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November 15, 2019

Chairman Kristine L. Svinicki
Commissioner Jeff Baran
Commissioner Annie Caputo
Commissioner David A. Wright
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Chairman Svinicki and Commissioners:

I am hereby transmitting to the Commission, on behalf of a group of petitioners calling ourselves SCAR (Sensible Controls on Administrations of Radioactive Iodine), the attached petition for rulemaking. (The acronym SCAR is in recognition of the surgical scar which those of us who are thyroid cancer patients bear on our necks.) Most of us are veterans of treatment with radioactive iodine, and many face the prospect of further such treatments. Others of us are citizens whose interest in the subject matter is simply that we do not wish for our children or ourselves to be exposed to potentially harmful doses of radiation, without our knowledge, while traveling on public transportation. We also want to be sure that we and our loved ones are not checking into hotel rooms that have been contaminated with radioactivity by a previous guest.

The petition asks the NRC to revise its rules on the release of patients made radioactive by treatment with high doses of radioactive iodine 131 (I-131). This may be the only area of the Commission's jurisdiction where members of the public, above all children, are directly at risk from NRC-licensed activities. It is also the only area where NRC standards lag far behind those of the rest of the world, and, as far as I know, where the NRC staff lacks confidence that the radiation dose limits to the public, set by the agency's regulations, are currently being met.

All this is information that the NRC staff itself has told the Commissioners (or tried to, since the Advisory Committee on the Uses of Medical Isotopes has sometimes intervened to prevent it), as I described in detail in a September 5, 2018, letter to the Commission.

There is no need to describe once again how the Commissioners of the 1990's fell into error. In a nutshell, they were captured by partisans of the doctrine of "hormesis," (*i.e.*, radiation is good for you). Reversing decades of NRC and Atomic Energy Commission precedent, they followed the lead of an eccentric "expert" who once wrote that the health effects of a major nuclear accident would not be harmful and might be beneficial.

The present Commissioners bear no direct responsibility for that radical departure from mainstream science, but they are obligated, once the defects in the current rule have been made clear, to correct them. That is what this petition asks. There is today abundant evidence that in this area, the NRC is not meeting its duty under the Atomic Energy Act to provide adequate protection to the American public – above all to children, who are most at risk from the harmful effects of radiation, including cancer and mental retardation.

The key points of the petition are the following:

- The NRC position on the safety significance of internal doses of I-131 directly contradicts the expert views of the Centers for Disease Control. On medical issues, the NRC should defer to the CDC.

- To remedy the current deficiencies in public protection from released I-131 patients, the NRC staff continues to put its faith in more and better guidance to licensees, while also stressing that such guidance is voluntary and can be disregarded with impunity. This approach, having failed dismally in the past, has no realistic chance of succeeding now.

- The most crucial requirement of a reasonable patient release rule is that it ensures that inpatient treatment, paid for by insurance, will be available to patients whose family situations require it. That used to be case, but since 1997, has not been.

The NRC is now, and has been for more than 20 years, an outlier in the world radiation protection community. It is five years since the NRC staff informed the Commissioners that the radiation protection afforded to Bangladeshi children is stronger than what American children receive. Knowing as many of us do from personal experience the human consequences of cancer, we consider this unacceptable. We ask for rapid action on our petition, and also for a public meeting at which the Commissioners themselves can hear not only from us, but also from the Centers for Disease Control and from stakeholders on all sides of the patient release issue.

Yours truly,

Peter Crane, NRC Counsel for Special Projects (retired)
Acting Secretary, Sensible Controls on Administrations of Radioactive Iodine (SCAR)

SENSIBLE CONTROLS ON ADMINISTRATIONS OF RADIOACTIVE IODINE [SCAR]

PETITION FOR RULEMAKING

SUBMITTED PURSUANT TO 10 CFR 2.802 TO THE

U.S. NUCLEAR REGULATORY COMMISSION

American thyroid cancer patients and their loved ones deserve the best radiation protection in the world, but today have the worst. From Britain to Bangladesh, other countries have far stricter rules to protect children from the effects of radiation exposure, including cancer and mental retardation, than the United States. If Malaysia, South Africa, and Iran can protect their children adequately, so can the U.S. We, the undersigned, believe that it is medically and morally wrong that American children continue to be put at risk by sub-Third World radiation protection.

The responsibility for the gap between foreign and U.S. practice lies solely with the U.S. Nuclear Regulatory Commission, which in 1997 followed the advice of a scientific eccentric and deregulated medical treatments involving radioactive isotopes, with disastrous effects. By far the most dangerous medical isotope is radioactive iodine 131 (I-131), a standard treatment for thyroid cancer. Thyroid cancer patients, their families, and the public have been paying the price ever since for the NRC's grave error. Meanwhile the agency's leadership has turned a blind eye to the growing body of evidence that current protections are grossly inadequate.

Given by mouth, I-131 is eliminated from the body in bodily fluids and breath. Staggering amounts of radiation are involved. A single patient may give off more radiation than a nuclear power plant emits in a year. And yet today, that patient may be sitting next to you or your child on a bus or subway, without your knowing it. The patient, moreover, may be on the way home to a household with small children, because the treating hospital, under pressure from an insurance company, gave him or her no choice in the matter.

The NRC's two modest attempts to use voluntary guidance to doctors and hospitals as a substitute for amending the rule have been a failure. Because these non-binding suggestions collide with financial considerations, they are being ignored, something the NRC knows but is unwilling to admit. Instead it continues to push the idea that more and better non-binding guidance is the answer.

Under the NRC's pre-1997 rules, high doses of I-131 could only be given on an inpatient basis, which meant that insurance companies had no choice but to cover the cost of the inpatient care.

After the 1997 deregulation, insurers began refusing to pay for inpatient care, on the grounds that it was no longer mandatory. Providers, rather than deal with the possibility of not being reimbursed, began to send all their patients home, even when there were small children in the home who might be exposed to harmful amounts of radiation. In fairness to providers, the NRC deregulation had put them over a barrel, torn between what they knew was right for their patients and what insurers were willing to pay for.

The NRC made the 1997 rule change in reliance on a supposed expert, the late Dr. Myron Pollycove, who was, whether the agency knew it or not, a crusader for the doctrine of "hormesis" – the notion that radiation is good for you. On record as believing that I-131 could not cause cancer, Dr. Pollycove also co-authored an article arguing that if a major nuclear accident occurred, the health effects, if any, would be beneficial.

Hormesis, in the view of such mainstream authorities as the National Academies of Science, is utterly meritless. (The hormesis partisans, such as Dr. Edward Calabrese of the University of Massachusetts, would reply that the NAS is part of a 70-year worldwide conspiracy to conceal the benefits of radiation from the public.)

Before 1997, the NRC had taken the correct and mainstream position that the danger from I-131 patients to loved ones and the public was two-fold, coming both from **external exposure** – the result of being near a patient with the isotope in his or her body – and from **internal exposure**. Internal exposure results from inhaling, ingesting, or absorbing, through touch, the isotope that the patient is excreting.

In the 1997 rulemaking, however, the NRC flip-flopped, and declared, without explaining its reversal, that internal exposure was not a significant issue after all. It has clung to that position ever since, notwithstanding a wealth of information to the contrary from authoritative sources. For example, in 2002, the Centers for Disease Control wrote:

> "**Exposure to I-131, especially in childhood, increases the risk for hypothyroidism, thyroid nodules, and cancer. ... A child's thyroid dose from ingestion can be up to 20 times that of an adult because the same amount of energy is deposited in a smaller tissue mass. A child's thyroid dose from inhalation can be twice that of an adult, and is 15–20 times higher than the overall dose to the rest of the body.**"

The NRC does not have a single medical doctor on its payroll. It should either defer to the

superior knowledge of the Centers for Disease Control or plainly articulate why, on this medical issue, it claims to know better. Just as the CDC does not presume to offer judgments on nuclear power plant safety, the NRC should not presume to contradict the CDC on the health effects of I-131 on children.

Some of the evidence pointing most strongly to the inadequacy of the current rule comes from the NRC itself. **An NRC staff analysis from 2014 declared: "all exposure scenarios indicate that transportation scenarios pose a radiation concern for members of the public.**" In concrete terms, the analysis explained, a patient treated with 100 millicuries of I-131 – a typical dose, though far less than many patients receive – can, within just 42 minutes of boarding public transportation, deliver a radiation dose of 100 millirems to a person standing nearby. According to national and international authorities, 100 millirems (about one third of what we receive annually from background radiation) is the most that a person should be exposed to in a year from NRC-licensed activities. It represents about one third of what Americans receive annually from natural background radiation.

According to the NRC staff, between five and ten percent of the tens of thousands of thyroid cancer patients given I-131 treatments each year go to hotels and motels after treatment, either because they live far away from the provider or because they want to protect their loved ones from the radiation in their systems. Though the NRC has "strongly discouraged" providers from sending patients to hotels, it has not banned the practice, and has even stressed that this advisory is non-binding. The result is that hotel rooms are being contaminated, and that the hotel workers who clean the rooms and bathrooms and change the sheets are receiving doses of I-131 without their knowledge. If they are pregnant or nursing, the isotope is being passed on to their babies, both born and unborn.

In sum, the problems with the current patient release rule include the following:

(1) patient release is based upon calculated external dose, on the assumption that internal dose is unimportant, when in fact, according to the Centers for Disease Control and other national and international authorities, internal dose is critically important for children, who are far more at risk than adults are from the effects of radiation exposure;

(2) the NRC allows radiation doses to family members and the public that are five times what national and international standards call for;

(3) non-binding guidance has so far proved completely ineffective in correcting the

inadequacies in current protection, so that it is delusional to imagine that more and better non-binding guidance will make any difference;

(4) the rule has been interpreted to permit newly treated patients to go to hotels, where they contaminate the rooms they stay in and the linens they sleep on, to the point that the next person to occupy the room can have measurable radiation on the skin (this has in fact happened);

(5) the NRC has outsourced the protection of the public from providers, where it belongs, to the conscience of the individual patients, who may or may not be adequately informed, and even if informed, may or may not care what happens to the stranger whom they expose to radiation;

and, first and foremost,

(6) the rule allows insurance companies, who look primarily at the financial bottom line, to dictate whether patients and their families receive adequate radiation protection, to the anguish and frustration of both patients and providers.

For all these reasons, we say: enough is enough. Year after year, we have explained to the NRC the deficiencies in the current rule, but the result has always been the same: evasion, foot-dragging, and half-measures that in practice turn out to be non-measures. That Third World nations, with no money to spare for unnecessary medical treatment, should nevertheless protect their children so much better than we do, should be a cause for shame.

We are not contending that inpatient treatment is an absolute necessity in every case. Rather, we are saying that inpatient treatment, paid for by insurance, needs to be available in appropriate cases. That is not the case today, at least not in the United States. Inpatient care does not have to be in a hospital, with all the expensive bells and whistles of a hospital room. All that is needed is isolation.

The Patient Release Rule needs to be amended, for the sake not only of thyroid patients and their loved ones, but also of the public. That includes the pregnant passenger on the bus or subway who happens to be standing next to a radioactive I-131 patient, and the traveler who checks into a hotel room just vacated by a patient who has contaminated the room with I-131. It includes also the pregnant hotel worker, whose job it is to change the contaminated sheets and clean the contaminated sink and toilet.

There are different acceptable ways that these goals can be achieved. The NRC could reinstate an activity cap, perhaps at 10 or 15 millicuries of I-131. Alternatively, the NRC could reduce the current dose limit from 500 millirems to 100 millirems, as national and international authorities recommend. All of these options and more can be explored once a rulemaking has been initiated, but first the NRC needs, at long last, to face up to the fact that the current rule is deeply flawed, and that only an actual change in the rule can properly deal with its deficiencies.

We ask that this petition be acted on swiftly. If the NRC's answer is positive, let the process of amending the rule begin as soon as possible. If, on the other hand, the answer is negative, a prompt denial will allow us to place the matter before one of the United States Circuit Courts of Appeals without delay. This is a matter that deserves expedited handling, as it affects real people in the real world every day.

Respectfully submitted,

Sensible Controls on Administrations of Radioactive Iodine (SCAR)

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The following persons have either personally signed this petition, at the Thyroid Cancer Survivors Association annual conference in Denver, Colorado, in October 2019, or have indicated, through Facebook or by email, their wish to be added to the list of signatories. A list of signatories at the conference is attached; an asterisk designates someone who signed in person, at the Denver conference; a pound sign designates someone who communicated electronically.

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