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June 27, 2017

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

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2017 JUL -7 PM 2:22
RULES AND DIRECTIVES BRANCH USNRC

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

Dear Ms. Bladey:

The bottom line: In-patient care, paid for by insurance, must be available to those I-131 patients who need and want it, and must be mandatory for those who may be a hazard to others. This can only be accomplished by a change in the NRC's regulations.

Attached are my responses to the NRC's request for input from the public on issues related to the release of patients made radioactive by the administration of radiopharmaceuticals. My comments relate only to a single isotope, iodine 131 (I-131), because it presents hazards unlike any other, is in wide use, and has special relevance to the thyroid cancer survivor community, of which I am a part.

Like the NRC's six questions, these answers, to be understandable, require some familiarity with the subject matter. In the interest of getting to the point, I will answer the questions first and then follow with a discussion of the background.

A. "Should NRC require an activity-based patient release threshold under which patients would be required to be maintained in a clinic-sponsored facility (e.g., a medical facility or facility under the licensee's control) until the standard for release is met."

Yes. The NRC needs a new rule that follows the approach, though not necessarily the exact numbers, of NCRP No. 37 (1970). It will be recalled that when petitions for rulemaking were before the NRC in 1992, Dr. Leon Malmud, then head of the Society of Nuclear Medicine, proposed that the NRC simply incorporate NCRP No. 37 into the regulations. That would have meant a presumption in favor of inpatient treatment, but with exceptions possible, up to an absolute maximum of 80 millicuries of I-131. The NCRP No. 37 approach allowed outpatient treatment in exceptional circumstances above 30 millicuries, based on a realistic case-by-case

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analysis of probable external dose from the patient. The authors of NCRP No. 37 were of the view that 30 millicuries was actually too high a standard, and that an 8 millicurie limit for outpatient treatment would be preferable.

I am not now in a position to recommend what the precise limits should be. That could be developed in a rulemaking. We have to make provision for the fact, among other things, that the hyperthyroid patient retains more I-131 than the cancer patient, and that a one-size-fits-all approach may not be appropriate.

B. "Should the NRC amend the regulations to clarify the time frame for the current dose limit in 10 CFR 35.75(a) for releasing individuals?"

Yes, the NRC should amend the regulations, and one of the issues worth considering is whether outpatients should be asked to remain in the facility, in an isolated environment, until a certain number of hours have passed, in order to allow some of the I-131 to pass out of the system through urination and also to ensure that the patient is not in danger of vomiting. There have been cases of patients vomiting in public buses and on arrival in hotel rooms, and this could be avoided by a waiting period.

C. "Should the NRC continue to apply the same dose criteria of 5 mSv (0.5 rem), to all members of the general public, including family members, young children, pregnant women, caregivers, hotel workers, and other members of the public when considering the release of patients?"

No, the 500 millirems for all persons is an obsolete and indefensible standard. Both the NCRP and the ICRP recommend a limit of 100 millirems for doses from licensed activities. Under no circumstances should children, pregnant women, nursing mothers, fetuses, embryos, or members of the public with no connection to the patient receive more than 100 millirems from a patient. With respect to a family member who is caretaker, 500 millirems is an appropriate limit in most cases, but that should be waivable, based on informed consent. The parent who wants to assume the risk of being close to a child under treatment, for the benefit of the child, should be permitted to do so, in the hospital or out.

D. "Should the NRC include a specific requirement for the release of a patient who is likely to expose young children or pregnant women to doses above the public dose limit?"

See answer to previous question. Yes, if a patient is likely to expose a pregnant woman or a child to doses in excess of the public limit – which as noted above, should be 100 millirems

– release should not be permissible. But "likely" is the wrong word, in this context, as it connotes "more probable than not." A better standard would be "reasonably foreseeable." If you ride home from the hospital on public transportation with a high dose of I-131 in your system, it is reasonably foreseeable that you will expose a pregnant woman or a child to more than 100 millirems, but it cannot be said that you are "likely" to do so. If you accept a ride home from an adult, non-pregnant friend, then it is not reasonably foreseeable that you will expose a pregnant woman or a child.

E. "Should the NRC have a specific requirement for the licensee to have a patient isolation discussion with patients in sufficient time prior to the administration to provide the patient time to make isolation arrangements or the licensee to make plans to hold the patient, if the patient cannot be immediately released?"

Yes. This is a subject where some providers balk at the idea of a written requirement, because they say that they already take care to have timely discussions of isolation issues, and need no requirement written into the rules. The answer to that is that the concern is not for the good performers – and it can be presumed that the sort of institutions that take the trouble to participate in discussions of this kind with the NRC are in that category – but for the deficient ones, to bring them up to adequate standards. There are too many examples of people being given guidance either at the last minute or not at all, so that they have no time to prepare their residences, arrange alternative housing for themselves or their children, etc. This is an area where, in cases that require immediate treatment, there should be provision for the licensee to depart from the time requirements, simply by recording the fact and explaining the circumstances for the files.

F. "Should the NRC explicitly include the time frame for providing instructions in the regulations (e.g., the instructions should be given prior to the procedure)?"

Yes, for the same reasons outlined in the answer to the previous question.

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Background:

The foregoing answers start from the presumption that excess radiation is undesirable, and that radiation exposures should therefore be kept "as low as reasonably achievable." That has been the approach of the NRC since its inception, and it is shared by regulators the world

over. There is, however, a small but vocal minority which believes, or pretends to believe, that even embryos, fetuses, small children, and pregnant women can safely be exposed to up to 10 rems (10,000 millirems) of radiation per year, on the grounds that doses in that amount cannot be harmful and may be beneficial. This is 100 times or more what responsible radiation protection authorities consider acceptable. There is no common ground to be found between these two diametrically opposed approaches, and no basis for compromise.

I-131, the NRC once declared, is the most radiotoxic isotope used in medicine, presenting hazards both from external and internal exposure. The released patient is a potential source of both. For that reason, the NRC for decades had an activity limit on the amount of radioactive iodine that could be in a patient at the time of release: 30 millicuries. Why was the limit set at 30 millicuries? Because that level of activity in the patient translated to a probable external dose to others that would not exceed 500 millirems, which was the dose limit to members of the public from NRC-licensed activities.

In codifying its rules on patient release in 1986, the NRC explained convincingly why an activity limit was necessary for the protection of public health and safety, and why a dose limit, based on estimating probable doses to others, was too speculative to be workable. Eleven years later, the NRC reversed itself, without ever explaining what was wrong with its earlier reasoning.

This is not the place to describe in detail the highly irregular process by which this occurred. Suffice it to say that the NRC adopted a dose-based standard, with a maximum 500 millirem dose to all persons, regardless of age, sex, pregnancy status, and relationship to the patient. All were treated alike, including caregivers, family members not involved in the patient's care, children, pregnant women, embryos and fetuses, and total strangers.

These are by far the loosest restrictions in the world, far below what is considered permissible even in such Third World countries as Iran and Indonesia. This may reflect the fact that in those other countries, the regulations on nuclear medicine are not made by medical specialists, rather than, as in the U.S., an agency headed by political appointees with expertise in nuclear reactors, without a single medical doctor on its staff.

In the case of the NRC Commissioners who approved the rule in 1997, they seem to have had little appreciation for the complexities of the issues involved, or for the magnitude of the change that the NRC staff was urging them to adopt. They were persuaded to enact what may be the most radical health and safety deregulation ever by a federal agency, under the impression that it was a minor and non-controversial measure. As a result, the defects came to light only after the rule was in place.

One central problem with the 1997 rule was that the NRC plainly assumed, as The relevant Federal Register notices make clear, that patients released from the hospital with more

than 30 millicuries of I-131 in their systems would immediately go home. It did not consider that in addition to (a) remaining in the hospital and (b) going home, there might be a third option: going to a hotel, either because treatment was occurring far from home or as a way to protect loved ones from exposure to radiation. The rule was therefore silent on whether patients could be released to hotels.

Once the NRC learned that in fact, something like five percent of patients were being released to hotels, it faced a choice, which was its to make without the need for an elaborate rule change. Should it interpret the rule as setting the conditions for when patients could be released to their homes, as the final notice of rulemaking implied? Or should it instead interpret it as describing the conditions for when patients could be released to any destination, so long as the 500 millirem limit was satisfied and the patient was given appropriate safety guidance? Regrettably, the NRC chose the second option.

This is only part of what is wrong with the current Patient Release Rule. The greater, overarching problem with it is that it is not working as planned (or at least, not as the Commissioners were made to understand that it was planned). The notion that it would benefit patients by giving them a greater choice in deciding whether to have inpatient treatment turns out to be a cruel joke. Outpatient treatment has become standard, even with high doses; insurance companies take advantage of the rule to deny coverage for inpatient treatment, even in cases where family situations require it; safety guidance for patients varies widely, and sometimes is not provided at all; many patients have to rely on the Internet and each other for information; the NRC's guidance to doctors, encouraging them to consider inpatient treatment when patients have children at home, and discouraging them from sending patients to hotels, is being ignored, simply because it is non-binding; patients are contaminating hotel rooms and bathrooms, without the knowledge of the hotel workers who will be cleaning them; etc., etc.

Unfortunately, for the past 20 years the Commission has been unwilling to do anything binding to correct this situation, and has contented itself with toothless entreaties that it knows are being ignored. I had an example of this just a few months ago, at a Seattle hospital, where I asked the head technologist in the Nuclear Medicine department whether they gave I-131 on an inpatient or outpatient basis. He told me that in the 10 years he had worked there, they had given a single inpatient treatment. How much did they give on an outpatient basis, I asked. Up to 250 millicuries, he replied. Do some of those patients go to hotels, I asked. Sure, he replied, some of them come from Alaska for treatment, and they can't go home. I asked whether he knew that the NRC "strongly discouraged" that practice. Yes, he said, that was taken into account. I asked whether he knew that a similar advisory had come from the State of Washington. Yes, he said, that was also taken into account.

Already years ago, the NRC staff wanted to tell the Commissioners (until the Advisory

Committee on the Medical Uses of Isotopes intervened to prevent it) that it could not say for sure that the current rule kept doses to the public below 500 millirems. It must be borne in mind, too, that this refers only to external dose, and when we are dealing with doses to family members, internal dose from patients presents the even greater threat. As Dr. Carol S. Marcus quite correctly wrote to the NRC in 1992:

> "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."

The hard reality is that the present system is badly broken, and nothing short of a rule change can fix it, notwithstanding that this would undoubtedly displease some within the nuclear medicine community. If the Commission, knowing what it now knows, is nevertheless unwilling to take the concrete steps needed to protect the public, it should ask Congress to be relieved of its responsibilities over radiopharmaceuticals. It could be that the Food and Drug Administration would do no better than the NRC has done, but at least such a change would relieve the NRC of a 20-year burden of evasion and failure.

Respectfully submitted,

Peter Crane
NRC Counsel for Special Projects (retired)