerns. He sees danger to caretakers and family members from vomiting, nosebleeds, and bodily excretions, and he says:

The hospitals I service respect my recommendation, however, they also ignore my concerns because they must compete in the market place. It is totally up to the regulators to keep our community safe for the patient's caretakers, since the free-market place otherwise eliminates all safety procedures that are a fiscal burden.

Mr. Steward speaks from experience. This is the real world of 21st century medicine, and the evidence for that is all around us. Few of us, I suspect, lack personal knowledge of cases in which some important medical procedure was delayed or never took place, either because an insurance company declined to pay for it or an HMO did not have the capacity to perform it in-house.⁸

⁷ I made this clear in my comments of August 25, 1994, on the proposed rule, where I wrote: "No one should have the illusion that this rule change would simply give patients and doctors a choice between inpatient and outpatient treatment. In practice, the pressure to contain costs would probably mean that insurance companies would pay only for the cheapest possible option, creating pressure on practitioners to find a way to justify out-patient treatments. In such cases, patients will not realistically have a choice, unless they are able to pay for hospitalization out of their own pockets. Most, whether they like it or not, will be outpatients, living at home, and their families will be getting unnecessary radiation doses, so long as it is possible to calculate, on paper, a set of restrictions by which doses can be kept to .5 rem."

⁸ In a striking example of the role of cost considerations in medical decisionmaking, Dr. Grigsby, who has an MBA as well as a medical degree, published an article entitled "Cost minimization analysis and utility of pretreatment and posttreatment total body iodine-131 scans in patients with thyroid carcinoma" in the March 1, 1998, issue of the journal *Cancer*. The article is summarized at PubMed, a service of the National Library of Medicine and the National Institutes of Health, accessible on the Internet.

(A preliminary word of explanation is in order. Thyroid cancer patients typically receive comparatively small diagnostic doses of radioiodine to look for the presence of thyroid tissue in the body. Thyroid tissue, benign or cancerous, normally takes up iodine. The patient lies motionless on a table, while a scanner, mounted above the table, moves down the length of the patient's body, creating a cumulative picture of the entire body. Areas of high radiation uptake, indicating the presence of thyroid tissue, will show up on the scan. If the patient is then given a large treatment dose of radioiodine, a second scan, *after* treatment, is an opportunity to find sites of disease which did not show up on the earlier diagnostic scan. No additional administration of radioactive material is needed; the

Ideally, every physician would be in a position to act in accordance with the following sound and responsible advice, taken from an online tutorial posted on the Internet by Dr. Carol Marcus (at <http://www.acnp-cal.org/radiopharmaceuticals.html>):

Physician judgment concerning the likelihood of patient compliance must not be overridden by economic considerations of managed care organizations or insurance companies. Attempts to coerce physicians into 'deciding' to treat all patients as outpatients must be successfully countered, either by the physician, the professional regulated community, or the state radiation regulator.

Physicians whose practices include a large percentage of economically disadvantaged and poorly educated patients may find that they seldom give large doses of NaI-131 to patients as outpatients; this is to be expected.

I am confident that when Dr. Marcus believes that a patient needs to be treated as an inpatient, she prevails. But what about the doctor who is a salaried employee of Group Health, or Kaiser Permanente, or some similar organization, where cost containment is an extremely high priority? Will that doctor have the same clout, knowing that his or her performance is likely to be measured in part by success in keeping the employer's costs to a minimum?

Just a few months ago, I met a woman in her twenties who was operated on two years ago for papillary thyroid cancer, with lymph node involvement. Receiving her health care from one of the big HMO's, she had her surgery and all follow-up care provided by HMO employees. In practice, this meant that she had a total thyroidectomy, along with the removal of either 14 or

only inconvenience is that the patient has to lie still on a table for a period of time.)

Dr. Grigsby's study identified previously unknown foci of uptake in the necks of 6 of the 63 subjects. From this, he drew the following conclusions, according to the PubMed summary: "CONCLUSIONS: Posttreatment total body I-131 scans yielded additional information in only 10% (6 of 63) of the study patient population treated with postoperative I-131 for thyroid carcinoma. Therefore, the cost, and the associated inconvenience for the patient, of performing a posttreatment total body I-131 scan can be eliminated for most patients."

I, for one, would draw just the opposite conclusion from this statistic: that a procedure involving no additional radiation burden, and likely to identify additional sites of abnormal uptake in 10% of patients, is abundantly worth performing. On this point, the country's leading thyroidologists have just spoken out. In *THYROID*, the journal of the American Thyroid Association, vol. 16, no. 2 (2006), the American Thyroid Association presents its definitive "Management Guidelines for Patients with Thyroid Nodules and Differentiated Thyroid Cancer." Developed by a panel of eminent thyroid specialists, the guidelines have this to say, at p. 13:

"Posttherapy whole body iodine scanning is typically conducted 1 week after the radioactive iodine therapy to visualize metastases. **Additional metastatic foci have been reported in 10%-26% of patients scanned after high-dose radioiodine treatment** compared to the diagnostic scan. The new abnormal uptake was found most often in the neck, lungs, and mediastinum, and **the newly discovered disease altered the disease stage in approximately 10% of the patients, affecting clinical management in 9%-15%.** ...A posttherapy scan is recommended after radioiodine remnant ablation." [Emphasis added, citations omitted.] (This is one of the Guidelines' "B" recommendations, which means that it is "based on fair evidence that the service or intervention can improve important health outcomes.")

18 (I no longer recall) cancerous lymph nodes, in a line extending from the base of her neck to just under her ear, *on an outpatient basis*. She was sent home with a prescription for Vicodin, for post-operative pain. Unfortunately, the breathing tube had irritated her throat during the operation, and she could swallow neither the Vicodin nor anything else, so she experienced considerable pain. Three days later, she was back at the HMO, being treated for dehydration. She has since had two outpatient I-131 treatments, the second of which was 140 millicuries. The guidance she received was to sleep apart from her husband for three days.

4. Is vomiting a valid concern?

Dr. Grigsby, in his comments of December 27, 2005, reports that since 1997, he has performed "about 1,000" outpatient I-131 treatments, ranging from 25 to 250 millicuries, and says, "None of my patients reported vomiting after the I-131 administration."

Not every practitioner, however, reports the same. Drs. Ernest L. Mazzaferri and Richard T. Kloos, in their 2001 article, "Current Approaches to Primary Therapy for Papillary and Follicular Thyroid Cancer,"⁹ wrote, in describing acute complications of I-131 therapy:

About two thirds of patients given 200 mCi or more develop mild radiation sickness characterized by headache, nausea, and vomiting that begins about 4 h after I-131 administration and resolves within 24 h.

Procedure guidelines issued in 2002 by the Society of Nuclear Medicine state: "In patients with thyroid cancer, early side effects of I-131 may include nausea, occasional vomiting, pain and tenderness in the salivary glands....[etc]."

In 2003, on an Internet site called "Ask the Expert," Dr. Carol Marcus responded to a questioner who asked, "Are there any 'bad' side effects that a person may suffer from having a nuclear medicine treatment?" Her reply included the following:

There may be an episode of nausea and/or vomiting a few hours after a large dose of I-131 sodium iodide due to stomach irritation. If it happens at all, it is usually only a single event, and can be avoided by the use of common antiemetics such as compazine.

The RADSAFE bulletin board, for the exchange of information related to radiation safety, is a source of further data. See, for example, the message from Chris Alston, dated February 11, 1998:

Last night at 8:00 PM, my Nuc. Med. Physician informed me that a patient who was

⁹Journal of Clinical Endocrinology and Metabolism, Vol. 86, No. 4 (2001).

administered 29.9 mCi of I-131 for Hyperthyroidism at 6:00 PM, vomited on the floor of her daughter's car on the way home! The daughter was driving on the highway at the time and could not pull over to get her infirm mother out of the car in time. She attempted to clean up the spill on her own after she got her mother home with hot water and no gloves! Her mother was apparently nervous before the administration and refused to eat anything before administration. Therefore, she apparently had an empty stomach at administration and threw up about 45-60 minutes later.

The next day, February 12, 1998, Kathleen Kaufman, whose e-mail address identified her as an employee of the health department of Los Angeles County, wrote:

Actually, we had an even worse situation where a patient vomited on a public bus. The bus continued in use all day, with people walking over, sitting around, the mess. We've had several other instances of vomiting in parking lots, & other public places. We now suggest to licensees that they always provide an emesis bag, with written instructions to upcheck [*sic*] in the bag & return it to the hospital.

Responding to this the same day, Dr. Marcus wrote:

Maybe physicians should give compazine before I-131 more often than they do. I usually do so for medium to large doses.

On the following day, February 13, 1998, an Australian correspondent reported on a patient who vomited in the toilet about 40 minutes after receiving a 100 mCi dose of I-131. She added that six or seven years earlier, when I-131 began to be given in capsule form at her hospital, rather than as a liquid, "we noticed an increase in the number of patients complaining of nausea."

On September 15, 1999, a correspondent whose facility was updating its emergency response program wrote asking about the volatility of I-131, in the event that a therapy dosage of 100 - 200 millicuries either spilled, before being given to a patient, or was vomited soon thereafter. Dr. Marcus replied the same day:

My own, rather extensive experience of patients vomiting is that they very, very rarely do this as soon as the dose is administered. They usually do it some hours later. ... We never had a spill, and the patients, if they vomited at all, vomited in the toilet so that there was no problem with airborne emissions.¹⁰

¹⁰ Elsewhere in the same message, Dr. Marcus wrote: "Back in the years when NRC, for absurd reasons, forbid Syncor to stabilize its NaI-131, I measured the airborne losses from two such doses at 10% and 16%. I then went on the warpath and demanded that Syncor be permitted to stabilize preparations, charging that NRC was a bigger danger to public health than all of nuclear medicine combined. I finally threatened Admiral Carr (then Chairman) that I would go to the Washington Post and the wire services to expose him if he did not relent. He did

I don't want to belabor the point. Suffice it to say that notwithstanding the perfect record reported by Dr. Grigsby, there is ample evidence that vomiting, with its potential effect on family members and members of the public, is and always has been a valid issue.

It should be noted that there are several possible ways to address the issue of patient vomiting, including (but not necessarily limited to) one or more of the following: (1) administering compazine (a prescription drug) or some similar medication, in line with Dr. Marcus's suggestion; (2) having outpatients remain in the hospital for a period of hours, until the maximum danger of vomiting is past, as a nationally prominent thyroidologist suggested to me several months ago; or (3) reverting to the 30-millicurie rule for I-131, as proposed in my petition. These are the types of issues that could usefully be explored during a properly conducted rulemaking proceeding.

5. Legal issues.

Dr. Marcus, in her comments, expresses surprise and indignation that my petition for rulemaking was deemed to meet the threshold for publication, instead of being dismissed out of hand. I will do my best to explain why some of her many letters to the NRC, asserting that the NRC asked her to file the patient release criteria rulemaking petition, have created a legal problem for the agency. As I will make clear, if there is fault here, it is not with her, but with the agency.

About 20 years ago, the NRC's then Chairman, Lando W. Zech, Jr., sent a memorandum to all employees entitled "Arm's-length Regulation," in which he cautioned that though interaction between the regulators and the regulated was essential to the NRC's business, an appropriate distance had to be maintained to preserve the integrity of the regulatory process.

When the NRC staff perceives a need for changes to NRC regulations, it can and frequently does propose them to the NRC Commissioners. NRC procedures also allow individual staff members to raise concerns on their own. There is no need, therefore, to enlist outside parties to propose such changes. Yet according to Dr. Marcus's recent comments, Mr. Richard Cunningham of the NRC staff "ardently requested" her, in 1989, to file the petition that resulted in the so-called Radiopharmacy Rule, and assigned Mr. Norman McElroy to help her write it. (Note that this was the first of two petitions for rulemaking filed by Dr. Marcus; the patient release criteria petition was not filed until 1990.)

Since the NRC staff, in forwarding her petition to the Commissioners with a recommendation that it be granted, did not reveal its own role in procuring it, the Commissioners had no way of

relent...."

knowing that the staff was passing judgment on its own work. In all probability, moreover, they would never have known this, if Dr. Marcus had not revealed this fact in a number of public communications, including, most memorably, a letter of November 9, 1992, to the NRC Secretary, in which she declared, "It was an 'inside' job from the start." The quoted sentence suggests that Dr. Marcus herself recognized that there was something irregular about the rulemaking.

The NRC responded to the revelations about that rulemaking by enacting a new rule, published in the Federal Register on March 12, 1991, and codified at 10 CFR 2.802(b). It limits the assistance that the NRC staff may give prospective petitioners to describing the procedures for filing and responding to petitions; clarifying existing regulations and their bases; and "assisting the prospective petitioner to clarify a potential petition so that the Commission is able to understand the nature of the issues of concern to the petitioner." The rule states explicitly that "the NRC staff will not draft or develop text or alternative approaches to address matters in the prospective petition for rulemaking." The rule is thus a stricture not on outside parties, but on the NRC's own employees.

For a further gloss on what 10 CFR 2.802(b) means, we turn to a February 23, 1994, memorandum from James M. Taylor, NRC Executive Director for Operations, entitled "Staff Assistance to Prospective Petitioners for Rulemaking."¹¹ The memo, addressed to "All NRC Employees," was distributed to every NRC employee. It began:

Each year since 1991, I have issued an announcement to all NRC employees to clarify the permissible scope of staff interaction with a prospective petitioner for rulemaking. The purpose of this announcement is to remind the staff of the limitations on the assistance that the NRC staff may provide a prospective petitioner.

In other words, this was a subject on which the Executive Director of Operations, the head of the NRC staff, felt strongly enough to have written annual memos for four years. No one in a position of responsibility at NRC, including the Chairman and the General Counsel, could have been ignorant of it.

The memo went on to describe the contents of 10 CFR 2.802(b) and then explain:

...[T]he NRC staff will not draft or develop text or alternative approaches to address matters in a prospective petition for rulemaking. This means that NRC employees may not prepare or assist an external party in the preparation of a petition for rulemaking. **NRC employees may not negotiate wording for revisions nor encourage a**

¹¹ It was the fourth in a series of annual memos on this topic; though I do not have all of them at hand, it is reasonable to assume that they all said about the same thing.

prospective petitioner to submit a petition for rulemaking, thereby bypassing normal agency procedures that provide for employee concerns regarding changes to 10 CFR Chapter I (Parts 0-199). ...

Should any staff assistance be provided to a prospective petitioner regarding technical or substantive issues, that assistance must be disclosed to the Commission in the paper forwarding the rulemaking action for approval. Staff assistance must also be noticed in any public notice regarding the petition and in any rulemaking that may result from the petition that is published in the Federal Register.
[Emphasis added.]

There is no need for me to repeat in detail here the account I gave in my petition of Dr. Marcus's assertion, in her letter of January 24, 1995, to then Chairman Ivan Selin, that "it was NRC that asked me to write a petition on the subject [patient release] in the first place...." In her recent comments on my petition, she writes:

My second petition [i.e., on patient release criteria] was written at the urging of Hal Peterson, who had nothing to do with the [NRC] Medical Section (as I recall, he was in the Chairman's office), and who provided not one shred of assistance. ... Not only did I not get any assistance from the Medical Section, but I had to assist *them*, because none of them understood how to do the math pathophysiology (ask Don Cool about this).

There is nothing to be gained by quibbling about who was actually helpful to whom, and how much. The point is that the NRC's rules, as clarified by Mr. Taylor's memorandum to all staff members, declare that if the staff has given "assistance" to a petitioner, *as defined by the NRC*, that fact must be disclosed to the Commission in the paper forwarding the rulemaking action for approval, and public notice of it must be given in any rulemaking notice published in the *Federal Register*. "Assistance," as defined by the NRC, includes encouraging a prospective petitioner to submit a petition.

The NRC staff, and the NRC in its rulemaking notices in the *Federal Register*, did not mention any such encouragement to Dr. Marcus to file the petition. This leads to one of only two conclusions: the NRC did not mention it either because (1) it determined that such encouragement never took place, contrary to Dr. Marcus's assertions, or (2) it made a conscious decision to ignore its own procedural regulations. The third possibility, an inadvertent failure of NRC to disclose this fact, can be ruled out, in light of my docketed but unanswered February 23, 1995 letter to Chairman Selin, drawing his attention to Dr. Marcus's statements, and explaining the legal cloud that her claims had placed over the rulemaking, then still in progress.

I believe Dr. Marcus when she says that the NRC staff, or a member of the staff, asked her to file her petition. I would like to make crystal clear to Dr. Marcus that I am not suggesting that she did anything in violation of the NRC's regulations; indeed, she may have had good cause to

feel that she was unselfishly performing a civic duty.¹² (It is important to know, however, whether Dr. Marcus, then a member of the Advisory Committee on the Medical Uses of Isotopes, billed the NRC for the time spent preparing the petition, for if so, then not only did the request for the petition come from NRC, the agency also paid Dr. Marcus for writing it, a fact that should surely have been revealed in the rulemaking documents.¹³)

As discussed earlier, licensees and members of the public cannot violate 10 CFR 2.802(b); it applies, rather, to the NRC and its employees. If there is a legal problem here, as I believe there is, it is the NRC's, not Dr. Marcus's.¹⁴ Likewise, if Dr. Marcus's account of her September 1994 meeting with Chairman Ivan Selin is accurate (and it has never been controverted), and he in fact told her that he agreed with her that the NRC staff's analysis of her petition contained "serious scientific, mathematical, and medical mistakes," that is a reflection on him, not her. If, as I described in my petition, the NRC staff's response to comments during the rulemaking was inadequate, suggesting an inexorable progress to a preordained conclusion, that is the NRC's problem as well, not Dr. Marcus's. Finally, if the NRC, in its final notice of rulemaking, was so at a loss to find plausible rationalizations for the rule that it invoked the diminished dose to members of the clergy (surely a notion which had never crossed anyone's mind during the whole course of the rulemaking), that too is a reproach to the NRC, not to Dr. Marcus or anyone else outside the agency.

In her comments, Dr. Marcus has some unpleasant things to say about my petition and me, but since these matters are so far removed from the actual policy and legal issues I have raised, I will deal with her charges in an addendum to this comment letter.

¹²Dr. Marcus misunderstands me to be saying that she was a shill for the NRC staff on her Patient Release petition. If she will reread the relevant part of my petition, I used the word with regard to the earlier radiopharmacy petition, which by her account was "ardently requested" by an NRC manager, drafted with the help of one of his subordinates, and prepared in accordance with strict guidelines dictated by the NRC manager.

Since a shill, as the term is used of auctions, works in collusion with the auctioneer to produce a given result, to the detriment of participants unaware of that prearrangement, the similarity between the hidden collusion of the NRC staff and the ostensibly outside party in the 1989 rulemaking makes the term an apt one, in my view. With regard to the patient release criteria petition, the situation seems different, since Dr. Marcus did all the work, by her account, and it does not appear that the same people encouraged submission of the petition and then evaluated it after it was received. (Incidentally, if Dr. Marcus had known more about NRC procedures, she might have told the NRC staffer who contacted her that if he saw a flaw in its regulations, he should initiate a correction himself, to be made by NRC, rather than try to outsource the job.)

¹³To make clear, I do not know that this is the case; I am only posing the question. The NRC should answer it in responding to my petition, and perhaps Dr. Marcus would like to speak to this point herself.

¹⁴Moreover, the 1990 petition was filed three months before 10 CFR 2.802(b) went into effect; thus if an NRC staff member asked Dr. Marcus to file the petition, as she maintains, he was violating no rule in effect at that time. The legal issue is whether, in documents prepared after the rule took effect, the NRC followed its rules on disclosure of assistance.

Conclusion.

I would like to conclude by acknowledging that I do not have all the answers. My proposed solution to the problem may not necessarily be the ideal one. There may be intermediate measures, or approaches not yet put forward, that would be more desirable than either the current rule or the old one. These are the sorts of questions that a truly legitimate rulemaking, one that does not start out with a preordained conclusion, can address, with the American Thyroid Association contributing, I hope, its vast collective expertise. For now, we need more information, and I urge thyroid patients, health care providers, and others with pertinent knowledge to assist the NRC by commenting on this petition – pro, con, or otherwise.

Sincerely,

Peter G. Crane

ADDENDUM: Response to Comments of Dr. Carol S. Marcus

For many years, some of us who care both about the NRC and about the maintenance of civility in public discourse have been troubled by the tenor of Dr. Carol Marcus's statements to and about the agency. The following example, from a letter to the NRC of January 24, 1992, is illustrative:

The Commission, with its oversimplifications of medical and pharmacy practice, required willing pawns to do its work. A sort of Darwinian evolution took place in which the scientifically unfit, a few individuals with very poor attitudes, and several cowards inherited the duty.... In order to support the Commission's desires, and advance their own power agendas, the present staff uses fraud in any convenient form. Data are misrepresented, omitted, ignored, or manufactured for convenience. ... The recent humiliation of NRC by staff of OMB when NRC's fraudulent version of the "Quality Management Rule" was uncovered is astounding but predictable. Instead of NRC's upper management retracting the material and apologizing, a delegation of NRC staff and management went into frenzied, paroxysmal "superlying" to cover the original lying, and earned the contempt of all concerned. Some of the statements made in writing by NRC staff to justify the Rule describes actual deaths of patients caused by physicians which in fact did not occur. This would itself constitute a libel suit, but in this case has no point; no damage will be done because no one believes the NRC anyway. Pitiful, isn't it? ... I do not believe that the Medical Use Program is compatible with honesty, integrity, or even simple human decency.¹⁵

The next excerpt is from a January 10, 1995, letter from Dr. Marcus to Dr. Carl J. Papierello, then Director of the NRC's Division of Industrial and Medical Nuclear Safety:

...[Y]our peculiar stubbornness on this issue is ignorant, irrational, and scientifically and medically without foundation. I cannot respect your opinion, and believe that if you do not even know what Nuclear Medicine is, you certainly are not entitled to any opinions about it.

Your gratuitous suggestion that the way to resolve the conflict ... is for us to stop being appropriate and start writing silly prescriptions that suit the staff in your non-medical "Medical Section" is the typical perversion of the more dysfunctional members of your Agency.

¹⁵At the time she wrote this letter, Dr. Marcus was a member of the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI). Notwithstanding these and similar letters, the Commission, under Chairman Ivan Selin, soon thereafter reappointed her to a second two-year term. If I remember correctly, Dr. Marcus was then quoted in the trade press -- *Inside NRC*, I believe -- as saying, "Can you believe it? They reappointed me." It was not a proud moment for NRC, and if Dr. Marcus was gloating, she had every right to do so.

The NRC is not the only recipient of such communications. Dr. Marcus's letters to the Food and Drug Administration are often along similar lines. See, for example, her letter to FDA of January 5, 2005:

"...FDA actions have killed tens of thousands of patients by depriving them of PET scans. While this hasn't made the front pages of the nation's newspapers, *it should*. The sordid and unforgivable details of a vicious and malevolent plot to destroy PET by the FDA was the subject of a federal lawsuit..." [Emphasis in the original.]

I don't want to belabor the point, though many other instances could be cited, none more extreme than in her postings to the Internet bulletin board RADSAFE.¹⁶

Dr. Marcus, in her comments of December 26, 2005, asserts that I am "terrified of radiation, especially I-131," and that my petition constitutes "classical anti-nuke nonsense," its "main points consisting merely of lies, distortions, and antinuclear hysteria." I won't bother with the accusation of lies and distortions, but I would like to address the charges of being "terrified of radiation," and of displaying "antinuclear hysteria."

There is a particular irony for me in being accused of this, as my former colleagues in the NRC's Office of General Counsel, where I spent 21 years, will appreciate. In the aftermath of the accident at the Three Mile Island Unit 2 nuclear plant, the NRC shut down the companion Unit 1 reactor, and committed itself to preparing an environmental impact statement under the National Environmental Policy Act before allowing Unit 1 to resume operation. A local citizens' group, People Against Nuclear Energy, argued that the impact statement should evaluate, among other things, local residents' fears of radiation, and the psychological impacts of renewed operations. My own view, strongly held, was that a scientific agency should make its decisions based on science; if local citizens were afraid of a possible release of radiation, the agency should evaluate how likely such a release was, not how afraid of it the citizens were. It therefore fell to me to draft what in effect became the Commission's decision in the case, and in the U.S. Court of Appeals for the D.C. Circuit, I argued that the NRC had properly excluded consideration of psychological impacts. I lost the case, 2-1. The then NRC General Counsel,

¹⁶ I will offer just a few examples, using asterisks where Dr. Marcus's language is especially pungent:

1. "[T]he criminalization of human error, much of which is insignificant and all of which is rare, is venomous, perverted, and terminally dysfunctional. It is amazing that the Commissioners cannot get this simple idea through their skulls." [Dr. Marcus to RADSAFE, December 20, 1999].
2. "The answer is to CHANGE THE STANDARD. ... Alas, for years, the NRC has not had the b*lls and brains to do this." [Dr. Marcus to RADSAFE, February 11, 2000.] (This last comment caused another RADSAFE subscriber to write that he was "getting a bit tired of your nasty diatribes against the NRC.")
3. "Unfortunately, the Commissioners have no competence in nuclear medicine or nuclear pharmacy, and succumb to whatever bullsh*t the staff and management con artists feed them. ... Will Chairman Meserve get smart enough to cut through this vicious circle, excrete [former Chairman] Jackson's mess and continue the good work started by Chairman Ivan Selin and Commissioner E. Gail de Planque?" [Dr. Marcus to RADSAFE, July 20, 2000.]

Leonard Bickwit, decided that I was the person best suited to persuade the Justice Department to seek reversal of the decision, and he appointed me Acting General Counsel for a day so that I would have a title in front of my name when I met with Solicitor General Rex Lee and his staff to urge that the case was worth taking to the Supreme Court. (The Solicitor General needed no persuasion.) I did not get to argue the case -- that honor went to Deputy Solicitor General Paul Bator -- but I had the perhaps childish pleasure of sitting at the counsel table of the U.S. Supreme Court for the first and only time in my life. The Supreme Court unanimously reversed the lower court, 9-0. See *Metropolitan Edison Co. v. People Vs. Nuclear Energy*, 460 U.S. 763 (1983). It is easy to look up the decision on the Internet; my name will be found as being on the Government's brief.

Some six years later, the Environmental Protection Agency, after a reversal of policy on radiation, proposed radiation standards (the acronym was NESHAPS) that would have drastically reduced permissible emissions of radiation, including radiation from hospitals giving nuclear medicine treatments. The NRC had serious legal and policy objections to those proposals for dual NRC and EPA regulation, and the issue happened to fall to me. It also happened that I was in the midst of I-131 treatments at the National Institutes of Health at the time, for recurrent thyroid cancer. When I learned from radiation safety personnel there of NIH's concern that the new NESHAPS could cripple its ability to give I-131 treatments, I wrote a memo on my laptop, while in radioactive isolation, explaining why the NESHAPS, in the interest of preventing hypothetical cancers in the future, could interfere with the treatment of quite non-hypothetical cancers in the present, including my own, as well as cases of hyperthyroidism, for which the then First Lady, Barbara Bush, had recently received I-131. I was told that the memo received wide circulation. In addition, former Commissioner Curtiss will no doubt remember an almost raucous meeting at the Executive Office Building on Halloween of 1990, I believe, in which, on behalf of NRC, I challenged EPA's bases for the NESHAPS, and read aloud from legal briefs, filed by EPA before its reversal of course, in which EPA had argued that such drastic standards were unwarranted. I do not for a moment claim credit for the quashing of the NESHAPS, but I certainly took a willing part in the fight.

My professional career thus belies Dr. Marcus's notions about my attitudes toward radiation, fear of radiation, and I-131. As to being anti-nuclear, I have always believed, since first joining the NRC in 1975, that a regulator's role is to be neither an advocate nor an opponent of nuclear energy, but rather to help ensure that if nuclear energy is used, it is used safely. But I must admit that as a thyroid cancer patient, cured of disease by multiple treatments with I-131, I am not impartial and agnostic when it comes to the use of I-131 in medicine. I view I-131 as an essential, invaluable, and irreplaceable tool in the treatment of thyroid cancer, and I do not know anyone knowledgeable about the disease who does not agree.

For that reason, I do not want anything to stand in the way of a patient's getting the I-131 he or

she needs for treatment. But that does not mean that I take casually the need to protect the patient's family members (and fellow bus travelers, for example) from the I-131 that he or she has been administered. That is what is at issue in this case. Allegations about "terror of radiation" and "anti-nuclear hysteria" are merely a distraction from the serious safety questions that deserve to be addressed.

From: Carol Gallagher
To: Evangeline Ngbea
Date: Wed, Feb 1, 2006 11:55 AM
Subject: Comment letter on PRM-35-18

Attached for docketing is a comment letter on the above noted PRM from Peter G. Crane that I received via the Rulemaking website on 1/31/06.

Carol

Mail Envelope Properties (43E0E7D9.21E : 3 : 886)

Subject: Comment letter on PRM-35-18
Creation Date: 2/1/06 11:54AM
From: Carol Gallagher
Created By: CAG@nrc.gov

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