



NUCLEAR ENERGY INSTITUTE

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May 15, 2002

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SUBJECT: Litigation Challenging EPA's Yucca Mountain Regulations

Dear John:

Enclosed, in accordance with our telephone discussion earlier this week, is the opening brief of the Nuclear Energy Institute, filed in its case challenging the groundwater protection standard embodied in EPA's Yucca Mountain regulations (40 C.F.R. part 197). Please let me know if you have any questions or if I can otherwise be of assistance.

Sincerely,

A handwritten signature in black ink that reads 'Mike'.

Michael A. Bauser

Enclosure

ORAL ARGUMENT: FEBRUARY 20, 2003

**UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT**

Case No. 01-1258 and consolidated cases

**NUCLEAR ENERGY INSTITUTE, INC., NATURAL RESOURCES
DEFENSE COUNCIL, AND STATE OF NEVADA,**

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondents.

**ON PETITION FOR REVIEW OF A FINAL REGULATION ISSUED BY
THE U.S. ENVIRONMENTAL PROTECTION AGENCY**

BRIEF OF PETITIONERS, NUCLEAR ENERGY INSTITUTE, INC.

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RESUBMITTED

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici. The persons who are or may be parties in this court are: (1) Nuclear Energy Institute, Inc.; (2) State of Nevada; (3) Natural Resources Defense Council, Inc.; and (4) U.S. Environmental Protection Agency. At the present time, there are no intervenors or *amici* in the instant proceeding.

B. Rulings Under Review. This petition seeks review of the Final Rule of the United States Environmental Protection Agency regarding the Yucca Mountain Repository, entitled “Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada; Final Rule,” 66 Fed. Reg. 32,074 (2001) (the “Yucca Mountain Rule”), issued on June 5, 2001 and published in the Federal Register on June 13, 2001.

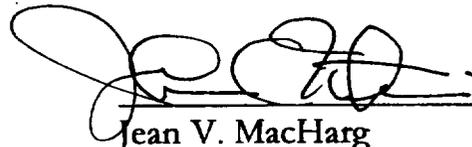
C. Related Cases. To Petitioners’ knowledge, all related cases have been consolidated in this Court, and there are no related cases pending in this Court or in any other court.

**NUCLEAR ENERGY INSTITUTE, INC.'S
CORPORATE DISCLOSURE STATEMENT**

The Nuclear Energy Institute, Inc. ("NEI"), a not-for-profit 501(c)(6) corporation, is a trade association representing the nuclear energy industry. NEI's objective is to ensure the development of policies that promote the beneficial uses of nuclear energy and technologies in the United States and around the world. As a trade association supported by its members, NEI does not have any parent companies, and no publicly-held or other company has any ownership interest in NEI.

Dated: May 7, 2001

Respectfully submitted,



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Authorities upon which we chiefly rely are marked with asterisks.

GLOSSARY OF ACRONYMS AND ABBREVIATIONS

AEA	Atomic Energy Act
APA	Administrative Procedure Act
DOE	United States Department of Energy
EDE	effective dose equivalent
EnPA	Energy Policy Act of 1992
EPA	United States Environmental Protection Agency
FGR	Federal Guidance Report
ICRP	International Commission on Radiation Protection
mrem	millirem
MCL	maximum contaminant level
NAS	National Academy of Sciences
NEI	Nuclear Energy Institute, Inc.
NRC	Nuclear Regulatory Commission
NWPA	Nuclear Waste Policy Act
SDWA	Safe Drinking Water Act

JURISDICTIONAL STATEMENT

Pursuant to 28 U.S.C. § 2342 *et seq.*, 42 U.S.C. § 2239(b) and FED. R. APP. P. 15, this Court has jurisdiction over NEI's petition for review of the Final Rule of the United States Environmental Protection Agency ("EPA") entitled "Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada; Final Rule," 66 Fed. Reg. 32,074 (2001) (EPA Docket No. A-95-12, Item V-A-2) (the "Yucca Mountain Rule"). The Hobbs Act, 28 U.S.C. § 2342, establishes jurisdiction in the U.S. Circuit Courts of Appeal over this agency action. The Yucca Mountain Rule was published in the Federal Register on June 13, 2001. Nuclear Energy Institute's Petition for Review was timely filed on June 29, 2001. *See* 28 U.S.C. § 2344.

TABLE OF AUTHORITIES FOR STATUTORY ADDENDUM

The following statutory and regulatory authorities have been supplied in an addendum bound with this brief:

<u>Citation</u>	<u>Addendum Tab</u>
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STATEMENT OF ISSUES PRESENTED FOR REVIEW

1. Whether EPA's inclusion in the Yucca Mountain Rule of separate groundwater standards, in addition to an all-pathways individual protection standard, is contrary to Section 801 of the Energy Policy Act of 1992.

2. Whether EPA's inclusion in the Yucca Mountain Rule of separate groundwater standards, in addition to an all-pathways individual protection standard, is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of the Administrative Procedure Act.

STATEMENT OF THE CASE

Petitioner Nuclear Energy Institute, Inc. ("NEI") challenges the Public Health and Environmental Radiation Protection Standards for Yucca Mountain, NV (the "Yucca Mountain Rule") promulgated by the United States Environmental Protection Agency ("EPA"). 66 Fed. Reg. 32,074 (2001) (codified at 40 C.F.R. Part 197) (EPA Docket No. A-95-12, Item V-A-2) ("Final Rule" or "Yucca Mountain Rule"), J.A. ___. Specifically, NEI challenges EPA's promulgation of a separate groundwater standard in addition to an all-pathways protection standard. NEI seeks relief under the Administrative Procedure Act on the grounds that the Yucca Mountain Rule's separate groundwater standard is arbitrary and capricious, an abuse of discretion and contrary to law, including, *inter alia*, the Energy Policy Act of 1992. NEI respectfully

requests that this Court sever and strike the separate groundwater standard from the remainder of the Yucca Mountain Rule, pursuant to 40 C.F.R. § 197.38.

STATEMENT OF FACTS

The Government has selected Yucca Mountain in Nevada as a potential disposal site for nuclear fuel and high-level radioactive waste currently stored at nuclear reactors across the country. EPA is responsible for setting the public health and safety standards that will apply if the Yucca Mountain repository is constructed. The Department of Energy (“DOE”) is responsible for planning the facility and preparing a license application. The Nuclear Regulatory Commission (“NRC”) is responsible for licensing the Yucca Mountain facility and regulating its construction. 42 U.S.C. §§ 10134(d), 10141(b).

SUMMARY OF ARGUMENT

EPA’s adoption of a separate groundwater standard at Yucca Mountain is contrary to Section 801 of the Energy Policy Act (“EnPA”). Under EnPA, (1) EPA must promulgate an effective dose equivalent (“EDE”) standard for protection of individuals from potential releases of radiation from the Yucca Mountain repository; (2) that standard must be consistent with the findings and recommendations of the National Academy of Sciences (“NAS”); and (3) that standard must consider potential releases from Yucca Mountain, not background radiation. EPA is not authorized to promulgate other types of standards. EPA ignored these restrictions.

EPA's adoption of the separate Yucca Mountain groundwater standard is also arbitrary and capricious because: (1) it is an "at the tap" standard which, when created, was not intended to apply to groundwater; (2) it is based on obsolete science; (3) it is inconsistent with EPA's own federal radiation guidance; (4) it provides inconsistent radiation protection to the public; and (5) it is not cost-effective despite EPA's acknowledgment that it must be.

EPA has admitted these defects. EPA acknowledges that the all-pathways, individual protection standard is sufficient to protect the public from potential releases from radioactive materials stored or disposed of at Yucca Mountain. The groundwater standard is thus unnecessary. Moreover, the groundwater standard is inconsistent with the evidence before the Agency, including EPA's own federal radiation guidance of the last 15 years. Evidently recognizing these shortcomings, EPA included a severability clause in its Yucca Mountain Rule, so that the all-pathways individual protection standard could remain in place if the groundwater standard were deemed unlawful. *See* Final Rule (Item V-A-2), 66 Fed. Reg. at 32,135 (40 C.F.R. § 197.38), J.A. __.

NEI respectfully submits that EPA's separate groundwater standard is both contrary to EnPA and arbitrary, capricious, and an abuse of discretion. Because that standard is severable from the Yucca Mountain Rule's individual protection standard, this Court may strike the groundwater standard from the Yucca Mountain Rule without remanding this issue to EPA for further proceedings.

ARGUMENT

I. STANDARD OF REVIEW

A. The Administrative Procedure Act

Under the APA, a reviewing court will hold unlawful and set aside a regulation if it is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law” or “in excess of statutory jurisdiction, authority, or limitations.” 5 U.S.C. § 706(2)(A), (C); *NRDC v. EPA*, 824 F.2d 1258, 1267 (D.C. Cir. 1987).

Agency action that exceeds statutory authority *per se* fails to pass muster under this standard of review. *See, e.g., Troy Corp. v. Browner*, 120 F.3d 277, 288 (D.C. Cir. 1997). Agency action is arbitrary and capricious and therefore unlawful if the agency fails to “examine the relevant data and articulate a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made.” *Motor Vehicle Ass’n of U.S. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotations and citation omitted). *See also Troy Corp.*, 120 F.3d at 288 (same). In addition,

an agency rule would be arbitrary and capricious if the agency has relied on factors *which Congress has not intended it to consider*, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt itself to make up for such deficiencies: We may not supply a reasoned basis for the agency’s action that the agency itself has not given.

Motor Vehicle Ass'n, 463 U.S. at 43 (internal quotations and citation omitted) (emphasis added). See also *Van Blaricom v. Burlington Northern R. Co.*, 17 F.3d 1224, 1225 (9th Cir. 1994). As demonstrated below, EPA failed to comply with these standards in promulgating the Yucca Mountain Rule.

B. Deference

Where an agency exceeds its statutory authority, its interpretation is entitled to no deference. 5 U.S.C. § 706(2)(C). See generally *Chevron, USA, Inc. v. Natural Resource Defense Council, Inc.*, 467 U.S. 837 (1984). Similarly, where a statute is clear on its face, no deference is due the agency. See, e.g., *Demarest v. Manspeaker*, 498 U.S. 184 (1991), *superseded by statute on other grounds*, *Wagner v. Brosnan*, 977 F.2d 594 (9th Cir. 1992). In determining whether deference is due to an agency, courts look to several factors, including the thoroughness of the agency's decision, the consistency of the agency's position, the agency's relative expertise, and the persuasiveness of the agency's position. *United States v. Mead Corp.*, 121 S. Ct. 2164, 2171 (2001).

NEI respectfully submits that EPA's interpretation of Section 801 of EnPA is entitled to no deference because it is contrary to the plain language of the statute. Further, EPA's position with respect to the groundwater standard is inconsistent with its previous positions, its own guidance and regulations, and with the positions of other agencies charged with development and licensing of the Yucca Mountain repository. *Mead Corp.*, 121 S. Ct. at 2171. EPA's position is inconsistent with sound science, and EPA itself has acknowledged that the groundwater standard is

unnecessary to protect public health and safety. *Id.* Accordingly, EPA's action is not entitled to deference.

II. EPA'S SEPARATE GROUNDWATER STANDARD IS CONTRARY TO LAW.

EnPA expressly requires that EPA promulgate "effective dose equivalent" standards as the "only" standards governing potential releases from the Yucca Mountain site:

Notwithstanding the provisions of [the Nuclear Waste Policy Act, the Atomic Energy Act,] and any other authority of [EPA] to set generally applicable standards for the Yucca Mountain site, [EPA] shall . . . promulgate, by rule, public health and safety standards for protection of the public from releases from radioactive materials stored or disposed of in the repository at the Yucca Mountain site. Such standards *shall prescribe the maximum annual effective dose equivalent to individual members of the public from releases to the accessible environment from radioactive materials stored or disposed of in the repository. The standards . . . shall be the only such standards applicable to the Yucca Mountain site.*

Energy Policy Act, Pub. L. No. 102-486, tit. VIII, § 801(a)(1), (2) *reprinted in* 42 U.S.C. § 10141 note (EPA Docket No. A-95-12, Item II-G-1) ("EnPA") (emphasis added), J.A. __.¹ Section 801 goes on to prohibit EPA from straying outside EnPA's statutory parameters in search of authority to regulate the site: "The provisions of this section

¹ *See also* H.R. CONF. REP. NO. 102-1018 at 390, *reprinted in* 1992 U.S.C.C.A.N. at 2481 ("These standards shall prescribe the maximum annual dose equivalent to individual members of the public from releases to the accessible environment from radioactive material stored or disposed of in the repository."), J.A. __.

shall apply to the Yucca Mountain site, rather than any other authority of [EPA] to set generally applicable standards for radiation protection.”²

In direct contravention of these statutory directives, EPA’s Yucca Mountain Rule nonetheless includes two separate regulatory limits: (1) an effective dose equivalent (“EDE”) standard that sets a total overall limit on radiation exposure to individuals from all sources (including groundwater); and (2) a separate, additional non-EDE standard applicable to groundwater. EPA’s separate groundwater standard also contravenes EnPA because it includes background radiation in addition to potential releases from Yucca Mountain.

A. EnPA Mandates An “Effective Dose Equivalent” Standard.

“Effective dose equivalent” (“EDE”) is a scientific term that Congress employed to restrict EPA’s regulatory authority under EnPA.³ EPA and other federal agencies have repeatedly acknowledged that “effective dose equivalent” denominates

² *Id.* § 801(a)(3) (emphasis added), J.A. __. See also H.R. CONF. REP. NO. 102-1018, at 390, reprinted in 1992 U.S.C.C.A.N. 2472, 2481, J.A. __.

³ Letter and Enclosures from Lake H. Barrett, Acting Director, Office of Civilian Radioactive Waste Management, Department of Energy, to EPA (date illegible) (Docket No. A-95-12, Item IV-D-36) (“DOE Comments”), Tab A at A-2 (EnPA “mandates” that EPA must express the Yucca Mountain standards as an “effective dose equivalent.”), J.A. __. In recognition of a sea change in radiation health science that was manifested in the 1977 publications of the International Commission on Radiation Protection, see Section III.B, Congress explicitly required EPA to base its Yucca Mountain standards on an “effective dose equivalent.” See EnPA § 801(a)(1) (Item II-G-1), J.A. __. See also Letter and Enclosure from Steven P. Kraft, Nuclear Energy Institute, to EPA (Nov. 23, 1999) (EPA Docket No. A-95-12, Item IV-D-17) (“NEI Comments”), Enclosure at 8-10, J.A. __; H.R. CONF. REP. 102-1018, reprinted in 1992 U.S.C.C.A.N. 2472, 2481, J.A. __.

a specific radiation dose measurement methodology. That methodology has been expressly incorporated into their guidance and regulations.⁴ Indeed, EPA employed this methodology when it promulgated the 15 millirem effective dose equivalent “all-pathways” limit for Yucca Mountain at 40 C.F.R. § 197.4.⁵ That provision regulates radiation from groundwater as well as from air, soil, direct contact and any other pathway to the accessible environment. Final Rule (Item V-A-2), 66 Fed. Reg. at 32,132, J.A. __; *id.* at 32,085-87, J.A. __. EPA, however, did not limit itself to the promulgation of that standard, but went on to promulgate an additional, separate groundwater standard.

⁴ In general, the “effective dose equivalent” methodology integrates and equates radiation effects on different organs and assigns weighting factors that take into account sensitivity to radiation. As discussed in Section III.B *infra*, the term originated with the dosimetric models introduced by the International Commission on Radiation Protection (“ICRP”) in the recommendations set forth in its Publications numbered 26 and 30. *See* ICRP, Recommendations of the International Commission on Radiation Protection (1977) (“ICRP Publication 26”); ICRP, Recommendations of the International Commission on Radiation Protection (1979) (“ICRP Publication 30”). ICRP Publications 26 and 30 reflected the same scientific knowledge; ICRP Publication 26 was a policy document while ICRP Publication 30 described methodology. For convenience, reference to this generation of radiation knowledge is referred to as ICRP Publications 26/30.

⁵ EPA’s rule requires the Department of Energy (“DOE”) to “ensure that no member of the public in the general environment receives more than an annual committed effective dose equivalent of 150 microsieverts (15 millirems)” from management and storage of radioactive material at the Yucca Mountain site. Final Rule (Item V-A-2), 66 Fed. Reg. at 32,132, J.A. __; 40 C.F.R. § 197.4.

B. EPA's Groundwater Limit Is Not An "Effective Dose Equivalent" Standard As Required By EnPA.

Despite EnPA's clear directive, EPA's groundwater standard does not provide an "effective dose equivalent" limit. Instead, EPA borrowed limits from the Safe Drinking Water Act that are based on a distinct, outdated "critical organ" methodology that was developed over forty years ago.⁶

Although EPA understood Congress's use of the term "effective dose equivalent," and has employed that methodology in its own radiation exposure guidance since 1987,⁷ the Agency flagrantly disregarded that requirement and promulgated a groundwater standard that is not based on EDE methodology. *See* Final Rule (Item V-A-2), 66 Fed. Reg. at 32,134 (Table 1), J.A. __. EPA's promulgation of a non-EDE standard ignores the clear language of EnPA Section 801(a), it exceeds the Agency's authority and must be stricken under the APA. *See* 5

⁶ The effective dose equivalent methodology prescribed by Congress was not adopted by the International Commission on Radiological Protection ("ICRP") until 1977. *See* discussion below in Section III.B.

⁷ By the time Congress enacted EnPA in 1992, EPA had already employed effective dose equivalent methodology for several years. Indeed, EPA used the methodology in its federal radiation exposure guidance beginning in 1987. *See, e.g.*, EPA, Federal Guidance Report No. 11: Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion and Ingestion (1988) (EPA Docket No. A-95-12, Item II-B-5) ("FGR 11") at 2 (when EPA adopted the recommendations in ICRP Publications 26/30 in its Federal radiation guidance in 1988, it noted that a "major change" from previous federal guidance was reliance on the "effective dose equivalent" rather than the "critical organ" approach), J.A. __, 219 (Glossary defines "critical organ" as the "basis for dose limitation under the 1960 Federal guidance"), J.A. __. *See* Section III.B for further discussion.

U.S.C. § 706(2)(c); *Troy Corp.*, 120 F.3d at 288 (agency must act within its delegated statutory authority).

C. EnPA Prohibits A Separate Standard In Addition To The Effective Dose Equivalent Standard.

That EnPA limits EPA to the effective dose equivalent standard is plain on the face of the statute:

Such standards shall prescribe the maximum annual effective dose equivalent to individual members of the public from releases to the accessible environment from radioactive materials stored or disposed of in the repository. The standards . . . shall be the only such standards applicable to the Yucca Mountain site.

Section 801(a)(1), (2) (emphasis added), J.A. __. That the statute uses the word “only” in describing EnPA’s limits plainly demonstrates Congressional intent: Congress mandated an effective dose equivalent standard and precluded employment of a different standard.

Neither may EPA argue that its regulation is justified for groundwater protection. Congress authorized “only” a standard intended to protect “individual members of the public.”⁸ Hence, EPA’s claimed “long-standing policy” to protect groundwater cannot justify the separate standard.⁹ Congress provided EPA with a

⁸ 138 CONG. REC. S17559 (daily ed. Oct. 8, 1992) (statement of Sen. Johnston) (should be a “health-based standard” that is expressed as “the maximum dose that is safe for an individual”), J.A. __.

⁹ See, e.g., Final Rule (Item V-A-2), 66 Fed. Reg. at 32,106, 32,108, J.A. __; *Status of the Department of Energy (DOE) program to develop a permanent geologic repository at Yucca Mountain, Nevada for spent nuclear fuel and high-level radioactive waste*: Oversight Hearing

very specific statutory directive: promulgate a site-specific, all-pathways, individual-protection, effective dose equivalent standard. EPA may not circumvent EnPA and Congress by invoking its “policy” to protect groundwater.

The reason for EnPA’s directive is apparent. Congress recognized that a separate limit in addition to the all pathways, effective dose equivalent standard would result in superfluous regulation. Indeed, EPA has expressly acknowledged that its separate groundwater standard is unnecessary to protect public health and safety: “Consistent with the recommendations of the National Academy of Sciences, the Individual Protection Standard is adequate in itself to protect public health and safety.” Final Rule (Item V-A-2), 66 Fed. Reg. at 32,129, J.A. __. Like Congress and the National Academy of Sciences, the Nuclear Regulatory Commission and the Department of Energy have also determined that a separate groundwater standard is unnecessary.¹⁰

Given EnPA’s unequivocal mandate that “only” an effective dose equivalent standard be promulgated, EPA’s separate groundwater standard is, *per se* unlawful.

Before the Subcommittee on Energy Power (testimony of Mr. Steve Page, Director, Office of Air and Radiation, U.S. EPA on June 23, 2000) <<http://com-notes.house.gov/cchea/hearings106.nsf/a317d879d32c08c2852567d300539946/f38f7c4d66b1087852569070066866c?OpenDocument>> (discussing EPA’s “long-standing policy of emphasizing the protection of ground water resources”), J.A. __.

¹⁰ Letter from William D. Travers, Executive Director for Operations, NRC, to Stephen D. Page, Director, Office of Radiation and Indoor Air, EPA (Nov. 2, 1999) (EPA Docket No. A-95-12, Item II-D-92) (“NRC Comments”), Letter at 1, J.A. __; DOE Comments (Item IV-D-36), Letter at 2, J.A. __.

See, e.g., Chevron, 467 U.S. at 842-43 (“If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”).

D. EnPA Precludes EPA From Relying On Other Statutes Or Policies To Justify A Separate Standard.

Section 801 of the Energy Policy Act (“EnPA”) circumscribes EPA’s Yucca Mountain rulemaking authority. EnPA provides that “notwithstanding” the Atomic Energy Act (“AEA”), the Nuclear Waste Policy Act (“NWPA”) and “any other authority of [EPA] to set generally applicable standards for the Yucca Mountain site,” the standards promulgated by EPA pursuant to EnPA “shall be the *only* such standards applicable to the Yucca Mountain site.” EnPA § 801(a)(1) (Item II-G-1) (emphasis added), J.A. __. The statute’s drafters further specified that, “[t]he provisions of [section 801 of EnPA] *shall* apply to the Yucca Mountain site, *rather than any other authority of [EPA] to set generally applicable standards for radiation protection.*” EnPA § 801(a)(3) (Item II-G-1) (emphasis added), J.A. __.

EnPA’s legislative history confirms Congress’s intention to restrict EPA’s Yucca Mountain rulemaking authority. The EnPA House Conference Report explains that EPA’s general authority under other statutes does not extend to the rulemaking for the Yucca Mountain site and expressly states that:

[t]he provisions of section 801 make clear that the standards established by the authority in this section would be the *only such standards* for protection of the public from releases of radioactive materials as a result of the disposal

of spent nuclear fuel or high-level radioactive waste in a repository at the Yucca Mountain site.

H.R. CONF. REP. NO. 102-1018, at 390 *reprinted in* 1992 U.S.C.C.A.N. 2472, 2481 (emphasis added), J.A. __. DOE, in its comment, reminded EPA that EPA is without authority to look outside of EnPA § 801(a) for regulatory authority.¹¹

There is no room for any suggestion that some separate statute—let alone, a generalized “policy”—would permit EPA to look outside section 801 of EnPA for authority to implement a separate regulation. Other than the specific type of individual protection standard mandated by section 801, the Agency is without authority to promulgate a regulation governing radiation exposure at the Yucca Mountain Site. EPA may not circumvent EnPA and Congress by invoking a “policy” to protect groundwater or “generic standards” applied elsewhere.¹² Final Rule (Item V-A-2), 66 Fed. Reg. at 32,108, J.A. __. Accordingly, the groundwater regulation is plainly contrary to law. *See, e.g., Chevron*, 467 U.S. at 842-43 (when statutory language is clear, agency “must give effect to the unambiguously expressed intent of Congress”).

¹¹ *See, e.g.,* DOE Comments (Item IV-D-36), Tab A at A-2 (EnPA is EPA’s “sole source of authority for establishing public health and safety standards for the Yucca Mountain site.”), J.A. __.

¹² As the NRC’s comments explain, EPA’s application of particular limits to a repository in New Mexico does not justify applying those limits to the Yucca Mountain site. NRC Comments (Item II-D-92), Enclosure at 9, J.A. __; Final Rule (Item V-A-2), 66 Fed. Reg. at 32,108 (same), J.A. __.

E. EPA's Separate Groundwater Limit Violates EnPA's Requirement That Its Standards Be Based Upon And Consistent With The Findings And Recommendations Of The National Academy Of Sciences.

EnPA requires that EPA's standards be "based upon and consistent with the findings and recommendations of the National Academy of Sciences." EnPA § 801(a)(1) (Item II-G-1), J.A. __.¹³ EPA's separate groundwater standard, however, also runs afoul of this statutory directive. The National Academy of Sciences ("NAS") specifically found that there was *no scientific basis* for EPA's establishment of a separate groundwater limit.¹⁴

Pursuant to the requirements of EnPA, NAS conducted extensive analyses and NAS published a report with its findings and recommendations. National Research Council, Technical Bases for Yucca Mountain Standards (1995) (EPA Docket No. 95-A-12, Item II-A-1) ("NAS Report"), J.A. __. The NAS Report concluded that, "an individual-risk standard would protect public health, given the particular characteristics of the site,"¹⁵ and found that an additional groundwater standard at

¹³ See also H.R. CONF. REP. 102-1018, reprinted in 1992 U.S.C.C.A.N. 2472, 2481-82, J.A. __; 138 CONG. REC. S17558 (daily ed. Oct. 8, 1992) (statement of Sen. Johnston) (It is appropriate for NAS, "the most distinguished scientific group in the world," to "make the scientific determinations" regarding the standards to be set for the Yucca Mountain repository.), J.A. __.

¹⁴ See, e.g., Letter from Michael Kavanaugh, Chair, and John Ahearn, Vice Chair, Board on Radioactive Waste Management, National Research Council, to Carol M. Browner, Administrator, EPA (Nov. 26, 1999) (EPA Docket No. A-95-12, Item IV-D-31) ("NAS Comments") at 11, J.A. __.

¹⁵ NAS Report (Item II-A-1) at 7, J.A. __.

Yucca Mountain was unnecessary. NAS Report (Item II-A-1) at 121 (emphasis added), J.A. __.

EPA ignored NAS's recommendations and proposed both an individual protection standard and a groundwater protection standard for Yucca Mountain. NAS then commented on EPA's proposed rule, not only reiterating its position that the groundwater standard was superfluous, but emphasizing that the standard had no scientific basis: "[NAS] concluded that an individual-protection standard would be sufficient to protect public health" and stated that it "does not believe that there is a basis in science for establishing such [separate groundwater] limits." NAS Comments (Item IV-D-31) at 11, J.A. __; Final Rule (Item V-A-2), 66 Fed. Reg. at 32,107, J.A. __.

According to NAS:

EPA is inconsistently proposing a carryover of 40 C.F.R. 191 to establish separate ground-water protection standards for purposes of protecting individuals and the general populations. Such separate limits may greatly complicate the licensing process and have but *a negligible impact on protection of the public.*

NAS Comments (Item IV-D-31) at 11 (emphasis added), J.A. __. *See also* NEI Comments (Item IV-D-17), Enclosure at 12-13, J.A. __.

EPA admits that it essentially ignored NAS's findings and recommendations, considering the NAS Report to be merely a "starting point" for its rulemaking. *See* 64 Fed. Reg. 46,976, 46,981 (1999) (EPA Docket No. A-95-12, Item III-A-1) ("Proposed Rule"), J.A. __. *See also* NAS Comments (Item IV-D-31), Enclosure at 12, J.A. __.

Thus, EPA's promulgation of a separate groundwater standard is inconsistent with the findings and recommendations of the NAS and violates EnPA. *See Troy*, 120 F.3d at 288 (agency must not exceed its delegated authority); *Mead*, 121 S. Ct. at 2171 (agency's position must be persuasive and consistent with its expertise); *Motor Vehicle Ass'n*, 463 U.S. at 43 (agency must rely on factors Congress intended it to consider).¹⁶

F. EPA's Consideration Of Background Radiation Levels Violates EnPA.

EPA's requirement that background radiation be included in the application of the groundwater standard also violates the clear language of EnPA. EnPA specifically requires EPA to establish a standard that addresses "releases to the accessible environment from radioactive materials stored or disposed of in the repository." EnPA § 801(a)(1) (Item II-G-1), J.A. __. EPA's groundwater standard, by contrast, applies not just to radiation released from materials stored in the Yucca Mountain repository, but also to radiation generated from any and all sources in the vicinity of the site, including background sources. *See, e.g.*, Final Rule (Item V-A-2), 66 Fed. Reg. at 32,114 ("We also require that DOE combine certain estimated releases from the

¹⁶ EPA's groundwater standard is also contrary to the recommendations of the Nuclear Regulatory Commission ("NRC"), the federal agency that Congress charged with licensing responsibilities relating to the Yucca Mountain repository. *See* Final Rule (Item V-A-2), 66 Fed. Reg. at 32,107-08 (discussing NAS's comments on EPA's proposed rule), J.A. __; *id.* at 32,134 (40 C.F.R. § 197.30, imposing groundwater standard), J.A. __; NAS Comments (Item IV-D-31), Enclosure at 11-12, J.A. __. Because EPA's interpretation of EnPA conflicts with that of NRC, EPA's interpretation would be entitled to no deference even if the statute were ambiguous

Yucca Mountain disposal system with the pre-existing naturally occurring or man-made radionuclides to determine the concentration limit in the representative volume.”), J.A. ___; Proposed Rule (Item III-A-1), 64 Fed. Reg. at 47,004 (similar language), J.A. ___; EPA, Response to Comments, Public Health and Environment Radiation Protection Standards for Yucca Mountain, Nevada (40 CFR Part 197) Final Rule (June 2001) (EPA Docket No. A-95-12, Item V-C-1) (“EPA Response to Comments”) at 6-18 to 6-19, J.A. ___; NEI Comments (Item IV-D-17), Enclosure at 17 (responding to item III.F), J.A. __. The groundwater standard therefore violates EnPA and should be stricken.

III. EPA’S GROUNDWATER STANDARD IS ARBITRARY AND CAPRICIOUS.

EPA’s inclusion of a groundwater standard at Yucca Mountain not only violates EnPA, it is also arbitrary and capricious. First, EPA has taken an “at the tap” drinking water standard intended for treated drinking water and applied it to the groundwater near the Yucca Mountain repository. Second, these drinking water standards are based on 40-year-old science that even EPA has recognized to be unsound. Third, EPA’s reliance on this outdated science is contrary to EPA’s own federal radiation guidance and inconsistent with other EPA radiation protection regulations, both of which reflect more current science. Fourth, the discredited standards imposed by EPA yield erratic health risks ranging well beyond both the high

with respect to the controlling force of the findings and recommendations of the NAS. NRC Comments (Item II-D-92), Letter at 1-3 & Enclosure at 8-9, J.A. ___.

and low limits of EPA's own risk range. Finally, despite EPA's commitment to conduct a cost-benefit analysis before applying the maximum contaminant levels ("MCLs") for radionuclides to Yucca Mountain and its assertion that these limits are cost-effective, EPA has never conducted the analysis it acknowledges is necessary. For these additional reasons, NEI respectfully urges the Court to strike EPA's separate groundwater standard.

A. EPA's Groundwater Standard Is Arbitrary And Capricious Because It Applies "At The Tap."

In the Final Rule, EPA incorporates standards it applies to public drinking water under the Safe Drinking Water Act ("SDWA") and applies them to groundwater in the area of Yucca Mountain. *See* 40 C.F.R. § 197.30; Final Rule (Item V-A-2), 66 Fed. Reg. at 32,106 ("we require protection of ground water that is a current or potential source of drinking water to the same level as the maximum contaminant levels (MCLs) for radionuclides that we established previously under the authority of the Safe Drinking Water Act"), J.A. __; Proposed Rule (Item III-A-1), 64 Fed. Reg. at 47,007 (same), J.A. __. EPA's requirement that drinking water standards be applied to groundwater in the area of Yucca Mountain and, indeed, EPA's failure to consider the implications of applying those SDWA radionuclide limits to Yucca Mountain, render its decision arbitrary and capricious.¹⁷

¹⁷ EPA never even discussed how these standards would actually be implemented at Yucca Mountain. "The MCLs are generally implemented through sampling and quarterly averaging; these concepts likewise are not applicable to and not incorporated

The SDWA MCLs apply “at the tap,” *after* the treatment of water that is used as drinking water by public water departments. *See, e.g.*, DOE Comments (Item IV-D-36), Letter at 2, Tab B at B-3, J.A. __; NRC Comments (Item II-D-92), Enclosure at 9, J.A. __. The radionuclide MCLs EPA has incorporated were “based on an analysis of treating contaminated water in public drinking water systems subject to the SDWA and not on an analysis of technology and costs of remediating groundwater at actual sites.” *See* NRC Comments (Item II-D-92), Letter at 2, Enclosure at 8, J.A. __. The SDWA limits were not designed, nor were they intended, to apply to groundwater sources *before treatment*. DOE Comments (Item IV-D-36), Tab B at B-3, J.A. __; NRC Comments (Item II-D-92), Letter at 2, Enclosure at 9, J.A. __. The application of these standards developed for post-treatment drinking water to pre-treatment groundwater at the Yucca Mountain site is arbitrary and capricious.

B. EPA’s Groundwater Standard Is Based On Obsolete Science.

EPA’s groundwater standards are derived from the 1959 recommendations published by the International Commission on Radiological Protection (“ICRP”) in its Publication 2.¹⁸ As EPA has recognized, radiation health science, and especially

into the proposed GPS [ground water protection standard].” DOE Comments (Item IV-D-36), Tab B at B-3, J.A. __.

¹⁸ ICRP, Recommendations of the International Commission on Radiological Protection, ICRP Publication 2 (1959) (“ICRP Publication 2”). EPA’s groundwater standards were adopted in the 1976 promulgation of EPA’s drinking water limits under the Safe Drinking Water Act. *See* EPA Background Information Document (Item III-B-2) at 2-12, J.A. __. Even when ICRP released Publication 2 in 1959, ICRP recognized that its guidance was based upon “very incomplete” information. ICRP

dosimetry, has advanced radically since ICRP 2.¹⁹ Nearly 25 years ago, in 1977 and again in 1979, the International Commission published the results of dramatic advances in metabolic modeling and physiological data in ICRP Publications 26/30.²⁰ The ICRP's new approach expressly superseded the methodology in ICRP's prior publications.²¹

Publication 2 at 2, 9, J.A. __. A particularly troubling limitation was the inability of ICRP 2 to combine doses to different organs into an integrated dose estimate for the entire body. FGR 11 (Item II-B-5) at 2, 3, 201 (The President, *Radiation Protection Guidance to Federal Agencies for Occupational Exposure; Approval of Environmental Protection Agency Recommendations*, 52 Fed. Reg. 2,822, 2,827 (1987)), J.A. __; ICRP, *Recommendations of the International Commission on Radiological Protection*, ICRP Publication 26 (1977) ("ICRP Publication 26") at 9, J.A. __. Cf. ICRP Publication 2 at xix, J.A. __.

¹⁹ See, e.g., FGR 11 (Item II-B-5) at 13-16, 17, 27, 30, J.A. __; EPA Background Information Document (Item III-B-2) at 2-17, J.A. __. Indeed, as discussed below in Section III.C, in virtually every context other than the SDWA MCLs, EPA has rejected the outdated methodologies in favor of updated science.

²⁰ The ICRP's new approach derived a new dose standard that integrated and equated radiation effects on different organs and assigned weighting factors for each organ to take into account the sensitivity of each organ to radiation. See, e.g., FGR 11 (Item II-B-5) at 201 (52 Fed. Reg. at 2,827), J.A. __. See also EPA Background Information Document (Item III-B-2) at 2-3, J.A. __; ICRP Publication 26 at 9, J.A. __. The nomenclature of the dose standard also changed to reflect this revolution in dosimetry: the "effective dose equivalent" or "EDE" standard developed in ICRP Publications 26/30 replaced the "critical organ" approach in ICRP's earlier guidance. See also effective dose equivalent discussion at Section II.B. See, e.g., ICRP Publication 2 at xix (using term "permissible dose"), J.A. __; ICRP Publication 26 at 3-6 (introducing basic concept of "dose equivalent" and "committed dose equivalent"), J.A. __.

²¹ See ICRP Publication 26 at 3, J.A. __; DOE Comments (Item IV-D-36), Tab B at B-15, J.A. __.

These advances in radiation health science have been universally recognized. As long ago as 1987, recommendations from ICRP Publications 26/30 were "in use, in whole or substantial part, in most" countries other than the United States, as EPA itself acknowledged.²² The NRC, as well as NAS and DOE, objected to EPA's use of obsolete science in setting EPA's groundwater standard.²³

Even EPA has repeatedly acknowledged these scientific advances. EPA has issued at least three generations of guidance on the topic since 1988, *all* of which uniformly reject the outmoded science used in the Yucca Mountain groundwater standard.²⁴ As far back as 1976, EPA emphasized that it intended to update the drinking water limits upon which Yucca Mountain's groundwater standard is based to "effective dose equivalent" limits to reflect scientific advances in the understanding of

²² FGR 11 (Item II-B-5) at 198, J.A. __.

²³ Congress expressly gave licensing responsibility for Yucca Mountain to NRC, in addition to giving scientific advisory responsibilities to NAS. Where, as here, EPA acts contrary to both these entities, it is entitled to no deference. *See* NAS Comments (Item IV-D-31) at 12 (advising EPA to base its Yucca Mountain standards on the "best available science"), J.A. __; NRC Comments (Item II-D-92), Enclosure at 8 (EPA's standards are no longer reasonable), J.A. __; DOE Comments (Item IV-D-36), Enclosure at B-15 to B-18 (EPA's standards should be based on recent science), J.A. __.

²⁴ *See generally* FGR 11 (Item II-B-5), J.A. __; EPA, Federal Guidance Report No. 12: External Exposure to Radionuclides In Air, Water, and Soil (1993) (EPA Docket No. A-95-12, Item II-B-7) ("FGR 12"), J.A. __; EPA, Federal Guidance Report No. 13: Cancer Risk Coefficients for Environmental Exposure to Radionuclides (EPA Docket No. A-95-12, Item V-A-20) ("FGR 13"), J.A. __. *See also* FGR 11 (Item II-B-5), preface at v (noting that FRG 11 supersedes FGR 10, which was based on ICRP 2), J.A. __.

radiation exposure and health effects.²⁵ More recently, in EPA's 1999 preamble to its proposed Yucca Mountain Rule, EPA indicated that it would apply updated drinking water standards reflecting newer science at Yucca Mountain, explaining that "[s]cientific understanding has evolved since 1975 and we are working to update the existing MCLs [drinking water standards] based upon a number of factors."²⁶ Indeed, EPA proclaimed that it intended to base its standards at Yucca Mountain on the "modern dose-calculation methods known as 'committed effective dose equivalent' (CEDE)." Proposed Rule (Item III-A-1), 64 Fed. Reg. at 46,983, J.A. __.²⁷

In the end, EPA did use the modern dose equivalent method for the individual protection (or "all pathways") standard at Yucca Mountain. Inexplicably, however, EPA departed from this methodology and adopted an additional groundwater standard based on discredited science that is more than 40 years old.²⁸ That EPA has

²⁵ See 41 Fed. Reg. 28,402, 28,409 (1976) ("When the ICRP recommendations are developed in final form they will be considered by EPA."), J.A. __.

²⁶ Proposed Rule (Item III-A-1), 64 Fed. Reg. at 47,000, J.A. __. See also Final Rule (Item V-A-2), 66 Fed. Reg. at 32,107, J.A. __.

²⁷ *Id.* ("[We] have begun a rulemaking to amend both 40 C.F.R. Parts 190 and 191. That rulemaking would update these limits to the CEDE methodology. We anticipate that we will finalize the amendments to parts 190 and 191 prior to the finalization of this rulemaking."), J.A. __.

²⁸ The use of obsolete science has a significant effect on the groundwater standard applied at Yucca Mountain. Not surprisingly, the more modern ICRP 26/30 values for translating risk into dose and concentration limits differ significantly from those in ICRP Publication 2. FGR 11 (Item II-B-5) at 2, 30, J.A. __. This in turn means that any limits based on ICRP 26/30 would also vary significantly from limits based on ICRP 2. See FGR 11 (Item II-B-5) at 2 (EPA acknowledging that the "new models yielded a number of values significantly different from those in ICRP Publication[]

selectively used updated science to set the fundamental standard but used old science to promulgate another standard within a single final rule is even more dramatic evidence that EPA has acted inconsistently and irrationally. *See also* Section III.D. Accordingly, EPA's application of that standard within the Yucca Mountain Rule contradicts all of the evidence before the agency and is entitled to no deference. The rule therefore is arbitrary and capricious. *See, e.g., Motor Vehicle Ass'n*, 463 U.S. at 43 (agency action is arbitrary and capricious when agency relies on factors that Congress has not intended it to consider, fails to consider an important aspect of the problem or ignores important evidence before the agency).

C. EPA's Outdated Groundwater Standard Is Inconsistent With EPA's Own Radiation Protection Regulations and Guidance.

EPA publishes radiation protection guidance for other Federal agencies to implement. *See, e.g.,* 65 Fed. Reg. 76,708, 76,711 (2000), J.A. __. Unlike EPA's drinking water standards, EPA's Federal Guidance Reports ("FGRs") have been regularly revised since 1988 to incorporate the advances in radiation knowledge and dosage methodology recognized by the ICRP. Indeed, as long ago as 1987, EPA explicitly acknowledged the need to revise numerical guides for measuring the effect of radiation to reflect important scientific advances. In a memorandum prepared for President Reagan, EPA described its policy on radiation science:

2."), 30 ("The use of revised metabolic and dosimetric models doses, however, cause major alteration in the derived guides of some radionuclides."), J.A. __. *See also* FGR 12 (Item II-B-7) at 6, J.A. __.

[EPA] confirmed the need for revising the previous Federal guidance, which was promulgated in 1960. Since that time, knowledge of the effects of ionizing radiation on humans has increased substantially. . . . As a result, some of the old numerical guides are now believed to be less and some more protective than formerly. . . . *These disparities and omissions should be corrected.* Drawing on this improved knowledge, the International Commission on Radiological Protection (ICRP) published, in 1977, new recommendations on radiation protection philosophy and limits for occupational exposure. These recommendations are now in use, in whole or substantial part, in most other countries. We have considered these recommendations, among others, and believe that *it is appropriate to adopt the general features of the ICRP approach in radiation protection guidance to Federal agencies[.]*

FGR 11 (Item II-B-5) at 198 (52 Fed. Reg. at 2,824), J.A. __.²⁹

Since preparing that 1987 memorandum, EPA's various Federal Guidance Reports on radiation have (1) acknowledged that ICRP Publication 2 and its "critical organ" dosimetry is outdated; (2) described the importance of incorporating the most recent scientific advances; and (3) relied on ICRP Publications 26/30 or subsequent publications.³⁰ Specifically, FGR 11 (1988) incorporated the "effective dose

²⁹ See also DOE Comments (Item IV-D-36), Tab B at B-16 (citing same), J.A. __; EPA, 40 CFR Part 61-NESHAP; Radionuclides, 54 Fed. Reg. 51,654, 51,662 (1989) (as long ago as 1989, EPA acknowledged that "specific organ doses and the whole body dose" methodology "is no longer consistent with current practices of radiation protection").

³⁰ See, e.g., FGR 11 (Item II-B-5) at 2 (noting ICRP Publication 26/30's substantial advances in the dosimetric and metabolic models), 3 ("The derived limits in Publication 30 (which superseded those presented in ICRP Publications 2 and 6) incorporate the considerable advances in the state of knowledge of radionuclide dosimetry and biological transport in humans achieved in the past few decades."), J.A. __.

equivalent” standards and methodologies of ICRP Publications 26/30 (1977/1979); FGR 12 (1993) incorporated the “equivalent dose” standards and methodologies of ICRP Publication 60 (1990); and FGR 13 (1999) incorporated the “equivalent dose” standards and methodologies of ICRP Publications 60 (1990) and 72 (1995).

EPA has incorporated those updates into its own regulations. For example, EPA’s CERCLA reportable quantities rulemaking (codified at 40 C.F.R. Part 302) “relied heavily on the health data and human intake limits” published in ICRP Publication 30.³¹ Similarly, in its radionuclide National Emissions Standards for Hazardous Air Pollutants (“NESHAP”) (codified at 40 C.F.R. Part 61), EPA adopted the effective dose equivalent (EDE) dosimetry methods.³² Indeed, outside EPA’s

³¹ See 54 Fed. Reg. 22,254, 22,530 (1989). See also DOE Comments (Item IV-D-36), Tab B at B-16 (citing same), J.A. ___.

³² See 54 Fed. Reg. 51,654, 51,662 (1989). See also DOE Comments (Item IV-D-36), Tab B at B-16 (citing same), J.A. ___.

Other agencies have also independently incorporated ICRP 26/30 dosimetry methods into their regulations. NRC uses ICRP Publications 26/30 in its “Standards for Protection Against Radiation” at 10 C.F.R. Part 20 (see 56 Fed. Reg. 23,360, 23,370 (1991)) and its radiation protection standards in its design basis accident dose limits for independent spent fuel storage and monitored retrievable storage installations codified at 10 C.F.R. § 72.106 (see 63 Fed. Reg. 54,559, 54,560 (1998)). DOE uses ICRP Publications 26/30 in “Derived Air Concentrations (DAC) for Controlling Radiation Exposure to Workers at DOE Facilities” at 10 C.F.R. Part 835, Appendix A, n.2, and “Derived Air Concentration (DAC) for Workers From External Exposure During Immersion in a Contaminated Atmospheric Cloud” at 10 C.F.R. Part 835, Appendix C. See 58 Fed. Reg. 65,458, 65,458 (1993). The Department of Health and Human Services recently proposed using ICRP Publication 60 in its “Methods for Radiation Dose Reconstruction Under the Energy Employees Occupational Illness Compensation Program Act of 2000” to be codified at 42 C.F.R. Part 82. See 66 Fed. Reg. 50,978, 50,987-88 (2001).

drinking water standards, NEI is not aware of even one other instance in which any federal agency has employed this outdated methodology during the past fifteen years. Thus, EPA's application of outdated radiation science at Yucca Mountain is inconsistent with its own federal radiation guidance and recommendations for the last 15 years, runs counter to all of the evidence before the agency, and is therefore arbitrary and capricious.

D. EPA's Groundwater Standard At Yucca Mountain Provides Inconsistent Protection From Different Radionuclides.

There are 168 beta particle and photon emitters regulated by EPA under the SDWA and therefore under EPA's Yucca Mountain regulations.³³ EPA claims to have set a "4 millirem" standard for each one of those radionuclides. *See* Final Rule (Item V-A-2), 66 Fed. Reg. at 32,134 (§ 197.30 & Table 1), J.A. __. In reality, it has not done so. EPA has admitted that when current science is used to more accurately estimate dose and risk, the actual dose, as well as the actual risk, associated with each of the 168 drinking water standards varies radically.³⁴ Thus, the protectiveness of

³³ "Many of the radionuclides at issue for the potential [Yucca Mountain] repository are not specifically addressed by the MCLs" enacted by EPA in 1976. DOE Comments (Item IV-D-36), Letter at 2, Tab B at B-3, J.A. __. EPA's failure to address these important radionuclides provides one more example of its arbitrary and capricious decision making. *See Motor Vehicle Ass'n*, 463 U.S. at 43.

³⁴ *See* EPA, National Primary Drinking Water Regulations; Radionuclides; Final Rule, 65 Fed. Reg. 76,708, 76,716 (2000) ("SDWA Final Rule") ("A newly proposed MCL expressed in mrem-ede could result in a more consistent risk level within the Agency's target risk range."), J.A. __; EPA, National Primary Drinking Water Regulations; Radionuclides; Notice of Data Availability, 65 Fed. Reg. 21,576, 21,582 (2000).

EPA's groundwater standard irrationally varies depending upon the particular radionuclide to which an individual is exposed.³⁵ Indeed, the level of protection varies so widely that the risk values associated with many of the regulated beta particle and photon emitter radionuclides *actually fall outside of EPA's own designated risk range.*³⁶ See SDWA NODA, 65 Fed. Reg. at 21,582, J.A. __.

EPA contends that "most" of the drinking water limits fall somewhere within EPA's target risk range, or can be *rounded*, to fall within that target risk range – a range, which, by the way, spans two orders of magnitude.³⁷ EPA, however, cannot

("SDWA NODA") (graph illustrating wide range of risk associated with the 1976 MCLs), J.A. __; *id.* at 21,605-14 (table indicating same).

EPA's use of FGR 13 in 2000 to re-estimate risks associated with each of the 1976 drinking water limits for beta particle and photon emitters shows that those limits do not, in reality, impose a constant level of either risk or dose. See, e.g., DOE Comments (Item IV-D-36), Letter at 2 (these MCLs "render differing and inconsistent exposure levels, depending on the radionuclide"), J.A. __; *id.* Tab B at B-3 (same); NRC Comments (Item II-D-92) at 1 (noting that EPA was not undertaking any efforts to modify the MCLs to ensure a uniform risk level), J.A. __; NAS Comments (Item IV-D-31), Enclosure at 12 (Yucca Mountain groundwater standard "lacks overall consistence and coherence"), J.A. __.

³⁵ There is, of course, no rationale for applying a different dose or risk level to different radionuclides. A four millirem dose is a four millirem dose; it does not matter from which particular radionuclide it arises.

³⁶ For example, the protection afforded by the MCL for I-134 is *1,500 times* that afforded by the MCL for In-115. Compare SDWA NODA, 65 Fed. Reg. at 21,609 (the MCL of In-155 has an associated lifetime risk of 450 per 1,000,000), J.A. __, *with id.* at 21,610 (the MCL of I-134 has an associated lifetime risk of 0.7 per 1,000,000), J.A. __.

³⁷ See SDWA NODA, 65 Fed. Reg. at 21,581, J.A. __; EPA Response to Comments (Item V-C-1) at 6-21 ("the risks associated with these concentrations, *while varying considerably, generally* these fall within the Agency's current risk target range for drinking water contaminants of 10^{-4} to 10^{-6} ." (emphasis added)), J.A. __.

deny that the 1976 MCLs reflect neither a uniform dose nor a uniform risk level, but rather a random set of risk and dose values that extends both below and above EPA's own risk range. This variability in the level of protectiveness renders the standards arbitrary and capricious. *See, e.g., Mead*, 121 S. Ct. at 2171 (agency's rule must be consistent with agency's own position and must be persuasive); *Troy Corp.*, 120 F.3d at 288 (agency must articulate a satisfactory explanation for its action).

E. EPA's Standard Is Arbitrary And Capricious Because EPA Claimed Its Standard Was Cost-Effective But Failed To Conduct Any Cost-Benefit Analysis.

In the preamble to the Yucca Mountain final rule, EPA claims that "because of the expenses and difficulties associated with remediation of contaminated groundwater, it is prudent and cost-effective to prevent the occurrence of such contamination [by imposing a groundwater standard]." Final Rule (Item V-A-2), 66 Fed. Reg. at 32,106, J.A. __. EPA, however, has no basis for this statement, because the Agency provides absolutely no analysis of the costs and benefits associated with its groundwater standard.³⁸

³⁸ Indeed, despite EPA's reliance in the Final Rule on the unsubstantiated claim that the drinking water limits are cost-effective at Yucca Mountain, EPA has also claimed that its decision whether to apply those limits should have nothing to do with costs and benefits. EPA Response to Comments (Item V-C-1) at 6-23 ("Application of the MCL limits to other site-specific waste disposal activities is a matter of Agency policy and not predicated on the outcome of site-specific cost-benefit analyses."), J.A. __.

Although EPA contends that it should conduct a cost-benefit analysis when it applies the Safe Drinking Water Act limits to other programs like Yucca Mountain,³⁹ EPA here provides no analysis, either quantitative or qualitative, of the benefits and costs associated with MCL application at Yucca Mountain. NRC, the agency with delegated authority for licensing the Yucca Mountain repository, contradicted EPA on this issue. *See, e.g.*, NRC Comments (Item II-D-92), Letter at 2 (“Therefore, in the absence of an appropriate and comprehensive cost-benefit analysis, EPA should not require the expenditure of potentially significant amounts of taxpayer money to prevent potential contamination of groundwater that may require treatment prior to use anyway.”).⁴⁰

By applying these drinking water standards to Yucca Mountain without any cost-benefit analysis, EPA acted inconsistently with its prior position, as well as its stated conclusions in the Final Rule, and its actions should be set aside as arbitrary and capricious under the APA. *See, e.g., Mead*, 121 S.Ct. at 2171 (agency’s position must be thorough, consistent, and persuasive); *Motor Vehicle Ass’n*, 463 U.S. at 43

³⁹ According to EPA, a cost benefit analysis *should* occur whenever EPA or any other agency imposes the SDWA drinking water limits on another regulatory program: “If another program or Agency applies these MCLs for other purposes (e.g., clean-up standards), then the costs and benefits of that application should be considered when evaluating that application.” SDWA Final Rule, 65 Fed. Reg. at 76,737, J.A. __.

⁴⁰ *See also* NEI Comments (Item IV-D-17), Enclosure at 9 (noting EPA proposes a groundwater standard “without showing any additional benefit to public health and

(agency's rule is arbitrary and capricious if it "entirely failed to consider an important aspect of the problem").

IV. THE GROUNDWATER STANDARD SHOULD BE SEVERED.

EPA was well aware that its groundwater standard was unnecessary to fulfill the Agency's regulatory obligations under EnPA and to protect public health and safety: "Consistent with the recommendations of the National Academy of Sciences, the Individual Protection Standard is adequate in itself to protect public health and safety." Final Rule (Item V-A-2), 66 Fed. Reg. at 32,129-30, J.A. __. See also 40 C.F.R. § 197.20. Because the groundwater standard was unnecessary, and, apparently anticipating as well that this standard might be overturned, EPA made clear that the groundwater standard was independent and severable from the remainder of the Final Yucca Mountain Rule by including an explicit severability clause:

§ 197.38 Are The Individual Protection and Ground Water Protection Standards Severable?

Yes. The individual protection and ground water protection standards are severable.

Final Rule (Item V-A-2), 66 Fed. Reg. at 32,135, J.A. __. The Preamble to EPA's final rule describes this clause in further detail:

notwithstanding the Individual Protection and Ground Water Standards have coincident compliance points and, as implemented by NRC, may have other similarities, *these two provisions are wholly severable.*

safety and without providing any cost benefit analysis"), J.A. __; DOE Comments (Item IV-D-36), Tab B at B-3, B-9, J.A. __.

Final Rule (Item V-A-2), 66 Fed. Reg. at 32,129-30 (emphasis added), J.A. __. EPA's severability clause thus provides this Court with the most appropriate remedy for EPA's violations of EnPA and its arbitrary and capricious action: striking EPA's unlawful groundwater standard from the regulation.

As with statutes,⁴¹ courts must consider the issue of severability whenever they hold portions of regulations invalid.⁴² If the invalid portion of the regulation is deemed severable from the remainder, the court will permit the valid portion of the rule to remain in force rather than invalidating and remanding the entire rule back to the agency.⁴³ When determining whether the invalid portion of a rule is severable from the remainder, the courts consider: (1) "whether severance and invalidation of [a portion] will . . . impair the function of the [regulation] as a whole;" and (2) whether there is any indication that the agency would not have issued the regulation without the invalidated portion. *K Mart Corp.*, 486 U.S. at 294. *See also MD/DC/DE*

⁴¹ The Supreme Court has indicated its preference for a surgical approach to statutes—wholly independent parts of statutes which are unconstitutional should be rejected and those portions which are constitutional should be kept. *See, e.g., Brockett v. Spokane Arcades, Inc.*, 472 U.S. 491, 502 (1985); *Tilton v. Richardson*, 403 U.S. 672, 684 (1971) ("The cardinal principle of statutory construction is to save and not to destroy.").

⁴² *See, e.g., K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988); *Community for Creative Non-Violence v. Turner*, 893 F.2d 1387, 1393-94 (D.C. Cir. 1990).

⁴³ *See Davis County Solid Waste Mgm't v. EPA*, 108 F.3d 1454, 1459-60 (D.C. Cir. 1997) (vacating a portion of EPA's 1995 emission standards and allowing another portion to remain in place).

Broadcasters Ass'n v. Federal Communications Comm'n, 236 F.3d 13, 22 (D.C. Cir. 2001), *cert. denied*, 122 S. Ct. 920 (2001).

EPA's Yucca Mountain Rule meets both criteria. The first criterion is clearly satisfied: severance of the groundwater protection standard would not impair the functioning of the regulation as a whole because the individual protection standard *would remain* in place to protect public health and safety and EPA has admitted that standard alone is sufficient. The second criterion is also met: EPA adopted an explicit severability clause and, in so doing, indicated that the remainder of the regulation was sufficient on its own, "for it said so in adopting the regulation." *See MD/DC/DE Broadcasters*, 236 F.3d at 22.

V. NEI'S CHALLENGE TO THE YUCCA MOUNTAIN RULE IS RIPE.

EPA previously challenged this case on standing and ripeness grounds, asserting that it was not clear that the Yucca Mountain repository would ever be approved.⁴⁴ This matter is ripe for the Court's consideration now and NEI has standing to raise its challenges. By the date of oral argument, any uncertainty about Yucca Mountain going forward will likely have been resolved, along with any questions of ripeness or standing. Nonetheless, to respond to EPA's challenge, NEI summarizes its position here.

⁴⁴ EPA Opposition to Nevada's Motion for Expedited Briefing; and Cross-Motion to Dismiss All Petitions for Lack of Jurisdiction (Nov. 21, 2001); NEI's Opposition to EPA's Motion to Dismiss (Dec. 14, 2001).

Since the government filed its motion to dismiss in November 2001, the Energy Secretary recommended the Yucca Mountain project to the President, the President recommended Yucca Mountain to Congress, and Nevada notified Congress of its disapproval of the site designation. The last remaining step in the Yucca Mountain approval process is for Congress to pass a resolution approving the site and overriding Nevada's veto, an action that must happen within 90 days, of continuous Congressional session, of the veto. 42 U.S.C. § 10135(c). There is thus no doubt that Congressional consideration will have been resolved by February 20, 2003, the date of oral argument in this matter. At that point, EPA may not complain that NEI's challenges are not ripe, or that NEI has not yet suffered sufficient injury to confer standing.

Even before resolution of Congressional approval, however, EPA's Yucca Mountain Rule is ripe for review: the rule is final, only purely legal issues remain (*i.e.*, whether EPA exceeded its statutory authority under EnPA or whether EPA's actions are arbitrary and capricious), and completion of the Congressional approval process would not provide a "more concrete setting" to benefit the Court. *See, e.g., George E. Warren Corp. v. EPA*, 159 F.3d 616, 621-22 (D.C. Cir. 1998), *amended*, 164 F.3d 676 (D.C. Cir. 1999).⁴⁵

⁴⁵ Courts regularly recognize standing when an injury turns, in part, on contingent events. *See, e.g., Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1289 (D.C. Cir. 2000).

Finally, NEI and its members have standing because they are already suffering and will continue to suffer a concrete injury if review is delayed. As generators and owners of nuclear waste, the customers of NEI members need the repository, and have financed its development through \$17 billion in fees for which they have a contract with DOE. The challenged groundwater standard has already increased the costs to NEI members due to increased interim storage costs for generated waste, delayed removal of encumbrances at decommissioned facilities, and increased repository planning and construction costs, which are already being incurred. Thus, NEI has standing and this matter is ripe for review.

CONCLUSION

EPA's groundwater standard violates EnPA and is arbitrary and capricious. NEI respectfully urges the Court to invalidate that standard and sever it from the remainder of the Final Rule.

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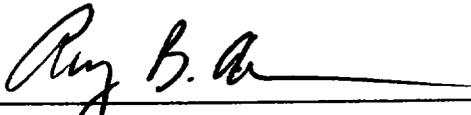


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CERTIFICATION OF WORD LIMIT

Pursuant to FED. R. APP. P. 32 and Local Rule 32, I hereby certify that the foregoing Brief of Petitioners NEI is 9,315 words in length as determined by the Microsoft Word word-processing system used to prepare this brief.



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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of Petitioner Nuclear Energy Institute, Inc. Brief was served on this 7th day of May, 2002, by federal express, on the following:

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TABLE OF AUTHORITIES FOR STATUTORY ADDENDUM

The following statutory and regulatory authorities have been supplied in an addendum bound with this brief:

<u>Citation</u>	<u>Addendum Tab</u>
Statutes	
5 U.S.C. § 706	1
42 U.S.C. § 10141 note, Energy Policy Act, Pub. L. No. 102-486, tit. VIII, § 801(a)(1)	2
Regulations	
40 C.F.R. § 197	3
Federal Register Notices	
Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada; Proposed Rule, 64 Fed. Reg. 46,976 (1999)	4
Public Health and Environmental Radiation Protection Standards for Yucca Mountain, Nevada; Final Rule, 66 Fed. Reg. 32,074 (2001)	5
Legislative History	
H.R. CONF. REP. NO. 102-1018 380, 390-91, <i>reprinted in</i> 1992 U.S.C.C.A.N. 2472, 2481-82	6
138 CONG. REC. S17558- S17559 (daily ed. Oct. 8, 1992) (statements of Sen. Johnston)	7
Oversight Hearing Before the Subcommittee on Energy Power (testimony of Mr. Steve Page, Director, Office of Air and Radiation, U.S. EPA on June 23, 2000)	8