Peter Crane / 6545 27th Avenue NW / Seattle, WA 98117 / peter46crane@gmail.com / 206-819-2661

May 12, 2017

(3)

Ms. Cindy Bladey, Office of Administration
Mail Stop OWFN-12-H08
U.S.N.R.C.
Washington, D.C. 20555

4/11/2017
82 FR 17465

RECEIVED
2017 MAY 25 PM 3:37
RULES AND DIRECTIVES BRANCH USNRC

Re: 82 FR 17465 (April 11, 2017), Docket No. NRC-2017-0094

Dear Ms. Bladey:

In comments dated April 19, 2017, Dr. Carol S. Marcus made a number of assertions relating to the history of the NRC's approach to radiation protection in medicine, as well as a personal attack on an NRC staff member. These call for a response separate from my comments on the six questions posed in the Federal Register notice, which will be submitted later.

The first thing to be said with respect to anything filed by Dr. Marcus is always: "consider the source." It was she, after all, who in a 1989 letter to the NRC, written on the letterhead of the University of California at Los Angeles, used the term "power-hungry horsesh*t" to describe a recent letter from an NRC staff scientist. (The asterisk is mine, not hers.) Surely there cannot be many letters to federal agencies on the letterhead of public universities that use this sort of rhetoric against an individual civil servant. A letter of this sort tells readers a great deal – not about the author's target, of course, but about the author.

On February 26, 1990, *Inside N.R.C.* published an article that began by citing "vicious," "grotesque," "bizarre," "horrible," and "hopelessly repulsive" as among the epithets used by Dr. Marcus in her letters to the NRC. (The article quoted her as describing herself as "a pretty aggressive person.") By the early 1990's, Dr. Marcus frequently assailed NRC staff members by name, impugning their abilities, motives, and on occasion even their sanity. In one case, she asked the NRC Commissioners to commit a senior official to a mental hospital, in a letter that he found hilarious, and posted at the door of his office for the amusement of his co-workers. Public servants, of course, do not have the option of writing their own replies to personal attacks of this kind. They must sit there and endure it, and hope that higher levels of their agencies will have sufficient loyalty to their employees to make clear that such abuse will not be tolerated. Sadly, the NRC's leadership in the early 1990's failed badly in that respect.

SUNSI Review Complete
Template = ADM – 013
E-RIDS= ADM-03
Add= D-B – Howe (dbh)
C. Prasapakse (CSP2)

In the present case, Dr. Marcus seems to think that one particular staff member is pursuing a personal agenda with respect to patient release issues, whereas in fact the NRC staff is merely following directions given by the Commissioners in 2014 in a memorandum co-authored by Chairman Allison Macfarlane and Commissioner William Magwood. The credit or blame, as the case may be, belongs to them, not to the staffers given the task of implementing their decision.

I will now address some of the factual assertions in Dr. Marcus's comment letter.

1. "NRC lowered the public exposure dose ... to 100 mrem simply because it seemed feasible to do so."

FALSE. NRC lowered the standard in Part 20 from 500 to 100 mrem because it was under instructions from President Ronald Reagan, who had issued an order directing all agencies to reduce allowable radiation limits, out of concern for the effects of radiation on unborn children. See 52 Federal Register 2822 (Jan. 27, 1987).

2. During the process of developing 10 CFR 35.75, "nearly all the issues in this requested information were exhaustively debated and discussed."

FALSE. There was no discussion, for example, of whether it was legally and medically appropriate to release patients to places other than their own residences, such as hotels and motels. (It is striking that Dr. Marcus's comment letter says not a word about the highly contentious issue of radioactive patients in hotels.) Nor was there a discussion of the sort of guidance that licensees were expected to provide to patients, or of its timing.

3. "No scientific basis was ever found for the AEC limit [of 30 millicuries], or the NRC limit. No one at the NRC or in the regulated community could figure out where it came from."

FALSE. The notion that the origin of the 30 millicurie is an insoluble mystery is a fiction which some in the nuclear medicine community have been ardently propagating, in one tendentious article after another, each new one citing the previous ones. (See, e.g., a July 2014 article in *Thyroid*, the official publication of the American Thyroid Association, co-authored by Drs. Jeffry Siegel and Edward Silberstein,"The AEC/NRC Thirty-Millicurie Rule: Regulatory Origins and Clinical Consequences for Iodine-131 Remnant Ablative Doses," which claimed that "historical uncertainty" surrounded the origin of the rule.) A myth remains a myth no matter

how frequently or vehemently it is repeated. In this case, it is easily disproved by reference to an earlier article in *Thyroid*, from 1997.

Some background is necessary. Before 1997, patient release was governed by the 30 millicurie rule, which, as the NRC had explained in codifying it a decade earlier, was a yardstick based on the hazards of I-131. That isotope was chosen because it was "the most commonly used therapeutic radiopharmaceutical" and also "the most radiotoxic byproduct material used for medical use." The NRC stressed the "special contamination hazards of radiopharmaceutical therapy patients," and rejected the idea, proposed by one commenter, of basing release on the probable exposure to others. The calculations themselves were straightforward, it said, but establishing the facts on which to base them – the probable distance from others, length of time of exposure, etc. – was too "tenuous" to be relied on. It concluded that at activity limit of 30 millicuries provided an "adequate margin of safety" for exposure to both external and internal doses. 50 FR 30616 (July 26, 1985) and 51 FR 36932 (Oct. 16, 1986.)

That the 30 millicurie rule was linked to the 500 millirem maximum permissible dose to a member of the public was well understood. The best evidence of this is an article published in April 1997 in *Thyroid* by Dr. Pat Zanzonico, a health physicist at Memorial Sloan-Kettering Cancer Center. (Zanzonico, P.B., "Radiation Dose to Patients and Relatives Incident to ^{131}I Therapy.") The context is important. At the time, the 30 millicurie rule seemed to be threatened by efforts on the part of EPA to reduce public exposures to radioactive iodine, and the point of the article was to argue that the 30 millicurie limit was sufficiently protective of the public, and therefore did not need to be lowered. Dr. Zanzonico was evidently unaware, as he was writing his article, that the NRC was on the verge of abandoning the 30 millicurie activity standard in favor of a dose-based approach, and that outpatient treatment with I-131 in much higher amounts than 30 millicuries would soon be common.

Dr. Zanzonico explained in his article that the maximum likely external dose to the family member of a patient receiving 30 millicuries of I-131 was 500 millirems. To quote the abstract:

> Based on actual measurements of thyroid activity and of external absorbed dose, the total thyroid and mean extrathyroidal absorbed doses to adult family members from immediately released 131I-treated patients are approximately 0.01 and approximately 0.02 rad/mCi administered, respectively, yielding an effective dose of approximately 0.02 rem/mCi. **A maximum permissible effective dose of 0.5 rem for adults therefore is consistent with a release criterion of retained 131I. Lower-activity release criteria therefore may be unnecessarily restrictive.** [Emphasis added.]

The obvious implication of what Dr. Zanzonico wrote was that any limit **higher** than 30 millicuries could result in external doses to others **exceeding** the 500 millirem maximum. He also observed, correctly: "**Of course, the overall hazard is a combination of both the external and internal radiation hazards.**" With respect to internal dose, he noted, again quite accurately, that "**saliva and urine [are] the primary sources of such contamination.**" [Emphasis added.]

The article also noted that the activity threshold for hospitalization of radioactive patients ranged "from as low as 2 mCi [millicuries] in some parts of Europe **to as high as 30 mCi in the United States.**" [Emphasis added.] Thus even **before** the 1997 deregulation, the NRC's 30 millicurie standard was as lax as any in the world. If we were already outliers then, one can imagine how far wide of the norm we are now.

No sooner had the 30 millicurie rule been abolished than doses much higher than 30 millicuries were being administered routinely on an outpatient basis. Sloan-Kettering, for example, gives outpatient treatments of up to 200 millicuries of I-131. (See, for example, Bath, C., How can patients who receive radioactive iodine treatment for thyroid cancer reduce the chance of radiation risks to others, ASCO POST 2:4 (March 2011).) The party line made an abrupt turnabout. The partisans of the nuclear medicine industry now sought to prove that rather than being **sufficiently** restrictive, and with a sound scientific basis, as Dr. Zanzonico had argued in his article, the 30 millicurie rule had actually been **overly** restrictive, and devoid of a scientific basis.

Regrettably, Dr. Zanzonico himself was part of this effort. Only thirteen years after his article appeared in *Thyroid*, he co-authored a 2010 report by a subcommittee of the Advisory Committee on the Medical Uses of Isotopes that included the following statement about the 30 millicurie rule: "The Subcommittee finds no scientific merit in returning to such activity-based release criteria, **which have no identifiable scientific basis.**" [Emphasis added.] If Dr. Zanzonico has ever addressed the contradiction between his views of 1997 and 2010, I am unaware of it. I hope he will do so now.

4. "Patient's [*sic*] had to be inpatients [under the 30 millicurie rule] in private rooms with private bathrooms for a number of days, and it was completely unnecessary. This is why the rule was changed to an absorbed dose-based rule, at a dose limit that is exceedingly low and not hazardous to anyone, including embryos, fetuses, and small children."

FALSE, to the extent that the claim is made that inpatient treatment "was completely unnecessary" and that the dose limit in the rule ensures that the released patient is "not hazardous to anyone." On this point, Dr. Marcus herself is an authority. In 1992, she wrote to the NRC:

> It should be realized that the calculation system utilized in NCRP no. 37 assumes that the patient is a "sealed source." It is important to consider situations in which the patient is a "leaky source." In such situations, more conservative considerations need to apply. It is important to consider the patient given NaI-131 in this context.
>
> I-131 appears in urine, feces, sweat, saliva, lacrimal fluid, nasal fluid, and emitted gases. **The radiation absorbed dose to the thyroid in individuals who share households with patients can be much more significant from contaminant I-131 than from the patient as a sealed source. Therefore, the limiting factor in deciding when a patient can go home should be contaminant levels of I-131 that can reasonably be expected to occur.** [Emphasis added.]

The clear implication of the phrase "the limiting factor in deciding when a patient can go home" is that even when the 500 millirem standard for **external** dose (as used in NCRP No. 37 and later adopted in the Patient Release Rule) is met, the contamination hazards created by the patient may nevertheless make hospitalization essential.

5. "This Federal Register article is slanted to give the impression that there is confusion over whether the 500 mrem dose is a per procedure dose or a yearly dose. **There is no confusion, and there never was. The 500 mrem limit is per procedure."** [Emphasis in the original.]

FALSE, to the extent that this comment suggests that the issue is resolved and beyond dispute. For many years, the NRC staff has taken the position that the dose is an annual limit, while the Advisory Committee on the Medical Uses of Isotopes has argued that it should be construed as a per-release dose. National and international bodies have always favored an annual limit. (*See, e.g.*, "The foregoing limits are annual totals and, therefore, do not apply to individual treatments but collectively to all treatments a patient may receive in a given year." National Council on Radiation Protection, Report No. 155, *Management of Radionuclide Therapy Patients* (2006), p. 145.) It is worth stressing, moreover, that NCRP 155, in accordance with the position of the NCRP and ICRP, makes clear that 100 millirems, not 500, is the appropriate dose limit for family members (other than a caregiver) and members of the public.

6. "Thank you for the opportunity to comment on this **abominable** Federal Register request. Do your homework, Mr. Collins—this is **disgusting**. Do you really think that busy physicians should waste their time on such **vicious** and **deceptive nonsense**?" [Emphasis added.]

I disagree that there is anything "abominable," "disgusting," "vicious," or "deceptive" about this Federal Register notice, or that it is "nonsense." In my opinion, it was a conscientious effort by the NRC staff to follow a directive from the Commission to address serious health and safety issues. Those responsible for preparing it deserve an apology from Dr. Marcus – not that they are likely to receive one. That would be too much to hope for. What **can** reasonably be hoped for, however, is that the present Commissioners will make clear that they will not allow NRC staff members to be abused with impunity, and will insist that future communications to the NRC conform to basic standards of civility and professionalism.

Respectfully submitted,

Peter Crane
NRC Counsel for Special Projects (retired)