
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**

BRIEF FOR RESPONDENTS

RONALD J. TENPAS
Assistant Attorney General

CHARLES R. SCOTT
Trial Attorney
United States Department of Justice
Environment & Natural Resources
Division
P.O. Box 23795,
L'Enfant Plaza Station
Washington, D.C. 20026-3795
(202) 514-4786

KAREN D. CYR
General Counsel

JOHN F. CORDES, JR.
Solicitor

ROBERT M. RADER
Senior Attorney
Office of the General Counsel
U.S. Nuclear Regulatory
Commission
(301) 415-1955

Dated: November 4, 2008

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**

BRIEF FOR RESPONDENTS

RONALD J. TENPAS
Assistant Attorney General

KAREN D. CYR
General Counsel

CHARLES R. SCOTT
Trial Attorney
United States Department of Justice
Environment & Natural Resources
Division
P.O. Box 23795,
L'Enfant Plaza Station
Washington, D.C. 20026-3795
(202) 514-4786

JOHN F. CORDES, JR.
Solicitor

ROBERT M. RADER
Senior Attorney
Office of the General Counsel
U.S. Nuclear Regulatory
Commission
(301) 415-1955

Dated: November 4, 2008

TABLE OF CONTENTS

TABLE OF AUTHORITIES.....	iii
GLOSSARY.....	viii
<i>JURISDICTIONAL STATEMENT</i>	1
<i>STATEMENT OF THE ISSUES</i>	1
<i>STATEMENT OF THE CASE</i>	2
<i>STATEMENT OF THE FACTS</i>	3
A. The earlier rulemaking on 10 C.F.R. §§ 20.1301 and 35.75.....	3
B. Petitioner's request for rulemaking in 2005.....	8
C. NRC's denial of petitioner's request for new rulemaking.....	10
<i>SUMMARY OF THE ARGUMENT</i>	12
<i>STANDARD OF REVIEW</i>	15
<i>ARGUMENT</i>	17
I. This Court lacks jurisdiction because petitioner has not shown standing and his claims are untimely.....	17
A. Petitioner's participation in the rulemaking and his policy concerns do not create standing.....	17
B. The petition for review should be dismissed as an untimely and belated challenge to NRC's 1997 rule.....	22
II. NRC reasonably denied, for lack of a strong technical basis, the petition for rulemaking to revoke its 1997 patient release rule.....	29
A. The totality of the record overwhelmingly supports NRC's decision not to revert to the 30 mCi patient release standard.....	30

B. NRC adequately considered petitioner’s objections to Section 35.75.....	37
1. The NRC’s 0.5 rem patient release standard is compatible with international radiation standards.....	37
2. NRC’s rule does not permit or encourage doctors to send treated patients to hotels.	39
3. NRC did not revisit the socioeconomic costs/benefits of the patient release rule because petitioner did not provide a sound technical basis for changing it.....	41
4. The NRC adequately considered a patient’s understanding of his doctor’s instructions.....	44
C. NRC adequately explained its reasons for issuing a Regulatory Issue Summary to medical use licensees and others to protect young children.....	47
1. NRC’s RIS responds to ICRP concerns for children.....	47
2. Formal rulemaking was not required to alert the medical community to the concerns of ICRP for children.	49
D. Any NRC staff encouragement or assistance to the 1991 rulemaking petitioner did not violate the law.....	55
CONCLUSION	58

TABLE OF AUTHORITIES

Cases

<i>Alameda Conservation Ass'n v. California</i> , 437 F.2d 1087 (9th Cir. 1971)	21
<i>American Trucking Ass'n, Inc. v. United States</i> , 755 F.2d 1292 (7th Cir. 1985)	16
<i>Animal Legal Def. Fund v. Veneman</i> , 469 F.3d 826 (9th Cir. 2006)	27
<i>Baltimore Gas & Elec. Co. v. NRDC, Inc.</i> , 462 U.S. 87 (1983)	55
<i>Bullcreek v. NRC</i> , 359 F.3d 536 (D.C. Cir. 2004)	17
<i>Central Arizona Water v. EPA</i> , 990 F.2d 1531 (9th Cir. 1993)	18
<i>Citizens Coal Council v. EPA</i> , 447 F.3d 879 (6th Cir. 2006)	17
<i>City of Benton v. NRC</i> , 136 F.3d 824 (D.C. Cir. 1998)	26
<i>City of Los Angeles v. Lyons</i> , 461 U.S. 95 (1983)	20
<i>Commonwealth Edison Co. v. NRC</i> , 830 F.2d 610 (7 th Cir. 1987)	12
<i>Defenders of Wildlife v. Gutierrez</i> , 532 F.3d 913 (D.C. Cir. 2008)	16
<i>Department of Transp. v. Public Citizen</i> , 541 U.S. 752 (2004)	51
<i>Diamond v. Charles</i> , 476 U.S. 54 (1986)	21
<i>Edison Elec. Inst. v. ICC</i> , 969 F.2d 1221 (D.C. Cir. 1992)	28
<i>Envtl. Def. Ctr., Inc. v. EPA</i> , 344 F.3d 832 (9 th Cir. 2003)	51
<i>Envtl. Def. Fund v. EPA</i> , 852 F.2d 1316 (D.C. Cir. 1988)	29
<i>First Alabama Bank, N.A. v. United States</i> , 981 F.2d 1226 (11 th Cir. 1993)	28, 57

<i>Fortyune v. American Multi-Cinema, Inc.</i> , 364 F.3d 1075 (9th Cir. 2004)	20
<i>Friends of the Earth, Inc. v. Laidlaw Env'tl. Serv., (TOC), Inc.</i> , 528 U.S. 167 (2000)	18
<i>Guerrero-Santana v. Gonzales</i> , 499 F.3d 90 (1st Cir. 2007).....	27
<i>HRI, Inc. v. EPA</i> , 198 F.3d 1224 (10th Cir. 2000).....	27
<i>Iacopi v. FCC</i> , 451 F.2d 1142 (9th Cir. 1971).....	47
<i>James v. United States Parole Comm'n</i> , 159 F.3d 1200 (9th Cir. 1998)	57
<i>Klamath Water Users Ass'n v. FERC</i> , 534 F.3d 735 (D.C. Cir. 2008).....	17
<i>Kelley v. Selin</i> , 42 F.3d 1501 (6 th Cir. 1995).....	28
<i>Kolender v. Lawson</i> , 461 U.S. 352 (1983).....	20
<i>Lands Council v. McNair</i> , 537 F.3d 981 (9th Cir. 2008).....	17
<i>Lands Council v. Powell</i> , 395 F.3d 1019 (9th Cir. 2005)	39
<i>Lujan v. Defenders of Wildlife</i> , 504 U.S. 555 (1992).....	18
<i>Massachusetts v. EPA</i> , 127 S. Ct. 1438 (2007).....	15, 19
<i>Midwest Ind. Transmission Sys. Operator, Inc. v. FERC</i> , 388 F.3d 903 (D.C. Cir. 2004)	15, 16, 29
<i>Murphy v. Hunt</i> , 455 U.S. 478 (1982).....	20
<i>Nat'l Ass'n of Reversionary Prop. Owners v. Surface Transp. Bd.</i> , 158 F.3d 135 (D.C. Cir. 1998)	28

<i>Nat'l Customs Brokers & Forwarders Ass'n of America Inc. v. United States</i> , 883 F.2d 93 (D.C. Cir. 1989).....	15
<i>Nat'l Mining Ass'n v. Dep't of the Interior</i> , 70 F.3d 1345 (D.C. Cir. 1995).....	27, 28, 29
<i>NRDC v. NRC</i> , 666 F.2d 595 (D.C. Cir. 1981).....	23, 26, 29
<i>Nuclear Info. & Res. Serv. v. NRC</i> , 457 F.3d 941 (9th Cir. 2006).....	12, 18, 19
<i>O'Keeffe's, Inc. v. CPSC</i> , 92 F.3d 940 (9th Cir. 1996).....	16
<i>Overton Power Dist. No. 5 v. O'Leary</i> , 73 F.3d 253 (9th Cir. 1996)	17
<i>Physicians Comm. for Responsible Medicine v. EPA</i> , 2008 WL 4185751 (9th Cir. 2008).....	19, 20
<i>Pony v. County of Los Angeles</i> , 433 F.2d 1138 (9th Cir. 2006)	18
<i>Prof'l Drivers Council v. Bureau of Motor Carrier Safety</i> , 706 F.2d 1216 (D.C. Cir. 1983)	29
<i>Public Citizen v. NRC</i> , 901 F.2d 147 (D.C. Cir. 1990).....	27
<i>Public Power Council, Inc. v. Bonneville Power Administration</i> , 442 F.3d 1204 (9th Cir. 2006).....	39
<i>Reytblatt v. NRC</i> , 105 F.3d 715 (D.C. Cir. 1997)	37
<i>Sierra Club v. EPA</i> , 292 F.3d 895 (D.C. Cir. 2002)	19
<i>State Farm Mut. Auto. Ins. Co. v. DOT</i> , 680 F.2d 206 (D.C. Cir. 1982).....	16
<i>State of Montana v. Clark</i> , 749 F.2d 740 (D.C. Cir. 1984).....	22
<i>Steel Co. v. Citizens for a Better Env't</i> , 523 U.S. 83 (1998).....	18
<i>Stone v. INS</i> , 514 U.S. 386 (1995).....	26

<i>United States v. L.A. Truck Lines</i> , 344 U.S. 33 (1952)	51
<i>USPS v. Gregory</i> , 534 U.S. 1 (2001)	56
<i>Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.</i> , 454 U.S. 464 (1982).....	20
<i>Vermont Yankee Nuclear Power Corp. v. NRDC, Inc.</i> , 435 U.S. 519 (1978).....	37, 51
<i>Warth v. Seldin</i> , 422 U.S. 490 (1975)	20
<i>Wright v. Dir., FEMA</i> , 913 F.2d 1566 (11th Cir. 1990).....	56

Statutes

5 U.S.C. § 706	57
The Hobbs Act, 28 U.S.C. § 2341	1, 22
28 U.S.C. § 2344	1, 22, 26

Federal Regulations

10 C.F.R. § 2.802.....	9
10 C.F.R. § 2.802(b).....	56
10 C.F.R. Part 20	4
10 C.F.R. § 20.1003.....	41, 51
10 C.F.R. § 20.1301.....	3, 4, 51
10 C.F.R. § 20.1301(a).....	6
10 C.F.R. § 20.1301(c).....	8
10 C.F.R. § 35.75.....	<i>passim</i>

10 C.F.R. § 35.75(a)	2, 4, 45
10 C.F.R. § 35.75(b)	2, 7, 44
10 C.F.R. § 35.75(b)(1)	7

Federal Register Notices

56 Fed. Reg. 23360 (May 21, 1991).....	3
56 Fed. Reg. 26945 (June 12, 1991).....	5
56 Fed. Reg. 37950 (July 26, 1994)	5
57 Fed. Reg. 8282 (Mar. 9, 1992)	5
57 Fed. Reg. 21043 (May 18, 1992).....	5
59 Fed. Reg. 30724 (June 15, 1994).....	6, 42
65 Fed. Reg. 44360 (July 17, 2000)	37
70 Fed. Reg. 75752 (Dec. 21, 2005)	9, 28

Miscellaneous

Draft Regulatory Guide DG-8015, <i>Release of Patients Administered Radioactive Materials</i> (June 1994).....	7
NUREG-1492, <i>Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material</i> (May 1994)	7, 37
NRC Inspection Manual, Procedure 87131, § 87131-03.01(g)	52

GLOSSARY

ACMUI – NRC’s Advisory Committee on the Medical Uses of Isotopes, which provides advice, as requested by the Director, Division of Materials Safety and State Agreements (MSSA), Office of Federal and State Materials and Environmental Management Programs (FSME), on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy.

ACNM - American College of Nuclear Medicine. Its stated purposes is to advance the science of nuclear medicine and improve its benefits to patients, encourage improved and continuing education for practitioners in nuclear medicine and allied fields and study the socioeconomic aspects of the practice of nuclear medicine. See <http://www.acnucmed.com/>

Agreement State - A state with which NRC has entered into an agreement under Section 274b of the Atomic Energy Act, 42 U.S.C. § 2021(b), permitting the state shared regulation of some licensed nuclear materials. See 10 C.F.R. § 35.2; *Mississippi Power & Light Co. v. NRC*, 601 F.2d 223, 233 (5th Cir. 1979).

ALARA – Acronym for "as low as (is) reasonably achievable." It means making every reasonable effort to maintain exposures to ionizing radiation as far below regulatory dose limits as practical, consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to the state of technology as well as benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest. See 10 C.F.R §§ 20.1003 and 1101(b).

AMA - American Medical Association. Its stated mission is to promote the art and science of medicine and the betterment of public health through core values of leadership, excellence and integrity/ethical behavior. See <http://www.ama-assn.org/>

CORAR - Council on Radionuclides and Radiopharmaceuticals, Inc. An association comprising companies in the United States and Canada that manufacture and distribute radiopharmaceuticals, sealed sources, and radionuclides primarily used in medicine and life science research. See <http://www.corar.org/>

Curie (Ci) – The basic unit used to describe the intensity of radioactivity in a sample of material. The curie is equal to 37 billion (3.7×10^{10}) disintegrations per second, which is approximately the activity of 1 gram of radium. A curie is also a quantity of any radionuclide that decays at a rate of 37 billion disintegrations per second.

ICRP - International Commission on Radiological Protection. The ICRP “considers the fundamental principles and quantitative bases upon which appropriate radiation protection measures can be established, while leaving to the various national protection bodies the responsibility of formulating the specific advice, codes of practice, or regulations that are best suited to the needs of their individual countries.” See <http://www.icrp.org/about.asp>

Millicurie (mCi) – Equals 0.001 curie.

Millirem (mrem) - Equals 0.001 rem.

NCRP - National Council on Radiation Protection and Measurements. Its stated mission is to formulate and disseminate information, guidance and recommendations on radiation protection and measurements that represent the consensus of leading scientific thinking. See <http://www.ncrponline.org>.

Radiation Safety Officer (RSO) – The person appointed by a licensee’s management under 10 C.F.R. § 35.24(b) responsible for implementing the licensee’s Radiation Protection Program, whose training is governed by the requirements of 10 C.F.R. § 35.50.

Rem - The acronym for “roentgen equivalent man” is a standard unit that measures the effects of ionizing radiation on humans. It is the product of the absorbed dose in rads (a special unit of absorbed dose) and the biological effectiveness of the radiation. A rem is sometimes expressed in the equivalent Sv (Sievert) where 1 rem equals .01 Sv.

TEDE - the sum of the deep-dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).

JURISDICTIONAL STATEMENT

The petition for review challenges a Nuclear Regulatory Commission (NRC) decision denying petitioner's request for rulemaking.¹ This Court generally has subject matter jurisdiction over denial of a petition for rulemaking under the Hobbs Act, 28 U.S.C. § 2341 *et seq.* Here, however, the Court lacks jurisdiction for two reasons. First, petitioner has not shown personal harm from the rulemaking denial, has not demonstrated that any harm would be redressed, and thus has not shown standing. Second, although the petition was filed within sixty days of NRC's denial as required by 28 U.S.C. § 2344, petitioner relies almost entirely on alleged flaws in an unchallenged rulemaking completed more than a decade ago, and thus his challenge now is untimely.

STATEMENT OF THE ISSUES

1. Whether this Court lacks jurisdiction to review NRC's denial of a petition for rulemaking, where petitioner has failed to establish the constitutional requirements for standing and where he seeks to revive previously forfeited and now out-of-time challenges to a 1997 rule.

2. Whether NRC reasonably turned down a petition for rulemaking to revoke a 1997 NRC rule establishing new "patient release" criteria, where doctors

¹ For clarity, we refer to the petitioner before this Court, Peter Crane, as petitioner. When referring to others who have filed rulemaking petitions, we shall identify them by name.

and medical organizations unanimously opposed the petition and NRC found no technical basis to launch a fresh rulemaking.

STATEMENT OF THE CASE

Millions of patients are treated each year with radioactive pharmaceuticals or compounds (“radiopharmaceuticals”) for diagnosis or treatment of disease or for human research. These patients can expose others around them to radiation until the radioactive material administered to them has been eliminated from their bodies or the radioactivity has decayed. To reduce the risk of exposure to others around the patient, NRC maintains regulations governing the release of patients from medical care after they are given radiopharmaceuticals. The current patient release criteria, adopted in 1997 (*see* Petitioner’s Excerpts of Record (ER) 35-48), are found at 10 C.F.R. § 35.75.

This petition for review challenges NRC’s denial of a request to revisit the 1997 rule. Among other things, that rule allows NRC medical licensees (*e.g.*, hospitals) to release patients “not likely” to expose other individuals to more than 5 mSv (0.5 rem; *see* Glossary) in “total effective dose equivalent” (TEDE; *see* Glossary). The rule also requires licensees to provide “instructions, including written instructions,” to patients on how to keep doses to others “as low as is reasonably achievable” if the total effective dose to any other individual is likely to exceed 0.1 rem. *See* 10 C.F.R. § 35.75(a), (b). Petitioner argued both in comments

during the original 1997 rulemaking and in a petition for rulemaking he filed in 2005 that NRC should utilize its former (pre-1997) rule – which, he argues, reflected a more “conservative radiation protection practice.” (Pet.Br.5)

NRC rejected the 2005 rulemaking petition, but nonetheless issued fresh guidance stressing the particular importance of protecting children against excessive exposures. (ER5) NRC reasoned that its 1997 rule already provided the public adequate protection and enjoyed broad support in the medical community. (ER3) The agency pointed to its limited resources and the lack of a strong technical basis to justify undertaking a fresh rulemaking on the patient release issue. (ER4)

STATEMENT OF THE FACTS

A. The earlier rulemaking on 10 C.F.R. §§ 20.1301 and 35.75.

The current rule results from rulemaking begun in 1991, which initially addressed the relationship between NRC standards for protecting the general public from radiation resulting from licensed activities and the more specific standards for protecting against radiation from patients administered radiopharmaceuticals. In 1991, NRC published a new rule that amended the general standards under 10 C.F.R. § 20.1301 setting dose limits for protecting members of the general public from radiation from licensed activities (the “Part 20 limits”). *See* 56 Fed. Reg. 23360 (May 21, 1991). This rule did not clarify, however, whether the general Part

20 limits on public exposure applied to exposures created by the release of patients under 10 C.F.R. § 35.75.

This created a dilemma for the medical community. Section 20.1301 lowered the permissible dose to members of the public generally from 0.5 rem/yr to 0.1 rem/yr. But Section 35.75(a), at that time, permitted physicians and hospitals (*i.e.*, medical licensees authorized to possess and use radioactive materials for their patients) to release treated patients from hospitals at which radioactive iodine-31 (I-131) had been administered once the level of radioactivity was less than 30 millicuries (mCi), or the measured dose rate from the patient was less than 5 millirems/hr at a distance of one meter. (ER1)

Because a patient with 30 mCi was likely to emit radiation at levels that would likely create exposure to family and others exceeding the 0.1 rem limit under Section 20.1301, medical professionals were concerned whether the new Part 20 limits applied to their patients. If Part 20 *did* apply, then inpatients treated with I-131 would have to remain hospitalized longer until their radioactivity receded. Also, patients treated or diagnosed with I-131 as outpatients might have to be hospitalized.

Dr. Carol Marcus, UCLA School of Medicine, petitioned for rulemaking, pointing out this practical problem:

If members of the public who are closest to the patient may not receive more than [0.1 rem per year], *patients who are now hospitalized would*

require hospitalization for appropriately longer times than they are now and many outpatients would have to be made inpatients.

[Respondents' Excerpt of Record (RER) 75; emphasis added]

According to Dr. Marcus, lowering the absorbed dose permitted non-patients from patient exposure "would be extremely expensive" and without scientific justification, given that no adverse health effects had been shown from naturally occurring radiation (*i.e.*, background) levels of 250 mrem. *Id.* NRC published notice of the rulemaking petition and invited comments. *See* 56 Fed. Reg. 26945 (June 12, 1991). Dr. Marcus later proposed to NRC an amendment to Section 35.75 authorizing release of a treated patient if exposure to others would not exceed 0.5 rem. (RER83)

Next, NRC published two other rulemaking petitions likewise seeking clarification/modification of patient release criteria. One was filed by the American College of Nuclear Medicine (ACNM). *See* 57 Fed. Reg. 8282 (March 9, 1992); 57 Fed. Reg. 21043 (May 18, 1992). The ACNM urged NRC to amend Section 35.75 because "temporary home confinement instead of mandating hospitalization . . . would provide efficient care and allow costs to be minimized without increased risk to the public." 57 Fed. Reg. 8282.

The other proposal was submitted by the American Medical Association (AMA). *See* 59 Fed. Reg. 37950 (July 26, 1994). Like Dr. Marcus, the AMA urged NRC to permit release of patients diagnosed or treated with I-131 if dose to

others from exposure were less than 0.5 rem/yr. The report of the AMA Council on Scientific Affairs stated that, absent NRC action: “[S]ome procedures utilizing radioisotopic materials that have routinely been performed on an outpatient basis now will require hospitalization, not for medical but for regulatory reasons. Enforced hospitalization will significantly increase the cost of medical care and possibly result in patients not being able to receive that care.” (RER95) The AMA declared that applying the 0.1 rem exposure limit to patients administered 30 mCi of I-131 would require hospitalization for “up to 10,000 [thyroid] cancer patients annually.” (RER95-96)

NRC handled these three related rulemakings in a single proceeding and, in 1994, proposed (1) to clarify that Section 35.75 released patient exposures were not covered by Section 20.1301(a), and (2) to change the patient release criteria under Section 35.75 “from 30 millicuries of activity in a patient or a dose rate of 5 millirems per hours at 1 meter from a patient, to dose-based criteria where the TEDE to an individual from exposure to a released patient is not likely to exceed 5 mSv (0.5 rem).” (ER3) This proposal thereby adopted the medical community’s recommendations to change the release limit from an activity-based standard (measuring the patient’s radioactivity) to a dose-based standard (measuring the predicted exposure of family and others in proximity). *See* 59 Fed. Reg. 30724 (June 15, 1994).

The proposed rule included a new 10 C.F.R. § 35.75(b) (1) requiring licensees to give released patients written instructions on how to minimize exposure to others, that is, to keep doses to others “as low as (is) reasonably achievable” (known as the ALARA standard; *see* Glossary), if the TEDE to another person was likely to exceed 100 mrem (0.1 rem) in any given year.

NRC concurrently issued draft regulatory guidance, DG-8015, “Release of Patients Administered Radioactive Materials,” on how to determine the dose of the individual likely to receive the highest exposure from treated patients, along with instructions on how to keep doses ALARA. Finally, NRC also prepared a draft analysis examining benefits/impacts of the proposed rule. *See* NUREG-1492, “Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material” (May 1994) (RER112)

NRC received 63 comments on the proposed rule and draft guidance, mostly from medical practitioners and medical organizations supporting the proposed 0.5 rem dose limit. (ER36) Petitioner himself participated in the proceeding, vigorously opposing the proposed rule. (RER88,107,113) In 1997 NRC adopted the new 0.5 rem release standard, explaining why its new dose-based standard would improve upon the activity-based standard used in the past:

The NRC is adopting a dose-based limit rather than an activity-based limit because the dose-based limit better expresses the NRC's primary concern for the public's health and safety. [ER37]

NRC preferred the dose-based approach because the activity-based approach posed a practical problem for protecting public health and safety: differing radionuclides with the same activity resulted in different doses. *Id.* NRC thus found that radiation exposure to families and others in proximity to the patient is better understood and regulated in terms of dose to those individuals rather than the radioactivity of the patient. *Id.* NRC noted that its new 0.5 rem standard was consistent with the underlying risk basis of the then current 10 C.F.R. § 35.75 as well as those provisions of 10 C.F.R. § 20.1301(c) pertaining to temporary situations in which justification exists for a dose limit higher than 0.1 rem. *Id.*

NRC issued supporting guidance calculations for practitioners to derive estimated dose to affected individuals from a corresponding activity level, using conservative assumptions and based on National Council on Radiation Protection and Measurements (NCRP) data. Significantly, NRC determined, as a practical matter, that the release limit of 0.5 rem (exposure to others) for I-131 corresponds to 33 mCi (the patient's radioactivity), "which is essentially the same as the current release quantity," that is, what is now the former release standard of 30 mCi. *Id.*

B. Petitioner's request for rulemaking in 2005.

Petitioner participated in the 1991-97 rulemaking and staunchly opposed the new rule, but did not seek judicial review. Instead, eight years after promulgation of the new Section 35.75, petitioner asked NRC to revoke its new dose-based rule

and reinstate its old activity-based rule. Specifically, petitioner wanted NRC to allow release of treated patients *only* if they have 30 mCi or less of I-131 in their bodies, as in the original Section 35.75. (ER88-105)

This petition was neither joined nor supported by doctors or medical organizations. To the contrary, doctors, Radiation Safety Officers and medical organizations unanimously opposed the petition. These organizations included the AMA, the American Society of Therapeutic Radiation Oncologists, the American Association of Physicists in Medicine, the American Board of Nuclear Physicians, the American Thyroid Association, the Endocrine Society, the American College of Radiology, the Society of Nuclear Medicine, the American Pharmacists Association, the National Association of Nuclear Pharmacists, and the Council on Radionuclides and Radiopharmaceuticals (CORAR). (ER2). In all, NRC received 48 comments. (ER2). Most opposed the petition; fourteen supported it. *Id.*

Pursuant to its usual practice (10 C.F.R. § 2.802), NRC published notice of the petition, describing in detail petitioner's objections to Section 35.75 and inviting public comment. 70 Fed. Reg. 75752 (Dec. 21, 2005). Petitioner supplemented his petition four times. (ER53,70,130,137)

Petitioner asserted legal as well as technical grounds for reinstating the 30 mCi activity standard. First, he repeated his accusation from the original proceeding that an NRC staff employee had encouraged Dr. Marcus, the initial

petitioner for the rule change in 1991, to submit her rulemaking petition. (ER92-96) Petitioner objected to this undisclosed support, as he had in the earlier rulemaking. Second, as in the earlier rulemaking, petitioner asserted that the 0.5 rem standard did not adequately protect patients' families, especially children, and other members of the public upon discharge. (ER96-105) In petitioner's view, NRC's rule did not deal adequately with the possibility of excessive exposures from vomiting, from use of public transport, from proximity to family members, and from an inability by hypothyroid patients to comprehend and follow medical instructions. (ER3-6)

C. NRC's denial of petitioner's request for new rulemaking.

NRC denied petitioner's request for rulemaking. First, the agency rejected petitioner's "legal" argument – his complaint that NRC staff had illicitly assisted Dr. Marcus's 1991 rulemaking petition – on the ground that "[h]owever initiated, the 1997 rulemaking involved broad participation with 63 commenters" and included "independent proposals" by the AMA and ACNM. (ER3) Thus, NRC said, "even assuming" procedural impropriety, no evidence showed that it caused a "substantive" deficiency that would justify reopening the rule. *Id.*

Next, NRC responded to petitioner's concerns for family exposure by issuing new guidance for medical licensees, reiterating the special care needed for limiting "exposure to children and infants from released patients." (ER4) NRC noted that

CORAR, while opposing the rulemaking petition, pointed out that a publication of the International Commission on Radiological Protection (ICRP) in 2004 now recommends that doses to children from released patients be no more than 0.1 rem, noting that “doses to children from patient contamination have the potential to be far greater than from external exposure.” (ER2; *see* RER53)

NRC noted this “departure from previous ICRP recommendations,” which had previously not made “a distinction for children or infants.” (ER4). NRC determined that instructing doctors to advise “patients to take precautions to maintain the dose to children and infants as low as is reasonably achievable (ALARA)” would be the approach “more likely to provide better protection for children and infants.” *Id.* Toward that end, NRC modified its guidance to physicians and its required instructions to patients “to stress the need to keep children and infants away from any possible sources of contamination.” *Id.*

On a broader front, NRC stressed that those opposing the petition – “doctors, medical physicists, and radiation safety officers, as well as several medical professional organizations” (ER2) – “stated that reverting from the current release criteria back to the 30 mCi rule would result in additional and unnecessary healthcare costs, and would unnecessarily limit access to treatment for patients who cannot afford hospitalization.” (ER2) NRC indicated that its current (1997) rule continued to provide the public “adequate protection,” and found petitioner’s

concerns about public transport, vomiting, and hypothyroid patients' inability to follow instructions unpersuasive, and unsupported by "specific data." (ER5) NRC pointed out that its rulemaking resources are "limited," and said there was not a "sufficiently strong technical basis to consider the issues in this petition in a rulemaking." (ER4)

SUMMARY OF THE ARGUMENT

This Court lacks jurisdiction to consider this lawsuit because petitioner has not shown standing and his merits claims are untimely. These are jurisdictional defects that cannot be waived and which NRC is therefore duty-bound to raise. *See Nuclear Info. & Res. Serv. v. NRC*, 457 F.3d 941, 949 (9th Cir. 2006); *Commonwealth Edison Co. v. NRC*, 830 F.2d 610, 612 (7th Cir. 1987). Even if jurisdiction exists, NRC's denial of the petition for rulemaking was entirely reasonable and should be upheld.

1. Petitioner has said nothing about his standing to challenge the denial of his rulemaking petition. Petitioners seeking judicial review have the burden to show standing, unless their standing is readily discernible from the record. Petitioner here has not satisfied his burden. At most, one can glean from the record that petitioner was a thyroid cancer patient treated with I-131 from 1988-91 and continues to have a strong opinion on the release of I-131 treated patients. Treatment long ago and personal interest and concern, however, do not constitute

particularized injury, actual or imminent, from NRC's denial of his rulemaking petition.

Moreover, any injury to petitioner by way of increased exposure from treated patients is not traceable to NRC's denial of his rulemaking petition. NRC rules regulate licensees and those who administer radioisotopes under licenses. NRC does not exert regulatory authority over patients, who are free to leave the hospital against medical advice. Conversely, Section 35.75 does not *compel* any physician to release a patient under its criteria; it only *permits* release if release criteria are met. Ultimately, therefore, patient release decisions are the product of physician-patient consultation, not NRC rules.

2. Petitioner's lawsuit is also untimely. As he acknowledges, he participated actively in NRC's "patient release" rulemaking in the 1990's – it culminated in a final rule in 1997 – and he could have challenged the rule then. His petition for rulemaking and his appellate brief in this Court essentially rehash the same grievances he had in 1997. Allowing suit on those claims now would defeat the purpose of the Hobbs Act's 60-day limit on seeking judicial review of NRC rules – finality – by rendering all agency rules ephemeral, always subject to reopening and fresh challenge.

3. Even if this Court were to reach the merits, the burden in convincing a court to reverse an agency's decision not to initiate rulemaking is singularly

difficult. Only a compelling showing of new information undermining the factual underpinnings of the rule or violations of law would suffice.

This case involves not just proposed rulemaking in a previously unregulated area; petitioner proposes rulemaking to overturn a rule seven years in the adoption and in effect for more than a decade – a rule unanimously supported by medical experts on the current rulemaking record and reasonable in its own right.

Petitioner argues passionately for an approach different from NRC's – indeed he argues for NRC's prior approach. But he does not show that NRC's current rule is unlawful or based on important facts that NRC ignored. He relies heavily on the original rulemaking record, on extra-record information, on points he did not raise in the rulemaking record below, on anecdotes, and on rhetoric questioning the integrity of the medical profession and NRC regulators. He does not make the case for a court order directing NRC to devote scarce resources to a fresh "patient release" rulemaking.

The single most telling point about petitioner's case is the overwhelming opposition of dozens of commenting physicians as well as nationally renowned medical organizations, all of whom have a direct, day-to-day stake in patient and family care under NRC's rule. Petitioner's concerns and policy preferences do not outweigh the collective wisdom of the medical profession expressed in the record and are insufficient to sustain his enormously heavy burden of proof.

Petitioner also asserts that NRC gave insufficient weight to international standards, the potential for hotel contamination by released patients, the emotional benefits of inpatient treatment, patient difficulty in understanding physician's instructions, and the particular risk of children's exposures. These arguments are unpersuasive. NRC indeed considered each of these issues during the 1997 and/or current rulemaking, but accounted for these concerns in a way that does not reflect petitioner's own policy preferences. Policy disagreements are not nearly enough to require a fresh NRC rulemaking.

Finally, petitioner argues that the 1997 rule resulted from inappropriate collaboration between NRC staff and a rulemaking proponent. This charge is belied by the 1997 rulemaking record, which includes substantial factual and expert support for NRC's approach. The procedural provenance of the 1997 rule is in any event immaterial, given that others, not just the doctor accused of inappropriate collaboration, sought the 1997 rule and given that what is before this Court today is a 2005 petition for rulemaking, not the 1997 rule.

STANDARD OF REVIEW

A court's review of an agency's refusal to promulgate rules is "extremely limited" and "highly deferential." *Massachusetts v. EPA*, 127 S. Ct. 1438, 1459 (2007), quoting *National Customs Brokers & Forwarders Ass'n of America, Inc. v. United States*, 883 F.2d 93, 96 (D.C. Cir. 1989). See also *Midwest Ind.*

Transmission Sys. Operator, Inc. v. FERC, 388 F.3d 903, 910, 913 (D.C. Cir. 2004) (court’s review of an agency’s decision not to conduct rulemaking is “particularly deferential,” and the agency has a “limited burden” to justify its refusal); *American Trucking Ass’n, Inc. v. United States*, 755 F.2d 1292, 1298 (7th Cir. 1985) (standard of review “is highly deferential”); *State Farm Mut. Auto. Ins. Co. v. DOT*, 680 F.2d 206, 221 (D.C. Cir. 1982), *vac. on other grounds*, 463 U.S. 29 (1983) (“Agency decisions not to conduct rulemaking . . . are tested under a ‘very narrow’ reading of the arbitrary and capricious test.” *See also O’Keeffe’s, Inc. v. CPSC*, 92 F.3d 940, 942 (9th Cir. 1996). An “agency’s refusal to institute rulemaking proceedings is at the high end of the range of levels of deference,” especially where “the proposed rule pertains to a matter of policy within the agency’s expertise and discretion.” *Defenders of Wildlife v. Gutierrez*, 532 F.3d 913, 919 (D.C. Cir. 2008).

Given agencies’ limited resources and their right and duty to establish their own priorities in the public interest, courts overturn rulemaking denials only in “the rarest and most compelling of circumstances.” *Midwest Ind. Transmission System Operator, Inc.*, 388 F.3d at 906 (internal quotation marks omitted). There must be a showing of “plain error of law” or a showing that a rule’s “factual premises” have so changed as to demand a fresh look at the matter. *Id.* at 910-11 (internal quotation marks omitted).

The subject of the rulemaking petition NRC denied here is one within its particular realm of expertise – protection of the public health and safety from radiation. In such cases, judicial review is extremely narrow. “Where the rulemaking involves review of the agency's technical or scientific evaluations and determinations, the highest level of deference to the agency is to be applied.” *Citizens Coal Council v. EPA*, 447 F.3d 879, 890 (6th Cir. 2006). *Accord Lands Council v. McNair*, 537 F.3d 981, 993 (9th Cir. 2008).

ARGUMENT

I. This Court lacks jurisdiction because petitioner has not shown standing and his claims are untimely.

A. Petitioner’s participation in the rulemaking and his policy concerns do not create standing.

While petitioner is a passionate advocate of released patients’ rights, a strong interest in the subject matter of a rulemaking is insufficient for standing to seek judicial review. “The Hobbs Act requires that a party participate in the underlying agency proceeding *and* meet the requirements of constitutional and prudential standing.” *Bullcreek v. NRC*, 359 F.3d 536, 540 (D.C. Cir. 2004) (emphasis added). “Petitioners do not have a right to seek court review of administrative proceedings merely because they participated in them.” *Klamath Water Users Ass’n v. FERC*, 534 F.3d 735, 738 (D.C. Cir. 2008) (internal quotation marks omitted). *See also Overton Power Dist. No. 5 v. O’Leary*, 73 F.3d

253, 257 (9th Cir. 1996).

Petitioner here has met the agency participation requirement, but not the constitutional (Article III) standing requirements. For constitutional standing, “a plaintiff must show (1) it has suffered an ‘injury in fact’ that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and 3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.” *Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 180-181 (2000). See also *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 102-103 (1998); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992); *Nuclear Info. & Res. Serv. v. NRC*, 457 F.3d at 949; *Pony v. County of Los Angeles* 433 F.3d 1138, 145-46 (9th Cir. 2006); *Central Arizona Water v. EPA*, 990 F.2d 1531, 1537 (9th Cir. 1993).

This is not a case where standing is self-evident, as when “the plaintiff is himself an object of the action.” *Lujan*, 504 U.S. at 561. Here, NRC is not regulating petitioner, but rather licensed health care providers authorized to possess and use radiopharmaceuticals. This renders petitioners' claim to standing substantially more difficult to establish. *Id.* at 562. And to show standing, a petitioner must support each element of its claim to standing “by affidavit or other evidence.” *Lujan*, 504 U.S. at 561). “[T]he petitioner must either identify . . .

record evidence sufficient to support its standing to seek review or . . . submit additional evidence to the court of appeals.” *Sierra Club v. EPA*, 292 F.3d 895, 899 (D.C. Cir. 2002). See also *Physicians Comm. for Responsible Medicine v. EPA*, 2008 WL 4185751, 1 (9th Cir. 2008); *Nuclear Info. & Res. Serv.*, 457 F.3d at 951.

Here, petitioner is silent on standing. This leaves us somewhat in the position of "flail[ing] at the unknown in an attempt to prove the negative." *Sierra Club*, 292 F.3d at 901. The only statement of interest to be gleaned from the record is petitioner's comment that "[b]etween 1988 and 1991, I had been treated as an inpatient five times at the National Institutes of Health, with I-131 doses totaling 700 millicuries, for recurrent cancer." (ER98) At that time, he was the father of two young children. (Pet.Br.15)

Without a statement of further treatments in his 2005 petition, it is reasonable to infer that none has occurred, and it is petitioner's burden to demonstrate facts that establish standing. In any event, petitioner concedes that his concern is not for himself, but for others – "real people – cancer patients – and their families, in the here and now." (ER105). He has not pointed to any personal "injury that is either actual or imminent," *Massachusetts v. EPA*, 127 S. Ct. at 1441, sustained as a result of the rulemaking denial.

Without claiming that his family is likely to be imminently exposed to his own radiation from I-131 treatment, petitioner is merely attempting to stand in the

shoes of all families whose loved ones might be exposed. This generalized grievance is insufficient for standing. *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 475 (1982); *Physicians Committee for Responsible Medicine*, 2008 WL 4185751, 2. Petitioner “still must allege a distinct and palpable injury to himself, even if it is an injury shared by a large class of other possible litigants.” *Warth v. Seldin*, 422 U.S. 490, 501 (1975).

Petitioner has described his experience with receiving I-131, but has not explained how he is currently affected by the denial of his rulemaking petition. Accordingly, petitioner has not met his burden to “establish a real and immediate threat” of injury, *City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983), that is “more than speculation.” *Id.* at 108. Standing requires a “credible threat,” *Kolender v. Lawson*, 461 U.S. 352, 355 n. 3 (1983), a “sufficient likelihood,” *Lyons*, 461 U.S. at 111, and more than “the mere physical or theoretical possibility,” *Murphy v. Hunt*, 455 U.S. 478, 428 (1982). Petitioner cannot, therefore, suggest potential harm “so remote as to preclude standing.” *Fortyune v. American Multi-Cinema, Inc.*, 364 F.3d 1075, 1081 (9th Cir. 2004).

Even if petitioner is well-informed on patient release issues, without personal injury, he would be cast in the role of a self-appointed “super-administrative agency . . . with the capability of over-seeing and of challenging the

action of the appointed and elected officials.” *Alameda Conservation Ass'n v. California*, 437 F.2d 1087, 1090 (9th Cir. 1971). “[Standing] is not to be placed in the hands of ‘concerned bystanders,’ who will use it simply as a vehicle for the vindication of value interests.” *Diamond v. Charles*, 476 U.S. 54, 61-62 (1986).

Finally, even assuming injury-in-fact, petitioner has not satisfied the standing requirements of traceability (causation) and redressability. NRC’s authority extends to licensed doctors and other medical users of I-131, not to patients. As we discuss below, a treated patient always has discretion to release himself from the hospital.² Hospitals are not prisons and doctors are not wardens. Petitioner acknowledges as much in recounting an episode of a patient who left a Boston hospital “before receiving permission from the Radiation Safety Officer.” (RER125) Whether under the old rule that petitioner prefers or the current rule, the treating doctor exercises medical judgment on whether a patient should be released. In short, because the patient ultimately controls his own release, guided by his doctor’s evaluation, any patient-caused radiation exposures are not legally “traceable to,” or caused by, NRC’s rule or its rulemaking denial.

² A patient might argue that his decision is controlled by the availability of medical insurance to cover hospital costs. Certainly, petitioner feels that way. (Pet.Br.53 n.28; ER135) Even assuming this to be so, it likewise shows that any injury through exposure to others upon release is attributable to the terms of reimbursement under the patient’s medical insurance policy, not NRC’s rulemaking actions.

B. The petition for review should be dismissed as an untimely and belated challenge to NRC's 1997 rule.

As this Court can readily see from petitioner's earlier arguments and commentary during the 1991-97 rulemaking, his 2005 petition was more or less a reiteration of points he made before, which the NRC dutifully considered but rejected. Under these circumstances, this Court should not countenance what amounts to an untimely appeal under the guise of a rulemaking petition that seeks nothing more than reinstatement of the old rule NRC replaced in 1997. Because petitioner filed no judicial challenge within sixty days after NRC's adoption of its final rule in 1997 – as required by the Hobbs Act's 60-day limitations period, 28 U.S.C. § 2244 – his current lawsuit should be dismissed as untimely. This is simply a case of a party who is trying “to restart the 60-day period by unilaterally seeking repeal of a long-standing regulation.” *State of Montana v. Clark*, 749 F.2d 740, 744 (D.C. Cir. 1984).

Petitioner was a party to the proceeding that culminated in the 1997 rule, and candidly admits he could and should have “taken the NRC to court then and there,” but chose not to do so for fear of “spreading myself too thin.” (ER95-96) He also concedes that missing this opportunity was “a mistake.” (ER96) However, the simple device of asking NRC to reinstate the old rule, based on arguments dusted off from 1997, does not give petitioner a second bite at the apple.

A similar belated suit was rejected in *NRDC, Inc. v. NRC*, 666 F.2d 595 (D.C. Cir. 1981), where the Court found that NRDC may not “now seek review of the procedure by which the amendments were promulgated, even though it could have but did not seek direct review thereof, by simply raising its objections in a petition for rulemaking and seeking direct review of the order denying the petition.” *Id.* at 601-02. The Court ruled that important Hobbs Act policies “would be frustrated if untimely procedural challenges could be revived by simply filing a petition for rulemaking requesting rescission of the regulations and then seeking direct review of the petition's denial.” *Id.* at 602. The same logic governing untimely procedural challenges applies equally to substantive challenges based on fundamentally unchanged policy disagreements.

Generally stated, petitioner's comments in the earlier rulemaking and his request for new rulemaking both start from a common premise: his strongly-held policy view that the safety of families and the public from exposure to an I-131 treated patient requires hospital isolation until activity levels fall below 30 mCi. Thus, in the first rulemaking, petitioner said:

[T]he issue here is of protecting my own family, families like mine, and the public at large from the risks associated with I-131. Patients who come home with 150 or more millicuries of I-131 in their systems will inevitably be delivering a larger radiation dose to their families than when they could not leave radioactive isolation until the level in their bodies dropped below 30 millicuries. [ER105 n.12]

In 2005, petitioner offered the same argument as a basis for renewed rulemaking:

Patients treated for thyroid cancer with radioactive I-131 are now being sent home to their families under conditions that guarantee that family members would receive larger and potentially harmful doses of radiation, under uncontrolled conditions. . . .

This petition asks for the revocation of the rule, insofar as it allows patients to be released from radioactive isolation with more than the equivalent of 30 millicuries of I-131 in their systems. [ER88]

And before this Court, petitioner makes the same point:

Today, under the 1997 rule, patients are routinely sent home to their families with vastly greater amounts of I-131 in their systems – 200, 300, even 400 millicuries [Pet.Br.32]

On its face, the 2005 petition for rulemaking makes clear that petitioner is quarreling with NRC's supposed mishandling of points he raised in the 1991-97 rulemaking, as shown by a simple comparison of his comments, now and then:

- Alleged procedural irregularities in NRC's assistance to Dr. Carol Marcus, one of three rulemaking petitioners (ER79-82,92-95; 135n.3,143).
- Comments by several Agreement States, questioning release of patients with more than 30 mCi of I-131. (ER96-97,100-02; 131-32,134)
- Views of NRC's Advisory Committee on the Medical Uses of Isotopes, including ACMUI Chairman Dr. Barry Siegel. (ER98; 132,136,140-143)

- Petitioner's "own comments on the 1992 [rulemaking] petitions" based "on my then recent experience as a thyroid cancer patient." (ER98-99; 130,138-40)
- Petitioner's recitation of comments filed by the National Institutes of Health in the earlier rulemaking. (ER100)
- Patient vomiting, creating contamination (ER 89-90) (noting that "NRC staff did a better job of responding to the comments in the [1997] final rule than it had in 1994" (ER77-79,89-90,101; 130,132,141)
- Consistency with International Basic Safety Standards, "noting that I raised this issue at the time of the earlier rulemaking." (ER73,90)
- Difficulty of hypothyroid patients understanding, remembering and following a doctor's instructions upon release. (ER90,99; 132)
- Relative emotional benefits to the patient and family of recovery at home versus hospitalization (ER97-98&n.8,100; 132-33,137,140)
- Particular hazards of I-131 radiation, especially for children (ER73-74,91,104; 143-44)
- Protection of non-family public from exposure (ER52-53; 132-33,141)
- Hospital costs and health insurance implications (ER75n.7,75-6n.8,76;

135,142)

- Difficulties in patient/family adjustments at home after outpatient treatment (ER71-72; 133-34,139,142-43)

Whatever procedural or substantive defects might have been raised as to the 1997 rulemaking, those arguments cannot be exhumed eight years later by a new petition that replows the same ground. We understand that petitioner, a skilled advocate, can likely point to this or that supposedly “new” information to support his petition. But the underlying truth remains that petitioner – openly remorseful that he failed to seek review in 1997 because he would have been “spreading myself too thin” (ER 95-96) – simply seeks another crack at this rule.

The Hobbs Act’s 60-day limitations period is not discretionary. *See* 28 U.S.C. § 2344. It is mandatory and jurisdictional, and may not be judicially altered or expanded. *Stone v. INS*, 514 U.S. 386, 405 (1995); *City of Benton v. NRC*, 136 F.3d 824 (D.C. Cir. 1998); *NRDC v. NRC*, 666 F.2d 595, 602 (D.C. Cir. 1981).

Because petitioner, in essence, challenges procedural and substantive flaws in the 1997 rulemaking, his petition is untimely. The Hobbs Act’s 60-day limit embodies the intent of Congress to impart “finality into the administrative process, thereby conserving administrative resources and *protecting the reliance interests of [those] who conform their conduct to the regulations.*” *NRDC*, 666 F.2d at 602 (emphasis added).

NRC enacted its 1997 rule only after painstaking and exhaustive scientific review lasting six years, which involved input from its own medical advisory group, participating medical organizations and doctors, international groups, Agreement States,³ and other commenters, including petitioner himself. When one considers the effort underlying the 1997 rule, it is hard to justify reinventing the wheel at petitioner's behest eight years later. Courts have never permitted parties "to sit idly by" rather than timely seek review to protect their rights. *Guerrero-Santana v. Gonzales*, 499 F.3d 90, 94 (1st Cir. 2007).

We anticipate two bases petitioner might offer for excusing untimeliness. The first is the so-called "reopener" doctrine "well established" in the District of Columbia Circuit, *HRI, Inc. v. EPA*, 198 F.3d 1224, 1239 (10th Cir. 2000). "The reopener doctrine allows judicial review where an agency has – either explicitly or implicitly – undertaken to 'reexamine its former choice.'" *Nat'l Mining Ass'n v. Dep't of the Interior*, 70 F.3d 1345, 1351 (D.C. Cir. 1995), quoting *Public Citizen v. NRC*, 901 F.2d 147, 151 (D.C. Cir. 1990).

³ Commentary by the Agreement States is particularly instructive on this issue. Petitioner notes that a few Agreement States originally questioned the current rule (Pet.Br.15), but ignores that the remainder, by their silence, agreed with, or at least did not oppose, the change. In the current rulemaking, only one Agreement State responded, affirmatively *supporting* the existing rule as providing "substantial" benefit to patient and families alike. (RER72).

Here, NRC never indicated *any* intention to reexamine the 0.5 rem patient-release standard. NRC merely gave public notice offering an opportunity for comment and explaining petitioner's reasons for his proposal. 70 Fed. Reg. 75752 (Dec. 21, 2005). Nowhere did NRC indicate second thoughts about its *existing* rule; it merely invited comments on *petitioner's* proposal.⁴ Compare *Nat'l Ass'n of Reversionary Prop. Owners v. Surface Transp. Bd.*, 158 F.3d 135, 142 (D.C. Cir.1998); *Nat'l Mining Ass'n*, 70 F.3d at 139; *Kelley v. Selin*, 42 F.3d 1501, 1515 n.3 (6th Cir. 1995). This Court should not embrace the reopener doctrine, as its application can only serve to encourage duplicative and untimely appeals. Even so, the doctrine is clearly inapposite here.

Second, petitioner might argue that denial of his rulemaking petition asking that former Section 35.75 be reinstated, entitled him to challenge anew the 1997 rule change. This doctrine, also from the District of Columbia Circuit, allows a renewed challenge, after denial of a rulemaking petition, for "a claim that agency action was violative of statute." *Edison Elec. Inst. v. ICC*, 969 F.2d 1221, 1229

⁴ It is of no consequence that NRC did issue fresh guidance (on children's exposures) as a result of this proceeding. (ER7) First, the guidance was not a rule change, either formally or in substance. As such, it does not "relate to rights accorded to individuals." *First Alabama Bank, N.A. v. United States*, 981 F.2d 1226, 1230 (11th Cir. 1993). Second, the guidance derived from a CORAR comment, not from petitioners' rulemaking petition. (RER51) Petitioner cannot perfect this Court's jurisdiction by the fortuitous filing of comments by a different entity after he filed his own rulemaking petition.

(D.C. Cir. 1992); *Nat'l Mining Ass'n*, 70 F.3d at 138; *Env'tl Def. Fund v. EPA*, 852 F.2d 1316, 1325 (D.C.Cir.1988). Petitioner, however, makes no claim that NRC acted *ultra vires*. Moreover, no procedural doctrine should allow a new petition for rulemaking to revive claims like petitioner's – that the original rule lacked adequate record support, reflected a poor policy choice, or rested on a suspect procedural pedigree. *See NRDC v. NRC*, 666 F.2d at 602.

II. NRC reasonably denied, for lack of a strong technical basis, the petition for rulemaking to revoke its 1997 patient release rule.

To overturn an agency decision denying a rulemaking petition, a challenger must make a “compelling” showing that the current rule lacks a legal basis or that its factual underpinnings have changed substantially. *See Midwest Ind. Transmission Sys. Operator, Inc.*, 388 F.3d at 910-11. NRC carefully considered petitioner's request to return to the old (pre-1997) patient release limit, but found it lacked the “strong technical basis” necessary to become an agency priority and have a claim on “limited agency resources.” (ER4) Petitioner's case does not even approach the threshold necessary to overturn NRC's “decision to refrain from amending the . . . established regulatory scheme.” *Prof'l Drivers Council v. Bureau of Motor Carrier Safety*, 706 F.2d 1216, 1221 (D.C. Cir. 1983).

A. The totality of the record overwhelmingly supports NRC's decision not to revert to the 30 mCi patient release standard.

Petitioner asks this Court to examine “the totality of the record,” but that is *exactly what petitioner has not done*. Rather than examining the record as a whole, petitioner has selected what he regards as vulnerable areas, based substantially on his personal experience and other anecdotal evidence. More than a few medical professionals warned NRC against relying on this “anecdotal evidence” instead of “evidence-based data” because changes drawn from anecdotes rather than verifiable facts could result in “unintended negative consequences for both patients and the nation’s health care system.” (RER47).

NRC, unlike petitioner, *did* examine the totality of the record. It noted that petitioner’s concerns regarding “doses to the family members and members of the public from released patients were extensively considered during the development of the current patient release criteria rule,” and decided that a dose-based rather than activity-based rule would best protect families and the public. (ER3). The activity-based rule was “not dependable,” NRC found, whereas “basing the patient release criteria on the dose to individuals exposed to a patient (*i.e.* dosed-based regulation) would provide a consistent, scientific basis for such decisions that treats all radionuclides on a risk-equivalent basis.” *Id.*

NRC stated that a dose-based rule would also “allow consideration of case specific factors to more accurately assess the dose to other individuals” (ER3),

following assurances by medical commenters that their patient assessments are case-specific. NRC's mission is to regulate exposure to radiation and to keep exposure within defined limits and "as low as [is] reasonably achievable" (ALARA). The new dose-based regulation accomplished this by defining dose limits and by guiding doctors in achieving ALARA levels through patient assessment and instructions to patients and caregivers. The former 30 mCi activity standard did not accomplish this. The 1997 rule's dose-based approach, in short, must be fairly seen as an *improvement* on the prior approach. It was anything but "deregulation," as petitioner would have it. (Pet.Br.8,31)

In contrast to petitioner's anecdotal support and personal opinions,⁵ NRC relied upon overwhelming expert evidence for its approach. This support comes from medical organizations and medical specialists alike. Doctors called the old 30 mCi "activity" standard, for example, "old-fashioned and obsolete" and "not a step forward" (RER29), and a "simplistic one-activity-fits-all release limit."

⁵ Many of petitioner's arguments are based on faulty technical analysis, proving the risk of going beyond the record and expanding into medical lore. For example, petitioner cites a patient administered 60 mCi of I-131, calculated to cause an exposure of 0.450 rem. He argues that typical thyroid cancer patients are given twice that dose, implying that their exposure would exceed 0.5 rem. (Pet.Br.53) But that hypothetical assumed an intact thyroid (*i.e.*, a hyperthyroidism patient). With the thyroid intact, one assumes no bodily elimination of I-131 because the thyroid absorbs it. Dose was therefore calculated from the *physical* half-life of I-131. (RER118; Example 1). For a cancer patient, the thyroid has been removed and I-131 circulates in the body. The *effective* half-life of I-131, which includes bodily elimination of I-131 as well as radioactive decay, is therefore far less. (RER120-21; Example 2) A treating doctor would understand this distinction.

(RER18) The Society of Nuclear Medicine, an international organization of more than 16,000 professionals, called the petition “misinformed” and “a significant step backward in protecting the public’s health.” (RER59)

Many cancer specialists voiced strong support for the current rule from their patients, who echoed the same reasons NRC gave in the original rulemaking and recent rulemaking denial. Among these was Dr. Perry W. Grigsby, Professor of Oncology at the Washington University (St. Louis) School of Medicine, who has “performed about 1000 outpatient I-131 procedures (25-250 mCi), including children and adults,” receiving “neither complaints nor reports of incidents caused by accidental exposure.” (RER11) Dr. Grigsby reported that “patients overwhelmingly prefer the new approach because of less disruption in their lives and the great cost savings of not having to be hospitalized for several days,” making outpatient treatment “a medical benefit to the thyroid patient to be treated on an outpatient basis.” *Id.* Dr. Grigsby said that “the existing rule is correct and that released patients pose no danger to anyone with whom they come in contact,” noting that the new rule was adopted only after “extensive studies were performed and the data stringently evaluated.” *Id.*

Dr. Jeffry A. Siegal stated that a return to the old 30 mCi rule “would indeed be regressive,” as “[t]here is no credible origin or rationale for this rule.” In fact, “there is no evidence demonstrating that 30 mCi would actually present a hazard to

the public health and safety. Empirical data [from patient's families] . . . support and confirm that there is no justification for the 30 mCi limit." (RER18)

James Krohauge, a Ph.D. chemist with the Harvard Medical School, Department of Radiology, who has clinical responsibilities with radiopharmacy for Harvard's teaching hospitals, was "astonished" by the "inaccurate and ill-conceived" petition for rulemaking. (RER71) He noted that a longer hospital stay "dramatically increases" hospital staff exposure to radiation as well as the patients' exposure to "opportunistic bacteria and viruses." *Id.* As a brain tumor survivor himself with 18 years clinical experience, Dr. Krohauge offered "first hand knowledge and experience." *Id.* Innumerable doctors concurred. (*e.g.*, RER22,57)

Numerous commenters pointed to a study by Dr. Grigsby (AMA Journal 2000) of the families of treated/immediately-released patients showing that the current rule is quite conservative in practice.⁶ (RER9,11-12,13,16,23,32) Measured family doses ranged from 1 to 109 millirem with a mean of 24, the latter equivalent to about one month's natural background radiation. (RER23). The actual measured maximum dose was about 1/5 the existing release limit of 0.5 rem under the current rule. (RER16,23) *See* RER32 (Grigsby study has "eloquently documented" the "practical success" of the new rule); RER57-58 (proves current rule's conservatism). Another study of 14 families showed all but two doses to be

⁶ Petitioner concedes the value of the Grigsby study, but questions, in effect, whether the doctors know how to control study groups. (ER70-72)

less than 0.3 rem, and the highest 0.501 rem. (RER26) A doctor with 27 years experience in nuclear medicine treated a patient with 203 mCi of I-131. His wife wore a dosimeter for a week, registering a 0.071 rem dose. (RER48)

Not only practitioners but also their professional associations joined in the chorus urging NRC not to revert to the old rule. The American Board of Nuclear Medicine, for example, stated that “no justification” exists for measuring dose to family and others from the “amount of radioactivity administered to a patient” – *i.e.*, the old 30 mCi standard. (RER13) It “steadfastly supports” the new rule and “is adamantly opposed” to reinstating the former one.⁷ (RER14)

The American Thyroid Association (ATA), whose 900 doctors specialize in thyroid diseases, concluded that “no compelling data or arguments have been made” to revert to the former rule. (RER38) The ATA cited numerous supporting studies, one of which monitored 14 patients treated with up to 187 mCi of I-131 (*i.e.*, six times the release limit petitioner advocates). The researchers found that, even assuming someone was *always* one meter away, the measure radiation did *not*

⁷ Petitioner suggested during rulemaking that the Advisory Committee on Medical Uses of Isotopes (ACMUI) had reservations about the 1997 rule. (ER98) Dr. Barry Siegal, then ACMUI Chairman, refutes this allegation and confirms that the ACMUI in fact “was quite supportive of the proposal and of the evolving regulatory guidance that would accompany a final rule,” and, ultimately, “unanimously agreed to the rule” with recommended changes. (RER36) Dr. Siegal adds that “[n]early a decade of subsequent clinical experience,” including his own extensive experience, “confirms that this advice has stood the test of time.” *Id.*

exceed the exposure permitted by NRC's current rule. (RER38) The ATA pointed out that NRC's regulatory limit of 0.5 rem in the current Section 35.75 "is about double the total overall background ionizing radiation exposure per year that the average citizen receives." *Id.*

Other medical organizations provided equally supportive and compelling arguments for not adopting petitioner's proposal:

- The Endocrine Society (Section 35.75 offers "the most effective and efficient care" for thyroid cancer patients"; reinstating the old rule "will likely have a negative impact on patient care and significantly increase health care costs by mandating unnecessary hospitalizations for patients that pose no risk to the public health.") (RER46)
- The American College of Radiology Association ("[T]he efficacy of the current release standard has been empirically borne out since the standard was adopted" and "the added cost of reverting to the prior standard – increased healthcare costs, patient access concerns, and patient inconvenience – is clearly unwarranted.") (RER49)
- The Council on Radionuclides and Radiopharmaceuticals ("[T]he existing regulatory framework provides adequate protection in accordance with recommendations of national and international standards-setting organizations.") (RER51-52)

- The Society of Nuclear Medicine (“The current standard, implemented after years of research by top nuclear medicine experts, NRC staff and advisory committee members, follows this more appropriate [dose-based] approach.”) (RER59)
- The American Society for Therapeutic Radiology and Oncology (“[We] strongly oppose” the petition, noting outpatient treatment “has significantly improved both patient comfort and safety,” (RER61) and provides patients with “significant emotional benefit,” while avoiding “the risks of nosocomial [hospital-related] infection and other adverse effects of hospitalization.”) (RER62)
- The American Association of Physicists in Medicine (Outpatient determinations “should continue to be based on an assessment by the authorized medical professionals involved, and not solely dictated by an overly simplistic regulation based on a defined quantity [30 mCi] of administered radioactivity.”) (RER65)

Given this outpouring of professional support for NRC’s current approach, and the dearth of technical support suggesting otherwise, NRC has no reason to explore in full-fledged rulemaking petitioner’s heartfelt, but contrarian, point of view.

B. NRC adequately considered petitioner's objections to Section 35.75.

1. The NRC's 0.5 rem patient release standard is compatible with international radiation standards.

Petitioner claims that NRC's patient-release rule directly contravenes Basic Safety Standards (BSS) of the International Atomic Energy Agency (IAEA). Pet.Br.38-40. Petitioner's passing referral to the BSS in his petition and comments (ER73,90) is scarcely sufficient to compel NRC's addressing the point he now vigorously advances. *Vermont Yankee Nuclear Power Corp. v. NRDC, Inc.* 435 U.S. 519, 554 (1978) (party must "do more to bring the matter to the agency's attention" than mere reference). Even when issuing a rule, much less when denying a petition for rulemaking, NRC "need not address every comment," regardless of its significance or prominence in the record. *Reytblatt v. NRC*, 105 F.3d 715, 722 (D.C. Cir. 1997).

In any event, NRC certainly *did* consider the views of the international community.⁸ As NRC explained, adopting the 0.5 rem release standard followed publication of an exhaustive study entitled "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material," NUREG-1492 (April

⁸ NRC keeps its regulations "compatible, to the extent appropriate, with those of the IAEA." 65 Fed. Reg. 44360, 44361 (July 17, 2000). This does not mean that NRC does or must adopt them *per se*.

1997). This analysis reviewed the exposure recommendations of the ICRP and NCRP, finding that “[b]oth ICRP and NCRP recommend that an individual be allowed to receive a dose up to 5 millisieverts (0.5 rem) in a given year in temporary situations where exposure to radiation is not expected to result in doses above 1 millisievert (0.1 rem) for long periods of time.” (RER112) Obviously, the temporary exposure of a family to an I-131 released patient for a few days is an exposure not expected to last for long periods of time. NRC earlier found that greater than annual treatments are rare. (ER36)

Petitioner notes the “close connection” between ICRP’s Recommendations and IAEA’s BSS. (Pet.Br.39-40; ER51) In fact, the BSS *must* follow the ICRP’s Recommendations: “The governing body of the IAEA has decided that the BSS have to take the Commission’s Recommendations into account. The BSS therefore have always followed the establishment of new Recommendations from the Commission.” (ER 51) By considering the ICRP’s Recommendations, NRC did in fact consider the BSS as well.⁹ Later in this brief, we demonstrate how this is also true with regard to ICRP dose recommendations for children, in particular.

⁹ NRC is always considering the appropriateness and adequacy of its radiological protection rules, including consideration of international standards (RER32-33). A likely upcoming rulemaking will consider all criteria, not just patient release criteria.

2. NRC's rule does not permit or encourage doctors to send treated patients to hotels.

Petitioner has pinned much of his hopes on an argument he developed *after* he submitted his petition. In an apparent afterthought filed in 2006, petitioner asserted a “practice, apparently widespread,” of “encouraging I-131 patients to go to hotels” when released, pointing to (but not citing) a rulemaking comment that “at least one hospital” has a regular arrangement for this practice. (ER53) Shortly afterwards, petitioner recanted, admitting that *no such comment had really been filed*, and that the story of this “widespread practice” came from a website. (ER52) This afterthought and other stories like it are *exactly* the kind of unverifiable and unscientific anecdotal support¹⁰ many doctors and medical organizations cautioned against in their comments.

¹⁰ Petitioner points to a recent (after the record closed) Minnesota directive on the risk of hotel stays. Pet.Br.42-43. NRC did, as petitioner suggested, make a telephone call to the Supervisor of the Minnesota Department of Health, Radioactive Materials Unit. (Pet.Br.43) NRC was told that the notice cited by petitioner related to a single, isolated incident, not a widespread practice, as petitioner implies. NRC does not ask this Court to vouchsafe our report any more than petitioner's implication of widespread noncompliance – we simply note that this Court ordinarily confines itself to the administrative record. *Public Power Council, Inc. v. Bonneville Power Administration*, 442 F.3d 1204, 1211 (9th Cir. 2006). Otherwise, “the federal courts would be proceeding, in effect, *de novo* rather than with the proper deference to agency processes, expertise, and decision-making.” *Lands Council v. Powell*, 395 F.3d 1019, 1030 (9th Cir. 2005).

Alleged incidents of released patients' checking into hotels is really just a roundabout way of saying that doctors will fail to give patients adequate instructions, or that patients will ignore them. Yet, NRC received a number of reassuring comments from doctors to the contrary:

The petitioner has apparently failed to consider that those of us who are responsible for treatment of patients with high doses of I-131, such as those used for treatment of thyroid cancer, *are not just technicians blindly following a standard protocol without regard to the ability of the patient to maintain safety in regards to bystanders in the household and in the proximate environment.* On the contrary, we routinely and carefully interview our patients and their family members accompanying them to assess their ability to understand and comply with the requirements of minimizing exposure to other household inhabitants and bystanders. *It is a responsibility we all take very seriously. We are well aware of the patients' hypothyroid status, which may well compromise their ability to follow instructions. . . .* We educate our patients as to all such guidelines with clear written instructions as required. When we deem that the patient is unable and/or unwilling to comply, then in-patient dosing is always available as an alternative in such circumstances. [RER2; emphasis added]

See also, e.g., RER34 (“[i]ndividuals are chosen for outpatient treatment-status only after an in-depth review of their home environment. Patients who are unable to do this are then offered in-patient admission”).

Moreover, the record is replete with affirmations that doctors along with RSOs perform the necessary calculations under Section 35.75 to assure public health and safety before releasing a treated patient. A few patient commenters have said otherwise, but their isolated, anecdotal experiences cannot fairly be extrapolated to paint the picture suggested by petitioner of the entire medical

community turning a blind eye to the welfare of their patients and families.

Doctors characterized petitioner's commentary on released patients as "patronizing" and "erroneous," noting that patients "who are determined to be incontinent of urine, incapable of self-care or unable to adhere to the instructions are treated as inpatients." (RER23). Another stated that "outpatient radiation precautions are straightforward" (RER28) and, in protecting children, are "explicit," adding, "my patients with young children have not had difficulty with this." (RER29). The short of the matter is that the record shows no routine use of hotel stays to deal with the patient release problem, and also shows that physician-provided precautions are workable and effective.

3. NRC did not revisit the socioeconomic costs/benefits of the patient release rule because petitioner did not provide a sound technical basis for changing it.

Petitioner asserts that, in rejecting his petition, NRC impermissibly considered economics and took a one-sided view of the psychological benefits of the current rule. (Pet.Br.35) This is no more than a straw man petitioner has invented. Nowhere does petitioner cite NRC reliance on economic cost-savings¹¹

¹¹ Petitioner confuses cost savings to *licensees*, which cannot be achieved at the expense of "adequate protection" of public health and safety (Pet.Br.35), and the socioeconomic benefits to *non-licensees* (i.e., patients and their families) once adequate assurance has been achieved. In fact, NRC's ALARA regulations explicitly consider "the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations." 10 C.F.R. § 20.1003.

or psychological benefits as a basis for rejecting his petition. In fact, NRC did *not* re-evaluate psychological or financial benefits to patients and their families, but instead determined that petitioner had not cited a sound technical basis for reverting to the old 30 mCi rule. See ER4 (“petitioner has not provided any data to refute” NRC’s regulatory analysis supporting the current rule); ER6 (proposed rule “is not warranted for the protection of public health and safety”); ER3 (“current NRC regulations provide adequate protection to family members and other members of the public”).

Nor was NRC obliged to revisit economic or psychological aspects of its prior rulemaking.¹² As it observed, “the concerns related to doses to family members and members of the public from released patients were *extensively considered* during the development of the current patient release criteria rule” adopted in 1997. (ER3; emphasis added) Certainly, the records of the earlier as well as current rulemaking *do* show that patients will indeed reap cost-savings

¹² In 1997, NRC recounted comments that the new standard is “beneficial to both the patient and the family because patients are able to return home earlier,” and that “hospitals can be a distressing experience for many cancer patients.” 59 Fed. Reg. 30724, 30726 (June 15, 1994). It also heard warnings that a 0.1 rem release limit “would require longer periods of hospitalization, that many outpatients would become inpatients, and this would be extremely expensive.” *Id.* Adopting the final rule in 1997, NRC found that shorter hospital stays would result in “lower health care costs” and “may provide emotional benefits to patients and their families.” (ER44) Many current commenters similarly cited outpatient treatment as a major benefit to patients. (*E.g.*, 2,11,3,39,51,62)

from outpatient treatment, and that other patients will benefit from the added availability of hospital beds. One doctor explained, for example:

The current rule is extremely helpful in minimizing healthcare costs (i.e., allowing release vs. isolative hospitalization for many patients saves overall healthcare costs), while not substantially increasing risk to others Moreover, release often results in more timely medical care, because scheduling of isolation hospital rooms can be problematic. [RER16]

See also RER 24 (Duke University Medical Center “has benefited by (a) being able to free scarce resources (radiation isolation rooms) for the patients who truly require them . . . and (b) not having to divert staff resources to cover over 55 additional patient bed-days per year for I-131 thyroid cancer patients”). But NRC decided those issues in 1997. Petitioner should not be allowed to raise these issues anew.¹³

Regarding emotional costs and benefits, petitioner argues that NRC has “refused to consider evidence from patients” (Pet.Br.44) that their emotional well-being is enhanced, knowing that, while hospitalized, their loved ones are not exposed to radiation. Here again, NRC did not reinvent the wheel from 1997, but indeed considered comments “from cancer patients” treated with I-131 and immediately released. (ER2) Some, like the five cited by petitioner (Pet.Br.44),

¹³ Another such concern raised anew was vomiting by released patients. Petitioner briefly alludes to this issue (Pet.Br.28,43n.21), but NRC heard from numerous doctors that vomiting rarely occurred outside the hospital and that patients and caretakers were adequately instructed on clean-up. (ER5, RER2,7,11,20,38,54,60)

“expressed concern that they had to take care of themselves” at home and about “exposure to family members and others.” (ER2)

But contrary experiences and opinions of the medical profession, based on a much larger sample, showed that their patients were emotionally *relieved* to go home, avoiding unnecessary disruption of family life. In no way belittling petitioner’s perspective or the difficult experiences of some patient commenters, these doctors’ comments on their patients’ *gratitude* for I-131 outpatient procedures reasonably supported NRC’s refusal to initiate rulemaking to reconsider psychological benefits issues it had resolved years ago. Congress entrusted NRC with the task of weighing such competing concerns and developing workable and safe approaches. That’s what the agency has done here.

4. The NRC adequately considered a patient’s understanding of his doctor’s instructions.

Petitioner expresses concern that “hypothyroid patients may have trouble fully taking in or remembering [medical] guidance” given by their doctor upon release (Pet.Br.3). But the medical community, as the record shows, does not share this view, as the NRC received no comments from physicians backing up this concern. Physicians are required by NRC rule, 10 C.F.R. § 35.75(b), to provide written instructions to the patient if the TEDE to any other individual is likely to exceed 0.1 rem, or to another adult if the patient is incapable of understanding or complying with instructions on maintaining doses to others

ALARA. (ER5). These instructions in NRC published guidance, which have not materially changed from the former 30 mCi rule to the new 0.5 rem rule, include: (1) maintaining distance from other persons, including separate sleeping arrangements; (2) minimizing time in public places; (3) precautions to prevent the spread of contamination; and (4) knowing how long the precautions should be in effect. (RER114-15).

Petitioner assumes that any patient calculated to cause dose to others of less than 0.5 rem will automatically be released, without medical assessment of the patient's circumstances. He claims that, under the 1997 rule, "patients are routinely sent home." (Pet.Br.32) This is simply not true. As discussed, Section 35.75 does not require release of patients treated with I-131. Rather, it allows release. Section 35.75(a) states that "[a] licensee *may* authorize the release from its control" certain treated patients. (Emphasis added) Doctors understand the distinction. (RER15). "Inherent in performing patient-specific calculations upon which patient release may be authorized is consideration of co-existing medical conditions and patient behavior which may [a]ffect occupancy factors and/or ability of the patient to follow radiation protection instructions." (RER15) Nowhere does Section 35.75 override medical judgment on the timing of a patient's release – a doctor always has the option of hospitalizing a patient who is unable to care for himself or follow instructions. (ER5).

Interestingly, the ICRP, whose Publication 94 petitioner invokes elsewhere (Pet.Br.49), does *not* recommend inpatient treatment across the board:

The decision to hospitalise or release a patient should be determined on an individual basis. In addition to residual activity in the patient [from which dose to others is calculated], the decision should take many other factors into account including the patient's wishes, occupational and public exposures, family considerations, the presence of children, cost and environmental factors. [RER101]

Even the commenters cited by petitioner acknowledge that outpatient status follows an examination of home life by a Radiation Safety Officer, and that patients correctly isolate themselves at home. (ER65-68) Yet, petitioner and some patient commenters question whether doctors are derelict in their professional assessment of outpatient treatment. Reliable data from patient studies, however, show that doctors are not ordering outpatient treatment willy-nilly. Over one-third of all thyroid cancer treatments in 2004 were performed as inpatient procedures. (RER66). Therefore, doctors as well as hospital Radiation Safety Officers are obviously exercising judgment in the release of I-131 treated patients. In any event, outpatient treatment is *not an NRC requirement*, and patients are free to be hospitalized, as some choose to do, if the doctor believes inpatient treatment is warranted. *See, e.g.*, ER67 (commenter "adamant that I be admitted to the hospital"); ER 66 (patient stayed two days in hospital).

Some commenters apparently believe that NRC should mandate inpatient treatment so that medical insurers will be compelled to pay. *See, e.g.*, ER61 ("If

the NRC set guidelines for hospital admission then rooms would have to be available.”); ER67 (insurer agreed to pay for inpatient care); ER64 (“Don’t let the insurance companies win.”). Certainly, petitioner believes that. He asserts, based on Internet postings, that “insurance companies are taking advantage of NRC’s rule change to deny coverage for inpatient treatment, even when doctors deem it medically necessary.” (Pet.Br.53 n.28) Not only is this charge unsupported by record, it contradicts the personal experience of commenting doctors discussed above. (E.g., RER2,15,23,28,29) Whatever the case, NRC is not in the medical insurance business and has no statutory authority to use its rulemaking proceedings to resolve insurance coverage issues.

C. NRC adequately explained its reasons for issuing a Regulatory Issue Summary to medical use licensees and others to protect young children.

1. NRC’s RIS responds to ICRP concerns for children.

NRC has issued a Regulatory Issue Summary (RIS) (ER7) to medical use licensees and others reiterating the greater risk to young children and infants posed by I-131 exposure, thus responding to the concerns of the ICRP in Publications 94 and 103. (ER 106;RER98) To this, petitioner says that the RIS was “incomplete and inadequate,” in effect, “good, but not good enough” (Pet. Br. 49) But this Court does “not sit as a super-agency to determine the wisdom of Commission policies” on release criteria for patients treated with radiopharmaceuticals. *Iacopi*

v. FCC, 451 F.2d 1142, 1147 (9th Cir. 1971).

NRC has acknowledged the scientific data and recommendations of ICRP Publications 94 and 103, which formed the basis of the RIS as well as petitioner's arguments on appeal.¹⁴ Specifically, NRC found: (1) "children's thyroids are very radiosensitive to carcinogenesis"; (2) children are more likely than adults to receive a dose from contamination (e.g., a parent's saliva); (3) for children and infants, the dose from contamination may exceed the dose from external exposure; and (4) accordingly, "restrictions following the release of patients should focus on infants and children." (ER4, *quoting in part* ICRP Publication 94)

Considering three options to implement the ICRP finding on contamination risks to young children, including a revised rule, NRC decided that the best option was revising its regulatory guidance to medical licensees and issuing an RIS to make them aware of ICRP's concern "about doses to children from patient contamination and the actions licensees and patients should take to keep children away from any sources of patient contamination." (ER4). The RIS recounted the

¹⁴ 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. In fact, the ICRP continues to recognize external exposure as the "major aspect of radiation therapy that needs to be controlled when releasing a patient." (RER100,104) No publications or data have "demolished" (Pet. Br. 55) NRC's approach. Neither ICRP No. 94 nor the RIS says that dose is greater by contamination than external exposure to the patient; they simply say that contamination is a more important exposure pathway for children than previously thought.

findings of ICRP Publication 94 (ER8,10) and reminded licensees that Section 35.75 currently requires a physician “to provide the released individual, or the individual’s parent or guardian” with written instructions to maintain doses to others at ALARA levels if the dose to another is likely to exceed 0.1 rem. (ER10).

Accordingly, NRC stated that, in light of the recent ICRP recommendations, licensees “should take into account whether the released patient may come into contact with infants or young children,” and “provide the patient with additional instructions in those situations.” (ER10) Further, licensees “should also consider *not* releasing patients administered I-131, whose living conditions may result in contamination of infants and young children.” (ER11; emphasis in the original)

NRC directed that these additional instructions should include:

- A recommendation to have patients avoid direct or indirect contact (e.g., indirect contact includes contamination from shared living space) with infants and young children for a specific period of time (e.g., consider having children stay outside the home with other family members).
- A recommendation for patients to have adequate living space at home (e.g., bedroom, bathroom) that can be used exclusively by the patient for a specific period of time.
- Information on the potential consequences, if any, from failure to follow these recommendations. [ER11]

2. Formal rulemaking was not required to alert the medical community to the concerns of ICRP for children.

The Court will note that petitioner has subtly segued from his own proposal

– a return to the 30 mCi activity-based standard for patient release – to the question of whether NRC has shown appropriate regard for the ICRP *dose-based* constraint of 0.1 rem for children and infants. (Pet.Br.26-28,31,33,39-40,49-59). Petitioner might believe that the new ICRP dose constraint for children and infants should be adopted as a regulatory limit, *but that is not what he asked the NRC to do*. His petition did not call for adopting *any ICRP dose-based constraints whatever*, but asked “for revocation of the [existing] rule, insofar as it allows patients to be released from radioactive isolation with more than the equivalent of 30 millicuries of I-131 [*an activity standard*] in their systems.” (ER88). As a result, petitioner’s “logic” now becomes: NRC should revert to an outdated and impractical activity-based standard of 30 mCi because, some years after the NRC’s adoption of a dose-based standard of 0.5 rem, the ICRP has recommended a more restrictive dose-based constraint of 0.1 rem for children and infants.

Petitioner thus asks for judicial relief on grounds nowhere mentioned in his rulemaking petition.¹⁵ If petitioner had advocated a dose-based release limit of 0.1 rem for children, NRC could have responded and, as importantly, offered that approach to the public and the medical community for comment. As it stands now, *no one* commented on what has become a mainstay of petitioner’s brief. “Simple

¹⁵ As noted, ICRP’s recommended dose constraint for children (ER3) was not raised by petitioner, but by a different commenter, CORAR, which “generally opposed the petition.” (ER2)

fairness . . . requires as a general rule that courts should not topple over administrative decisions unless the administrative body not only has erred but has erred against objection made at the time appropriate under its practice.” *United States v. L.A. Truck Lines*, 344 U.S. 33, 37 (1952). See also *Department of Transp. v. Public Citizen*, 541 U.S. 752, 764 (2004) (participants in agency proceeding must “structure their participation so that it . . . alerts the agency to the [parties’] position and contentions” to allow the agency to give the issue meaningful consideration, quoting *Vermont Yankee Nuclear Power Corp. v. NRDC, Inc.*, 435 U.S. at 553); *Env’tl Def. Ctr, Inc. v. EPA*, 344 F.3d 832, 879 n.66 (9th Cir. 2003).

That said, ICRP warns against interpreting its “dose constraint as a rigid annual dose limit,” as petitioner has done. (RER100,102) “Dose constraints” were *not* intended as recommended regulatory limits, but rather “represent a source [patient]-related system of control of exposures to the individual, below which optimization is carried out.” (RER102) “Optimization” is using medical judgment to analyze the likelihood of exposures to others. (RER103) Therefore, accepting ICRP’s pronouncement at face value does not translate a 0.1 dose constraint for children into a regulatory limit under 10 C.F.R. § 35.75.¹⁶ This is so because the

¹⁶ Dramatizing his case, petitioner claims that NRC regulates hyperthyroid cats treated with I-131 more strictly than humans. (Pet.Br.57-58). But cats cannot follow instructions, do not have separate bathrooms, and often sleep in their owners’ beds or sit on their laps. Treated cats are therefore regulated with *other non-human exposure sources* under Section 20.1301, not under Section 35.75.

regulation requires doctors to exercise sound medical judgment in assessing patient care at home before releasing the patient.

Much of petitioner's rhetoric on this point assumes or bluntly charges that treating doctors are incompetent or indifferent to the well-being of their patients and patients' families. But the record belies this notion. The record shows that, even before issuance of the RIS, doctors routinely considered the special sensitivity of children to I-131 radiation and the practical consequences of living conditions for a released patient upon children and infants:

We do not blithely send post I-131 treatment patients "out the door" On the contrary, we routinely and carefully interview our patients and their family members accompanying them to assess their ability to understand and comply with the requirements of minimizing exposure to other household inhabitants and bystanders. [RER2]

Other doctors attested likewise. (*E.g.*, RER7,16,20,29,34,46,53,65,69,73) This commentary refutes petitioner's accusation "that patients are routinely sent home with no inquiry about their actual living conditions." (Pet.Br.3)¹⁷

NRC decided not to adopt a new release limit for children and infants

¹⁷ Petitioner's accusations that the NRC has "stopped enforcing" Section 35.75 (Pet. Br. 56, 3, 35) are false. Formal inspection procedures in NRC Inspection Manual, Procedure 87131, § 87131-03.01(g), document licensee compliance (RER124), and random inspections are periodically conducted by NRC Regional inspectors. Had petitioner questioned enforcement in his petition – as opposed to his appellate brief – NRC could have discussed compliance in the record.

because it would be difficult for NRC to “meaningfully estimate,” by rule, the doses from contamination:

The factors involved in assessing such doses are largely indeterminate, and even assumptions are likely to be so much in error as to be meaningless. For example, the amount of iodine in the patient’s saliva is highly variable even for patients receiving the same treatment, and the amount of the saliva that may be ingested by a child is dependent on the details of the family’s living arrangements, family habits and the age of the child, and cannot be reliably assumed to assess the dose to the child or the infant. This makes a dose-based approach to protecting children from patient contamination an impractical choice. [ER4]

Petitioner attacks this explanation of why NRC eschewed a rule based on generalized assumptions (Pet.Br.56) by ignoring NRC’s confidence that treating doctors will be making informed, particularized decisions based “on the details of the family’s living arrangements, family habits and the age of the child.” (ER4) Likewise, he suggests unrealistic scenarios, including his claim that “[j]ust one kiss” from an I-131-treated patient “can double” a child’s risk of cancer.¹⁸

(Pet.Br.4,50) Yet, ICRP’s conservative analysis explicitly states that its suggested dose constraint of 0.1 rem for children *assumes no parental precautions to protect*

¹⁸ Based on “preliminary data” from the Chernobyl reactor accident, the ICRP postulated a parent’s kiss with 1 milliliter of saliva. (ER118). A milliliter (ml) of liquid occupies one cubic centimeter (cc), and a centimeter equals 0.3937 inches. This means a saliva cube roughly 0.4 by 0.4 by 0.4 inches is assumed to pass to the child. Scientists often make very conservative assumptions, but such conservatism must be understood in the real world. Even so, this risk exists *only* “if a parent did not follow precautions” against close contact (RER105). As discussed, doctors routinely advise released patients to move children out of the home temporarily, or at least isolate themselves from children, avoiding direct or indirect contact.

children. (RER105) (referring to “doses to a child’s thyroid . . . [if] a parent did not follow radiation protection instructions”).

Most importantly, none of the authorities upon which petitioner relies, including the ICRP publications, urges returning to the old 30 mCi release rule to address exposure of children to contamination. Petitioner glosses over this, calling the ICRP recommendation a strong argument “for at least considering a return” to the former 30 mCi (activity-based) release standard, failing to make any connection between the two (Pet.Br.56). As discussed, this is a *non sequitur* because ICRP has dose-based limits and constraints – it has not advocated 30 mCi or any other activity-based patient release standard. (ER4)

ICRP recommends precisely what the NRC has done: relate the patient’s radioactivity to predicted exposure, utilizing “realistic models that can be traced to dose measurement of the public” (RER107), repudiating petitioner’s activity-based standard:

[Some] reported that activity-based hospitalizations [petitioner’s proposal] may cause physicians to administer less activity than they would have liked, in order to avoid hospital stays. *The use of retained activity as the sole criterion for compliance has problems as this may have little to do with subsequent patient behavior and the ultimate dose to relatives and the public.* (RER107; emphasis added)¹⁹

With utter clarity, ICRP elsewhere states: “It is recommended that release of

¹⁹ ICRP discusses contamination risks, but adds: “[P]arental support of a child is very important, and considerations regarding separation of a child and parent should take the psychological cost of such separation into account.” (RER109)

patients should be based on their family situation (rather than retained activity and the worst-case scenario)." (RER110; emphasis added) The worst-case scenario, however, is what petitioner's case is all about. Accordingly, by treating ICRP's recommended dose constraint as "a rigid annual dose limit," and calling for an activity-based rule that ICRP itself disavows, petitioner has wandered far astray. Petitioner ignores that, when NRC is acting "within its area of special expertise," as here, "a reviewing court must generally be at its most deferential." *Baltimore Gas and Elec. Co. v. NRDC, Inc.* 462 U.S. 87, 103 (1983).

D. Any NRC staff encouragement or assistance to the 1991 rulemaking petitioner did not violate the law.

Petitioner cites a letter from Dr. Carol Marcus, whose rulemaking petition (in part) led to the 1997 rule. He charges that certain NRC staff encouraged Dr. Marcus to file her petition and helped her write it. (ER93) Petitioner concedes that any irregularity, if it occurred, was not a basis for voiding the 1997 rule, but argues that NRC should nonetheless resolve what happened more than a decade ago so that it can decide whether to initiate *his* proposed rulemaking. (Pet.Br.47)

NRC saw no purpose in the academic exercise of sorting out the precise "she-said, he-said" of what happened in 1991 or thereabouts. (ER3) Dr. Marcus acknowledged NRC staff prompting on an unrelated correction of Part 20 at that time, but denied petitioner's charge of staff assistance on her request to eliminate the 30 mCi patient-release standard, calling this "insulting" and "preposterous."

(RER5) Petitioner sees a quite different story – insidious NRC staff enlistment of an outside petitioner to advance a private agenda (Pet.Br.48), but acknowledged in 2005 that no collusion occurred “[w]ith regard to [Dr. Marcus’s] patient release criteria petition.” (ER82n.12) There, “Dr. Marcus did all the work, by her own account, and it does not appear that the same people encouraged submission of the petition and then evaluated it after it was received.” *Id.* Whatever happened, NRC reasonably concluded that its “decision to initiate rulemaking to adopt petitioner’s proposals could not rest on a question of staff compliance with internal NRC procedures.”²⁰ (ER3)

Rather than claim any APA or other statutory violation, petitioner instead points to an NRC housekeeping regulation issued in 1991, *after* the staff assistance had already been rendered. *See* ER3. This rule, 10 C.F.R. § 2.802(b), clarified the kinds of assistance staff may provide prospective rulemaking petitioners. The rule does *not* state that it shall have a retroactive effect, and agency rules are presumed to have a prospective effect. *Wright v. Director, FEMA*, 913 F.2d 1566, 1573 (11th Cir. 1990).

²⁰ NRC made no finding in 1997 whether any improper collusion occurred with respect to Dr. Marcus’s petition to change the patient release standard to 0.5 rem. A “presumption of regularity attaches to the actions of Government agencies.” *USPS v. Gregory*, 534 U.S. 1, 10 (2001). As noted in our timeliness discussion, alleged collusion is a stale argument petitioner could and should have raised on appeal in 1997.

Petitioner does not really disagree, but claims that disclosing the alleged collaboration was required. (Pet.Br.48) This ignores, however, that the regulation itself does not require public disclosure, although an NRC staff memorandum calls for disclosure. (ER49) But such “internal operating instructions” are “solely for in-house agency use and are not judicially enforceable.” *First Alabama Bank, N.A. v. United States*, 981 F.2d at 1230. *See also James v. U.S. Parole Comm’n*, 159 F.3d 1200, 1205-06 (9th Cir. 1998). In any event, NRC in 1997 was aware of the collusion issue, as was petitioner himself. (ER135n.3,143) Even if disclosure were legally required, any failure to disclose in these circumstances was not prejudicial and certainly insufficient to justify a fresh rulemaking many years after the fact. *See* 5 U.S.C. § 706 (“due account shall be taken of the rule of prejudicial error”).

More fundamentally, two prominent medical organizations, the ACNM and the AMA, filed their own petitions supporting elimination of the 30mCi release standard – separate and apart from Dr. Marcus’s – a result supported by most of the 63 commenters, including medical practitioners and other medical organizations. As NRC stated:

Their independent proposals as well as the broad participation by interested parties negate the inference drawn by the petitioner that the resulting rulemaking was merely the product of staff influence. [ER3]

Given the independent proposals for eliminating the 30 mCi release standard by like-minded doctors and medical societies in the original rulemaking, any initial NRC staff prompting for what became the 1997 patient release rule could not possibly be a basis for requiring a renewed rulemaking more than decade later.

CONCLUSION

In 1997, NRC concluded a six-year rulemaking proceeding that exhaustively considered views of the medical community on the most effective methodology for protecting public health and safety upon the hospital release of patients treated with radiopharmaceuticals, including thyroid cancer patients treated with I-131. No one appealed, including petitioner. Yet, eight years hence, armed with little more than the nagging thought that the entire medical community has been misguided all along, petitioner asked NRC to start all over.

Rather than summarily dismissing the petition, NRC went the extra mile and solicited comments. Now, undaunted by the thunderous chorus of disapproval he elicited from medical practitioners, petitioner asks this Court to step in. Considering the enormous professional, governmental and judicial resources drained by this belated request, one searches the record in vain for scientific justification for reinstating petitioner's preferred 30 mCi rule. Petitioner obviously does not share NRC's regulatory approach in this area. But his personal point of view, however strongly held, does not overcome the insurmountably high judicial

standard he faces, and his petition cannot succeed.

Accordingly, for the reasons discussed above, the petition for review should be dismissed for lack of jurisdiction or denied on the merits.

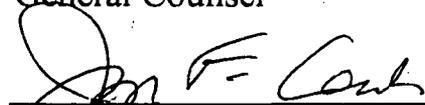
Respectfully submitted,

RONALD J. TENPAS
Assistant Attorney General

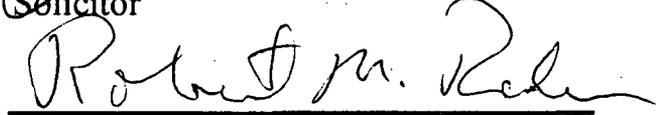
CHARLES R. SCOTT
Attorney
United States Department of Justice
Environment & Natural Resources
Div.
P.O. Box 23795
Washington, D.C. 20026-3795
(202) 514-2813 (voice)
(202) 514-8865 (fax)

Dated: November 4, 2008

KAREN D. CYR
General Counsel



JOHN F. CORDES, JR.
Solicitor



ROBERT M. RADER
Senior Attorney
Office of the General Counsel
U.S. Nuclear Regulatory Commission
(301) 415-1955 (voice)



OFFICE OF THE
GENERAL COUNSEL

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 9, 2008

Peter G. Crane, Esq.
6545 27th Avenue, NW
Seattle, WA 98117-5902

Re: *Crane v. United States Nuclear Regulatory Commission*, No. 08-72973

Dear Mr. Crane,

This confirms the extension granted by the Clerk today for the Government's answering brief, now due November 3, 2008, and moving back your reply brief an equivalent time.

Thanks again for consenting to the extension.

Yours truly,

A handwritten signature in black ink, appearing to be "Rader" or similar, written over a light blue horizontal line.

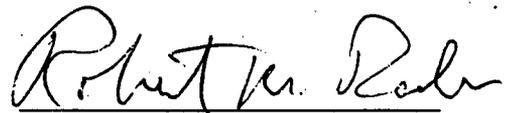
Robert M. Rader
Senior Attorney
Office of the General Counsel
Nuclear Regulatory Commission
(301) 415-1955 (voice)
(301) 415-3200 (fax)
Robert.Rader@nrc.gov (e-mail)

STATEMENT OF RELATED CASES

Respondents Nuclear Regulatory Commission and United States
know of no related case pending in this Court.

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)(7)(C)

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C), I certify that the foregoing brief is proportionately spaced, has a typeface of 14 points, and as calculated by my word processing software (Word), contains 13,947 words.

A handwritten signature in cursive script, reading "Robert M. Rader", is written over a horizontal line.

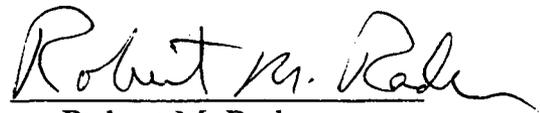
Robert M. Rader

November 4, 2008

CERTIFICATE OF SERVICE

I certify that, on this date, I caused to be served two copies of Brief of Respondents and two volumes of Respondents' Excerpts of the Record, by overnight mail, upon counsel for the parties as follows:

Peter G. Crane
6545 27th Avenue, NW
Seattle, WA 98117


Robert M. Rader

Date: November 4, 2008