
No. 08-72973

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

PETER G. CRANE,

Petitioner,

v.

UNITED STATES NUCLEAR REGULATORY COMMISSION and
THE UNITED STATES OF AMERICA,

Respondents.

On Petition for Review of the Denial of Petition for Rulemaking by the
United States Nuclear Regulatory Commission

REPLY BRIEF FOR PETITIONER PETER G. CRANE

Mark E. Chopko
Stradley Ronon Stevens & Young LLP
1250 Connecticut Avenue, NW – Suite 500
Washington, D.C. 20036
(202) 419-8410
mchopko@stradley.com

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Preliminary Statement

Radioactive iodine (I-131) is essential in the treatment of thyroid cancer, but it can *cause* thyroid cancer and other thyroid disorders, especially in children, both from "external dose," the radiation dose caused by mere proximity to a radioactive patient, and "internal dose," when radioactive contamination is passed from the patient to another person by close contact. Before 1997, a period of isolation was required for a high dose I-131 treatment, typically a night or two in a hospital until the radiation activity inside patients had subsided so that it was presumed safe to discharge them into the general public. In 1997, the Nuclear Regulatory Commission (NRC) amended its long-standing rules to authorize the immediate discharge of patients based on a doctor's finding that the potential radiation dose to other persons – caregivers, for example – would not exceed 500 millirem. This was a radical break with the past. Following the 1997 rule, medical providers began routine discharge of treated patients¹ and health insurers began to exclude

¹ A recent survey conducted by *USA Today* discusses the real world impact of the 1997 rule change. There, Dr. Paul Ladenson, a nationally known thyroid cancer specialist, told the newspaper that where formerly he hospitalized two patients a week for I-131 treatment, he now hospitalized just two a year. See "It Kills Thyroid Cancer, but is Radiation Safe?" http://www.usatoday.com/news/health/2007-11-18-thyroid-cover_N.htm. See the comment of the Endocrine Management Center of Richmond, VA, which described itself as an "exclusively-outpatient nuclear facility." RER073.

costs of isolation.² Despite NRC assurances, concerns about the potential safety and health impacts on patients and their families persist.

In 2005, petitioner, a thyroid cancer patient, filed a request that NRC reconsider its 1997 rule. Petitioner pointed to serious adverse effects on patients, their families, and the public – effects not experienced prior to the 1997 rule. Patients affected by the rule change put family, friends, and an unwitting public at risk of exposure from their radiation. He noted evidence that some patients were being directed or encouraged to go to hotels when radioactive, a practice raising multiple health and safety issues. He also stressed the conflict between the permissive NRC rules and the far more conservative International Basic Safety Standards (BSS) issued by the Atomic Energy Agency (IAEA).

NRC's denial of the petition in May, 2008 mentioned neither patients in hotels nor the BSS. NRC did mention a 2004 monograph by the International Commission on Radiation Protection (ICRP 94), a publication not previously acknowledged by NRC and unknown to petitioner in 2005, but which was identified during the comment process on his petition. The denial acknowledges that ICRP 94, reflecting international safety standards, recommends doses to

² This point is noted in the record (see ER065, "I wasn't allowed to stay in the hospital – they don't cover inpatient RAI [radioactive iodine] treatments at 150mci [millicuries])," and is a constant theme on the internet listserv on which thyroid cancer patients exchange information about their experiences.

children of I-131 patients be kept to below 100 millirem, one fifth of the general NRC allowance for doses from nuclear medicine patients. In parallel to the denial, NRC provided additional regulatory "guidance" to licensees but refused to amend the rule or even discuss that this recent scientific information contradicts the assumptions underlying its rules.

Petitioner's request that this Court review the inadequacy of the denial of his rulemaking petition is met by NRC's skepticism about his standing and the timeliness of his requested relief. Its merits arguments essentially are that all comments by medical professionals are against the petitioner, and that deference to NRC's asserted expertise should carry the day. On their face these appear weighty arguments but do not withstand close examination. This reply brief establishes petitioner's standing for his timely challenge and responds to the NRC's key assertions on the merits.

Argument

I. Petitioner has standing to seek this relief.

Certainly, petitioner meets both Article III's case-or-controversy requirement, as well as non-constitutional or prudential standing requirements. *Nuclear Information and Resource Service, et al. [NIRS] v. NRC*, 457 F.3d 941, 949 (9th Cir. 2006); *Ashley Creek Phosphate Co., v. Norton*, 420 F.3d 934, 938 (9th Cir. 2005). Petitioner may establish standing at any point in the litigation, including through this reply brief. *NIRS*, 457 F.3d at 950-51. For Article III standing, petitioner must show a concrete injury that is fairly traceable to the agency action under review and can be remedied through this litigation. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 573 n.8 (1992). The non-constitutional or prudential standing requirement may be summarized as whether petitioner “has been granted a right to sue by the statute under which he ... brings suit.” *NIRS*, 457 F.3d at 950, quoting *City of Sausalito v. O’Neill*, 386 F.3d 1186, 1199 (9th Cir. 2004). NRC notes that the petitioner meets the agency participation requirement³ and *only* challenges whether he satisfies the constitutional Article III standing requirements. NRC Brief at 18. He does.

³ Lest there be any doubt, Petitioner timely challenges final agency action denying *his* petition for rulemaking. The petition for rulemaking is permitted under the Administrative Procedure Act (5 U.S.C. §553(e)) and NRC rules (10 CFR §2.802). Final agency action is subject to judicial review (5 U.S.C. §702) in this Court (28 U.S.C. §§2342(4), 2344 and 42 U.S.C. §2239).

Petitioner *is* a thyroid cancer patient now in remission. Whether that remission is permanent or temporary cannot be known at this time; like others with papillary thyroid cancer, he will require regular monitoring for the rest of his life to look for recurrences.⁴ He has already had one such recurrence, which required treatment with I-131, and in the event of another, it is reasonable to expect additional I-131 treatments. See ER138. He thus has a direct and personal stake in the rules he seeks to have reconsidered. Based on self-interest and the concern that he has for his family, friends, and others around him,⁵ he petitioned NRC to reconsider its 1997 rule, in light of actual experience implementing the rule. He

⁴ Thyroid cancer, unlike some other forms of cancer, can recur decades after its last appearance. See, e.g., “Long-term Follow-up of Thyroid Cancer,” Weill Cornell Medical College: “Papillary thyroid cancer will recur or persist in about 25% of patients.... In papillary thyroid cancer ... recurrence can occur up to 45 years after surgery.... All patients with a history of well-differentiated thyroid cancer should have yearly cervical ultrasound scanning, thyroglobulin and thyroglobulin antibodies. ... Accurate surveillance for possible recurrence and treatment in patients thought to be free of disease is a major goal of long-term follow-up.”
<http://www.cornellsurgery.org/pro/services/endocrine/thyroid-follow-up.html>.

⁵ He has a depth of experience and longstanding concern for the health and safety of himself, his family, and others who are similarly situated. His contributions to the field of radiation protection and thyroid-related public health have been recognized by the international community, which has brought him to Moscow and to Cambridge, England, as a speaker; by the American Thyroid Association, which has welcomed him as a speaker and carries an article of his on its website; and by NRC itself, which in early 2001, granted his only previous rulemaking petition, with the result that nationwide protection against radiation-caused thyroid cancer, resulting from acts of terrorism or nuclear accidents, was substantially upgraded.

has a well-founded anxiety about the inadequacy of the current radiation regulatory scheme to protect him and his family from harm in the event that he requires further I-131 treatment.⁶

In the foreseeable event that he requires further I-131 treatment, he will face dilemmas that may entail harm to the safety of his family and the public, and will almost certainly involve economic harm to him. Petitioner will face the stress that comes from knowing that one may be a hazard to family members and the public: deciding how to get home without endangering the person providing transportation (since patients are hypothyroid, and cannot safely drive themselves); facing the problem of nausea and vomiting, if away from a hospital with personnel equipped to deal with radioactive patients; and so forth.

Or, he can try to find a facility that still offers inpatient care, but shoulder the full cost of hospitalization himself. If he accepts the outpatient treatment that has now become standard practice, he would disregard a suggestion he go to a hotel, but would send his family to protect them from radiation -- again, at his

⁶ NRC essentially urges standing to pursue this case be limited to a petitioner scheduled for or receiving I-131 radiation treatment now. Given the length of years it takes NRC to review and respond to petitions, given the length of time for agency action, any such person would probably have completed treatment and therefore lack standing. See "Nuclear agency responds to Vermont group's petition on radiation dangers 32 years late," *International Herald Tribune*, April 1, 2008, describing NRC's rejection of a petition filed in 1975. The article quoted the NRC spokesman as quipping, "No petition before its time."

expense.⁷ Although NRC dismisses these concerns as speculative because it does not license insurance companies, no one can responsibly dispute the cause-and-effect behavior of insurance companies reacting to changes in practice from the 1997 rule. What medical practitioners may no longer require as a matter of routine protection for patient and public was quickly translated into an insurance exclusion, passing the expense of radiological isolation to worried patients. The rule change has effects on the actual delivery of health care, and thus on the health of petitioner and his family and friends.

Plainly petitioner has the requisite stake in the outcome. The theme of petitioner's case is that NRC failed in its obligation to explain its reasons for denying his petition for rulemaking directed at the inadequacy of NRC's 1997 rule as it has been implemented. Petitioner alleges that NRC's adamant refusal to revisit the 1997 rule ignores evidence of a serious regulatory gap, and ignores internationally-accepted scientific positions that cast into doubt the public-protection assumptions on which the 1997 rule is based, thus subjecting him and other members of the public to risk. These claims are important, because standing analysis must reflect what this case is about. Petitioner's interests relate to basic

⁷ To add to his expense, if his home radioactive trash sets off radiation monitors at the local landfill, he may have to pay for the search for the source of the contamination, RER42, and for decontamination of the facility, as described in ICRP Publication 94, ER120.

issues about how he and his family are protected under NRC's rules, and the specific claims pursued in this petition for review relate to the inadequacy of the agency's explanation of its denial of rulemaking.⁸

Finally, petitioner satisfies the other Article III factors. Traceability and redressibility are not measured by what patients might do (NRC Brief at 21), but against the procedural nature of the instant case. The law in this Circuit does not require him to show with certainty that the NRC will adopt his (or any) particular position before Article III standing is established. *Natural Resources Defense Council v. EPA*, 542 F.3d 1235, 1246 & n. 6 (9th Cir. 2008). As this Court has specifically stated:

The Supreme Court has noted that suits to force an agency to engage in a procedure do not require the same certainty that the result of that procedure will have the desired effect. *See Massachusetts v. EPA*, 549 U.S. 497, 127 S.Ct. 1438, 1453 ... (2007) (*citing Lujan*, 504 U.S. at 572 n.7). A party can therefore enforce a procedural right "so long as the procedures in question are designed to protect some threatened concrete interest" *Lujan*, 504 U.S. at 573 n.8; *see also Massachusetts v. EPA*, 127 S.Ct. at 1453 (stating that a litigant vested with a procedural right "has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision"....).

⁸ Petitioner has a right under the Administrative Procedure Act to file a rulemaking petition and to a proper agency response. The scope of a procedural injury is currently at issue in the Supreme Court. *Earth Island Inst. v. Ruthenbeck*, 490 F.3d 687 (9th Cir. 2007), *cert. granted*, 128 S. Ct. 1118 (U.S. Jan 18, 2008) (No. 07-463) (sub judice).

NRDC, 542 F.3d at 1246 n. 6. *Accord. C. & S. W. Serv., Inc. v. EPA*, 220 F.3d 683, 698-99 (5th Cir. 2000) (noting the requirements in a procedural case are “somewhat more lenient” once a petitioner has established a concrete injury).

Petitioner argues only for a fair appraisal of the existing rules in light of evidence that, as implemented, they have had serious and very different public safety impacts from what NRC envisioned at promulgation in 1997. A remand directing the agency to reconsider its administrative action would give him the relief he is entitled to by law, and links the asserted injuries to the sought-after relief.

Petitioner has standing to challenge the denial of his petition for rulemaking raising these issues.

II. The petition is timely.

NRC asserts that petitioner's real grudge is with the 1997 rule. Petitioner participated as a commenter in that rulemaking and, the agency asserts, there is nothing new in what he says. Thus, NRC says, he should have challenged the rule then and not waited eleven years. What the agency accuses him of, in essence, is seeking through some procedural legerdemain to obtain a benefit to which is not entitled. This argument does not withstand even passing consideration.

There is a world of difference between challenging an agency's rule prospectively, based on an apprehension of the harm it seems likely to cause, and

seeking reconsideration of that rule, retrospectively based on the harm it has actually caused. The fact that there is some overlap between the problems predicted with the 1997 rule and the harm that is occurring today does not mean that there is a complete identity of issues. Petitioner was explicit that his concern was with the rule's effects in practice: "patients are *not* getting appropriate care, and their family members and the general public are *not* being adequately protected." ER096.

Moreover, some of the adverse effects that the 1997 rule has had were completely unforeseen, such as the reality that radioactive patients would neither be hospitalized nor sent home, but would instead be directed or encouraged to check into hotels. Rather than commence litigation in 1997 (if indeed he could),⁹ petitioner waited for relevant experience to come to his attention before filing his petition.¹⁰ And, in the process of this rulemaking petition, petitioner (and the

⁹ Had petitioner filed for pre-enforcement review of the 1997 rule, not as one of the petitioners but simply as a commenter, his petition might well have been attacked on the grounds that hypothesized health effects of the rule change were speculative and that it would be prudent to wait for actual experience under the rule. *See Lujan v. National Wildlife Federation*, 497 U.S. 871, 891 (1990) (regulation ordinarily not ripe until facts develop sharpening the controversy).

¹⁰ As noted in petitioner's opening brief (at 20-22), NRC would not have been alerted to problems under the rule. The Commission had denied a staff request to require licensee reports of any patient difficulties. In its brief, NRC claims enforcement through regular inspection of its licensees. But one searches in vain NRC's description of its enforcement process (see RER 123-124) for any evidence *how* a possible over-exposure in a patient's family or contamination of

public) became aware of ICRP 94, which NRC had before it since 2004, and which undercuts the justification for the 1997 rules.

Petitioner's rulemaking request, based on new data, was prudent and timely. *Accord. Natural Resources Defense Council v. NRC*, 666 F.2d 595, 602 and n. 49 (D.C. Cir. 1981). The instant rulemaking petition was not an attempt to evade the consequences of the passage of time. Rather, it was an attempt to bring to NRC the experiences of real patients and the scientific community over the intervening time since the promulgation of the 1997 rule. NRC's arguments to the contrary are meritless.

III. NRC fails to explain credible evidence that its 1997 rule has created unexpected risks to patients, family members, and the public.

The petition for rulemaking highlighted ways in which the 1997 rule, as applied in practice, has resulted in real or potential harm, health-related and/or economic, to patients, their loved ones, and the public. The petitioner cited the accounts of patients and also of professionals with experience in dealing with I-131 patients discharged after receiving high doses of I-131; *see, e.g.*, ER077-78. The petitioner's concerns were amply supported by the 14 thyroid cancer patients, all of

a member of the public would come to the licensee's, much less the agency's, attention. One goal of a thorough rulemaking would be to allow members of the public to discuss their own experiences and concerns, not just through surveys. Note 1, *supra*.

whom had experience with I-131, who filed comments. See Petitioner's brief at 40. Some of those patients were describing not only their own experiences, but those of a multitude of other patients. See, e.g., ER061. NRC's refusal to give these views balanced treatment is a central element of petitioner's argument that the denial of rulemaking was arbitrary and capricious.

NRC's response in this Court repeats that the petitioner failed to show an adequate technical basis for his claims, and it simply refuses to credit patients' own experiences. NRC's argument boils down to one assertion – the doctors and their associations are against petitioner's proposal even if a few patients are for it. In a real sense, NRC asserts, the comments of the doctors on the experiences, needs, wishes, and interests of patients are more probative than comments from the patients themselves. NRC Brief at 30-6. An apt illustration of this bias is that a doctor's personal experience as a cancer survivor is credited (NRC Brief at 33), while patients' experiences are dismissed as anecdotes (*id.* at 30). NRC continues to avoid treatment of contrary experience, which allows it to obscure evidence that demonstrates a gap in its regulatory program, which it does not explain in the denial or in this Court.

NRC had an obligation, which it entirely failed to meet, to address the issues raised and the comments received. As amplified in those comments, the main points raised by petitioner – the risks from internal contamination of those who

come in contact with treated patients (and their nausea, vomiting, and other reactions to treatment), the risks to hotel guests and workers from those who choose (at their own expense) to isolate themselves from family and friends, and other issues – did not receive a response by NRC, except to say in effect that the reports of petitioner are (at best) overblown.

The issue of patients sent or encouraged to go to hotels deserves special mention, for several reasons. First, it illustrates a lacuna in the 1997 rule, which assumed a binary choice: either hospitalization, or isolation in the home. Cf. ER038, ER041. No one took account of the possibility that doctors, faced with patients who might be a danger to others in the home, would recommend a third option, going to a hotel. Second, in these cases at least, a meaningful individualized calculation as contemplated in NRC rules cannot occur. There is no way for a doctor to know how close the patient will be to others (such as guests in adjoining rooms or hotel staff) and for how long. Third, it points to the economic burden that the rule, which has prompted insurance companies to deny coverage to patients for hospitalization, has thrown on patients who need to protect their families from their own radioactivity. Fourth, this possible pathway to exposure – both from proximity and contamination – was not contemplated in 1997. It exposes the gross error NRC made in 1997 when it declared that contamination by

patients' bodily fluids was a non-issue, and that patient release could be decided based solely on external dose, from proximity to others.

NRC's response in the denial of the petition is silence. NRC's denial never mentioned the issue of patients in hotels, although this point had been raised by the petitioner in three separate filings (ER072, ER053, ER052) and by a number of commenters. Rather than acknowledge this omission, or address the issues raised, NRC's brief directs its fire against the petitioner, suggesting that he first confabulated the concern about hotel exposures and then "recanted." NRC Brief at 39. Neither is true, as reference to the documents in question – ER053 and ER052 – makes apparent at a glance. Petitioner's brief at 40 listed the numerous patient commenters who discussed patients sent to hotels.

As noted above, the "hotel issue" implicates the issue of the kind of analysis that providers must perform before a patient can be approved for release from outpatient treatment. The regulatory guidance on patient release envisioned only one destination for a released patient: a home situation. It lays out elaborate calculations by which the external radiation exposure to persons in the home can be estimated, to the millirem (but, as noted above, considers internal exposure from contamination relatively unimportant). ER023, ER034. The Statement of Considerations that accompanied the 1997 rule also made clear that such an individualized calculation of the dose that others will actually receive was a

prerequisite to releasing patients. ER039. But one can search NRC's denial of the petition, and the Regulatory Issue Summary, and its brief in this case, without finding a clear declaration of what the rule – as currently interpreted by NRC – actually requires.

Nothing would have been easier than for NRC to say – anywhere – whether such calculations are required in all circumstances. It did not say so.¹¹ In its brief, NRC is careful to cite only what the medical commenters said; it does not tell this Court how NRC itself interprets the rule's requirements. Thus the NRC brief (at 40) includes a reference to “patient-specific calculations upon which patient release may be authorized,” but this is a quotation from a commenter, and as such, does not necessarily represent NRC's own views. A review of the comments filed by members of the medical community indicates that some practitioners and facilities perform patient-specific calculations to determine the likely radiation dose to those in the home, see e.g. RER7, RER20, RER64, but others make no such claim, e.g. RER28, RER34. There is at least a suggestion in the latter submissions that these licensees have instead made a blanket determination that it is sufficient to provide released patients with cautionary guidance on release, on

¹¹ Nor was the issue addressed in either NRC's denial of the petition or the Regulatory Issue Summary (RIS). It might seem self-evident that NRC, sending an advisory about I-131 patients to all its medical licensees, would want to use the occasion to remind them of their legal responsibilities, but NRC elected not to, opting instead for vagueness.

the theory that conformity with these guidelines will insure that no one is placed at risk. Leaving aside whether such a conclusion is sound, it is not what the NRC directed in its 1997 rule, and it exacerbates the regulatory gap created by those encouraged to isolate themselves in hotels. All of this should and would have been evaluated in a rulemaking. The failure to account for this crucial information bearing on public safety under the 1997 rule warrants remand of the NRC's denial.

IV. In refusing to revisit the 1997 rule, NRC refuses to account for its contravention of two separate international radiation protection guidelines.

Central to the merits of this case is the irrefutable fact that NRC's approach to patient release contradicts the separate recommendations of two authoritative international bodies, the IAEA and the ICRP:

1. The IAEA's Basic Safety Standards include a 30 millicurie activity standard for the hospitalization of I-131 patients – a limit which NRC's rule rejects.
2. The ICRP, which employs a dose-based standard rather than an activity standard, now believes that in light of information from Chernobyl about the cancer risk to children from I-131 exposure, the dose limit to children exposed to radiation from treated patients should be reduced from 500 millirems to 100 millirems – a recommendation which NRC's denial rejects.

The two international organizations' complementary approaches to radiation protection render NRC's refusal to reconsider its contrary rules arbitrary and

capricious.¹² NRC's response is that petitioner failed properly to raise the issue of conformity with international standards; that NRC nevertheless "considered" the IAEA's Basic Safety Standards (though it does not dispute that it never mentioned them in its denial of the petition); and that "ICRP recommends precisely what the NRC has done," NRC brief at 54. These contentions are wholly without merit.

A. Petitioner properly raised the issue of NRC compliance with the International Basic Safety Standards (BSS).

NRC's brief declares: "Petitioner's passing referral [*sic*] to the BSS [Basic Safety Standards] in his petition and comments (ER73,90) is scarcely sufficient to compel NRC's addressing the point he now vigorously advances." NRC Brief at 37. For this proposition, it cites *Vermont Yankee Nuclear Power Corp. v. NRDC, Inc.*, 435 U.S. 519, 554 (1978), and *Reyblatt v. NRC*, 105 F.3d 715, 722 (D.C. Cir. 1997). In reality, petitioner brought this issue to NRC's attention four times in all, once with considerable specificity. He did so as an urgent plea that NRC face an issue of seemingly self-evident significance: the conflict between U.S. radiation protection standards and international health and safety standards. NRC did not

¹² As the NRC recognizes in its brief, at p. 38, the Basic Safety Standards of the IAEA are derived from ICRP Recommendations. The current BSS, issued in 1996, were based on ICRP Recommendations published in 1990. ER051. The fact that the ICRP Recommendations have since changed, and now urge greater conservatism to protect children from I-131 contamination by released patients, coupled with the fact that European countries now regard the 30 millicurie standard of the BSS as insufficiently protective, strongly suggests that the BSS will again be tightened. See ER124-25.

mention, much less discuss, the Basic Safety Standards until it filed its brief in this case, and now blames this on the petitioner.

Petitioner's initial petition, asking for a return to the 30 millicurie standard, stated that it was consistent with the BSS, and observed that the NRC had not acknowledged that fact when it eliminated the 30 millicurie standard. ER090. This, to be sure, was brief. However, in his 18-page filing of January 30, 2006, ER070, which NRC said that it considered along with the original petition, ER001, petitioner dealt at length with the question of whether the 30 millicurie standard was arbitrary. He discussed the International Basic Safety Standards by name in two successive paragraphs, ER073, pointing out that the 30 millicurie standard continued to be part of the BSS, which the U.S. Government supports, and noting that he had raised the issue even before the 1997 rule was issued.¹³ Surely petitioner's statement that he had been "surprised and disappointed that the NRC did not even discuss these long-established international standards, and the NRC's reasons for disregarding them," ER073, gave ample notice to the NRC that he

¹³ This was a reference to a letter of February 23, 1995, to NRC Chairman Selin, with a copy to the docket file, item #67 in the Revised Certified Index of Record. Petitioner's fourth and final effort to induce the NRC to focus on the conflict between its regulation and the Basic Safety Standards came on April 21, 2008, in a letter to Chairman John Dingell of the House Committee on Energy and Commerce, with a copy to NRC Chairman Dale Klein, sent by certified mail.

regarded not only the Basic Safety Standards, but also the agency's failure to discuss them, as important.

All this was hardly the kind of "cryptic and obscure reference," coupled with a refusal to clarify contentions, that was faulted by the Supreme Court in *Vermont Yankee*. 435 U.S. 519, 554. Nor is the reference to *Reytblatt*, in which an individual engaged in the "substitution of invective for a reasoned explanation" of his views, in any way apposite. If anything, there is a reversal of roles between the petitioner and the agency in that in *Vermont Yankee*, NRC "continually invited clarification" of the petitioner's position, while the petitioner "not only ... decline[d] to further focus its contentions, it virtually declined to participate...." *Id.* Here it was the petitioner who "continually invited clarification" of the agency's position on the Basic Safety Standards, and the agency which declined to discuss it. When an issue *has* been "forcefully presented" – repeatedly, in good faith, with ample detail and explanation, and at all times with civility – then for an agency to assert the opposite, in order to justify its evasion of the issue, is surely no more acceptable than the conduct criticized in *Vermont Yankee*.

B. NRC cannot reasonably claim to have "considered" the Basic Safety Standards when it never mentioned them.

NRC's claim that it "did in fact consider the BSS," notwithstanding that it never mentioned the BSS in the denial, can be disposed of briefly. NRC reasons that the BSS follow the Recommendations of the ICRP; that NRC also considered

ICRP Recommendations; and therefore, “By considering the ICRP’s Recommendations, NRC did in fact consider the BSS as well.” (NRC Brief at 38.)

The argument fails on both legal and logical grounds. An appellate court’s “review of an administrative agency’s decision begins and ends with the reasoning that the agency relied upon in making that decision.” *Safe Air for Everyone v. EPA*, 475 F.3d 1096, 1099 (9th Cir. 2007) (cited cases omitted). Such reliance must be articulated by the agency in its decision, *id.* at 1118, and cannot be established after the fact by the representations of appellate counsel. NRC’s brief is engaging in precisely the kind of post-hoc rationalization consistently deprecated by this and other Courts. *Safe Air for Everyone* at 1115, *citing Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 212 (1988). Even if this were not a barrier to this Court’s acceptance of the NRC’s argument, simple common sense would compel its rejection. The fallacy in NRC’s logic – that if both A and B proceed from a common source, then A has “considered” B even if it does not mention it – is too obvious to require extended discussion.

In *Bowen*, the Supreme Court, after reiterating the principle that judicial review of an agency’s decision must be based on the reasoning articulated in the decision itself, commented: “Even if we were to sanction departure from this principle in some cases, we would not do so here,” where the agency’s position, as presented in court, was “[f]ar from being a reasoned and consistent view.” 488

U.S. at 212. The Court continued: “Deference to what appears to be nothing more than an agency’s convenient litigating position would be entirely inappropriate.”

Id. at 213. The same could be said here.

C. NRC’s claim that “ICRP recommends precisely what NRC has done” is frivolous.

In a variety of ways, ICRP Publication 94 undermines the regulatory assumptions on which the 1997 rule was based. Publication 94 makes clear that there is a difference between adults and children in the pathway by which they are at risk from I-131 patients: for adults, the greatest risk is from external exposure, while for children, the greatest risk is from contamination, resulting in internal exposure. ER114. NRC’s brief seems not to dispute the well-recognized fact that children are more at risk from released I-131 patients than are adults.¹⁴

NRC asserts, in footnote 14 on page 48 of its brief:

Petitioner says that the current rule is based on the assumption that external dose is “what mattered” and internal dose “could be ignored” (Pet.Br.54) and that NRC’s RIS concedes the flaws in this approach. (*Id.* at 55.) This is flatly wrong.

¹⁴ “Radiation Exposure from Iodine 131,” a website created by the Agency for Toxic Substances and Disease Registry of the Department of Health and Human Services, declares, “Children are the most sensitive group for exposure to I-131,” and explains: “For an equivalent uptake of I-131, a child’s thyroid receives a higher radiation dose because the same amount of energy is deposited in a smaller tissue mass.... [F]or the same ingested radioactivity, ... the absorbed dose is about 8 times higher for children under 1 year old and 4 times higher for children 5 years old.”
http://www.atsdr.cdc.gov/csem/iodine/whosat_risk.html, p. 11.

Flatly wrong? The current rule was and is grounded in a 1997 Regulatory Analysis which declared that “internal exposures will not be considered in this analysis other than for the breast-feeding infant,” ER34, whereas NRC’s Regulatory Issue Summary (RIS) of 2008 candidly states:

NRC’s current patient release criteria were based, in part, on the assumption that internal doses to an individual from a patient released after therapeutic administration of a radionuclide, such as oral sodium iodide I-131, was small compared with doses from external exposures. However, in 2004, ... ICRP Publication 94 ... cautioned that the internal dose to the thyroid for infants and young children who may come in contact with a patient who was administered therapeutic quantities of I-131, such as oral sodium iodide I-131, has the potential to be far greater than the dose of external exposure.” ER010.

Surely the message of the RIS was this: “In 1997, we underestimated the risks from internal exposure, and we are trying to compensate with this new guidance, intended to reduce the likelihood that children will receive internal exposures from contamination.” NRC might with reason have claimed credit for frankness in conceding, in the RIS, the shortcomings of the 1997 approach.¹⁵ But instead NRC’s brief argues, notwithstanding the plain language of the RIS, that no such concession was made.

¹⁵ As late as January 2008, rather than rely on the 2004 ICRP 94 monograph, NRC guidance, relying on studies from 1995 and 1997, was still advising licensees that internal dose was “relatively unimportant.” ER023-024.

NRC says that the petitioner “suggests unrealistic scenarios,¹⁶ including his claim that ‘[j]ust one kiss’ from an I-131-treated patient ‘can double’ a child’s risk of cancer.” NRC Brief at 53. But petitioner did not invent this scenario, nor proffer it as his own opinion; he simply described what ICRP Publication 94 reported, at ER118. Petitioner’s Brief at 49-50.

NRC’s brief also stresses, at 53, that the ICRP’s recommendation of a lowered dose limit for children was based on the assumption of parents’ failure to follow radiation protection instructions. But the same paragraph of ICRP Publication 94 that included the words “the natural risk would be doubled” (referring to the risk of thyroid cancer in a child kissed by a radioactive patient who failed to follow precautions) also said that one study, which measured actual levels of iodine in the children of treated patients, found that “some parents did not receive, understand, or follow the precautions.” ER119.

¹⁶ NRC heatedly asserts that petitioner “asks for judicial relief on grounds nowhere mentioned in his rulemaking petition,” namely, “whether NRC has shown appropriate regard for the ICRP *dose-based* constraint of 0.1 rem for children and infants.” NRC brief at 50. The implication is that petitioner has made a new and different request, which is for NRC to adopt the 0.1 rem (100 millirem) dose standard for children that Publication 94 recommended. Petitioner has done nothing of the kind. His point, rather, was that NRC is in a poor position to claim that its RIS, which drew attention to ICRP Publication 94 more than four years after its publication, constituted a wholly adequate response to the safety issues described in that document, given that NRC rejected the ICRP’s recommended solution. Petitioner’s brief, at 56-57, should have left no room for doubt on that score.

The NRC brief attempts to parlay the fact that the ICRP's standards are dose-based (not activity-based, like the Basic Safety Standards of the IAEA) into a claim that the ICRP "recommends precisely what the NRC has done," and "has not advocated 30 mCi [millicuries] or any other activity-based standard." NRC Brief at 54. To say this is to distort the ICRP's position. The ICRP itself has noted, in discreetly phrased language, what it clearly views as misinterpretations of its position. In ICRP Publication 104, "Scope of Radiological Protection Control Measures," Annals of the ICRP Volume 37 Issue 5, the ICRP wrote (at p. 58):

It seems that *Publication 94* has lent credence to the idea that this is a properly regulated area, and that the practical consequences of discharge have been shown to be minimal over many years of study (Bradley, 2006) on the basis of assessment of doses to members of the public and carers following release of a patient. ... As a result of these interpretations of the Commission's intentions, it seems that, in some countries, patients following treatment are released with a very short or non-existent hospital stay. At 58.

Despite all attempts to complicate the issue, it remains in essence quite straightforward. Petitioner asked NRC to address the dichotomy between its standards and the Basic Safety Standards; NRC declined to discuss them. Those Basic Safety Standards, like the NRC rules abolished in 1997, reflected the reality that radiation exposure to family members and the public from a high-dose I-131 patient can come both through external dose and through contamination, and saw a period of radiological isolation as necessary to protect family members and the public. The 30 millicurie activity criterion of the BSS, the cutoff for determining

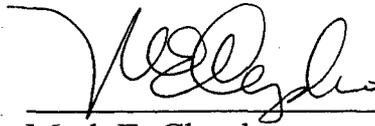
when hospitalization was essential, was geared to ICRP recommendations that said that radiation dose to family members of patients should be kept at 500 millirems or below.

The NRC, in abolishing its 30 millicurie limit in 1997, was ostensibly opting for a different method of achieving the same goal, *i.e.*, ensuring that no one's exposure exceeded 500 millirems. Since 1997, however, two inescapable problems with this approach have revealed themselves. The first is that the NRC's approach involved discounting the role played by internal dose from contamination, and by 2004, if not sooner, NRC knew that in the eyes of the international community, internal dose to children, creating a risk of thyroid cancer, was the central safety issue with respect to released patients. The second problem was that the international community was also moving away from the 500 millirem standard, as applied to children. Today, NRC wants to claim credit for having notified its licensees, in 2008, of the ICRP's warnings, in 2004 and again in 2007, about the danger to children, at the same time that it rejects the ICRP's recommendation of a tighter dose standard for children. It simply cannot have it both ways.

Conclusion

For the foregoing reasons, the NRC decision not to institute rulemaking should be vacated, and the case remanded to the agency for the full and fair examination that it signally failed to make.

Respectfully submitted,



Mark E. Chopko
Stradley Ronon Stevens & Young, LLP
1250 Connecticut Avenue, N.W.
Suite 500
Washington, D.C. 20036
Telephone (202) 419-8410
Fax (202) 822-0140
mchopko@stradley.com

CERTIFICATE OF COMPLIANCE

I certify that, pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C) and Ninth Circuit Rule 32-1, the attached Reply Brief is proportionately spaced, has a typeface of 14 points, contains 6,502 words as calculated by my word processing software (Word).



Mark E. Chopko, Esq.

December 5, 2008

CERTIFICATE OF SERVICE

On December 6, 2008, two copies of the foregoing Reply Brief were mailed, postage pre-paid, to the following counsel for Respondents:

John Cordes, Solicitor
Robert Rader, Senior Attorney
Office of the General Counsel
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

Charles R. Scott, Attorney
Environment & Natural Resources
U.S. Department of Justice
P.O. Box 23795
Washington, D.C. 20026-3795



Mark E. Chopko, Esq.