NOT YET CALENDARED FOR ORAL ARGUMENT

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 04-71432

NUCLEAR INFORMATION AND RESOURCE SERVICE, et al.,
Petitioners,

v.

UNITED STATES NUCLEAR REGULATORY COMMISSION
and the UNITED STATES OF AMERICA,
Respondents.

ON PETITION FOR REVIEW OF AN ORDER OF THE
U.S. NUCLEAR REGULATORY COMMISSION

# BRIEF FOR THE FEDERAL RESPONDENTS

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## *JURISDICTIONAL STATEMENT*

This petition for review challenges a Nuclear Regulatory Commission ("NRC") rule. We agree with petitioners (Br.1) that under the Hobbs Act this Court has subject matter jurisdiction to consider the petition for review. *See* 28 U.S.C. § 2341 *et seq.*

## *ISSUES PRESENTED*

1. Whether petitioners -- citizen groups alleging no particularized harm from an NRC rule that (a) lowered radiation doses from transportation and (b) conformed to new international and Department of Transportation standards -- have standing to challenge the NRC rule.

2. Whether petitioners, after participating in an NRC rulemaking, may supplement the administrative record with additional evidence in sworn declarations presented to this Court but never brought before the NRC.

3. Whether the NRC acted reasonably under the National Environmental Policy Act in finding that the agency's new transportation rule, which on average would lower radiation doses, would cause no significant adverse environmental impacts.

## *STATEMENT OF THE CASE*

A. *Nature of the Case*

In 2004 the NRC issued a final rule amending its regulations in 10 C.F.R. Part 71, pertaining to the transportation and packaging of radioactive materials. (EUR 3:634).[1] The Part 71 amendments were designed primarily to harmonize the NRC's transportation regulations with international transportation regulations of the International Atomic Energy Agency (IAEA), and with domestic transportation regulations of the Department of Transportation ("DOT"). (EUR 3:635).

The NRC's final rule is accompanied by an extensive rulemaking record. Petitioners' lawsuit focuses primarily on the NRC's adoption of the IAEA's new methodology for exempting low-level radioactive materials from transportation regulations. The agency issued an Environmental Assessment ("EA"), which found that changing to the new methodology would not have a significant environmental impact. (EUR 3:525).

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[1]"EUR" refers to petitioners' "Excerpts of Undisputed Record."

Petitioners challenge this finding. They rely on sworn declarations prepared especially for this litigation -- but not submitted to the NRC during the Part 71 rulemaking -- which allegedly show that the NRC's EA was inadequate in various ways.

Like the NRC, DOT issued a final rule adopting the new IAEA methodology for exempting materials with very low concentrations of radioactivity from transportation regulation.[2] Petitioners challenged the DOT rule in federal district court. But the district court dismissed petitioners' complaint on the ground that exclusive jurisdiction to review the DOT regulations resides in the courts of appeals.[3]

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[2] *Hazardous Materials Regulations; Compatibility with the Regulations of the International Atomic Energy Agency*, 69 Fed. Reg. 3632 (Jan. 26, 2004) ("DOT Final Rule").

[3] *Nuclear Information and Resource Service v. United States Dep't of Transportation Research and Special Programs Admin.* No. C. 04-4740 MHP (N.D. Cal., May 31, 2005) (unpublished), *appeal pending*, No. 05-16327 (9th Cir.)

B. *Regulatory and Historical Background*

1. The IAEA's long-term goal is "harmonization of radiation protection and safety standards internationally." (SER 06).[4] Such standards do not and cannot have as their goal eliminating all risk from radioactivity:

> Radiation and radioactive substances are natural and permanent features of the environment, and thus the risks associated with radiation exposure can only be restricted, not eliminated entirely. Additionally, the use of human made radiation is widespread. Sources of radiation are essential to modern health care.

*Id.*

Prior to adopting the regulation at issue here, the NRC applied a uniform "activity concentration" standard to exempt transportation of low-radioactivity material from regulation. "Activity concentration " refers to the number of nuclear disintegrations per second in a gram of material. The most convenient unit of measurement is the *Becquerel* -- one radioactive disintegration per second, named in honor of the physicist who in 1896 discovered spontaneous radioactivity. Formerly, the NRC set 70-Becquerels per gram ("Bq/g")

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[4]"SER" refers to our "Supplemental Excerpts of Record."

as a uniform activity concentration exemption standard. Radioactive material with fewer than 70 nuclear disintegrations per second in a gram was exempted from NRC regulation during transportation. (Before and after transportation, however, material licensable under the Atomic Energy Act ("AEA"), 42 U.S.C. § 2011 *et seq.*, remained subject to NRC regulation.)

A conceptual difficulty with basing exemptions on a uniform activity concentration standard is that activity is not directly correlated with the radiation health risk. The risk to health from radioactive material is determined by the *dose* which the radiation can cause. Dose depends not only on the number of disintegrations per second but also on the type and energy of the radiation emitted by a nuclear disintegration. Exposure to radioactive materials having the same activity but different nuclear emissions may result in a significantly different dose.

Under the NRC's new Part 71, the exempt activity concentration is no longer the same for all nuclides. Some activity concentrations are greater than 70 Bq/g (*i.e.* a relaxation of the previous standard for

exemption) while others are less (stricter regulation). (EUR 2:321, 3:647). The average radiation dose associated with the transportation of exempt material is lower than under the previous rule. (EUR 3:321; 3:651).

2. The NRC and DOT co-regulate transportation of radioactive material in the United States, the NRC under the AEA, and DOT under the Hazardous Materials Transportation Act, 49 U.S.C. § 5101 *et seq.* Under the AEA, the NRC has broad jurisdiction to license and regulate the receipt, possession, use, and transfer of radioactive material defined under the AEA as "byproduct material," "source material," and "special nuclear material." *See* 42 U.S.C. §§ 2071-2114. The NRC's statutory mandate is to protect public health and safety and assure the common defense and security of the United States. *See* 42 U.S.C. § 2012(d). Historically, the NRC and DOT have coordinated their regulation of radioactive material transportation. (EUR 1:009).

As part of its regulatory function, the NRC establishes occupational and public dose limits for exposure to radioactive

materials. 10 C.F.R. Part 20. These dose limits are expressed in "rems" or "millirems" ("mrem").[5] For example, the current NRC limits for occupational dose and dose to members of the public due to licensed activities are 5000 mrem per year and 100 mrem per year, respectively. *See* 10 C.F.R. §§ 20.1201(a)(1)(i) and 20.1301(a)(1).

3. At the request of the Economic and Social Council of the United Nations, in 1958 the IAEA began developing international regulations for the safe transportation of radioactive materials. *See* DOT final rule, 69 Fed. Reg. at 3632. The IAEA's ensuing regulations -- Regulations for the Safe Transport of Radioactive Materials, IAEA Safety Series No. 6, ("IAEA Safety Series No. 6") -- were issued in the 1960s and used by member states (including the United States and most other industrialized nations) as the basis for national and international transportation regulations. *Id.*

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[5]A "rem" is a unit of dose measurement. *See* 10 C.F.R. § 20.1004. For perspective, the yearly dose from natural background radiation averages roughly 300 mrem (about one-third rem), although there is substantial variation. *See In re TMI Litigation*, 193 F.3d 613, 644 n. 50 (3d Cir. 1999).

IAEA Safety Series No. 6 established a methodology to exempt low level radioactive material from regulation during transportation. In rulemakings undertaken in the 1960's, the Atomic Energy Commission (the NRC's predecessor agency) and DOT revised their transportation regulations to conform to the IAEA Safety Series No. 6 methodology. *See, e.g., Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions*, 31 Fed. Reg. 9941 (July 22, 1966). The IAEA used a uniform "activity concentration" value of 70 Bq/g (*i.e.*, 70 Bequerels per gram) to define a material as subject to transportation regulation. If the specific activity concentration of a material was equal to or below this 70 Bq/g value, it was exempt from NRC and DOT regulation during transportation. That standard remained in effect until the NRC (and DOT) adopted the revised methodology that petitioners have challenged in this lawsuit.

Over the years the IAEA updated IAEA Safety Series No. 6 in

areas not related to exemption thresholds. (EUR 2:315-16).[6] Both the NRC and DOT are participating members of the IAEA and have direct input into the development of IAEA transportation standards. Each time IAEA Safety Series No. 6 changed, both the NRC and DOT revised their transportation regulations to make them compatible with the IAEA's. (EUR 2:316).

C. *NEPA Requirements*

Under the National Environmental Policy Act ("NEPA"), whenever a federal agency proposes a "major federal action[] significantly affecting the quality of the human environment," the agency must prepare an environmental impact statement ("EIS"), explaining the impacts of the proposed action and evaluating alternatives to the proposed action. 42 U.S.C. § 4332(C). The Council on Environmental Quality ("CEQ") has promulgated regulations to assist federal agencies in complying with NEPA

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[6]*See also Hazardous Materials Regulations; Compatibility with the Regulations of the International Atomic Energy Agency*, 67 Fed. Reg. 21328-29 (April 30, 2002) ("DOT Proposed Rule).

obligations. 40 C.F.R. § 1500.3.[7] Under these regulations, an agency must prepare an EIS or an environmental assessment ("EA") for any action not "categorically" excluded under agency regulations. *See* 40 C.F.R. § 1501.4.

An EIS is a detailed report subject to extensive conditions regarding format, content, and methodology. *See* 40 C.F.R. Part 1502. An EA, by contrast, is a "concise public document" that "briefly provides" sufficient evidence and analysis for determining whether an EIS is required. 40 C.F.R. § 1508.9. If, on the basis of an EA, the agency determines that a full EIS is not required, the agency may make a finding of no significant impact, briefly explaining why an action will not have a significant effect. *See* 40 C.F.R. § 1501.4(e) & 1508.13.

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[7]The CEQ regulations do not directly apply to the NRC, an independent agency, but the agency has agreed "to take account of the regulations. . .voluntarily, subject to certain conditions." 10 C.F.R. § 51.10(a). *See generally Limerick Ecology Action v. NRC*, 869 F.2d 719, 725 (3d Cir. 1989); *Sierra Club v. NRC*, 862 F.2d 222, 228 (9th Cir. 1988).

D. *Statement of the Facts*

1. *IAEA's Revision to Methodology for Calculating Exemption Values.*

To reflect scientific and technical advances and accumulated experience, and with the active participation of IAEA member states, including the United States, the IAEA in 1996 completed a major revision to its transportation regulations, replacing IAEA Safety Series No. 6 with "Regulations for the Safe Transport of Radioactive Material, TS-R-1" (EUR 2:315-16). Among other things, the revisions changed the IAEA's uniform "70 Bq/g" approach to calculating threshold exemption values for transportation. (EUR 2:321). As working members of the IAEA, both the NRC and DOT participated in developing the revised exemption thresholds. (EUR 3:650).

The IAEA determined that there was no technical justification for using a single activity concentration value of 70 Bq/g as the transportation exemption threshold for all radionuclides. (EUR 2:321; 3:647). The IAEA concluded that a technically sound

approach required dose-based exemption thresholds. Because of differences in energy and types of radionuclide emissions, dose-based thresholds would result in different transportation exemption values (*i.e.*, activity concentrations) for each of the 380 different radionuclides.

To develop a dose-based approach for transportation exemption values, the IAEA began with safety standards incorporated into a 1996 IAEA study -- the "BSS" study.[8] That study used a nuclide-specific, dose-based approach to calculate exemption values for radioactive materials in *fixed* facility scenarios (*e.g.*, medical use of radiopharmaceuticals in nuclear medicine applications). For each radionuclide, the study established an exemption threshold that would limit an effective annual dose to 1 mrem or less per year. (EUR 2:321; 3:655).

Because the BSS (fixed facility) exposure scenarios and pathways did not explicitly address transportation of radioactive

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[8]Safety Series No. 115, International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources.

material, the IAEA performed calculations on a subset of BSS scenarios pertinent to transportation and additional transport-specific scenarios, including accident scenarios. (EUR 1:020; 2:321; 3:647, 651). Consistent with the BSS model, the IAEA calculated (for the 20 most commonly transported radionuclides) the "activity concentration" values needed to limit the effective annual dose to 1 mrem or less to a transport worker. The IAEA found that the transportation-specific activity concentration values differed from the fixed facility BSS values by less than two orders of magnitude. (EUR 2:321).[9] The IAEA concluded that this difference did not justify imposing two different sets of exemption threshold values (*i.e.*, one for fixed facility exemptions and another for transportation exemptions).

The IAEA's calculations showed that the average annual transportation dose to transport workers based on the BSS (fixed facility) exemption values -- about 23 mrem per year -- exceeded the IAEA's target dose limit of 1 mrem per year for exempting

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[9]*See also* DOT Proposed Rule, 67 Fed. Reg. at 21331.

radioactive materials from regulation in fixed facilities, but would be less than half the average dose based on the existing 70 Bq/g value -- about 50 mrem per year. (EUR 2:321; 3:630-32, 655). The IAEA's calculations also showed that the variability in doses would be far less using the BSS's exemption values than the 70Bq/g value.[10] Accordingly, the IAEA adopted the fixed facility BSS values for nuclide-specific transportation exemptions.

2. *Course of the Rulemaking Proceeding and Public Comments*

In 2002, after soliciting public input through an early public-participation process, the NRC published a notice of proposed rulemaking and an accompanying draft EA. (EUR 2:315). The NRC proposed revising the Part 71 regulations to incorporate, *inter alia*, the IAEA's revised transportation exemption values. (EUR 2:321). The notice discussed in detail the impact on public health and

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[10]IAEA calculations showed that the annual transport worker dose (from the 20 most commonly transported nuclides) ranged from 0.002 mrem to 230 mrem using the uniform 70 bq/g exemption value, and from 0.3 mrem to 42 mrem using the BSS's nuclide-specific exemption values. (EUR 3:630-32). *See also* DOT Proposed Rule, 67 Fed. Reg. at 21331.

safety and the scientific basis for changing to a nuclide-specific dose-based approach. (EUR 2:321-23). The NRC explained that the proposed nuclide-specific approach would reduce the average annual doses to transport workers and the public from the most commonly transported radionuclides. (EUR 2:321).

The NRC allowed 90 days for public comment and also held two public meetings. The NRC received almost 200 comment letters on various issues addressed in the proposed rule. Approximately twenty comment letters addressed the NRC's proposal to adopt the IAEA's methodology for calculating exemption thresholds. (EUR 2:417–515). Most of the commenters opposing the change in methodology, including petitioners, criticized the proposed rule itself. They said nothing about the draft EA.

Petitioners' comments focused primarily on dose levels that would result from the proposed rule change. They said the dose levels in the NRC's proposed rule were too high. They objected to NRC's reliance on scientific authorities such as the International Commission on Radiological Protection ("ICRP") regarding the health

effects of exposure to low doses of radiation. They asked that the NRC depart from widely held consensus views among ICRP and other scientific authorities regarding the risks of low-level radiation. (EUR 2:464-66, 504; 3:648, 654). They also maintained that the NRC's new transportation exemption thresholds would facilitate "deregulation" as well as purposeful illegal "release" of radioactive materials into daily commerce. (EUR 2:461, 505).

With respect to the draft EA, the NRC received just two comment letters, *see* EUR 2:427 (Johnsrud letter); 2:482 (Halstead letter), and comments from two individuals during one of the agency's public meetings. *See* EUR 2:381; 2:385 (Mr. Halstead); 2:393 (Mr. Dilger). One of the commenters objected to any exemption of radionuclides from regulatory control, opposing even a threshold exemption level that would result in a dose of 1 mrem per year. EUR 2:422; 2:427 (Johnsrud letter). The other two commenters criticized the EA for not developing more quantitative data, including data on exempt shipping volumes. *See* EUR 2:381 (Mr. Halstead); 2:384-85 (Mr. Halstead); 2:393 (Mr. Dilger); 2:483

(Halstead letter).

3. *The NRC's Rule Adopting A Nuclide-Specific Approach for Calculating Threshold Exemption Values*

(a) *The NRC's Explanation of its Substantive Rule*

In its proposed and final rules, the NRC described the impact of replacing the uniform "70 Bq/g" exemption methodology -- which, the NRC noted, lacked a technical basis (EUR 2:321; 3:647) -- with a radionuclide-specific approach. The NRC identified all radionuclides for which threshold exemption values either rose or fell relative to the prior 70 Bq/g threshold. (SER 12-24; EUR 3:673-79). The NRC acknowledged that some new radionuclide-specific concentration values were higher than 70 Bq/g. (2:321; EUR 3:652). Likewise, the NRC made clear that transportation doses would differ, higher or lower, from the BSS 1 mrem standard for fixed facilities, depending on the particular radionuclide being transported. (EUR 2:321; 3:651). But, the NRC pointed out, from the 20 most commonly transported radionuclides, transport workers would receive an average annual dose estimated at about 23 mrem,

less than half the average annual average dose of about 50 mrem per year under the prior 70 Bq/g exemption standard. *See, e.g.*, EUR 2:321; 3:655. The NRC noted that the radionuclide-specific approach reduced the variability in doses that were likely to result from exempt transport activities. (EUR 3:647).

To comments that an average annual dose level of 23 mrem for transport workers was still too high, compared to the 1 mrem/year standard used for fixed facility scenarios, the NRC responded that 23 mrem was low under NRC regulatory standards for occupational workers and also low under prevailing standards of the domestic and international scientific community. (EUR 3:640, 642, 654, 655).

The NRC observed that the estimated doses were based on highly conservative transportation scenarios, with exposure periods and exposure distances "that overstate actual exposures to workers and greatly overstate actual exposures to the public." (EUR 3:655). The NRC indicated that the resulting dose estimates were sufficiently low that any actual multiple exposures would also be

acceptably low and well below regulatory limits. (EUR 3:652). No information existed, the NRC pointed out, to suggest that multiple exposures under the longstanding 70 Bq/g exemption level had been a problem in the past. (EUR 3:655).

Responding to comments about the health effects of low-level radiation exposures, the NRC explained, *inter alia*, that for low levels of radiation exposure "health effects are so small they may not be detected." (EUR 3:640). The NRC explained that it actively and continually monitors research programs on the effects of low-level radiation, and that it is co-funding a review of the Biological Effects of Ionizing Radiation (BEIR) by the National Research Council. *Id.*

Although the NRC responded to comments regarding the health effects of low radiation levels, it made clear that a fundamental reevaluation of radiation dose effects was beyond the scope of the rulemaking. (EUR 3:654). The NRC indicated that the purpose of its rulemaking was to harmonize the NRC's threshold exemption levels for transportation with international standards while continuing to maintain the safety of shipments of radioactive

materials consistent with current regulatory standards and prevailing scientific views. (EUR 3:653).

"[W]hile promulgating lower exemption levels could reduce the already low public health risks," the NRC said, "the exemption values offer the best balance between economic and public health concerns." *Id.* "Failure to adopt the new system would [not only] put the U.S. at a competitive disadvantage in international commerce without commensurate benefit to public health and safety [but would also allow] the continued shipment of exempt materials that are calculated to produce higher doses to workers and members of the public." (EUR 3:651).

The NRC addressed comments claiming that revising the threshold exemption levels would facilitate "release" or "deregulation" of radioactive materials and dispersal of nuclear material into daily commerce and household items. The NRC explained that the revisions would not result in a new regulatory scheme for releasing radioactive material from other regulatory controls or to unauthorized persons. (EUR 3:647, 648). The NRC

indicated that, as with the existing 70 Bq/g exemption provision, radioactive materials meeting the revised exemption thresholds were only exempt from additional transportation requirements (such as special packaging rules), not from other regulatory requirements for controlling the possession, use, and transfer of radioactive materials. (EUR 3:647, 648). *See* 10 C.F.R. Parts 30, 40, and 70.

The NRC also noted that it had considered the accident history of nuclear transportation in estimating shipping risks resulting from the Part 71 revisions. The NRC concluded that the new rule would provide adequate protection of the public and workers in normal transport conditions and in accident conditions. (EUR 3:644).

With respect to comments that the EA should have included quantitative data on the volume of exempt shipments, the NRC explained that no data existed on the number or frequency of exempt packages shipped in the United States under the existing 70 Bq/g exemption standard, because exempt shipments are not subject to reporting requirements. (EUR 3:639, 649). The NRC said that quantifying such shipments would impose a significant burden

without commensurate benefit to public health and safety. (EUR 3:652).

Throughout the rulemaking the NRC reiterated that the dose criteria used in determining the activity concentrations for exempt materials ensure that doses from either single or multiple sources will be low and far below public dose limits. *See, e.g., id.* The NRC also observed that a large majority of commercial radioactive materials are shipped in highly purified forms that far exceed exemption levels, and that this was expected to continue under the revised exemption thresholds. (EUR 3:649).[11]

(b) *The NRC's NEPA Documentation*

(i) Along with its final rule, the NRC provided an EA that found no significant environmental impact from the new rule. (EUR

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[11]In a Part 71 provision unrelated to transportation exemptions and on which only brief comments were received (*see* EUR 2:463, 466, 511-12), the NRC also revised the definition for a subclass of "Low Specific Activity" ("LSA") material to conform to DOT regulations. LSA material is defined in 10 C.F.R. § 71.4 as material of "limited specific activity" (but greater than exempt activity concentrations). (EUR 3:669). LSA material is generally subject to packaging regulations. *See* 10 C.F.R. § 71.14, EUR 3:672.

3:525). Lacking data on exempt shipments, the EA analyzed data pertaining to regulated shipments. (EUR 3:549). It considered a 1985 report prepared by the Sandia National Laboratories, which estimated the number of regulated packages shipped for various nuclides. *Id.* Based on the 1985 report, the EA included a table showing the six nuclides comprising the largest number of regulated shipments and gave the exemption level that would apply to these nuclides. *Id.* Of the six, two would have a higher exemption level under the new rule and four would have a lower exemption level, *i.e.* be more strictly regulated, a change which "could lead to a decrease in the number of exempted shipments." (EUR 3:549-50).

The EA addressed radioactive isotopes with much higher exemption levels (1000 Bq/g or higher) under the new rule. The EA noted that only two of these (Ni-63 and Xe-133) "contribute 0.01 per cent or more of the total curie amount transported." (EUR 3:550). These isotopes "are generally found only in fission products, and are shipped as spent fuel or high-level waste," *i.e.*, the shipments do not involve exempt packages and therefore should not be affected by the

rule change. *Id.*

The EA also addressed other commonly transported isotopes that might be affected by the rule change -- plutonium and neptunium. The EA noted that for these isotopes the new exemption levels are 1 Bq/g or lower, making packages previously exempt under the 70 Bq/g rule now subject to regulatory requirements. The EA said that this change will either cause a decrease in the number of shipments "and/or some level of improved protection for the shipments that continue to be made." *Id.*

(ii) As the NRC noted in its substantive rule discussion (SER 09-10, EUR 3:665), another environmental document exists that is pertinent to domestic transportation of radioactive materials -- the NRC's generic transportation EIS, issued in 1977. (SER 01). The generic EIS described the overall impacts of regulated, non-exempt shipments (*i.e.*, transportation of radioactive material with specific activity concentrations greater than the 70 Bq/g exemption threshold). It comprehensively evaluated, among other things,

collective doses and doses from transportation accidents. (SER 03-04).

(c) *The NRC's Conclusion Regarding Health Impacts*

In sum, the NRC found that the new IAEA methodology would, overall, reduce already-low radiation doses to transport workers and to the general public. (EUR 3:655). The NRC concluded that, "[b]ecause the annual doses estimated to result from the use of the radionuclide-specific exemption values are low, and on average are lower than the dose estimates for the current 70 Bq/g activity concentration, the NRC believes that changing from the 70 Bq/g value to the radionuclide-specific exemption values will result in no adverse impact on public health and safety." *Id.*

## ***SUMMARY OF ARGUMENT***

1. Petitioners must show standing to sue – *i.e.*, they must show how the new NRC transportation rule causes "particularized" harm that this Court can redress. In their opening brief, petitioners do not mention standing, much less show it. They claim that the new NRC rule exposes the general public, particularly transport

workers, to excessive radiation. But under traditional Supreme Court doctrine harm to the general public, as opposed to particular individuals, is too diffuse to support standing. As for transport workers, petitioners – all of whom are organizations – have offered no evidence suggesting they represent such workers.

2. Petitioners' use of extra-record evidence -- purportedly to demonstrate alleged NRC "failures" to examine environmental impacts -- is impermissible. The rare exceptions for allowing such evidence do not apply here. Petitioners had ample opportunity to contribute to the agency's record during the comment period but did not offer the information they now present in litigation declarations.

3. On the merits, the NRC's consideration and disclosure of the human health impacts of revising the transportation exemption thresholds comply with NEPA.

(a) The NRC's new transportation exemption thresholds are considerably more protective than the old threshold, a fundamental point that petitioners' NEPA arguments essentially ignore. At bottom, petitioners are simply challenging the fact that the NRC did

not adopt the particular exemption thresholds that petitioners want -- *i.e.*, exemption thresholds that would result in an annual effective dose of 1 mrem or less.

Petitioners misstate several aspects of the NRC's rule. A key misstatement is that the NRC had adopted a dose standard of 1 mrem per year for transportation exemption thresholds. But the NRC had not. Another critical misstatement is that the NRC's rule would result in doses exceeding all federal regulatory standards. In fact, the estimated overall doses to transport workers would be lower than under the pre-existing exemption rule and far below the current occupational dose limits for NRC licensed activities.

While petitioners now challenge the NRC's rule on NEPA grounds and complain about the EA, in the agency rulemaking petitioners themselves focused only on the substantive rule. They filed no comments on the EA. The NRC thoroughly discussed the rule's impacts in its rulemaking notices, so any inadequacy in the EA itself would not be prejudicial error.

(b) A fundamental reexamination of radiation dose effects was

not within the scope of the NRC's exemption rule. Thus, the existence of differing views regarding the health effects of low doses of radiation did not create a "controversy" triggering the need for an EIS in the context of the NRC's rule. In any event, technical agencies like the NRC are accorded substantial discretion to rely on the reasonable opinions of their own qualified experts. The NRC's conclusion that doses resulting from the revised rule would be low, even lower than doses from the prior rule, is consistent with the opinions of leading experts in the field of nuclear science.

(c) Petitioners insist that the NRC ought to have collected more data about exempt shipments. But such an effort would have been costly and unnecessary. Exempt shipments by definition are not regulated and have no reporting requirements. The NRC acted reasonably in using available data to extrapolate exempt shipment information and tiering to a generic EIS that had comprehensively evaluated the public health risks from non-exempt transportation of radioactive materials. Given the lower overall doses resulting from the new rule, exempt shipment data was not essential to assessing

the health impacts of the rule.

(d) Petitioners misunderstand the NRC's new LSA-I regulations and fail to perceive that the redefined LSA-I subclass is *more restrictive* than the subclass it replaces. In addition, DOT's rule does not eliminate packaging requirements for this subclass of material as petitioners misleadingly claim, but permits more efficient and effective "industrial packaging" for bulk shipments in this subclass.

(e) Because doses resulting from the new rule are low, additional analyses regarding collective doses, transportation accident doses, and cumulative impacts would not have yielded significant new information regarding the health impacts of the revised exemption thresholds. In any event, the NRC's generic transportation EIS comprehensively evaluated collective doses and transportation accident doses resulting from transportation of non-exempt radioactive materials, and transportation accident scenarios were included in the IAEA's development of a dose-based exemption approach. In addition, petitioners' "cumulative impacts" complaint

is not relevant to the NRC's new exemption thresholds for transporting low-dose radioactive materials -- extremely low radiation doses like those at issue here, even when considered in combination with other sources of radioactivity, have no "cumulative" impact.

(f) The NRC's EA was not deficient regarding analysis of "precedential effects." The new NRC exemption rule did not establish a "precedent," binding or otherwise, for exempting low-levels of radioactive material during transportation or for other "deregulatory" activities. The NRC (and DOT) regulations for exempting low level radioactive materials during transportation had been in place for over forty years.

## ***ARGUMENT***

### ***STANDARD OF REVIEW***

Agency decisions challenged under NEPA are reviewed under the "arbitrary and capricious" standard of the Administrative Procedure Act, 5 U.S.C. § 706(2)(A). *Morongo Band of Mission Indians v. FAA*, 161 F.3d 569, 573 (9th Cir. 1998); *Greenpeace Action*

*v. Franklin*, 14 F.3d 1324, 1331 (9th Cir. 1993). "In determining whether an agency's decision is arbitrary or capricious, the court 'must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error judgment.'" *Morongo*, 161 F.3d at 573 (*quoting Marsh v. Oregon Natural Resources Council*, 490 U.S. 360, 378 (1989)). This "'inquiry must be searching and careful, but the ultimate standard of review is a narrow one.'" *Id.* The "court may not substitute its judgment for that of the agency regarding environmental consequences of the agency's actions." *Id.* "Rather, the court must simply 'ensure that the agency has adequately considered and disclosed the environmental impact of its actions. . . .'" *Id.* (*quoting Baltimore Gas & Elec. Co. v. Natural Resources Defense Council, Inc.*, 462 U.S. 87, 97-98 (1983)).

To the extent that a challenge to an agency's compliance with NEPA presents "a factual dispute the resolution of which implicates substantial agency expertise," a reviewing court is to defer to an "agency['s]. . .re[liance] on the reasonable opinions of its own

qualified experts even if, as an original matter, a court might find contrary views more persuasive." *Marsh*, 490 U.S. at 378. *Accord Wetlands Action Network v. United States Army Corps of Engineers*, 222 F.3d 1105, 1121 (9th Cir. 2000); *Morongo*, 161 F.3d at 577; *Greenpeace Action*, 14 F.3d at 1332. "NEPA does not require that [a court] decide whether an [agency's impact analysis] is based on the best scientific methodology available, nor does NEPA require [a court] to resolve disagreements among various scientists as to methodology." *Friends of Endangered Species, Inc. v. Jantzen*, 760 F.2d 976, 986 (9th Cir. 1985). Rather, when examining "scientific determinations" within an agency's "area of special expertise," a "reviewing court must generally be at its most deferential." *Baltimore Gas & Elec. Co.*, 462 U.S. at 103.

## *I. Petitioners Have not Demonstrated Standing to Challenge the NRC's Exemption Rule*

The Supreme Court has made clear that all who challenge government action in court must show standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-62 (1992). *Accord Bell v. Bonneville Power Admin.*, 340 F.3d 945, 951-52 (9th Cir. 2003). Petitioners fail

to meet that burden.

To establish standing, a party 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 government action; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision. *See Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 180-81 (2000). *Accord Bell*, 340 F.3d at 951.

Sometimes standing is self-evident, as when "the plaintiff is himself an object of the action." *Lujan*, 504 U.S. at 561. But here the NRC is not regulating petitioners themselves – four non-profit citizens groups – but NRC licensees who transport nuclear materials. This renders petitioners' claim to standing "substantially more difficult to establish." *Id.* at 562. To show standing, a petitioner "must support each element of its claim to standing 'by affidavit or other evidence.'" *Sierra Club v. EPA*, 292 F.3d 895, 899 (D.C. Cir. 2002) (quoting *Lujan*, 504 U.S. at 561). Petitioners' opening brief, however, says nothing at all about standing.

Petitioners' silence on standing leaves us somewhat in the position of "flail[ing] at the unknown in an attempt to prove a negative." *Sierra Club*, 292 F.3d at 901. But petitioners' standing seems so problematic that this Court must inquire into it as a threshold jurisdictional matter. *See Bell*, 340 F.3d at 951. On its face, petitioners' lawsuit seemingly falls well short of meeting established judicial standing requirements.

The *sine qua non* of standing is "injury in fact," an injury that is: 1) concrete and particularized, and 2) actual or imminent, not merely speculative. *See, e.g. Friends of the Earth, Inc. v. Laidlaw*, 528 U.S. at 180; *Cent. Arizona Water v. EPA*, 990 F.2d 1531, 1537 (9th Cir. 1993). Here, petitioners' brief simply complains in general terms that the NRC's new transportation rule fails to comply with NEPA and may expose unidentified members of the public to excessive radiation doses. The brief points to no concrete harm to particular persons.

Petitioners here are organizations, not individuals. But, like individuals, organizations cannot sue without concrete and particularized injury. An organization has standing to bring suit on

behalf of its members only if (among other requirements) "its members would otherwise have standing to sue in their own right." *Hunt v. Washington State Apple Adver. Comm'n*, 432 U.S. 333, 343 (1977). *See also Oregon Advocacy Ctr. v. Mink*, 322 F. 3d 1101, 1109 (9th Cir. 2003).

Although an organization whose members are injured may represent those members, a mere general interest in a problem, "no matter how longstanding the interest and no matter how qualified the organization is in evaluating the problem, is not sufficient." *Sierra Club v. Morton*, 405 U.S. 727, 739 (1972). However well-informed members of a public interest organization might be, "they may not by uniting create for themselves a super-administrative agency ... with the capability of over-seeing and of challenging the action of the appointed and elected officials...There are other forums where their voices and views may be effectively presented..." *Alameda Conservation Ass'n v. California* 437 F.2d 1087, 1090 (9th Cir. 1971). A petitioner "seeking relief that no more directly and tangibly benefits him than it does the public-at-large" lacks standing. *Lujan*, 504 U.S. at 573-74.

Petitioners in this case have not demonstrated that their organizations, or any of their members, have been injured in a "concrete" and "particularized" way. The closest petitioners come is their repeated claims that the NRC's new rule potentially will result in excessive occupational radiation doses to transport workers, "the maximally exposed individuals and cohorts." *See* Br.58; *see also id.* at 40-46. But petitioners nowhere claim to represent transport workers or allege that members of their organization are transport workers who will receive increased doses.

Petitioners, in short, do not show, or even argue, that the new NRC regulation will increase radiation exposure to any of their members or otherwise cause them harm. Even if petitioners' reply brief supplies affidavits or other evidence in an effort to fix this problem, petitioners face an uphill climb. The fact is that, when compared to the NRC's former regulation, the new regulation significantly *reduces* radiation doses on average. (EUR 3:655). How does an overall reduction in radiation doses harm petitioners? Petitioners do not explain. It is true that for some discrete isotopes, potential doses under the new regulation rise slightly. But to show

harm petitioners presumably must show that their members are exposed to those isotopes in transportation, a showing they have not even tried to make.

Petitioners, at bottom, offer merely their point of view that the NRC's new regulation will expose the public-at-large to excessive radiation. Petitioners' disagreement with the NRC regulation does not amount to a showing of "concrete" and "particularized" harm ("injury-in-fact") sufficient for standing.

Petitioners also must meet the remaining standing requirements – traceability (causation) and redressability. In NEPA cases this Court takes a "relaxed" approach to these requirements. See *Bell*, 340 F.3d at 951. Even so, they are a "constitutional necessity" and cannot be ignored altogether. *Id.* Because the NRC and DOT rules both implement the IAEA's standards, and the DOT rule is not before this Court, petitioners -- in addition to showing "injury-in-fact"-- need to explain how a judicial decree setting aside the NRC rule alone will provide them meaningful relief.

## *II. Petitioners Improperly Rely on Extra-Record Evidence*

Extra-record evidence on appeal of agency action is generally

prohibited. "[T]he focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973). *See also, e.g., Inland Empire Public Lands Council v. Glickman*, 88 F.3d 697, 703 (9th Cir. 1996). This rule applies to review of all agency action, including review under NEPA. *See City of Auburn v. U.S.*, 154 F.3d 1025, 1032 n. 8 (9th Cir. 1998); *Friends of the Payette v. Horseshoe Bend Hydroelectric Co.*, 988 F.2d 989, 997 (9th Cir. 1993).

Limiting the scope of review to the agency record keeps the decision-making process where it has been vested – in the agency itself. "Were the federal courts routinely or liberally to admit new evidence when reviewing agency decisions, it would be obvious that 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). This Circuit allows extra-record evidence in rare cases where it is the only feasible means to determine whether the agency

has considered all relevant factors and has adequately explained its decision. *See Lands Council*, 395 F.3d at 1030; *Nat'l Audubon Soc'y v. United States Forest Serv.*, 46 F.3d 1437, 1447 (9th Cir. 1993); *Animal Defense Council v. Hodel*, 840 F.2d 1432, 1436-37 (9th Cir. 1988).

Petitioners allege that their extra-record evidence -- "declarations" prepared for this litigation -- is admissible to demonstrate a host of purported "failures" to examine the environmental impacts of the revised exemption values. Br. 20. But, as we demonstrate in Point III below, here the NRC examined and disclosed the human health impacts of its revised exemption thresholds and thus has met its obligations under NEPA. Petitioners in any event had ample opportunity to contribute to the agency's record during the comment period. They offered no comments along the lines of their current litigation declarations. Alternatively, under standard NRC practice, petitioners might have brought their information before the agency in a petition to modify or rescind Part 71. They still can. *See* 10 C.F.R. § 2.802. It is

unfair to the NRC to invoke new factual evidence for the first time in an appellate court.

"Normally, if an Agency's administrative record is incomplete, we would expect litigants to seek to supplement the record in the agency before seeking to expand the record before the [] court." *Lands Council*, 395 F.3d at 1030 n. 10. Petitioners made no effort to do so. Hence, we oppose petitioners' request to introduce extra-record evidence in this case.[12]

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[12]Petitioners also claim that because the NRC and DOT coordinated their transportation rulemakings, the NRC was required to respond to all public comments filed with DOT, even those never filed with the NRC. Br. 21. None of their various record citations, including citations to agency discussions during workshops that pre-date the proposed rule, supports their claim. While the NRC coordinated its rulemaking with DOT, the two agency rulemakings were independent because each agency operates under a different statutory authorization. The NRC noted that DOT's rule provided additional useful historical background and context regarding IAEA-related subjects within the rule's scope (EUR 2:316), but it never committed to responding to DOT-only comments. Accordingly, we object to petitioners' attempt to introduce DOT-only comments as matters the NRC should have considered.

## III. *The NRC's Finding of No Significant Impact Under NEPA was not Arbitrary and Capricious*

### A. *Overview*

We begin our merits discussion with several overarching observations. First, the NRC's new exemption thresholds are considerably more protective than the old 70 Bq/g threshold -- a fundamental point that petitioners' NEPA-based attack on the rule obscures. Second, during the NRC rulemaking petitioners offered no NEPA-related comments whatever, despite a full opportunity to do so. Third, while the NRC's EA is concise, it is amply supported when read together with other documents in the record, including the final rulemaking notice itself. And, finally, petitioners' opening brief rests on gross misconceptions, including (for example) a claim that the NRC's new exemption thresholds violate the agency's own 1 mrem dose standard -- a standard that in fact does not exist.

We elaborate on these points below, before moving to a point-by-point rebuttal of petitioners' scatter-shot array of arguments.

1. *The NRC's Explanation of the Environmental Impacts of its Exemption Rule Complies with NEPA*

(a) Petitioners maintain that their challenge to the NRC's adoption of a new exemption methodology rests on NEPA grounds. They claim that the agency "failed" to consider purportedly relevant "environmental" factors. At bottom, though, petitioners are simply challenging the fact that the NRC did not adopt the particular exemption thresholds that petitioners want -- *i.e.*, thresholds that would result in an annual effective dose of 1 mrem or less.

Here, as we show in detail later in this brief, the NRC adequately considered and disclosed the impact of the revised exemption thresholds and examined whether the new levels "may cause significant degradation of some human environmental factor." *Wetlands Action Network*, 222 F.3d at 1119. NEPA requires no more.

Petitioners' own brief demonstrates that they understood the NRC's explanation of the new thresholds' impacts. Petitioners note that the revised activity concentration limits will result in an

estimated average annual dose to transport workers (*i.e.*, those most impacted by the rule) of 23 mrem and range up to an estimated 42 mrem per year. *See, e.g.*, Br. 25.[13] They acknowledge -- while vigorously disagreeing with -- the NRC's conclusion that these doses are low and well below regulatory limits. Br. 34. And they subtly acknowledge that the final rule will in fact reduce the average annual dose to transport workers by more than fifty percent. Br. 32-33. This goes a long way toward defeating petitioners' NEPA claims.

(b) While petitioners now vigorously fault the EA's relatively brief discussion of the revised exemption thresholds (Br. 29-31), petitioners themselves filed *no* comments whatsoever on the EA in the rulemaking proceeding. In their brief, petitioners cobble together multiple citations to the record (including citations

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[13]While petitioners repeatedly highlight the upper range of doses resulting from the revised dose-based exemption values -- *i.e.*, up to 42 mrem per year -- they pointedly do not mention that the upper range of doses resulting from the pre-existing uniform exemption value was much higher – *i.e.*, up to to 230 mrem per year. *See* n. 10, *supra*.

predating the notice of proposed rulemaking) in an attempt to create the impression that the NRC received extensive comments on the EA consistent with the NEPA contentions now being made on appeal. *See* Br. 14-16. But an examination of petitioners' record citations reveals that the NRC in fact received very few comments from anyone relating to the EA. The overwhelming majority of negative comments received on the rule, including those of petitioners, concerned the substantive rule itself. Moreover, the few comments on the EA that the NRC did receive, primarily complaining about the lack of exempt shipping data, were brief and conclusory. They entirely ignored the reduction in average annual doses to transport workers.

In short, none of the EA-related comments served to "'alert[] the agency to the [parties'] position and contentions,' in order to allow the agency to give the issue[s] meaningful consideration" during the rulemaking proceeding. *DOT v. Public Citizen*, 541 U.S. 752, 764 (2004) (*quoting Vermont Yankee Nuclear Power v. NRDC*, 435 U.S. 519, 553 (1978)). The NRC received no comments

regarding the EA that did more than "merely state that a particular mistake was made." *Vermont Yankee Nuclear Power*, 435 U.S. at 553. None "show[ed] why the [alleged] mistake was of possible significance in the results." *Id.* The lack of substantive comments directed to the EA in the agency's rulemaking record explains why petitioners now find it necessary to resort to extra record affidavits to support their NEPA challenge to the NRC's rule.

(c) The EA accompanying the NRC's final rule contains a relatively brief discussion of the exemption aspect of the rule. But the NRC rulemaking notices discussed the impacts of the revised exemption thresholds thoroughly.[14] As we show below, these discussions together with the EA and the generic transportation EIS

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[14]Petitioners cite several district court cases for the proposition that, under the CEQ regulations, discussion outside the EA cannot substitute for an adequate EA. Br. 32, n. 111. However, with the exception of one case, *NRDC v. Duvall*, 777 F.Supp. 1533 (E.D.Cal. 1991), the issue does not appear to have been in controversy. The issue likewise does not appear to have been in controversy in the cases relied upon in *NRDC* to support the conclusion that under CEQ regulations the EA must be the "sole permissible source of justification for an agency's conclusions." *NRDC*, 777 F. Supp. at 1538.

demonstrate that the "agency has adequately considered and disclosed the environmental impact of its actions." *Baltimore Gas & Electric Co.*, 462 U.S. at 98.

Thus, any inadequacy in the EA itself or any failure of the NRC to comply strictly with CEQ's regulations would not be prejudicial error.[15] A remand to cure technical deficiencies would serve no "benefit to the public. . . and [provide] no genuine service to the policies NEPA advances." *Friends of the River v. FERC*, 720 F.2d 93, 107 (D.C. Cir. 1983). Indeed, because the NRC's statutory mission is to protect public health and safety from radiological hazards, it must assess "human environmental factor[s]"[16] quite apart from its

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[15]*See* 5 U.S.C. 706 (reviewing court to apply rule of prejudicial error); *County of Del Norte v. United States*, 732 F.2d 1462, 1466-1467 (9th Cir. 1984) (no relief for insubstantial nonprejudicial error in complying with CEQ regulations). *Accord Warm Springs Dam Task Force v. Gribble*, 621 F.2d 1017, 1022-1023 (9th Cir. 1980); *Realty Income Trust v. Eckerd*, 564 F.2d 447, 456 (D.C. Cir. 1977). *See also Ocean Advocates v. United States Army Corps of Eng'rs*, 402 F.3d 846, 866 (9th Cir. 2005) (indicating that courts can look outside the EA for a "statement of reasons obviating the need for an EIS").

[16]*See Wetlands Action Network*, 222 F.3d at 1119.

obligations under NEPA. Other Circuits have held that where agencies like the NRC are "'engaged primarily in an examination of environmental questions, where substantive and procedural standards ensure full and adequate consideration of environmental issues, then formal complance with NEPA is not necessary, but functional compliance is sufficient.'" *Cellular Phone Taskforce v. FCC*, 205 F.3d 82, 94 (2d Cir. 2000) (*quoting Environmental Defense Fund v. EPA*, 489 F.2d 1247, 1257 (D.C. Cir. 1973)). An agency need not be instructed "to redo, under the proper heading, what has already been done." *Friends of the River*, 720 F.2d at 108.

2. *Basic Premises Underlying Petitioners' Challenge to the NRC's Compliance with NEPA are Flawed*

(a) Throughout their brief, petitioners maintain, misleadingly, that the NRC had "expressly adopted" a dose standard of 1 mrem per year as the radiation dose standard applicable to exemption threshold values. *See, e.g.*, Br. 12, 25, 26, 28, 29, 38, 50. Their essential argument is this: the NRC's finding of no significant impact was arbitrary and capricious because the revised exemption

thresholds would result in doses that exceed the 1 mrem dose standard that the NRC had (allegedly) adopted. Br. 25-28.

The short answer to petitioners' argument is that the NRC did *not* adopt a 1 mrem dose standard for revising transportation exemption thresholds. Petitioners' representation to the contrary is simply wrong.

In both its final and proposed rules, the NRC explained at some length the history and methodology underlying the IAEA's adoption of the BSS nuclide-specific exemption values. The NRC referenced the 1 mrem dose standard simply to explain how the BSS study used that dose standard when developing exemption values for *fixed* facilities. (EUR 2:321; 3:655). The NRC *nowhere* stated that it was "adopting" the 1 mrem dose criterion as an *NRC* regulatory goal for *transportation* exemption values. Indeed, the NRC made clear that the new transportation doses would differ, higher or lower, from the BSS 1 mrem standard for fixed facilities, depending on the particular radionuclide being transported. (EUR 2:321; 3:655).

(b) Other fundamental misconceptions pervade petitioners' brief.

(i) Petitioners claim that "[t]he significance of NRC's rulemaking, and the need to prepare an EIS to address public health effects, is also evident from the fact that the acknowledged doses, ranging up to 42 millirems per year, [] exceed essentially *all current radiation protection standards for public exposure promulgated by federal agencies.*" Br. 27 (emphasis added). But the dose level resulting from the NRC's new exemption threshold is not outside current regulatory limits -- not even close. For example, the NRC's current limit for occupational dose from licensed activities is 5000 mrem per year. 10 C.F.R. § 20.1201(a)(1)(i). The limit for dose to members of the public from licensed activities is 100 mrem per year. 10 C.F.R. § 20.1301(a)(1). The estimated average annual doses to workers resulting from the exemption rule (*i.e.*, ranging from 0.3 mrem to 42 mrem, with an average dose of 23 mrem) are *well below* these regulatory limits. Doses to members of the public would be much smaller.

(ii) Petitioners complain that these doses would exceed the "1 millirem individual dose standard for deregulation of radioactive material identified by other scientific bodies. . . ." Br. 26. However, the 1 millirem dose standard petitioners point to is the recommended dose for *complete release or deregulation of radioactive materials under all circumstances. See* EUR 3:655 (explaining that the BSS 1 millirem standard was for exemption of practices at fixed facilities "without further consideration"). The NRC's rule would not result in a "release" or deregulation of radioactive materials. Rather, radioactive materials below the revised exemption values would only be exempt from certain regulatory requirements temporarily, while in transport; apart from transportation, the NRC would continue to license and regulate the possession, use, and transfer of these same radioactive materials. (EUR 3:647, 648).

(iii) Petitioners also claim that the NRC "inconsistently backed away from its analysis of average doses in an effort to downplay the significance of transport worker exposures." Br. 33. Petitioners maintain that the NRC's discussion of the conservative assumptions

underlying the transportation scenarios used in the IAEA's development of exemption thresholds amounted to a "repudiation of the NRC staff's own calculation of the average dose to transport workers. . ." Br. 33-34.

Petitioners once more are wrong. As is clear from the record, the NRC *never* "repudiated" the calculation showing that the average annual dose to transport workers under the revised exemption values would be 23 mrem. In the portion of the record cited by petitioners, the NRC explained that the IAEA had calculated the dose effects of the BSS's values based on conservative scenarios, with exposure periods and exposure distances that overstated actual exposures to transport workers and greatly overstated actual exposures to the public (EUR 3:655). The NRC's purpose in engaging in this analysis was simply to point out that 23 mrem per year was a conservative dose estimate -- *i.e.*, that the average annual dose to transport workers may be even *lower* than 23 mrem. The NRC nowhere "repudiated" this dose estimate.

### B. *Disagreement with the NRC's Technical Judgment Regarding the Radiation Dose Effects of the Revised Exemption Values did Not Create a Public Controversy Requiring the Preparation of an EIS*

Petitioners argue that an EIS was required because of a "controversy," within the meaning of a CEQ regulation, about the effects of low levels of radiation. 40 C.F.R. § 1508.27(b)(4). Petitioners claim that a "substantial dispute"[17] was created when commenters cited "expert opinion that the health effects of low doses of radiation have been understated," and when commenters disputed the use of radiation models and standards used by leading

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[17]Petitioners create the misleading impression that a "substantial" number of public comments were filed on the effects of low dose radiation. Br. 36-38. However, a controversy is not created within the meaning of the CEQ regulations by the sheer number of commenters filing in disagreement with the agency. *See, e.g., Northwest Envtl. Defense Ctr. v. Bonneville Power Admin.*, 117 F.3d 1520, 1536 (9th Cir. 1997); *LaFlamme v. FERC*, 852 F.2d 389, 400-01 (9th Cir. 1988); *Foundation for N. Amer. Wild Sheep v. USDA*, 681 F.2d 1172, 1182 (9th Cir. 1982). In any event, an examination of petitioners' record citations (Br.36-38) reveals that in response to the proposed rule, the NRC received only a few comments on this issue, none of which addressed the EA except for one letter (the Johnsrud letter), which did so in a cursory fashion. EUR 2:422; 2:427. Lacking record support on the "controversy" issue, petitioners improperly rely upon an extra record affidavit and public comments that pre-date the NRC's proposed rule.

health organizations. Br. 37-38. Petitioners attempt to create the impression that the NRC ignored this category of comments by simply "reaffirming its reliance" on the ICRP and other scientific authorities, and in so doing ignored the purported "controversy" created by these comments. Br. 38-40.[18]

1. Contrary to petitioners' claims (Br. 39), the NRC did respond substantively to comments about the health effects of low dose radiation,[19] but the NRC also made clear that reexamining radiation dose effects was beyond the scope of the rule. (EUR 3:654). While there may be some controversy about biological effects of low-

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[18]Petitioners also fault the NRC for not explaining in the EA itself why there was no controversy over low dose radiation. Br. 29-31. But virtually all comments (including those of petitioners) expressing concern about low-dose radiation were directed to the substantive rule rather than to the sufficiency of the EA. Understandably, therefore, the NRC provided its response to those comments in its substantive rule explanations. *See* n. 14, *supra*, and accompanying discussion.

[19]For example, the NRC explained that "[a]lthough radiation can have health effects at high doses and dose rates, for low levels of radiation exposure at low dose exposure rates, the incidence of biological effects is so small that it may not be detected." (EUR 3:640).

level radiation, that controversy played no part in the NRC's rulemaking here.

But even if it had, the science underlying radiation dose effects and dosimetric modeling "implicates substantial agency expertise." *Marsh*, 490 U.S. at 376. Petitioners' position amounts to a fundamental disagreement with the NRC's scientific opinion -- and the opinion of the leading scientific organizations on which the NRC relies -- about the health effects of low doses of radiation. A "controversy" necessitating an EIS is not created simply because of the existence of disagreement, or purported disagreement, among experts. There is no "merit to the contention that an EIS must be prepared whenever qualified experts disagree." *Greenpeace Action*, 14 F.3d at 1335. If an agency may not act whenever "some scientists dispute [an agency's] analyses and conclusions, . . . agencies could only act upon achieving a degree of certainty that is ultimately illusory." *Id.* at 1336.

Rather, agencies are accorded "discretion to rely on the reasonable opinions of its own qualified experts" when "specialists

express conflicting views." *Marsh*, 490 U.S. at 378. This is so, "even if, as an original matter, the court may find contrary views more persuasive." *Id.* *See also* *Morongo*, 161 F.3d at 577. Courts reviewing government action are "in no position" to resolve disagreements between government experts and outsiders. *See* *Inland Empire Pub. Lands Council v. Schultz*, 992 F.2d 977, 981 (9th Cir. 1993). *See also Friends of Endangered Species, Inc.*, 760 F.2d at 986.

The NRC's analysis of the health effects of low radiation doses is consistent with the opinions of preeminent experts in the field of nuclear science. The agency's conclusion that doses resulting from the revised exemption thresholds would be low, even lower than doses from the prior rule, is precisely the type of expert determination entitled to the highest level of judicial deference. *Baltimore Gas & Electric Co.*, 462 U.S. at 103. *See also, e.g.*, *Ranchers Cattlemen Action Legal Fund United Stockgrowers of America v. United States Department of Agriculture*, Case No. 05-35264, 2005 WL 1731761, at 10 (9th Cir. July 25, 2005) ("Deference

to the informed discretion of the responsible federal agencies is especially appropriate, where. . .the agency's decision involves a high level of technical expertise.").

2. Petitioners imply that the NRC acted arbitrarily and capriciously in relying upon the IAEA and expert organizations such as the ICRP in revising its exemption thresholds. Br. 39. But the NRC did not defer blindly to these organizations. As the principal domestic agency charged with regulating the public health and safety in the use of nuclear materials, the NRC in fact played a major role in developing the IAEA standards. (EUR 3:650).

In any event, a technical agency like the NRC may properly rely on the opinion of standard setting bodies and expert organizations in adopting rules, even without universal agreement among experts. *See Seattle Comty. Council Fed'n v. FAA*, 961 F.2d 829, 831, 833 (9th Cir. 1992); *see also Cellular Phone Taskforce*, 205 F.3d at 87. What the NRC did in adopting the IAEA exemption thresholds was "not to have abdicated its responsibilities, but rather to have properly credited outside experts." *EMR Network v. FCC*, 391 F. 3d 269, 273

(D.C. Cir. 2004).

In short, contrary to petitioners' position (Br. 39), the NRC did not arbitrarily and capriciously "dismiss controversy"; the existence of differing views regarding the health effects of low doses of radiation simply did not create a "controversy" triggering the need for an EIS in the context of the NRC's rule.

### C. *NEPA Did not Require the NRC to Generate Empirical Data on Exempt Shipment Volumes*

Petitioners claim that the NRC's finding of no significant impact was arbitrary and capricious because the NRC did not gather and assess empirical data on the quantity and type of exempt shipments that would occur under the revised exemption thresholds. Br. 41. But considering the difficulty of obtaining additional data, the NRC's prior generic EIS on transportation, and the already low radiation doses at issue, the NRC proceeded reasonably when it acted on the information it had.

1. Petitioners argue that compiling more shipment data was necessary because the risks of the new rule were "highly uncertain" with respect to collective exposures to the public and multiple

exposures to transport workers. Br. 40-42. Petitioners note (Br. 40) that an EIS is required "where 'effects are highly uncertain or involve unique or unknown risks'" and "further collection of data" may resolve the high degree of uncertainty. *Nat'l Parks & Conser. Ass'n v. Babbit*, 241 F.3d 722, 731-32 (9th Cir. 2001) (citation and internal quotation marks omitted). But here, the health impacts of the revised exemption thresholds were not "highly uncertain" and did not involve "unique or unknown risks." Indeed, petitioners' contrary assertion simply reflects their basic disagreement with prevailing expert views about the health effects of low-dose radiation.

As the NRC explained, doses to the segment of the population *most* affected by exempt shipments, *i.e.*, transport workers, would be well within regulatory limits and more than fifty percent lower than under the pre-existing rule. *See, e.g.*, EUR 3:652, 655. It is implicit in the NRC's analysis that members of the public not actually involved in transportation would receive much lower doses. Moreover, as the NRC explained, because estimated doses were

calculated using conservative assumptions, the actual transport worker doses (as well as doses to the public) were likely to be even lower. *Id.*

"[I]nherent in NEPA and its implementing regulations is a 'rule of reason,' which ensures that agencies determine whether and to what extent to prepare an EIS based on the usefulness of any new potential information to the decisionmaking process." *DOT v. Public Citizen*, 541 U.S. 752, 767 (2004) (*citing Marsh*, 490 U.S. at 373-74). NEPA "'does not require the government to do the impractical.'" *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1215 (9th Cir. 1998) (citation omitted). Given the calculated low-dose impact on transport workers, it was reasonable for the NRC to conclude that collecting exempt shipment data was not essential for determining health impacts, would be costly, and thus "would impose a significant burden without commensurate benefit to public health and safety." (EUR 3:652). An agency need not gather additional data that "would be unlikely to provide definitive results." *Stop H-3 Association v. Dole*, 740 F.2d 1442, 1458 (9th Cir. 1984).

*See also Cellular Phone Taskforce*, 205 F.3d at 92. Particularly because collective doses or exposures to transport workers likely would be higher under the pre-existing rule, shipment data were not essential to the NRC's assessment of the health impacts of the revised exemption thresholds.

2. Moreover, the NRC had already prepared a generic EIS that comprehensively evaluated the public health risks from non-exempt transportation of radioactive materials, including an evaluation of collective population doses and doses resulting from multiple exposures to transport workers, as well as doses resulting from accidents. (SER 03-04).[20] The NRC referred to this EIS in its rulemaking notices. (SER 09-10; EUR 3:665). *See* 40 C.F.R. § 1508.28 (encouraging "tiering," which "refers to the coverage of general matters in broader environmental impact statements...with subsequent narrower statements of environmental analyses...."); *see*

[20]The NRC reaffirmed the generic EIS's basic conclusions regarding doses from transportation in 1981. *See Radioactive Material; Packaging and Transportation by Air*, 46 Fed. Reg. 21619, 21620 (April 13, 1981).

*also Kern v. United States BLM*, 284 F.3d 1062, 1076 (9th Cir. 2002); *Kelley v. Selin*, 42 F.3d 1501, 1519 (6th Cir. 1995), *cert. denied*, 515 U.S. 1159 (1995). The generic EIS considered regulated transportation of radioactive materials in activity concentrations above the exempt level (a uniform 70 Bq/g at the time) and found that collective doses and other impacts from regulated transportation were acceptably low. Although these results do not apply directly to unregulated transportation of materials below the exempt level, the exempt level was chosen conservatively. Thus, there is no reason to believe that the impacts of transporting exempt materials would differ significantly, unless quite possibly they would be smaller. *Cf. Salmon River Concerned Citizens v. Robertson*, 32 F.3d 1346, 1357 (9th Cir. 1994) (finding that Forest Service "reasonably anticipate[d]" herbicide doses from unevaluated sources of exposure by assessing "worst case doses").

3. Petitioners' claim that relevant data regarding exempt shipments were available or not difficult to obtain relies on a declaration (the "Resnikoff Declaration") never submitted to the

NRC. But petitioners' extra-record affidavit trivializes the complexity of gathering meaningful data about exempt shipments, which by definition are not regulated and have no reporting requirements. Notably, the NRC's notice of proposed rulemaking sought shipment data from commenters (EUR 2:319), but none was forthcoming. (EUR 3:639, 649).

(a) Petitioners cite comments by the Department of the Army that supposedly "revealed" large shipments of "remediation waste." Br. 42. A look at the Army's comments (EUR 1:275) in fact reveals that the material in question "is not anticipated to be regulated by the NRC or Agreement states." The Army describes its concern about the proposed regulations *as applied by DOT* to the shipment of a unique class of material (waste from the early atomic weapons program). The Army states that anticipated dose *reductions* to transportation workers and the public will provide "no significant benefit" to offset the burden of additional procedures. (EUR 1:277). Clearly the Army's comments provide no help for petitioners' case.

(b) As further purported proof that exempt shipment data are "readily available," petitioners refer to "Department of Energy [DOE] studies" supposedly demonstrating that "millions of cubic yards of low level waste meeting the exempt or LSA-I criteria" are poised for shipment. Br. 43-44. Because the NRC does not regulate these DOE shipments and because LSA-I material is not "exempt," the potential relevance of such data is not at all clear. Moreover, petitioners' case benefits even less from DOE's comments on the proposed rule:

> To accurately assess the cost implications of the proposed regulatory changes, an accurate estimate of the shipment volumes is needed. Since these estimates were unavailable at this time, a detailed cost/benefit analysis is not possible, but the costs are expected to be very significant.

EUR 1:265.

In short, DOE comments support the NRC's position that shipment data are difficult to obtain. The comments also make clear that DOE believed the proposed rule would tighten rather than relax regulation of DOE's waste shipments.

4. Contrary to petitioners' implication, the NRC did not fail to analyze shipping data altogether. Rather, in the absence of empirical data about exempt shipments, the NRC used the best data available to extrapolate information regarding the type and quantities of radioactive materials that would likely be shipped under the revised exemption thresholds levels. *See* EUR 3:549-50. The NRC stressed that the large majority of commercial shipments of radioactive materials would exceed exemption thresholds and would be subject to full regulation. (EUR 3:649).

Petitioners cite several cases for the proposition that an agency cannot rely on the absence of data in deciding not to prepare an EIS. Br. 40, n. 145. But in those cases, the missing data were central to the determination of environmental impacts of the agencies' actions. *See Nat'l Parks*, 241 F.3d at 732-33 (EA established that necessary information "would be of substantial assistance in the evaluation of the environmental impact of the planned vessel increase"). *See also Anderson v. Evans*, 350 F.3d 815, 835 (9th Cir. 2003); *Blue Mountains Biodiversity Project*, 161

F.3d at 1213.[21] Here, in contrast, because of the low doses to persons subject to the highest exposure (*i.e.*, transport workers), the NRC did not need shipping data to conclude that the new exemption thresholds would not have a significant environmental impact. In short, the NRC's assessment of the health impacts of the revised exemption thresholds, using the best available data, was reasonable.[22]

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[21]Cases like these are also distinguishable because the information at issue may have been reasonably obtainable. *See, e.g., Ocean Advocates*, 402 F.3d at 870 (EA provided no justification regarding why more definitive information could not be provided); *Nat'l Parks*, 241 F.3d at 732 (EA established that "information may be obtainable...."). In contrast, here the NRC forthrightly explained in both the EA and its substantive rule discussions that exempt shipment data would be extremely difficult to obtain. (EUR 3:549, 649).

[22]*See Greenpeace Action*, 14 F.3d at 1336 (upholding agency's finding of no significant impact despite agency's "less [than] rigorous" analysis where "there [was] little data available to analyze [] effects"); *Friends of Endangered Species, Inc.*, 760 F.2d at 985 (upholding agency decision not to prepare an EIS despite lack of data where agency considered best available data).

### D. *Petitioners' Arguments Regarding LSA-I, Collective Doses, Doses from Transportation Accidents, Cumulative Impacts, and Precedential Effect Are Without Merit*

1. *LSA-I.* The NRC revised its regulations for Low Specific Activity material to be consistent with the new DOT regulations. (EUR 3:662, 669). *See* n. 11, *supra.* Petitioners argue that "the EA failed to evaluate the environmental effect of changes to LSA-I regulations." Br. 47. But there was no reason for the NRC to expect these changes to cause significant environmental impacts.

Petitioners evidently misunderstand the LSA-I regulations. They complain that under the new regulation "LSA-I material is permitted to be 30 times as radioactive as exempt material." Br. 48. This should come as no surprise. LSA material is not exempt from regulation during transportation, so of course LSA-I material is permitted to be more radioactive than exempt material.

The revised 10 C.F.R. § 71.4, in relevant part, includes as an LSA-I subclass "other radioactive material in which...the estimated average specific activity material does not exceed 30 times the value for exempt material activity concentration...." (EUR 3:669). What

petitioners fail to perceive is that this LSA-I subclass is more restrictive than the subclass it replaces. The previous §71.4 definition of LSA-I material included: "[m]ill tailings, contaminated earth, concrete rubble...and activated material in which...the average specific activity does not exceed $10^{-6} A_2/g$." 10 C.F.R. § 71.4 (2003). This definition imposed no limit on the activity of certain LSA-I material because some $A_2$ values are "unlimited." *See* Part 71, Appendix A, Table A-1, EUR 3:673. But exempt material activity concentrations are finite. *Id.*, Table A-2. Accordingly, "30 times the value for exempt material activity concentration" always limits the activity of material that may qualify for LSA-I status. This is a new restriction, one not present in the previous rule. Petitioners' claim, Br. 48, that "LSA-I shipments permitted under the new rule may have a significant impact on public health," has no basis.[23]

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[23]Compounding petitioners' misdirection is their assertion that occupational doses to transport workers ---which they say "could be as high as 800 millirems"--- would "clearly exceed all radiation protection standards for public exposures." Br.48. As we have (continued...)

Equally misleading is the petitioners' remark that the NRC conformed its rules on LSA-I shipments to comply with DOT's regulations "knowing that DOT was relaxing those regulations to permit transportation of bulk LSA-I material without packaging." Br. 47-48. Petitioners imply that the NRC collaborated in "relaxing" transportation regulations, but they have left out the significant part of DOT's modification. DOT made clear that its revised regulations do not permit bulk LSA-I material to be shipped "without packaging." DOT Final Rule, 69 Fed. Reg. at 3642. Rather, they permit a more efficient and effective "industrial packaging." The NRC had no reason to expect this change to have significant, or any, adverse impacts on public health.

2. *Purported unanalyzed dose impacts.* Petitioners argue that the NRC's finding of no significant impact was arbitrary and

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[23](...continued)
already noted in describing petitioners' several misstatements and exaggerations (*see* Point A.2.(b)(i), *supra*), the NRC's occupational dose limits for adults include "the total effective dose equivalent being equal to 5 rems [5000 millirems]." 10 CFR § 20.1201(a)(1). This standard exceeds the petitioners' postulated 800 millirems by more than a factor of six.

capricious because the NRC did not evaluate purported "relevant areas of concern" regarding transportation of exempt material. Br. 47. They cite various analyses that they claim the NRC was required to conduct before determining whether the revised exemption thresholds would have a significant health impact. These include: collective population dose impacts, dose impacts from accident risks, and cumulative impacts.

The NRC received no comments that the NRC's EA was deficient regarding these purported critical "relevant areas of concern" that petitioners now raise for the first time in their brief, and this alone defeats petitioners' new claims. The NRC cannot be faulted for failing to address criticisms not brought to its attention. *See Friends of Endangered Species, Inc.*, 760 F.2d at 986. In any event, none of petitioners' various arguments is persuasive.

(a) *Collective doses and transportation accident doses.*

(i) The NRC's generic transportation EIS comprehensively evaluated collective doses and transportation accident doses resulting from transportation of radioactive materials with activity

concentrations above the exempt level. It was reasonable for the NRC's EA to tier to those analyses. *See* discussion at Point C.2., *supra.*

Moreover, the IAEA's calculations in developing a dose-based approach to transportation exemptions were based in part on transportation accident scenarios. (EUR 1:020). Petitioners acknowledge that the IAEA's exemption values incorporated transport accident scenarios. Br. 52. Petitioners then rely wholly on the extra-record declaration of Dr. Resnikoff to challenge the IAEA's use of the so-called "Q-system" to evaluate doses for transportation accidents. Br. 52-53. The NRC has had no opportunity to respond to this highly technical argument or determine its relevance. The NRC did address the Q-system in response to a comment asking how exemption values could be calculated from the maximum activities of radioactive materials permitted in "Type A" packages (*i.e.*, "$A_1$ and $A_2$ values"). (EUR 3:673). *See* 10 CFR § 71.4 (definition of $A_1$ and $A_2$ values), EUR 3:668. It was in this context that the NRC stated, as quoted by

petitioners, that "the Q-system cannot be used to calculate activity limits for exempt consignments or exempt activity concentrations." (EUR 3:651). Contrary to petitioners' claim, this narrowly-targeted statement can hardly be taken as an NRC repudiation of the entire IAEA exemption value analysis.

(ii) A determination of what analyses should be conducted, and of the "extent" to which particular analyses would yield useful new information, is within "the special competency of the appropriate agencies." *Kleppe v. Sierra Club*, 427 U.S. 390, 414 (1976). The analyses petitioners now demand would not have yielded critical new information regarding the health impacts of the revised exemption thresholds. Whatever the collective doses and doses from transportation accidents might be, these doses would be extremely low, well within regulatory limits, and lower overall than doses resulting from the pre-existing rule. Accordingly, it was reasonable for the NRC to rely on existing analyses of these dose impacts, particularly given the extensive difficulty in obtaining relevant exempt shipment data.

(b) *Cumulative impacts.* Petitioners claim, under the rubric of "cumulative impacts," that "the EA should have evaluated the radiation doses from transportation activities in combination with other existing and reasonably foreseeable sources." (Br.54). Although CEQ regulations governing EAs "do not specifically mention cumulative impact analysis," this Court has held "that an EA may be deficient if it fails to include" one. *Kern*, 284 F.3d at 1076. "Cumulative impacts" are those that arise out of "individually minor but collectively significant" agency actions. *See* 40 C.F.R. § 1508.7. *See also Selkirk Conser. Alliance v. Forsgren*, 336 F.3d 944, 958 (9th Cir. 2003).

In the rulemaking at issue in this case, no one asked the NRC to provide a cumulative impacts analysis in the EA, and the EA did not provide one.[24] This is not surprising. An agency is required to

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[24]In opposing any exemption standard whatever, one commenter -- but not any of the petitioners -- referred to the impacts of small doses "in concert with other contaminants." (EUR 2:423). This commenter did not develop the point or even mention the EA. Hence, petitioners have seen fit to try to supplement the administrative record, which is barren of information on

(continued...)

analyze "cumulative impacts" only if they are relevant. *See, e.g., Greenpeace Action*, 14 F.3d at 1332 (agency decision must be "founded on a reasoned evaluation of the relevant factors'") (*quoting Marsh*, 490 U.S. at 373-74). "Cumulative impacts" analysis is *not* relevant to the NRC's new exemption thresholds for transporting low-dose radioactive materials.

Low radiation doses like those at issue here, even when considered in combination with other sources of radioactivity, have no "cumulative" impact in a meaningful sense. A person receiving a low radiation dose has a small increased risk of developing cancer, but the amount of increase is not affected by previous or subsequent doses. Dose effects are linear. They are evaluated as though there is no radiation dose "threshold" above which the carcinogenic risk first begins or goes up at a higher rate.[25] The

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[24](...continued)
"cumulative impacts," with a litigation declaration. (Br.55). As we argued above, this Court should not consider such extra-record material.

[25]*See, e.g.*, the most recent report of National Research (continued...)

health impact of low doses from transporting exempt materials thus is unaffected by "other past, present, and reasonably foreseeable future actions." *Selkirk Conser. Alliance*, 336 F.3d at 958.[26]

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[25](...continued)
Council's Committee on the Biological Effects of Ionizing Radiations ("BEIR VII Committee"):

> The BEIR VII Committee concludes that there is a linear dose-response relationship between exposure to ionizing radiation and the development of radiation-induced solid cancers in humans. The Committee further judges that it is unlikely that a threshold exists for the induction of cancers but notes that the occurrence of radiation-induced cancers at low doses, will be small.

*Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII Phase 2 (2005)*, Prepublication copy, p.20 (http://www.nap.edu/books/030909156X/html).

[26] As the NRC observed in an adjudicatory decision, the "expression 'cumulative impacts,' as used in NEPA analysis, frequently is misunderstood":

> [C]umulative impacts analysis considers whether the sum may be greater than its parts. Not all projects will have cumulative impacts. The impacts from separate actions or regions may simply not be "environmentally inter-related." *See Kleppe v. Sierra Club*, 427 U.S. at 411 & n. 25 (1976).

*Hydro Resources, Inc.*, CLI-01-4, 53 NRC 31,57-58 (2001). The NRC itself has on occasion mischaracterized environmental impacts as (continued...)

This is not a case where the NRC was required to perform a "cumulative impacts" analysis to assess a synergistic impact. *See Natural Resources Defense Council, Inc. v. Hodel*, 865 F.2d 288, 297 (D.C. Cir. 1988). There are no synergistic health effects in the low radiation dose region relevant to Part 71. Petitioners themselves do not argue that the NRC's new exemption standard, in combination with other sources of radiactivity (*e.g.*, background radiation), elevates overall radiation doses above some level that exacerbates public risk.

In any event, as we have stressed throughout this brief, the NRC's new exemption thresholds involve radiation doses -- an

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[26](...continued)
"cumulative" when they were not. This happened in the NRC Draft EIS for Solids Disposal, cited by the petitioners in material outside the record. (Br.56, citing ERE1:1013-1016). The proposed rule which that draft EIS was intended to support has since been withdrawn. Petitioners point to proposed EPA and DOE actions dealing with low-level radioactivity. (Br.55-56). Again, however, it is unclear that low-dose radiation sources cause "cumulative" effects. The DOE and EPA proposals, in any event, were not before the NRC. Rulemaking would prove impracticable if agencies were routinely obliged to consider other agencies' *proposed* actions.

average annual dose of 23 millirem to "maximally" exposed transport workers (as compared, say, to a typical background dose of 300 millirem) -- that are very low in an absolute and relative sense. In these circumstances, the NRC did not act arbitrarily in not addressing cumulative impacts.

(c) *Overall low-dose impacts.*

For all their elaborate rhetoric about what the NRC failed to do, petitioners never explain how analyses of collective doses, accident doses, and cumulative impacts could undermine the NRC's decision to adopt the revised exemption thresholds, which would result in a greater than fifty percent overall *reduction* in doses (as well as a *decrease* in the variability of doses[27]) over the pre-existing rule to persons most affected. Petitioners' arguments ignore the clear beneficial impact of the new exemption rule. Indeed, they ignore the fact that average doses to transport workers, collective population doses, doses from transport accidents, and cumulative impacts (even if relevant) would be

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[27]*See* n. 10, *supra.*

*higher* if the old rule were to remain in place.[28]

At bottom, what petitioners seek in the form of a NEPA claim is a comprehensive reevaluation by the NRC of radiation health effects. However, that was not the subject of the NRC's rulemaking. Petitioners are certainly free to file a petition for rulemaking under 10 C.F.R. § 2.802 requesting a fundamental reexamination of NRC dose limits in 10 C.F.R. Part 20, but the NRC has to date received no such petition.

3. *Precedential effects.* In their final argument, petitioners cite another factor included in CEQ regulations as guidance for agencies in determining whether impacts are significant. *See* 40

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[28]We note that if petitioners were to prevail, domestic and international transporters alike could be faced with having to comply with two different sets of exemption values for shipments within the United States – *i.e.*, DOT's radionuclide-specific values and the pre-existing uniform activity concentration exemption value of 70 bq/g. This would be an unwieldy and inefficient system, likely leading to confusion and errors and thus a *reduction* in safety. Indeed, petitioners have ignored the fact that the NRC's ultimate regulatory goal in engaging in this rulemaking was to increase safety, by reducing doses from exempt shipments and harmonizing its exemption values with domestic and international standards.

C.F.R. § 1508.27(b) (6). Petitioners claim that the NRC should have evaluated the "precedential effects" of revising the exemption thresholds. Br. 57-59. They say that the purported "precedent" the NRC set by "adopting dose-based criteria for deregulating material" will "likely propel" further "deregulation actions" by the NRC and other agencies. Br. 57-58.

This Court has held that agency action does not establish a "precedent" within the meaning of the CEQ regulations unless the agency action is "binding" on future regulatory decisions. *See Anderson v. Evans*, 371 F.3d 475, 493 (9th Cir. 2004). The NRC's revision of its exemption thresholds in no way "binds" future regulatory decisions by the NRC or any other agency.

Moreover, petitioners misleadingly imply that the NRC's exemption rule established a brand new category of "deregulated" material. But the NRC established no "precedent" for "deregulation" in adopting a radionuclide-specific approach to transportation exemption values. As petitioners are surely aware, the NRC did not suddenly decide to "deregulate" radioactive

material for transportation. To the contrary, a regulation for exempting low level radioactive materials during transportation -- *i.e.*, the uniform 70 Bg/g exemption level -- had been in place for over forty years, since the 1960's. In the current rule, the NRC did nothing more than revise its methodology for calculating transportation exemption thresholds, after concluding that the new approach -- *i.e.*, the dose-based radionuclide-specific approach -- had a better scientific basis and reduced the overall dose impacts to transport workers. Thus, the new NRC exemption rule did not establish a "precedent," binding or otherwise, for exempting low-levels of radioactive material during transportation.

In sum, none of the above alleged flaws or failures in the NRC's environmental analysis has significance in the context of the scope of the challenged rule and the scope of the EA. Because petitioners have not raised "substantial questions" about whether the challenged rules will have significant environmental impacts, the NRC's finding of no significant impact should be upheld. *Wetlands Action Network*, 222 F.3d at 1119-20.

## *CONCLUSION*

For the foregoing reasons, this Court should deny the petition for review.

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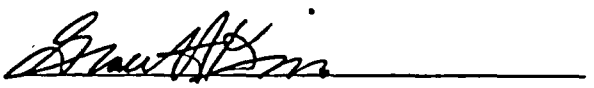
Dated: August 8, 2005

**Certificate of Compliance Pursuant to to Fed. R. App. P. 32(a)(7)(C) and Circuit Rule 32-1 for Case Number 04-71432**

Pursuant to Fed. R. App. P. 32(a)(7)(C) and Ninth Circuit Rule 32-1, the undersigned counsel for U.S. Nuclear Regulatory Commission certifies that the attached brief for respondents is proportionately spaced, has a typeface of 14 points, and contains 13,839 words, excluding Table of Contents, Table of Authorities, Statutory and Regulatory Appendix, and signatures, as counted by the Corel WordPerfect program.



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## CERTIFICATE OF SERVICE

I hereby certify that on August 8, 2005, two copies of the Brief for the Federal Respondents and one copy of the Supplemental Excerpts of Record were served by mail, postage prepaid, upon the following counsel:

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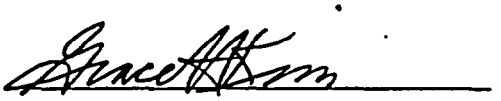

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