May 22, 2020

Chairman Kristine L. Svinicki Commissioner Jeff Baran Commissioner Annie Caputo Commissioner David A. Wright Margaret Doane, Executive Director for Operations Marian Zobler, General Counsel Annette Vietti-Cook, Secretary

## Re: PRM-35-21(NRC) NRC-2020-0037-0004 (regulations.gov)

Dear Chairman Svinicki and Commissioners:

As the Commission knows, I filed a rulemaking petition in November 2019, with many co-signatories, on behalf of Sensible Controls on Administrations of Radioiodine (SCAR). It asked that the U.S. be brought back into conformity with international practice, which is normally to hospitalize patients given high doses of radioactive iodine 131 (I-131), because of the risk they pose to others, especially children. The petition related exclusively to I-131, the most dangerous of all medical isotopes. Among other things, the petition pointed to the fact that the NRC was in conflict with expert guidance from the Centers for Disease Control on the risks posed by inhaled and ingested radioactive iodine, and with standards of both national and international radiation protection bodies.

Several months later, the coronavirus crisis struck. A March 16, 2020, letter from me to the Commission, pasted in below, asked that all work on SCAR's petition be suspended for the time being. It explained that in view of the likely demand for hospital beds for COVID patients, this was no time to be altering the status quo with respect to the hospitalization of I-131 patients. Secondarily, I did not want NRC personnel taking risks by coming to work to deal with non-urgent matters. (I was unaware that the NRC had already instituted work from home.)

But evidently some glitch in transmission took place, because the NRC's Secretary informed me yesterday that her office had never before seen that letter. It can therefore be assumed that the NRC staff also did not have a chance to see and respond to it.

The changed circumstances that the March 16 letter cited as a reason to delay NRC action on the petition in fact call for SCAR to withdraw it, without prejudice to refiling it at a later date.

This approach, arguably a procedurally cleaner path to the same result, has ample support in law and Commission precedent. See, e.g., the Commission's order dated March 12, 2015, dealing with a petition from the Nuclear Energy Institute on Personnel Access Authorization Requirements for Nuclear Power Plants: "The U.S. Nuclear Regulatory Commission (NRC) is announcing the withdrawal, without prejudice to a future filing, of a petition for rulemaking (PRM), PRM-73-16, filed with the Commission by the Nuclear Energy Institute (NEI or the petitioner) on January 25, 2013." <u>https://www.nrc.gov/docs/ML1505/ML15050A037.pdf</u>

If SCAR's petition is later refiled, it will not be until the coronavirus pandemic is fully behind us, and its implications, if any, for the patient release issue are clear. This will also allow any necessary revisions to the petition to be made.

An NRC notice dated April 3, 2020, and sent to the rulemaking docket on April 13, 2020, said that because the agency already knew all it needed to on the subject matter, it was not accepting public comment on the petition. The point is now moot, given the withdrawal of the petition, but if and when it is refiled, we will expect normal notice and comment procedures to be followed.

This letter replaces a version sent to the NRC yesterday. I request that this letter be sent to the NRC docket, to ensure that it forms part of the administrative record.

Respectfully submitted,

/s/

Peter Crane, Counsel for Special Projects, USNRC (retired) Acting Secretary, SCAR (Sensible Controls on Administrations of Radioiodine)

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March 16, 2020

Dear Chairman Svinicki, Commissioners, Ms. Doane, Ms. Zobler, and Ms. Vietti-Cook:

Given the national health crisis that we are in, I would like to ask that all work on my petition for rulemaking on the patient release issue be put on temporary hold. In the first place, at a time when hospital capacity promises to be stretched to the breaking point, we need to preserve the status quo for the time being. I would much rather have the employees of the NRC, some of whom are personal friends, safely at home with their loved ones, in self-quarantine, than coming to their offices to work on anything of less than the most immediate urgency.

By the same token, I would like to ask for a freeze on the consideration of the work of the Advisory Committee on the Medical Uses of Isotopes on the patient release issue. Basically, the ACMUI and NMSS management appear as adamant as always that they know more about the health risks of internal doses of iodine 131 ("small or negligible" says the most recent draft ACMUI subcommittee report, dated February 24, 2020) than the Centers for Disease Control, which said this in 2002:

"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."

Is this the moment in our national history for an agency without a single medical doctor on its staff to go on record declaring that it knows better than the CDC on an issue of public health? There are also serious procedural questions as to whether the ACMUI has afforded adequate notice of its activities on this issue, but they too can wait for another time.

I wish good health to all, and to their loved ones, and hope to hear soon that the NRC has decided to keep as many employees as possible at home, for their own and others' safety.

Respectfully submitted,

Peter Crane, NRC Counsel for Special Projects (retired)

## **McCloskey**, Bridin

From:	Peter Crane <peter46crane@gmail.com></peter46crane@gmail.com>
Sent:	Thursday, May 21, 2020 4:24 PM
То:	Vietti-Cook, Annette
Subject:	[External_Sender] Withdrawal of petition for rulemaking without prejudice to later refiling
Attachments:	2020.May 21SCARwithdrawal.pdf

## Hi Annette --

Could you kindly see that the attached letter gets to the addressees, and to the docket file? I had hoped that the NRC staff would temporarily suspend work on the SCAR petition, as I had requested, but since it has declined to do so, I am withdrawing the petition, without prejudice to possibly refiling it at a later date, once the pandemic is behind us.

Hope all is well with you and both your home and office families. Take care.

-- Peter