Complex Case

ORAL ARGUMENT SCHEDULED FOR NOVEMBER 20, 2002

UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 01-1028 and consolidated cases

CITY OF WAUKESHA; NUCLEAR ENERGY INSTITUTE, INC.; NATIONAL MINING ASSOCIATION; AND RADIATION, SCIENCE & HEALTH, INC.

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

VILLAGE OF SUSSEX WATER COMMISSION, et al.,

Intervenors.

Petition for Review of Regulations of the United States Environmental Protection Agency

---

JOINT BRIEF OF PETITIONERS

John N. Hanson, Esq.
Brian L. Doster, Esq.
Justin A. Savage, Esq.
Beveridge & Diamond, P.C.
1350 I Street, N.W., Suite 700
Washington D.C. 20005-3311
(202) 789-6000
Counsel for City of Waukesha

Jean V. MacHarg, Esq.
John C. Martin, Esq.
Susan M. Mathiascheck, Esq.
Patton Boggs LLP
2550 M Street, N.W.
Washington, D.C. 20037-1350
(202) 457-6000
Counsel for Nuclear Energy Institute, Inc.

Michael B. Wigmore, Esq.
Swidler Berlin Shereff Friedman, LLP
3000 K Street, N.W., Suite 300
Washington D.C. 20007
(202) 424-7500
Counsel for Radiation Science & Health, Inc.

David C. Lashway, Esq.
Shaw Pittman LLP
2300 N Street, N.W.
Washington, D.C. 20037
(202) 663-8000
Counsel for National Mining Association

Initial Date: May 21, 2002
Final Date: October 17, 2002

Curt R. Meitz, Esq., City Attorney
Vincent D. Moschella, Esq., Asst. City Atty.
City of Waukesha
201 Delafield Street
Waukesha, WI 53188-3616

Donald P. Gallo, Esq.
Pamela Schaefer, Esq.
Reinhart, Boerner, Van Deuren, Norris & Rieselbach, S.C.
1000 North Water Street
Milwaukee, WI 53203-3400
Counsel for Petitioner, City of Waukesha and Bruce Zivney

H. Stanley Riffle, Esq.
Arenz, Molter, Macy & Riffle
720 N. East Avenue
P.O. Box 1348
Waukesha, WI 53186-1348
Counsel for Intervenor Village Of Sussex Water Commission

Phillip J. Eckert, Esq.
O'Meara Law Firm, LLP
622 Elm Street
West Bend, WI 53095-0348
Counsel for Intervenor, Village of Hustisford

Paul F. Reilly, Esq., City Attorney
City of New Berlin
720 Clinton Street
Waukesha, WI 53187
Counsel for Intervenor, City of New Berlin

John S. Noble, Esq., City Attorney
Weiler & Noble, P.C.
425 Williamsburg Avenue
Geneva, IL 60134
Counsel for Intervenor, City of Batavia

Richard M. Glidden, Esq.
Law Office of Richard M. Glidden
522 Chief Street, P.O. Box 738
Benkelman, NE 69021
Counsel for Intervenor, City of Benkelman

Katie Sweeney, Esq.
Associate General Counsel
National Mining Association
101 Constitution Ave., N.W., Suite 500
Washington, D.C. 20002

Anthony J. Thompson, Esq.
Law Offices of Anthony J. Thompson, P.C.
1225 19th Street, N.W., Suite 200
Washington, D.C. 20036
Counsel for National Mining Association

Robert W. Bishop, Esq.
Ellen C. Ginsberg, Esq.
Nuclear Energy Institute, Inc.
1776 I Street, N.W., Suite 400
Washington, DC 20006-3708

James B. Harvey, Esq.
McKeown, Fitzgerald, Zollner, Buck, Hutchison & Ruttle
2455 Glenwood Avenue
Joliet, IL 60435
Counsel for Intervenor, Village of Plainfield, Illinois

Suzanne K. Schalig, Esq., City Attorney
City of Brookfield
2000 North Calhoun Road
Brookfield, WI 53005
Counsel for Intervenor, City of Brookfield

William Von Arx, Esq.
Von Arx Law Office
218 South Kingston Street,
Caledonia, MN 55921
Counsel for Intervenor, City of La Crescent

Dennis M. Duffy, Esq.
Wieting, Calewarts, Duffy & Maxwell
716 Pine Street
Green Bay, WI 54305
Counsel for Intervenor for Petitioner, Village of Ashwaubenon

CERTIFICATE AS TO PARTIES, RULINGS AND RELATED CASES

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and D.C. Circuit Rules 26.1 and 28(a)(1), Petitioners City of Waukesha, the Nuclear Energy Institute, Inc., the National Mining Association, and Radiation Science and Health, Inc. submit the following.

Parties and Amici

The following parties are Petitioners in this case: City of Waukesha, Wisconsin, Bruce Zivney, Nuclear Energy Institute, Inc., the National Mining Association, and Radiation, Science & Health, Inc. The Respondent in this case is the United States Environmental Protection Agency ("EPA").

Intervenors are Village of Sussex Water Commission; Village of Plainfield, Illinois; Village of Hustisford, Wisconsin; City of Brookfield, Wisconsin; City of New Berlin, Wisconsin; City of La Cresent, Minnesota; City of Batavia, Illinois; Village of Ashwaubenon, Wisconsin; City of Benkelman, Nebraska.

Rulings Under Review

Petitioners challenge EPA's final rule entitled "National Primary Drinking Water Regulations; Radionuclides; Final Rule." EPA published this rule at 65 Fed. Reg. 76708 (Dec. 7, 2000). It is reproduced in the Statutory and Regulatory Addendum to this brief.

Related Cases

This case has not been before this Court or any other court.

CORPORATE DISCLOSURE STATEMENTS

The City of Waukesha ("Waukesha") is a municipality that operates a community water system in Wisconsin. Waukesha does not have outstanding shares or debt securities in the hands

of the public, and does not have any parent, subsidiary, or affiliates that have issued shares or debt securities to the public.

Nuclear Energy Institute, Inc. ("NEI") is an international not-for-profit incorporated trade association responsible for establishing nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, nuclear materials licensees, organizations involved in research and the uses of nuclear technologies in medical diagnosis and treatment, universities, and other organizations and individuals involved in the nuclear energy industry. 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.

The National Mining Association ("NMA") is a national, not-for-profit incorporated trade association whose members include the producers of most of America's coal, metals, and industrial and agricultural minerals; manufacturers of mining and mineral processing machinery, equipment and supplies; electric utilities; transporters of mineral products; and engineering and other firms that serve the mining industry and other industries. NMA has no parent companies, subsidiaries or affiliates that have issued shares or debt securities to the public.

Radiation, Science & Health, Inc. ("RSH") is an international not-for-profit organization of independent experts on radiation and public policy, committed to applying current scientific data and theories to radiation protection policy. RSH does not have any outstanding securities in the hands of the public, nor does it have a publicly-owned parent company.

Dated: October 17, 2002

Respectfully submitted,

John N. Hanson, Esq.
Brian L. Doster, Esq.
Justin A. Savage, Esq.
Beveridge & Diamond, P.C.
1350 I Street, N.W., Suite 700
Washington D.C. 20005-3311
(202) 789-6000
Counsel for Petitioner, City of Waukesha

Curt R. Meitz, Esq., City Attorney
Vincent D. Moschella, Esq., Asst. City Atty.
City of Waukesha
201 Delafield Street
Waukesha, WI 53188-3616

Donald P. Gallo, Esq.
Pamela Schaefer, Esq.
Reinhart, Boerner, Van Deuren, Norris & Rieselbach, S.C.
1000 North Water Street
Milwaukee, WI 53203-3400
Counsel for Petitioner, City of Waukesha and Bruce Zivney

David C. Lashway, Esq.
Shaw Pittman LLP
2300 N Street, N.W.
Washington, D.C. 20037
Counsel for National Mining Association

Katie Sweeney, Esq.
Associate General Counsel
National Mining Association
101 Constitution Ave. N.W., Suite 500
Washington, D.C. 20001

Anthony J. Thompson, Esq.
Law Offices of Anthony J. Thompson, P.C.
1225 19th Street, N.W., Suite 200
Washington, D.C. 20036
Counsel for National Mining Association

Michael B. Wigmore, Esq.
Swidler Berlin Shereff Friedman, LLP
3000 K Street, N.W., Suite 300
Washington D.C. 20007
Counsel for Radiation Science & Health, Inc.

Jean V. MacHarg, Esq.
John C. Martin, Esq.
Susan M. Mathiascheck, Esq.
Patton Boggs LLP
2550 M Street, N.W.
Washington, D.C. 20037-1350
Counsel for Nuclear Energy Institute

Robert W. Bishop, Esq.
Ellen C. Ginsberg, Esq.
Nuclear Energy Institute, Inc.
1776 I Street, N.W., Suite 400
Washington, D.C. 20006-3708

TABLE OF CONTENTS

TABLE OF AUTHORITIES

FEDERAL CASES

*Authorities on which we chiefly rely are marked with asterisks

DOCKETED CASES

FEDERAL STATUTES

FEDERAL REGULATIONS

LEGISLATIVE HISTORY

STATE STATUTES

GLOSSARY OF ACRONYMS AND ABBREVIATIONS

AEA	Atomic Energy Act
ANPRM	Advanced Notice of Proposed Rulemaking
APA	Administrative Procedure Act
ATSDR	Agency for Toxic Substances and Disease Registry
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
EDE	Effective Dose Equivalent
EPA	Environmental Protection Agency
FGR	Federal Guidance Report
HRRCA	Health, Risk, Reduction and Cost Analysis
ICRP	International Commission on Radiological Protection
LNT	Linear Non-Threshold
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
NEI	Nuclear Energy Institute, Inc.
NMA	National Mining Association
NODA	Notice of Data Availability
NPDWR	National Primary Drinking Water Regulations
RfD	Reference Dose
RSH	Radiation, Science & Health, Inc.
SDWA	Safe Drinking Water Act

BASIS OF JURISDICTION

Petitioners seek review of the National Primary Drinking Water Regulations ("NPDWRs") for radionuclides promulgated by the Environmental Protection Agency ("EPA" or "the agency") under Section 1412 of the Safe Drinking Water Act ("SDWA").[1] Under Section 1448(a) of the SDWA,[2] this Court has exclusive jurisdiction over all actions pertaining to the establishment of NPDWRs. Petitioners have timely filed their petitions for review, with the first petition filed by the City of Waukesha on January 18, 2001.[3] The agency=s action is also subject to review by this Court under the Administrative Procedure Act ("APA")[4] and Rule 15 of the Federal Rules of Appellate Procedure.

STATEMENT OF ISSUES

1. Whether EPA acted arbitrarily and capriciously, abused its discretion, or violated the cost-benefit analysis requirements[5] of the SDWA when it failed to conduct, publish, seek comment on, and use a "health risk reduction and cost analysis" that:

   a. Evaluated all the costs and health benefits of the radium Maximum Contaminant Level ("MCL") that the agency adopted and the alternative MCLs that were under consideration.

   b. Evaluated all the costs and health benefits of the uranium MCL of 30 ug/L, and applied consistent conclusions.

---

[1] 42 U.S.C. § 300g-1.

[2] 42 U.S.C. § 300j-7(a).

[3] Other petitioners filed from January 19-22, 2001.

[4] 5 U.S.C. §§ 701-706.

[5] *See* 42 U.S.C. § 300g-1(b)(3)(C).

c. Considered the impacts of the beta/photon and uranium MCLs on Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA") sites and other facilities, and under state law.

d. Evaluated the costs and health benefits of the beta/photon MCLs.

2. Whether EPA acted arbitrarily and capriciously, abused its discretion, or violated the SDWA mandate to use the best available, peer-reviewed science[6] when it:

a. Neglected to consider relevant data or to provide a rational explanation for setting the radium MCLs solely on the results of a general risk assessment model that used assumptions contradicted by more specific data on people who had ingested various concentrations of those radium isotopes.

b. Established an MCLG of zero and an MCL of 30ug/L for uranium, where there is no evidence in the record that shows a carcinogenic effect from the ingestion of uranium in drinking water, and where the agency did not adequately consider relevant scientific data and respond to comments.

c. Established beta/photon MCLs that (i) are based on discredited 40-year-old science, (ii) are inconsistent with 14 years of EPA guidance and EPA regulation, (iii) and provide inconsistent radiation protection to the public.

3. Whether EPA's failure to respond adequately to comments submitted by the public that refuted EPA's use of a linear non-threshold model to support the promulgated drinking water standards for radionuclides was arbitrary and capricious and in violation of the APA.

[6] *See* 42 U.S.C. § 300g-1(b)(3)(A).

STATUTES AND REGULATIONS

Pertinent statutes and regulations appear in a separately-bound addendum.

STATEMENT OF THE CASE

This case involves a challenge to the December 7, 2000 action of the EPA promulgating final regulations under the SDWA to limit the concentration of radionuclides (radium, uranium, and beta/photon emitters) in drinking water.[7] This matter is on direct review to this Court and has not been before any other court. Four parties filed Petitions for Review that were consolidated by order dated January 24, 2001. Nine municipalities obtained leave to intervene and join the brief of petitioners.

STATEMENT OF FACTS

The NPDWRs for radionuclides under review here are part of the massive group of rules issued in the last three months of 2000. EPA's proposed rule for radionuclides had been pending since July 1991. EPA did not act on that proposal until April 2000 when the agency issued a Notice of Data Availability ("NODA") which identified and sought comment on new scientific information and EPA's plans to adopt a final regulations for uranium and final regulations for radium and beta/photon radionuclides different than those proposed in 1991. In December 2000, nearly six months after the close of the comment period on the NODA, EPA issued the Final Rule for radionuclides. In its rush to do so, the agency violated the SDWA and the APA.

The Safe Drinking Water Act

The SDWA charges EPA with developing NPDWRs for drinking water contaminants that "may have an adverse effect on the health of persons" and that are "known" or substantially

[7] National Primary Drinking Water Regulations; Radionuclides; Final Rule, 65 Fed. Reg. 76708 (Dec. 7, 2000) (JA 874).

likely to occur in public water systems.[8] The principal component of an NPDWR is the MCL, which establishes the highest permissible concentration level of a contaminant in public water supplies.[9] As part of the standard-setting process, EPA is required to first establish a Maximum Contaminant Level Goal ("MCLG") for such contaminants. MCLGs are non-enforceable health goals that identify the level at which "no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."[10] The agency then sets an enforceable MCL that is as close as "feasible" to the MCLG,[11] allowing for consideration of factors such as costs and available treatment technology.[12] As a result of 1996 Amendments to the Act, EPA must also consider whether the costs of a feasible MCL are justified by the benefits.[13]

Regulation of Radionuclides

EPA defines "radionuclide" as "any . . . element which emits radiation in the form of alpha or beta particles, or as gamma rays."[14] The radiation emitted by radionuclides is referred to as "ionizing radiation." The radionuclides regulated under the SDWA include uranium, radium-226, radium-228, gross alpha particles, and beta particle and photon ("beta/photon") emitters. Many radionuclides are naturally occurring and are commonly found in ground water in the Midwest and Western United States.

---

[8] 42 U.S.C. § 300g-l(b)(l)(A).

[9] 42 U.S.C. § 300f(1); 42 U.S.C. § 300f(3).

[10] 42 U.S.C. § 300g-1(b)(4)(A).

[11] 42 U.S.C. § 300g-1(b)(4)(B).

[12] 42 U.S.C. § 300g-1(b)(4)(D).

[13] *See, e.g.,* 42 U.S.C. §§ 300g-1(b)(3)(C), b(4), (b)(6)(A).

[14] EPA, Radionuclides Notice of Data Availability Technical Support Document (March 2000), at I-10 ("Technical Support Document") (Docket Index ("DI") I-B-15) (JA 162).

EPA's Method For Establishing MCLGs and MCLs

When establishing MCLGs for contaminants that are known carcinogens and for which EPA does not have a sufficient scientific understanding of how the contaminant causes cancer (its "mode of action"), EPA generally sets the MCLG at zero based on a default assumption known as the linear non-threshold ("LNT") assumption.[15] EPA assumes that some risk of cancer exists at every dose no matter how low (no threshold exists below which no cancer occurs)[16] and that the cancer incidence decreases in direct proportion to the dose down to zero (the dose-response curve is straight or linear).[17] EPA sets MCLGs for known carcinogens at zero because the LNT says this is the only level where there are no known or anticipated adverse effects.

To determine MCLs, EPA in most cases conducts risk assessments to identify the concentration levels of a contaminant that produce an excess lifetime cancer risk within EPA's acceptable range of 10^{-4} and 10^{-6}. In EPA's view, an MCL with a risk in this range meets the SDWA requirement that an MCL be as close to the MCLG as feasible.[18]

---

[15] *See generally* National Primary Drinking Water Regulations; Radionuclides; Proposed Rule, 56 Fed. Reg. 33050, 33070 (July 18, 1991) (JA 1388).

[16] *See* EPA, Comment-Response Document for the Radionuclides Notice of Data Availability (April 2000), at 3-5 (Nov. 2000) (Comment No. 3.A.1) (DI II-B-16) ("CRD-NODA") (JA 938).

[17] EPA's Proposed Guidelines for Carcinogen Risk Assessment; Notice, 61 Fed. Reg. 17960, 17968 (April 23, 1996) ("1996 Cancer Guidelines"); EPA, Cancer Risk Coefficients for Environmental Exposure to Radionuclides: Federal Guidance Report No. 13, at v (Sept. 1999) (DI I-B-14) ("FGR-13") (JA 79). The LNT assumption is based on the theory that chemicals may cause cancer by acting directly on the DNA in cells of the body (this is known as a "genotoxic" mode of action), and that very low levels of exposure to such substances (even exposures to a single molecule) can alter DNA to cause cancer. Absent evidence to the contrary, EPA assumes that the mode of action is genotoxic and therefore that no threshold exists for the potential cancer risk.

[18] *See* 56 Fed. Reg. at 33080 (JA 1398); National Primary Drinking Water Regulations; Radionuclides; Notice of Data Availability; Proposed Rule, 65 Fed. Reg. 21576, 21580 (Apr. 21, 2000) (JA 6).

The 1976 Rule

EPA first regulated radionuclides in drinking water in 1976 when it promulgated Interim Primary Drinking Water Regulations for radium-226 and radium-228, gross alpha particle radioactivity, and beta/photon radioactivity.[19] Those interim standards became effective in 1977.[20] EPA set an interim MCL of 5 picocuries/liter ("pCi/L") for radium-226 and radium-228 combined, based on a finding that this standard produced an acceptable cancer risk.[21] The 1976 standard did not require monitoring for radium-228 unless the concentration of radium-226 exceeded 3 pCi/L.[22] Attempting to achieve a risk level of 5.6×10^{-5}, EPA established a 4 millirem/year ("mrem/year") acceptable risk dose for beta/photon radionuclides and published MCLs that it believed to represent that risk and dose, based on a scientific approach published in 1959.[23] A standard for uranium was not established in 1976. In 1983, EPA issued an Advance Notice of Proposed Rulemaking ("ANPRM") announcing that the agency was considering standards for uranium and radon and revisions to the interim standards for radium and beta/photon emitters in accordance with the procedure then required by the SDWA.[24]

The 1986 Reauthorization of the SDWA

Displeased with EPA's progress in completing standards for drinking water contaminants, in 1986 Congress re-authorized and amended the SDWA.[25] The amendments

---

[19] Interim Primary Drinking Water Regulations; Promulgation of Regulations on Radionuclides, 41 Fed. Reg. 28402, 28403 (July 9, 1976).

[20] *Id.*

[21] Technical Support Document at III-4 (JA 176).

[22] *See* 41 Fed. Reg. at 28404.

[23] *See Id.*

[24] National Revised Primary Drinking Water Regulations, Advanced Notice of Proposed Rulemaking, 48 Fed. Reg. 45502 (Oct. 5, 1983).

[25] Pub. L. No. 99-339 (1986).

required EPA by June 1989 to simultaneously promulgate new MCLGs and MCLs for 83 substances, including radium-226 and radium-228, gross alpha particle radioactivity, beta/photon radioactivity, uranium, and radon. The amendments also converted the 1976 interim standards into final NPDWRs.[26]

In a subsequent ANPRM, EPA stated its intent to fulfill the requirements of the 1986 amendments by the 1989 deadline.[27]

The 1991 Proposed Rule

EPA did not meet the 1989 deadline for final action on the radionuclide standards and was sued.[28] EPA finally issued a proposal in 1991 to change the existing radionuclide standards and to adopt standards for radon and uranium.[29] All MCLGs for radionuclides were proposed at zero, based on the LNT assumption.[30] EPA proposed: (i) establishing an MCL of 20 ug/L for uranium; (ii) revising the beta/photon MCLs to a 4 mrem "effective dose equivalent" standard using a more advanced scientific methodology; (iii) and replacing the combined radium-226 and radium-228 standard of 5 pCi/L with separate MCLs of 20 pCi/L for radium-226 and 20 pCi/L for radium-228.[31] EPA based the higher radium standards on the results of a risk assessment model (called RADRISK) that were reconciled with data from people who had actually ingested

[26] 42 U.S.C. § 300g-1(a)(1).

[27] National Primary Drinking Water Regulations; Radionuclides; Advanced Notice of Proposed Rule Making, 51 Fed. Reg. 34836 (Sept. 30, 1986) (JA 1454).

[28] *Miller v. Browner*, Case No. 89-6328-HO (D. Oregon filed Aug. 31, 1989).

[29] 56 Fed. Reg. at 33051 (JA 1369).

[30] 56 Fed. Reg. at 33051, 33070 (JA 1369, 1388).

[31] 56 Fed. Reg. at 33051 (JA 1369).

radium.[32] EPA also proposed separate monitoring for radium-228 that was not contingent on the monitoring results for radium-226.[33] In the litigation, EPA agreed to a consent order requiring final action on the radionuclides standards by the close of 2000.[34]

The Safe Drinking Water Act Amendments Of 1996

While the 1991 proposed rule was pending, Congress amended the SDWA in 1996. Although Congress had always required EPA to use science to set standards, the 1996 amendments explicitly required that EPA use the "best available, peer-reviewed science" when setting drinking water standards.[35] Congress also required that EPA conduct a comprehensive cost-benefit analysis for each standard "being considered" in "any" proposed NPDWR and determine whether the benefits of a proposed MCL justify its costs.[36] The agency was given authority to set an MCL at a level less stringent than "feasible" if the benefits did not justify the costs.[37] Congress also changed the 1986 requirement that EPA review and revise standards as appropriate every three years to a six-year review, and added a requirement that EPA maintain the level of human health protection provided by the existing standard.[38]

The April 2000 NODA

In April 2000, EPA published a NODA in which it requested comment on newly available data relevant to the pending 1991 proposal and on EPA's plans to rely on that data to

---

[32] 56 Fed. Reg. at 33056, 33073 (JA 1374, 1391); EPA, Final Draft for the Drinking Water Criteria Document for Radium (June 14, 1991) at VIII–31 to VIII–34 (DI III-D1-c) ("Radium Criteria Document") (JA 1536-1539).

[33] *See* 56 Fed. Reg. at 33081-83, 33105 (JA 1399-1401, 1423).

[34] Stipulated Fed. R. Civ. P. 60(b)(6) Motion for Relief from Judgment, *Miller v. Browner*, No. 89-6328-HO (D. Oregon Nov. 19, 1996).

[35] 42 U.S.C. § 300g-1(b)(3)(A).

[36] 42 U.S.C. §§ 300g-1(b)(3)(C), (b)(4)(C), (b)(6)(A).

[37] *See* 42 U.S.C. § 300g-1(b)(6)(A).

[38] 42 U.S.C. § 300g-1(b)(9).

issue a final rule for uranium and a final rule for radium and beta/photon radionuclides different from that proposed in 1991.[39] EPA reiterated its view that because all "radionuclides emit ionizing radiation," the agency would use the LNT assumption "to set a zero MCLG for radionuclides."[40] EPA also announced its intent to rely for the first time on its new model, known as Federal Guidance Report No. 13 ("FGR-13"), to assess the risk of the proposed MCLs for radionuclides.[41] The agency concluded that the RADRISK model used to develop the 1991 proposal was "now-outdated."[42] EPA said the FGR-13 model, which relied on the LNT assumption and new data from survivors of the atomic bombs at Hiroshima and Nagasaki, estimated more risk from exposure to radionuclides than the RADRISK model.[43] Therefore, EPA proposed to lower the MCLs, lest they exceed the agency's acceptable risk range.[44]

Although the agency claimed to use its new FGR-13 model as the basis for its MCLs, EPA continued to rely on old science to justify its standards for beta/photon radionuclides. Absent from EPA's conclusions regarding higher cancer risk based on "the newest science," including FGR-13, was any discussion of uranium. EPA did not lower the proposed uranium MCL but merely asserted that it was subject to the LNT assumption and an MCLG of zero.[45]

---

[39] 65 Fed. Reg. at 21579-88 (JA 5-14).

[40] *Id.*

[41] 65 Fed. Reg. at 21579-80 (JA 5-6). EPA develops Federal Guidance Reports ("FGRs") for other agencies to use when considering radiation health effects.

[42] 65 Fed. Reg. at 76710 n.1 (JA 877).

[43] 65 Fed. Reg. at 21579 (JA 5); FGR-13 at 173 (JA 110).

[44] 65 Fed. Reg. at 21579 (JA 5).

[45] *See* 65 Fed. Reg. at 21586-88 (JA 12-14).

The December 2000 Final Rule

Almost ten years after the 1991 proposal, but less than six months after receiving comments on the new approach announced in its NODA, the agency published its Final Rule for radionuclides on December 7, 2000.[46] EPA adopted an MCLG of zero for all radionuclides, based on its LNT assumption.[47] EPA "assumed that any exposure to radiation may be harmful (or may increase the risk of cancer)" even while admitting that "at very low exposures (*e.g.* drinking water exposures below the MCL), the estimated increases in risk are very small and uncertain" such that "cancer rates in populations receiving very low doses of radiation may not show increases over the rates for unexposed populations."[48]

EPA adopted a final standard for radium that was proposed in the NODA – an MCL of 5 pCi/L for both radium-226 and radium-228 with separate monitoring for radium-228 regardless of the concentration of radium-226.[49] For this MCL, EPA relied solely on the results of the FGR-13 model. The agency did not incorporate the specific data on ingestion of radium-226 and radium-228 into its analysis or adjust the model's predictions to be consistent with this data, as EPA had done in 1991.

EPA attempted to satisfy its cost-benefit analysis obligation under Section 1412(b)(3)(C) of the SDWA for radium, but the agency did not evaluate all the costs it was required to consider.[50] EPA did not conduct any cost benefit analyses for its beta/photon or its existing

---

[46] 65 Fed. Reg. at 76708 (JA 875).

[47] *Id.* at 76722 (JA 889).

[48] *Id.* at 76720 (JA 887).

[49] *Id.* at 76710-11, 76719 (JA 877-878, 886).

[50] *See* Preliminary Health Risk Reduction and Cost Analysis (Jan. 2000), at ES-2 (DI I-B-16) ("PHRRCA") (JA 221); EPA, Economic Analysis of Radionuclides: National Primary Drinking Water Regulations (Nov. 2000) (DI II-B-23) ("Economic Analysis") (JA 1108-1366).

radium MCLs. EPA also excluded any consideration of costs arising from MCL compliance at CERCLA sites.

EPA adopted an MCL of 30 ug/L for uranium as opposed to the 20 ug/L level proposed in 1991.[51] In so doing, EPA relied for the first time on its discretionary authority under the 1996 Amendments to set an MCL at a level above the "feasible" level if the benefits of a stricter standard do not justify the costs.[52] Although EPA determined that an MCL of 20 ug/L was feasible, EPA promulgated a final MCL of 30 ug/L in part because "in the Agency's judgment, . . . there is not a predictable difference in health effects due to exposure between . . . 20 ug/L and a level of 30 ug/L,"[53] and because the "likelihood of any significant effect in the population at 30 ug/L is very small."[54] EPA also concluded that the high costs of an MCL of 20 ug/L were not justified by the benefits of an MCL at that level.[55] EPA, by first announcing the 30 ug/L MCL in the Economic Analysis of November 2000, prevented petitioners from commenting on the analysis which lead EPA to set the final MCL at 30 ug/L and prevented petitioners from commenting on the 30 ug/L itself.[56]

EPA repromulgated the 1976 standards for beta/photon radionuclides. The agency chose not to employ FGR-13 to set new standards, preferring to retain standards that reflect 40-year-old science, with the understanding that it would revisit the subject. EPA claimed that more of the 1976 risk values were either within EPA's risk range or could be "rounded" to be within that

---

[51] 65 Fed. Reg. at 76722 (JA 889).

[52] *Id.* at 76712 (JA 879).

[53] *Id.* at 76713 (JA 880).

[54] *Id.* at 76714 (JA 881).

[55] *Id.* at 76715 (JA 882).

[56] *See* Economic Analysis at 1-4 (JA 1116).

range.[57] EPA did not analyze the health risk reduction benefits or the costs associated with retaining the 1976 standards.

Petitioners

Waukesha operates a community water system subject to the SDWA for its 65,000 residents.[58] Radium-226 and radium-228 naturally occur in the City's aquifer at levels above the 5 pCi/L MCL but below the 20 pCi/L MCLs proposed by EPA in 1991.[59] Compliance with an MCL of 5 pCi/L will cost Waukesha more than $67 million to build a treatment plant and to handle the radioactive waste from the plant.[60] Waukesha signed an enforcement agreement with the State of Wisconsin pending the outcome of EPA's 1991 Proposal.[61]

NEI represents the nuclear energy industry. Its members' facilities are potential sources of beta/photon radionuclides that are the subject of the Final Rule. NEI members also own many facilities that are potentially subject to the beta/photon MCLs at decommissioned facilities under CERCLA.[62]

NMA's members operate public water systems and therefore will be affected by the new drinking water standards. NMA's members' facilities are also potential sources of the radionuclides that are the subject of the Final Rule. In addition, NMA members own and operate facilities that are subject to the radionuclide standards through EPA's application of the standards under CERCLA and the Atomic Energy Act ("AEA"). NMA members will likely face greater liability under CERCLA and the AEA as a result of the Final Rule.

---

[57] 65 Fed. Reg. at 21581 (JA 7).

[58] Comments of City of Waukesha, Attachments at 565 (DI I-I1-10) ("Waukesha Comments") (JA 586).

[59] *Id.*

[60] *Id.*

[61] *Id.* at 566. (JA 587).

[62] 42 U.S.C. §§ 9601 to 9675 (2001).

Radiation, Science & Health, Inc. ("RSH") is a non-profit association whose individual members may be subject to increased costs for drinking water due to the regulations issued.

STANDARD OF REVIEW

When a statute is clear on its face, no deference is due the agency and the Court must find any agency action contrary to that clear language invalid.[63] Even when a "statute is silent or ambiguous with respect to the specific issue," an agency's interpretation must be "based on a permissible construction of the statute"[64] and be "reasonable in light of the Act's text, legislative history, and purpose."[65] "[T]he court must avoid an interpretation that undermines congressional purpose considered as a whole when alternative interpretations consistent with the legislative purpose are available."[66]

Even if EPA permissibly construes its statutory authority, the agency may not apply that authority in a manner that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[67] An agency rule is "arbitrary and capricious" when:

> [it] 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.[68]

---

[63] *Chevron U.S.A. v. NRDC*, 467 U.S. 837, 842-43 (1984).

[64] *Id.* at 843.

[65] *S. Cal. Edison Co. v. FERC*, 116 F.3d 507, 511 (D.C. Cir. 1997).

[66] *United States v. Braxtonbrown-Smith*, 278 F.3d 1348, 1352 (D.C. Cir. 2002) (citing *American Trucking*, 310 U.S. at 543, *Haggar Co. v. Helvering*, 308 U.S. 389, 394 (1940))

[67] 5 U.S.C. § 706(2)(A); *see also Chlorine Chemistry Council v. EPA*, 206 F.3d 1286, 1291 (D.C. Cir. 2000) (SDWA rulemakings subject to arbitrary and capricious review pursuant to APA Section 706); *Edison Elec. Inst. v. EPA*, 2 F.3d 438, 446 (D.C. Cir. 1993) (EPA's rulemakings must "pass muster" under the APA and *Chevron*).

[68] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

While the "arbitrary and capricious" standard of review is more deferential when EPA is "evaluating scientific data,"[69] courts do not "merely . . . rubber stamp agency actions" based on an agency's "reminders that . . . scientific determinations are entitled to deference."[70] Even when science is involved, an agency must "cogently explain why it has exercised its discretion in a given manner; and that explanation must be . . . 'the product of reasoned decisionmaking.'"[71] An agency may not rely solely on general data or blanket assumptions when the record contains specific information showing a contrary result.[72] Rather, "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made."[73] That explanation must be reasonably discernable from the record and not the mere *post-hoc* musings of its counsel.[74]

Rational decision-making also requires that EPA "give reasoned responses to all significant comments in a rulemaking proceeding."[75] Section 553(c) of the APA requires agencies, "[a]fter consideration of the relevant matter presented, . . . [to] incorporate in the rules adopted a concise and general statement of their basis and purpose."[76] The "basis and purpose statement is inextricably intertwined with the receipt of comments."[77] EPA must show that it

---

[69] *Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992).

[70] *NRDC v. Daley*, 209 F.3d 747, 755 (D.C. Cir. 2000).

[71] *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1491 (D.C. Cir. 1995) (quoting *State Farm*, 463 U.S. at 48, 52).

[72] *See, e.g., Leather Indus. of Am. Inc. v. EPA*, 40 F.3d 392, 403 (D.C. Cir. 1994); *Tex Tin Corp. v. EPA*, 992 F.2d 353, 355 (D.C. Cir. 1993).

[73] *State Farm*, 463 U.S. at 43 (internal quotations omitted).

[74] *State Farm*, 463 U.S. at 43, 50.

[75] *Int'l Fabricare*, 972 F.2d at 389.

[76] 5 U.S.C. § 553(c).

[77] *Action on Smoking & Health v. Civil Aeronautics Bd.*, 699 F.2d 1209, 1216 (D.C. Cir. 1983).

considered all significant points raised by the public.[78] The agency cannot reply to comments in an unsupported and conclusory fashion when presented with specific and detailed scientific evidence contrary to its position.[79]

Where EPA relies on a general model to evaluate a specific situation, that model is arbitrary and capricious when it "bears no rational relationship to the reality it purports to represent."[80] Although a model "need not fit every application perfectly," the agency "must provide a full analytical defense" of the model.[81] This includes "examin[ing] key assumptions" of the model "as part of" EPA's "affirmative burden of promulgating and explaining a non-arbitrary, non-capricious rule."[82] "The more inflexibly the agency intends to apply the model, . . . the more searchingly will the court review the agency's response when an affected party presents specific detailed evidence of a poor fit between the agency's model and that party's reality."[83]

---

[78] *NRDC v. EPA*, 859 F.2d 156, 188 (D.C. Cir. 1988).

[79] *See Chemical Mfrs. Ass'n v. EPA*, 28 F.3d 1259, 1266 (D.C. Cir. 1994).

[80] *Columbia Falls Aluminum Co. v. EPA*, 139 F.3d 914, 923 (D.C. Cir. 1998) (internal quotation marks and citation omitted).

[81] *Id.* (internal quotation marks and citation omitted).

[82] *Id.* (internal quotation marks and citation omitted).

[83] *Chemical Mfrs. Ass'n,* 28 F.3d at 1265.

SUMMARY OF ARGUMENT

SDWA standards must be based upon sound science and subjected to a cost-benefit analysis. The standards in this case meet neither requirement.

First, EPA violated the SDWA's cost-benefit analysis requirements. EPA did not comply with Sections 1412(b)(3)(C) and (b)(4)(C) and related provisions of the SDWA that require the agency: (1) to prepare and seek comment on a cost-benefit analysis of any proposed MCL; (2) to publish at the time of proposal a determination as to whether the benefits of a proposed MCL are cost-justified; and (3) to use those cost-benefit analyses in establishing MCLs. EPA did not conduct any cost-benefit analysis for the beta/photon radionuclides or the radium MCLs established in 1976, or for the radium MCL proposed in 1991. EPA may not avoid those requirements by arguing that the MCLs established in 2000 are unchanged from the 1976 standards. Congress requires the agency to perform those analyses so that their results can be used when MCL levels are being established. In any event, the 1976 radium and beta/photon standards are not the same as the MCLs established in 2000. The agency was thus required to comply with the Act's cost-benefit requirements.

Although EPA conducted cost-benefit analyses for the final uranium and radium MCLs, those analyses did not satisfy statutory requirements. EPA failed to consider all relevant costs, risks, and health risk reduction benefits. And, rather than performing analyses of various possible MCLs for uranium and making a choice based on the results of those analyses, EPA applied inconsistent conclusions, picked an MCL of 30 ug/L, and then did an analysis to justify its choice, without providing opportunity for comment.

Second, EPA did not use the best available science. EPA acted arbitrarily and capriciously under the APA and contrary to the best science mandate in Section 1412(b)(3)(A) of

the SDWA when it promulgated an MCLG for uranium, and MCLs for radium, uranium and beta/photon radionuclides without adequately considering and using best available science.

In promulgating the radium MCLs, EPA disregarded specific data on the health effects observed in people who ingested radium that were considered when the agency proposed higher MCLs in 1991. EPA established the radium MCLs solely on the basis of the cancer risk projected by its generic FGR-13 model, which employed assumptions contrary to the specific ingestion data, resulting in an overestimation of the risk. Unlike its action when proposing radium MCLs in 1991, in 2000 EPA did not demonstrate a rational connection or reconcile inconsistencies between the assumptions in its model and the specific effects observed in people who ingested radium. Although it identified several alternative methods for assessing the risk of ingesting radium, EPA did not explain why it was reasonable in the final rule to rely solely on its model.

In developing the uranium MCL and MCLG, EPA disregarded scientific evidence. EPA set an MCLG of zero for uranium based solely on a default assumption, even though that assumption is contrary to the evidence in the record. The record lacks any human clinical or animal data establishing that natural uranium has a carcinogenic effect when ingested in drinking water. EPA did not adequately consider a 1999 study by the Agency for Toxic Substances and Disease Registry ("ATSDR") that found no evidence linking oral exposure to uranium with human cancer. The agency arbitrarily relied on evidence relating to inhalation of enriched uranium or high activity uranium, rather than naturally occurring uranium, to support its zero MCLG. EPA also disregarded studies concerning kidney toxicity showing very little, if any, relative risk when setting the MCL.

EPA's 1976 beta/photon MCLs were based on a "critical organ" approach that reflected 1950s science. Although required to update its standards periodically, EPA did not reconsider the 1976 interim standards until 1991. Then, based on post-1976 scientific advances, EPA proposed revisions to the beta/photon MCLs, including adoption of a 4 mrem "effective dose equivalent"/year dose. These were never finalized. In the 2000 rule, rather than incorporating these and other scientific advances, EPA ratified the 1976 beta/photon MCLs. EPA's re-promulgation of the beta/photon MCLs is arbitrary and capricious and contrary to law because: (i) the beta/photon MCLs are based on discredited science; (ii) the MCLs are inconsistent with EPA's federal radiation guidance, regulations, and prior interpretations of its statutory mandate; and (iii) the MCLs provide inconsistent radiation protection to the public.

Finally, EPA insufficiently responded to comments on the use of the linear non-threshold assumption. EPA failed to address adequately, as required by the APA, comments that refute EPA's use of a linear non-threshold model to set drinking water standards for radionuclides. EPA's use of the model relies on default assumptions for which EPA provides no direct support at low-dose exposures to ionizing radiation. Petitioners commented on the inadequacy of the LNT model for low-dose exposures, providing evidence from peer-reviewed, scientific studies that contradict EPA's default assumptions and that support the use of a non-linear model.

EPA's responses are blanket, general statements that only reiterate the agency's default assumptions and do not address the contradictory evidence. EPA was arbitrary and capricious by failing to provide a reasoned analysis of the significant issues raised and an adequate rebuttal to support the model, and by ignoring important comments regarding relevant factors.

For these reasons, Petitioners respectfully request that the Court remand the beta/photon and radium MCLs, and vacate and remand the uranium MCLG and MCL.

ARGUMENT

I. THE FINAL RULE VIOLATED THE COST BENEFIT ANALYSIS REQUIREMENTS OF THE SDWA.

In 1986, Congress added Section 1412(a)(1) to the SDWA.[84] It made final the 1976 interim standards for radium-226, radium-228, and beta/photon radionuclides, among others.[85] Congress also directed EPA to simultaneously publish MCLGs and MCLs for those radionuclides.[86] In 1996, Congress added Section 1412(b)(3). It requires EPA to prepare and publish for comment a Health, Risk Reduction and Cost Analysis ("HRRCA").[87] A HRRCA must analyze the following: the quantifiable and nonquantifiable health risk reduction benefits and costs associated with any proposed MCL; the incremental costs and benefits of any proposed MCL; and any increased health risk that may occur as a result of compliance with any proposed MCL.[88] Congress also added Section 1412(b)(4)(C) in 1996.[89] It requires EPA to use the HRRCA as the basis for a determination EPA must publish at the time an MCL is proposed as to whether the MCL is cost-justified.[90] EPA must also use a HRRCA when the agency considers setting an MCL as close to an MCLG as feasible,[91] and when the agency exercises discretion to adjust an MCL to a level that maximizes health risk reduction benefits at a cost that is justified by its benefits.[92]

---

[84] 42 U.S.C. § 300g-1(a)(1).

[85] *Id.*

[86] 42 U.S.C. § 300g-1(b)(2); 42 U.S.C. § 300g-1(a)(3).

[87] 42 U.S.C. §§ 300g-1(b)(3)(C), (b)(4)(C).

[88] 42 U.S.C. § 300g-1(b)(3)(C)(i).

[89] 42 U.S.C. § 300g-1(b)(4)(C).

[90] *Id.*

[91] *See* 42 U.S.C. § 300g-1(b)(3)(C)(i); 42 U.S.C. § 300g-1(b)(4).

[92] 42 U.S.C. § 300g-1(b)(6).

EPA's Final Rule did not comply with these Congressional mandates.

A. EPA VIOLATED THE SDWA BY NOT PREPARING A HRRCA FOR ALL THE PROPOSED RADIUM AND BETA/PHOTON MCLS.

Pursuant to Section 1412(b)(2)'s mandate,[93] in 1991 and 2000 EPA proposed and requested comment on: (1) separate 20 pCi/L MCLs for radium-226 and radium–228 ("1991 proposed radium MCLs"); (2) the interim 1976 radium MCL that set a combined 5 pCi/L MCL for radium-226 and radium–228 combined and only required systems to monitor for radium-228 when radium-226 levels exceeded 3 pCi/L ("interim radium MCL"); and (3) a combined 5 pCi/L MCL for radium-226 and radium–228 that included a requirement that water systems monitor radium-228 regardless of radium-226's monitored concentration ("final radium MCL").[94] Similarly, in the 1991 proposal, EPA requested comment on a 4 mrem/year "effective dose equivalent" MCL for beta/photon emitters based on updated science and later, in the NODA, EPA reverted to repromulgation of the 1976 mrem/year dose MCLs.[95] No HRRCA was ever prepared for the repromulgated beta/photon MCLs.

1. EPA Violated Sections 1412(b)(3)(C) And 1412(b)(4)(C) By Failing To Prepare A HRRCA For Each MCL It Was Proposing And By Failing To Determine Whether Each Proposed MCL Was Cost-Justified.

EPA admits that no HRRCA was prepared for each proposed MCL,[96] asserting, without explanation, that a HRRCA is only required for "new" MCLs.[97] EPA's assertion ignores the plain language and purpose of the statute.

---

[93] *See, e.g.,* 56 Fed. Reg. at 33052 (JA 1370); 51 Fed. Reg. at 34837.

[94] *See, e.g.,* 65 Fed. Reg. at 21578, 21580, 21583-85, 21623-24 (JA 4, 6, 49-50); 56 Fed. Reg. at 33082-85, 33105 (JA 1400-1403, 1423).

[95] *See, e.g.,* 65 Fed. Reg. at 21578, 21581 (JA 4, 7); 56 Fed. Reg. at 33113 (JA 1431).

[96] *See, e.g.,* 65 Fed. Reg. at 76736 (JA 903).

[97] *See, e.g.,* 65 Fed. Reg. at 76712 (JA 879); 65 Fed. Reg. at 21579 (JA 5).

The mandate of Section 1412(b)(3)(C) applies "[w]hen [EPA is] proposing any" MCL, not just when EPA is proposing a new MCL. Congress directed that HRRCA analyses be prepared, commented on, and considered when EPA was proposing "any" MCL so that information can inform EPA's decision on which MCL to set.[98] Because EPA did not prepare a HRRCA for each MCL it was proposing after 1996, the agency could not consider those analyses when deciding which MCLs to set, as Congress intended.[99]

EPA's assertion that HRRCAs are only required for "new" MCLs is likely based on Section 1412(a)(1).[100] It exempts from "the standards" of Section 1412(b)(4) MCLs that were established before 1986 unless the agency establishes "different" MCLs thereafter. Here, EPA claims to have established the same MCLs for radium and beta/photon emitters in 2000 as it established in 1976.

Even if EPA's claim about the MCLs is accurate, its assertion about the law is not. Section 1412(a)(1) does not mention Section 1412(b)(3). Had Congress intended (a)(1)'s exemption to excuse EPA from (b)(3)'s HRRCA requirements, it would have said so.[101] Instead, the provision only refers to subsection (b)(4), leaving intact all of EPA's HRRCA obligations under subsection (b)(3).

Also, Section 1412(a)(1)'s exemption concerns only the "standards" in Section 1412(b)(4). Those standards are in subsections (A) and (B). They were established in 1986, as

---

[98] *See* 42 U.S.C. § 300g-1(b)(3)(C)(i); 42 U.S.C. § 300g-1(b)(4); 42 U.S.C. § 300g-1(b)(6).

[99] For example, EPA could not consider whether a 5pCi/L final MCL that will cost the 65,000 citizens of Waukesha $67 million, versus the 20 pCi/L MCL proposed in 1991 that would cost them nothing, is cost-justified. Waukesha Comments at 565 (JA 586).

[100] 42 U.S.C. § 300g-1(a)(1).

[101] *See, e.g., Troy Corp. v. Browner,* 120 F.3d 277, 286 (D.C. Cir. 1997) ("[W]here Congress includes particular language in one section of the statute but omits it in another, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (citation and internal quotation marks omitted)).

was the exemption.[102] The HRRCA provisions in Sections 1412(b)(3)(C) and (b)(4)(C), are procedural requirements established in 1996.[103] Their purpose is to provide information during EPA's deliberative process. That information must be available early because EPA must use it to "publish a determination" at the time an MCL is proposed as to whether any MCL being considered is cost-justified.[104] Until the agency gathers and considers that information and makes its cost-justification determination, it cannot know whether it will establish an MCL that differs from an MCL that was established before 1986. Therefore, Congress did not exempt EPA from the procedural requirements of Sections 1412(b)(3)(C) and 1412(b)(4)(C).

Accordingly, because EPA did not prepare and consider a HRRCA for each radium and beta/photon emitter MCL it proposed, the MCLs established for those radionuclides should be remanded.

2. Even If The HRRCA Requirements Only Apply To "New" MCLs, EPA Violated The SDWA Because EPA Proposed And Established New Radium And Beta/Photon MCLs Without Preparing A HRRCA.

The final radium MCL set a combined 5 pCi/L MCL that included a requirement that water systems monitor radium-228 regardless of radium-226's monitored concentration.[105] The interim radium MCL did not require monitoring for radium-228 unless the monitored concentration of radium-226 exceeded 3 pCi/L.[106] Therefore, under the interim radium MCL there was effectively no limit on radium-228 as long as radium-226 was less than 3 pCi/L. EPA

[102] *See* Pub. L. No. 99-339 § 101(b) (1986).

[103] *See* Pub. L. No. 104-182 § 102(b) (1996).

[104] 42 U.S.C. § 300g-1(b)(4)(C).

[105] *See, e.g.*, 65 Fed. Reg. at 76716, 76734, 76736 (JA 883, 901, 903).

[106] *See, e.g.,* 41 Fed. Reg. at 28404.

called this "legal noncompliance"[107] and a "loophole[ ] that allow[s] systems to 'legally' exceed the current [radium] MCL[ ]."[108] In the final radium MCL, EPA closed this "loophole." Now approximately 300 community water systems must comply with the new radium limit.[109]

Similarly, given the substantial changes EPA recognizes in risk estimates between 1976 and 2000, EPA's final beta/photon MCL is not the same standard as it was in 1976. EPA's 2000 model showed that the 1976 standard provided a highly erratic dose and risk levels.[110]

Accordingly, even if the HRRCA requirements only apply when the agency establishes a new MCL, they applied to the beta/photon and final radium MCLs established in 2000. EPA ignored those requirements.

B. EPA VIOLATED THE HRRCA REQUIREMENTS.

For the beta/photon final MCLs, interim radium MCL, and 1991 proposed radium MCLs, EPA conducted no HRRCA analysis. For the final radium MCL and the uranium MCL, EPA issued a "Preliminary" HRRCA a few months before the NODA, and issued an "Economic Analysis," less than a month before the final rule. EPA claims that it has satisfied its HRRCA obligations.[111] EPA is wrong.

---

[107] *E.g.,* Economic Analysis at 1-5, 2-19, 2-26 (JA 1117, 1143, 1150).

[108] PHRRCA at ES-2 (JA 221); *see also* Economic Analysis at 7-3 (JA 1263).

[109] *See, e.g.,* 65 Fed. Reg. at 76734 (JA 901).

[110] *See* Section II.C., *infra.*

[111] *See* 65 Fed. Reg. at 76736 (JA 903).

1. EPA Neglected To Evaluate The Costs And Benefits Arising From MCL Compliance At CERCLA Sites, Other Facilities And Under State Law.

EPA's radium, uranium and beta/photon MCLs will be applied at CERCLA sites, other facilities, and under state law.[112] EPA did not analyze these impacts[113] and therefore violated the SDWA. EPA asserted that the statute's exclusion of costs resulting "from compliance with other proposed or promulgated regulations" excuses the agency from considering costs arising in these other contexts.[114] The plain language of the SDWA and CERCLA, as well as the purpose and legislative history of the SDWA, belie that assertion.

First, the exclusion of costs associated with regulations has no bearing on the agency's obligation to assess "health risk reduction benefits" under 1412(b)(3)(C)(i). Subsection (I) of Section 1412(b)(3)(C)(i) is clear. EPA must analyze "[q]uantifiable and nonquantifiable health risk reduction benefits" associated with any MCL that is "being considered" and "each alternative level that is being considered." No statutory language limits the required analysis to

---

[112] *See, e.g.,* 42 U.S.C. § 9621(d)(2)(A)(i); Memo from Timothy Fields, EPA, "Interim Final Evaluation of Facilities Currently or Previously Licensed NRC Sites Under CERCLA," OSWER No. 9272.0-15P at 3-8 (Feb. 17, 2000) (DI I-I2-8, Att. 2) (JA 843-848); USEPA, Memorandum (Nov. 6, 2001) at 2 (JA 1796) (stating Uranium MCL is a "relevant and appropriate requirement" for remediation of current or potential drinking water sources); Comments of NEI, at 11-13 (June 26, 2000) (DI I-I2-8) ("NEI Comments") (JA 834-836) (discussing impact on nuclear industry when MCLs are applied to CERCLA sites, disposal of low-level radioactive waste, and decommissioned nuclear sites); Memo from Stephen Luftwig and Larry Weinstock to Addressees, "Establishment of Cleanup Levels for CERCLA Sites with Radioactive Contamination," OSWER 9200.4-18 (Aug. 22, 1997) (DI I-B-11) (JA 55-61) (EPA will impose CERCLA cleanup standards, including radionuclide MCLs, at nuclear facilities decommissioned by the NRC); Letter from Carol Browner, EPA Administrator to Shirley Ann Jackson, NRC Chairman (Feb. 7, 1997) (DI I-I2-8, Att. 1) (JA 837-838) (indicating sources of potential drinking water should be protected at MCL levels); Letter from Shirley Ann Jackson, NRC Chairman to Carol Browner, EPA Administrator (Feb. 21, 1997) (DI-I2-8, Att. 3) (JA 850-854). *See also* 65 Fed. Reg. at 76730 (JA 897).

[113] *See* 42 U.S.C. § 300g-1(b)(3)(C)(i)(III); NEI Comments at 11-12 (JA 834-835).

[114] *See, e.g.*, CRD-NODA at 15-12 (Comment 15.A.15) (JA 1069); *id.* at 15-13 to 15-15 (Comments 15.A.18, 15.A.19, 15.A.20) (JA 1070-1072).

costs and benefits associated with public drinking water systems.[115] Under any reading of subsection (b)(3), EPA was required to assess the health benefits of radium, uranium, and beta/photon MCLs under CERCLA.

Further, because application of the MCL is derived from the CERCLA "statute," the costs associated with CERCLA compliance must be evaluated.[116] The policy underpinning this approach is apparent. Where a statute mandates application of MCLs, the agency has no opportunity to address costs associated with that MCL application. By contrast, where an MCL's application is a result of APA rulemaking, the process provides an opportunity for public comment on costs and benefits.

The legislative history confirms that excluding costs and benefits is appropriate only if these benefits and costs have been evaluated elsewhere:

> [T]he Administrator is not to consider the benefits (or costs) that are attributable to compliance with other proposed or promulgated regulations, if those benefits and costs are considered in a determination as to whether benefits justify costs under those regulations.[117]

In addition, many states use MCLs as enforceable groundwater protection standards.[118] Some states adopt MCLs as groundwater clean up standards.[119] EPA's failure to consider the costs resulting from such state statutes violates the SDWA.

---

[115] To the extent that the agency determines that beta/photon radionuclides probably will not be present in public water systems, without considering the use of any standard in non-SDWA contexts, it is impossible for the agency to conclude that any benefits are "likely to occur." 42 U.S.C. § 300g-1(b)(3)(C)(i).

[116] *See* 42 U.S.C. § 9621(d)(2)(A)(i) (contaminants on site must meet SDWA standards).

[117] S. Rep. No. 104-169 at 29-30 (JA 1765-1766).

[118] *See, e.g.,* Ariz. Rev. Stat. § 49-223.A.

[119] *See, e.g.* Pa. Con. Stat. Ann. § 6020.504, 6026.303 (2001); W.Va. Code § 22-12-4 (2001).

EPA has acknowledged the necessity of evaluating benefits and costs of MCLs at CERCLA sites and committed to conduct such an analysis. In its Preliminary HRRCA, EPA referred to "the use of MCLs in site clean-up decisions" and committed that the subject "*will be taken into account* in the final selection of the regulatory options to be implemented."[120] EPA listed as a "key limitation" to its preliminary cost analysis the fact that "[t]his report also does not consider the impact of the regulations on other programs, such as the use of MCLs in site clean-up decisions."[121] In the Economic Analysis, EPA left that commitment unfulfilled. EPA's inconsistent positions entitle it to no deference.[122]

EPA's failure to analyze beta/photon MCL costs and benefits in other contexts is especially troubling because EPA has made clear that those radionuclides are unlikely to appear in community water systems and thus those MCLs will only be used in alternative contexts at CERCLA sites, other facilities, and under state law.[123] EPA has practically eliminated monitoring requirements for beta/photon radionuclides in public water systems.[124] Unless costs and benefits are analyzed in these other contexts, EPA eludes the SDWA's HRRCA requirements altogether.

---

[120] PHRRCA at ES-10 to ES-11 (JA 229-230) (emphasis added). *See also id.* at 3-31 to 3-32, 4-24, 6-8 (JA 308-309, 333, 352) (same); Economic Analysis at 3-32, 4-28 (JA 1190, 1219) (admitting failure to consider impact of regulatory options on other programs, including uranium MCL as cleanup standard).

[121] PHRRCA at 6-8 (JA 352).

[122] *See, e.g., United States v. Mead Corp.*, 533 U.S. 218, 227 (2001); *Seldovia Native Ass'n v. Lujan*, 904 F.2d 1335, 1345 (9th Cir. 1990).

[123] *See, e.g.*, 65 Fed. Reg. at 21583 (JA 9); 65 Fed. Reg. at 76716-17 (JA 883-884).

[124] *See* 65 Fed. Reg. at 76719 (JA 886).

2. EPA Violated The SDWA By Ignoring The Compliance Costs Imposed By The Final Radium MCL.

Congress directed EPA to evaluate all costs that "are likely to occur solely as a result of compliance with" each MCL being considered.[125] Congress also directed that EPA's HRRCA examine the "incremental costs and benefits associated with each alternative" MCL "considered."[126] EPA only evaluated the incremental costs of the final radium MCL, *i.e.*, the costs to comply with the 5 pCi/L combined radium limit because of separate radium-228 monitoring.[127]

Because EPA failed to consider communities' costs to remain in compliance with the 5 pCi/L MCL standards,[128] EPA did not analyze all the costs "likely to occur" as a result of compliance with the final radium MCL.[129] EPA also failed to consider costs to local communities to come into compliance with those standards, characterizing them as "deferred" costs attributable to the interim radium MCL, rather than the final radium MCL.[130] The Act, however, does not exclude "deferred" costs, or costs to comply with an MCL that EPA is re-proposing. EPA knew that hundreds of local water systems had not yet complied with those standards.[131] Waukesha, a city of 65,000, faces compliance costs of $67 million that were not considered by EPA.[132]

---

[125] 42 U.S.C. § 300g-1(b)(3)(C)(i)(III); *see also* S. Rep. No. 104-169, at 36 (1995).

[126] 42 U.S.C. § 300g-1(b)(3)(C)(i)(IV).

[127] *See, e.g.,* Economic Analysis at Chp. 2, 4, 7 (JA 1125-1158, 1192-1220, 1261-1281).

[128] *See, e.g., id.* at 4-3 (JA 1194) (water treatment generates ongoing capital, operations, maintenance, and disposal costs).

[129] *Compare* 42 U.S.C. § 300g-1(b)(3)(c)(i)(III), *with* 42 U.S.C. § 300g-1(b)(3)(c)(i)(IV).

[130] 65 Fed. Reg. at 76736 (JA 903).

[131] *See, e.g.,* Economic Analysis at 2-19 (JA 1143).

[132] Waukesha Comments at 565 (JA 586).

EPA's exclusion of those compliance costs ignores the fact that "[a]s early as 1988 . . . U.S. EPA informed states with systems exceeding the [1976] radium MCL to discontinue enforcement actions because the radium MCL would soon be changed to 20 pCi/L for each radium isotope," pursuant to the 1991 proposal.[133] Because of that, "states stopped pursuing enforcement of the combined radium MCL of 5 pCi/L."[134]

3. EPA Violated The SDWA And The APA With Regard To The Costs Of Uranium Disposal

EPA also failed to consider disposal costs for waste stream residuals from uranium treatment. Community water systems will be subject to a flurry of low-level radioactive waste disposal costs resulting from the operation of uranium water treatment systems. In its November 2000 Economic Analysis, EPA alleged that it accounted for these costs, but gave no explanation of how it did so. This blanket, general statement is insufficient. EPA was arbitrary and capricious by failing to provide a satisfactory explanation.[135]

4. EPA Failed To Evaluate Increased Health Risks That May Occur Because Of The Radium And Uranium MCLs.

A HRRCA must address "[a]ny increased health risk that may occur as the result of compliance" with any MCL that is being considered.[136] EPA ignored that requirement.

The treatment methods to remove radium and uranium in drinking water create solid and liquid wastes that concentrate radionuclides, ranging as high as 100,000 picocuries per gram.[137]

---

[133] Minnesota Department of Health Comments on the NODA, at 3 (June 9, 2000) (DI I-I1-07) (JA 513).

[134] *Id.* at 3-4 (JA 513-514). For example, Wisconsin and Waukesha entered into an enforcement "stand-still" agreement pending the outcome of the 1991 Proposal.

[135] *See* Economic Analysis at 6-19 (JA 1249); *see also State Farm,* 463 U.S. at 43 (a conclusory statement does not in itself provide the "satisfactory explanation" required in rulemaking.).

[136] 42 U.S.C. § 300g-1(b)(3)(C)(VI).

[137] *See, e.g.*, EPA, "Draft Suggested Guidelines for Disposal of Drinking Water Wastes Containing Radioactivity," at 1-19, A-5 through A-9 (June 1994) (DI I-F-02) ("1994 Disposal Guidelines") (JA 402-

(continued)

Those concentrated wastes may pose increased health risks to employees who manage them.[138] Radium treatment waste, for example, emits radon gas at levels that – in EPA's view – may pose a "pronounced" risk to workers.[139] The public may face increased health risk from the disposal of the radioactive treatment wastes.[140] Drinking water treatment wastes are presently put in landfills, sewers, surface waters, and other areas subject to "little regulatory control."[141] EPA failed to analyze these potential risks.

C. EPA'S URANIUM STANDARD VIOLATES THE SDWA AND THE APA.

1. Petitioners Were Not Allowed To Comment On The HRRCA And The 30 ug/L Standard And EPA Did Not Use The HRRCA.

EPA violated the SDWA's requirement that the agency "publish, seek public comment on, and use" the HRRCA and take public comment on an MCL of 30 ug/L when it promulgated the final uranium rule.[142]

EPA's NODA and preliminary cost analysis proposed uranium MCLs of 20, 40, and 80 ug/L. EPA first discussed a 30 ug/L standard in the Economic Analysis issued five months after the close of the comment period and less than one month before publication of the final rule.[143] EPA's Final Rule adopted a uranium MCL of 30 ug/L without "seek[ing] public comment on"

(continued)
420, 456-460); National Research Council, "Evaluation of Guidelines for Exposures to Technologically Enhanced Naturally Occurring Radioactive Materials," at 69 (1999) ("TENORM Report"), available at <http:books.nap.edu/book/0309062977/html/index.html.> (JA 1777).

[138] *See, e.g.*, 1994 Disposal Guidelines, at 13-14, 26-28, 39-43 (JA 414-415, 427-429, 440-444); Comments of DOE, Attachment 3, at 1-2, App. B.-C. (June 20, 2000) (DI I-I2-04) ("DOE Comments") (JA 791-792, 810-822).

[139] 1994 Disposal Guidelines at 28 (JA 429).

[140] *See, e.g.*, DOE Comments at 2-7, B2-3 (JA 778-783, 811-812).

[141] CRD-NODA at 20-9 (Comment 20.B.3) (JA 1081) (quoting TENORM Report at 68) (JA 1776).

[142] *See* 42 U.S.C. § 300g-1(b)(3)(C)(i). Section (b)(3)(C)(i) also requires EPA to use the HRRCA when adjusting an MCL from the feasible level pursuant to Section (b)(6)(A).

[143] *See* Economic Analysis at 7-2 (JA 1262).

30 ug/L as a proposed MCL, or on EPA's belated cost-benefit analysis. The SDWA requires EPA to "publish" and "seek public comment on" a HRRCA for the MCL being considered and, "each alternative … [MCL] being considered" at the time such level is *proposed*.[144] By not providing the public with an opportunity to comment on the Economic Analysis and the 30 ug/L level, EPA violated the SDWA.

EPA also failed to "use" the HRRCA. The agency put the cart before the horse. Rather than performing a HRRCA on possible MCLs and making a choice based on the results of those analyses, EPA picked the final MCL of 30 ug/L and then did an analysis to justify it. This is clear from the Economic Analysis which announces: "EPA now plans to set a uranium MCL of 30 ug/L."[145] To justify that decision, EPA extrapolated data for the 30 ug/L level from its data on 20, 40, and 80 ug/L instead of conducting independent research on the 30 ug/L level. The agency's attempt to use such *post hoc* rationalizations to justify its actions violates the SDWA and renders its actions arbitrary and capricious.[146] Moreover, EPA did not apply the "best available methods" when it extrapolated from existing data, rather than determining the actual costs and benefits of the 30 ug/L level and violated Section 1412(b)(3)(C)'s requirements.[147]

2. EPA Violated The APA In Promulgating The Final Uranium MCL

Because EPA published the HRRCA for the 30 ug/L level after the close of the NODA comment period, and less than one month before promulgating the final uranium standard, the agency deprived Petitioners of their right to comment on the HRRCA and the 30 ug/L proposal.

---

[144] 42 U.S.C. § 300g-1(b)(3)(C).

[145] Economic Analysis at 6-10 (JA 1240).

[146] *See Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 419 (1971); *America's Cmty. Bankers v. Fed. Deposit Ins. Corp.*, 200 F.3d 822, 835 (D.C. Cir. 2000).

[147] 42 U.S.C. § 300g-1(b)(3)(A)(ii) (requiring "best available methods" when "reliability of the method and the nature of the decision justifies use of the data").

The APA requires the agency "to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules."[148] "An agency commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary."[149] The public has a right to comment and have those comments considered before the agency takes final action.[150] EPA's failure to disclose the technical basis for the uranium rule in sufficient time for Petitioners to meaningfully comment constitutes "serious procedural error."

3. EPA Failed To Apply Consistent Conclusions When Setting The Uranium MCL In Violation Of The APA.

The SDWA gives EPA discretion to promulgate an MCL higher than the feasible level if analyses indicate that benefits of complying with the feasible level do not justify the costs.[151] EPA's belated Economic Analysis presented the incremental costs and incremental health benefits (in the form of cancer cases avoided) associated with four potential uranium standards: 20, 30, 40 and 80 ug/L.[152] EPA concluded that the cancer risk associated with 80 ug/L was unacceptable, but that 20, 30 and 40 ug/L all had acceptable risk levels. When EPA promulgated its Final Rule, it increased the uranium MCL from EPA's determined feasible level of 20 ug/L to 30 ug/L because the agency alleged that the "benefits do not justify the costs at the feasible level (20 ug/L)."[153]

---

[148] *Solite Corp. v. EPA*, 952 F.2d 473, 484 (D.C. Cir. 1991) (internal citations omitted).

[149] *Conn. Light & Power Co. v. NRC*, 673 F.2d 525, 530-31 (D.C. Cir. 1982).

[150] *See Nat'l Small Shipments Traffic Conference, Inc. v. Interstate Commerce Comm'n*, 725 F.2d 1442, 1451 (D.C. Cir. 1984).

[151] 42 U.S.C. § 300g-1(b)(6).

[152] 65 Fed. Reg. at 21587 (JA 13); 65 Fed. Reg. at 76714 (JA 881); Economic Analysis at 1-4 (JA 1116).

[153] 65 Fed. Reg. at 76715 (JA 882).

When EPA exercises its discretion under Section 1412(b)(6) to choose a limit other than the one it determines is "feasible," the limit it chooses must have a rational basis. When EPA selected from the acceptable uranium levels, EPA should have compared the cost per cancer case avoided for each proposed uranium MCL. EPA did not do that. Had the agency done so, it would have found that the incremental cost savings associated with raising the standard from 30 ug/L to 40 ug/L ($64.1 million) was even higher than the incremental cost savings that prompted EPA to raise the standard from 20 ug/L to 30 ug/L ($45.2 million) while still achieving an acceptable cancer risk. Thus, if EPA applied the same analysis to the cost differences between 30 ug/L and 40 ug/L, as it did to the costs between 20 ug/L to 30 ug/L, it would have concluded that an increase to 40 ug/L was appropriate.

The agency's adjustment from the feasible level of 20 ug/L to 30 ug/L based on cost, rather than to 40 ug/L (which would have resulted in even greater savings while maintaining in the agency's view an acceptable level of risk), is irrational. EPA failed to justify its decision to set the uranium MCL at 30 ug/L rather than 40 ug/L (or higher), given its inconsistent findings on costs. Had EPA applied consistent conclusions with regard to cost when setting the final MCL, it would have chosen a final MCL of 40 ug/L rather than 30 ug/L. Because the agency's decision lacks a rational basis the uranium rule should be vacated and remanded.[154]

II. EPA FAILED TO DEMONSTRATE THAT IT USED THE BEST AVAILABLE SCIENCE IN ESTABLISHING DRINKING WATER STANDARDS FOR RADIONUCLIDES

Under the following statutory mandate, EPA must use the best available scientific information in developing MCLGs and MCLs:

[154] *See Time Warner Entm't Co. v. FCC*, 240 F.3d 1126, 1137 (D.C. Cir. 2001) ("[T]o pass ... the arbitrary and capricious standard, the agency must at least reveal 'a rational connection between the facts found and the choice made.' ").

> In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use … the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices.[155]

The statute is unequivocal.[156] EPA must consider the best scientific evidence "available" at the time the agency sets a drinking water standard.[157] The agency may not ignore or override the best evidence in the record regarding the health effects of a drinking water contaminant.[158]

To incorporate advancements in science, the SDWA requires EPA to review and update drinking water standards at least every six years.[159] An updated drinking water standard must maintain, or provide greater, protection of human health.[160] This does not preclude EPA from considering science that supports promulgation of a higher MCL; "[i]f new science shows that a less stringent standard would provide the same level of health protection, the MCL may be revised upward."[161]

EPA must present scientific information on the public health effects of drinking water contaminants in a "comprehensive, informative, and understandable" manner.[162] The SDWA directs EPA to prepare a document that addresses the populations for which EPA estimated public health effects, the expected risks for specific populations, the upper and lower bound risks, the significant uncertainties in EPA's risk assessment, and the available peer-reviewed

---

[155] 42 U.S.C. § 300g-1(b)(3)(A).

[156] *Chlorine Chemistry*, 206 F.3d at 1290.

[157] 42 U.S.C. § 300g-1(b)(3)(A); *Chlorine Chemistry*, 206 F.3d at 1290-91.

[158] *See Chlorine Chemistry*, 206 F.3d at 1290.

[159] 42 U.S.C. § 300g-1(b)(9). Up until 1996, the SDWA required updates every three years.

[160] *Id*.

[161] S. Rep. No. 104-169, at 33 n.4.

[162] 42 U.S.C. § 300g-1(b)(3)(B).

studies on public health effects.[163] EPA must identify peer-reviewed studies that "support, are directly relevant to, or fail to support" the agency's estimates of public health effects and describe "the methodology used to reconcile the inconsistencies in the scientific data."[164] Congress wanted the agency to "do a better job of explaining the alternative interpretations of the scientific evidence that is used for, and produced by, risk assessments" and to "publish a document with each standard-setting regulation describing … alternative risk estimates that put the regulation in a broader public health context."[165]

A. EPA'S RADIUM MCLS VIOLATE THE SDWA AND ARE ARBITRARY AND CAPRICIOUS.

In 1991, EPA proposed separate MCLs of 20 pCi/L for radium-226 and 20 pCi/L for radium-228.[166] The proposal was based on a risk assessment model called RADRISK and epidemiological studies of people exposed to radium isotopes.[167] Those studies showed that ingestion of high doses of radium-226 and radium-228 caused only bone and head cancer.[168] Thus, EPA classified these isotopes as Category I carcinogens and proposed MCLGs of zero for both of them.[169] EPA then determined that MCLs of 20 pCi/L produced acceptable risks[170] using its RADRISK model with an adjustment to reconcile the predictions of the model with the epidemiological studies on actual exposure to radium-226 and radium-228.[171]

---

[163] *Id*.

[164] *Id*.

[165] S. Rep. No. 104-169, at 29.

[166] 56 Fed. Reg. at 33051 (JA 1369).

[167] *Id.* at 33071-74.

[168] *Id.* at 33072-73; Radium Criteria Document at VI-5 to VI-12 (JA 1491-1498).

[169] 56 Fed. Reg. at 33070-72, 33079-80.

[170] *Id.* at 33073-74, 33082.

[171] *Id.* at 33056, 33073; Radium Criteria Document VIII-31 to VIII-34 (JA 1536-1539).

In 2000, EPA reversed course and established a standard of 5 pCi/L for radium-226 and radium-228 combined with separate monitoring for each isotope.[172] The change was driven by EPA's decision to rely solely on the results of its FGR-13 model that predicted higher lifetime cancer risks from ingestion of radium-226 and radium-228 than EPA predicted in 1991.[173] The FGR-13 model assumed that low doses of all radionuclides cause several other types of cancers in addition to cancer in bone and the head.[174] In 2000, EPA did not use the available data on human ingestion of radium-226 and radium-228 to compare, verify, or modify its modeled risk estimates, as it had done in 1991. The agency did not explain in the final rulemaking why it was reasonable not to reconcile the model with the ingestion data. In the end, EPA's only explanation for relying solely on the general FGR-13 model to set the radium MCL was that FGR-13 is the newest model for predicting the risks of exposure to all radionuclides rather than the best model for radium-226 and radium-228 specifically.[175]

That is not a sufficient explanation under the law. The APA requires that EPA examine all the information relevant to the health effects of those isotopes and present a reasonable explanation for its decision.[176] Because a model formed the basis for EPA's MCL for radium-226 and radium-228, EPA had to show a rational relationship between that model and the situation to which it was applied, meaning that key assumptions of the model had to be consistent with the facts known about radium-226 and radium-228.[177] Moreover, the SDWA

---

[172] 65 Fed. Reg. at 76710-11 (JA 877-878).

[173] 65 Fed. Reg. at 21579-80, 21583-84, 21603 (JA 5-6, 9-10, 29); 65 Fed. Reg. at 76712.

[174] FGR-13 at 4-5 (JA 88-89).

[175] 65 Fed. Reg. at 21579-80, 21603.

[176] *See State Farm*, 463 U.S. at 43.

[177] *See Columbia Falls*, 139 F.3d at 923; *Chemical Mfgs.*, 28 F.3d at 1265.

requires that EPA use the best available science to establish the MCLs and to issue a document that identifies contradictory data and explains the methods used to reconcile inconsistencies in the data.[178] EPA failed to satisfy these obligations.

1. Although The Record Before EPA Contained Specific Data On The Health Effects Of Ingesting Radium-226 And Radium-228, EPA Established The MCL For Them Solely On The Results Of A Generic Model That Overstated Risk By Employing Assumptions Contradicted By The Specific Data.

Of the radionuclides regulated under the SDWA, radium-226 and radium-228 are unique because of the available scientific data on the health effects of exposure to these radium isotopes from people who actually ingested them. Workers who painted watch dials with luminescent paint containing radium-226 and radium-228 ingested these radionuclides when sharpening the tips of their brushes with their lips.[179] The peer-reviewed studies of these workers produced three relevant observations.

First, dial painters who ingested radium-226 and radium-228 contracted cancer in only two organ sites – the bone and the head.[180] Bone cancers were due to the preference of radium to accumulate in bone.[181] Head carcinomas were attributable only to ingestion of radium-226 because of the accumulation in the sinuses of radon gas that is created by the decay of radium-226 but not radium-228.[182] EPA concluded that "[n]o statistically significant increase in cancers other than bone sarcomas and head carcinomas have been found in cohorts of radium dial

---

[178] 42 U.S.C. § 300g-1(b)(3)(A)-(B).

[179] 56 Fed. Reg. at 33072; Technical Support Document at III-5 (JA 177).

[180] 56 Fed. Reg. at 33072-73; Technical Support Document at III-5 (JA 177); Radium Criteria Document at VI-5, VI-11 (JA 1491, 1497).

[181] Radium Criteria Document at I-3 (JA 1478).

[182] *Id.*

painters."[183] Furthermore, EPA's Science Advisory Board ("SAB") concluded that "[t]he epidemiological data show that bone sarcomas and head carcinomas represent the dominant risks of ingestion of radium."[184]

Second, bone and head cancers were only observed in dial painters who ingested high doses of radium-226 and radium-228 and not in people who ingested medium to low doses. Head cancers were only observed in persons with an initial systemic intake dose[185] equal to or greater than 25 microcuries of radium-226.[186] That dose is equivalent to the dose obtained by a lifetime of ingesting drinking water containing a concentration of 2,500 pCi/L of radium-226.[187] Bone cancers only occurred in people who received an initial systemic intake dose equal to or greater than 100 microcuries of radium-226 and radium-228 combined.[188] That dose is equivalent to the dose obtained by a lifetime of drinking two liters of water per day containing 10,000 pCi/L[189] of radium-226 and radium-228.[190]

---

[183] 56 Fed. Reg. at 33073.

[184] Science Advisory Board/Radiation Advisory Committee, *Review of the Office of Drinking Water's Criteria Documents and Related Reports for Uranium, Radium, Radon, and Manmade Beta-Gamma Emitters* (Dec. 30, 1990), at 15 (DI III-D2c-100) ("SAB Report") (JA 1595).

[185] Representing amount of ingested radium retained in blood. Rowland, R.E., Radium in Humans: A Review of U.S. Studies, at 65-66 (1994) ("Radium in Humans") (contained in Waukesha Comments at 231-475) (JA 566-567).

[186] Radium Criteria Document at VI-9 (JA 1495); Radium in Humans at 87 (JA 576).

[187] A systemic dose of 0.05 microcuries is equivalent to drinking water for a lifetime containing 5 pCi/L of radium. National Academy of Sciences, Health Risks of Radon and Other Internally Deposited Alpha-Emitters, at 205 (1988) (DI III-D3-40) ("BEIR IV") (JA 1639).

[188] Radium Criteria Document at VI-8 (JA 1494); Radium in Humans at 80 (JA 569).

[189] In contrast, the concentration of radium-226 and radium-228 in the ground water supply of Waukesha is between 5 pCi/L and 20 pCi/L. Waukesha Comments at 565 (JA 586). To determine whether its drinking water was causing harm to its citizens, Waukesha commissioned a peer-reviewed study by the Medical College of Wisconsin. It found no statistically significant increase in bone cancer among residents who consumed this water. Waukesha Comments at 1018-1060 (JA 589-631).

[190] *See* BEIR IV at 205 (JA 1639).

Third, the bone cancer incidence observed in the dial painters was best characterized by a quadratic-dose response curve.[191] EPA concluded, "bone sarcoma risk among dial painters . . . is best fit by a quadratic (dose-squared) response."[192]

The data on ingestion of varying doses of radium-226 and radium-228 by dial painters is significant. The National Academy of Sciences used the dial painter data for a quantitative risk assessment on radium in 1988.[193] Likewise, the SAB recommended in 1990 that "[f]or radium, the available human epidemiologic data should most definitely be used to determine risk, rather than a mathematical model."[194] The SAB observed that "[r]adium is in a different category from other radionuclides because there is direct human experience upon which the best estimates of risk are based."[195]

The FGR-13 model relies on general data and assumptions that contradict the specific observations from the dial painter studies. This increases the level of risk from ingesting low levels or radium-226 and radium-228 compared to the actual information coming from the dial painter studies.

First, the model assumes that exposure to radionuclides causes cancer in 13 organ sites (esophagus, stomach, colon, liver, lung, bone, skin, breast, ovary, bladder, kidney, thyroid, and red marrow (leukemia)) and in a residual risk category representing all remaining cancer sites

[191] 56 Fed. Reg. at 33055; Radium Criteria Document at VIII-18 (JA 1523).

[192] Radium Criteria Document at VIII-16 (JA 1521).

[193] BEIR IV at 176-244. (JA 1625-1659)

[194] SAB Report, Cover Letter at 2, Report at 8-9 (JA 1575, 1588-1589).

[195] SAB Report at 15 (JA 1595).

combined.[196] This increases the total risk from ingesting radium-226 and radium-228 by adding a risk of contracting cancer at organ sites where no cancer was observed in dial painters.[197]

Second, the cancer risk at most organ sites is based on studies of persons exposed externally to high doses of radiation from the explosion of the atomic bombs in Japan.[198] These studies show a statistically significant excess cancer mortality for leukemia and cancers of the esophagus, stomach, colon, liver, lung, breast, ovary, and urinary tract.[199] This increases risk because the dial painters who ingested varying doses of radium-226 and radium-228 showed no statistically significant increase in these cancers.

Third, FGR-13 models risk on the assumption that the dose-response curve for all radionuclides is linear.[200] A linear dose-response curve shows more risk in the low dose range than the quadratic dose-response curve that EPA concluded best fit the bone cancer data from the dial painter studies.[201]

Fourth, the model assumes that there is no threshold level of exposure below which no health effects are observed.[202] Thus, FGR-13 increases the risk by projecting an effect at lower exposure levels where cancers were not observed in dial painters.

---

[196] FGR-13 at 4-5 (JA 88-89); 65 Fed. Reg. at 76722; EPA, Comment-Response Document for Radionuclides Proposed Rule (July 1991), at 3-15 to 3-17 (Nov. 2000) (Comment 218ad) (JA 1105-1107).

[197] FGR-13 at 183, 186 ("The total risk is the sum over all cancer sites") (JA 120, 123).

[198] *Id.* at 173-178 (JA 110-115).

[199] EPA, Estimating Radiogenic Cancer Risks, at 1 (June 1994) ("Radiogenic Cancer Risks") (JA 1727).

[200] FGR-13 at v (JA 79).

[201] Radium Criteria Document at IX-4 to IX-5 (JA 1549-1550).

[202] FGR-13 at v (JA 79).

2. EPA Failed To Demonstrate A Rational Connection Between The General Assumptions Of The FGR-13 Model And The Specific Effects Of Ingesting Radium-226 And Radium-228 And Did Not Reasonably Reconcile The Inconsistencies Between EPA's Approach And The Dial Painter Data.

EPA does not explain why it was reasonable to set an MCL for radium-226 and radium-228 solely on the basis of its general model, even though that model is inconsistent with significant, specific information from the dial painter studies. Instead, EPA criticizes the dial painter studies, dismisses them, and points to the scientific institutions that support the linear non-threshold assumption in general.[203]

EPA ignored the dial painter studies in 2000 because the doses were estimated after-the-fact, the test population was small, skeletal pathology interfered with the metabolism of the subjects, and there was high mortality rate among certain subgroups.[204] While these observations may be accurate, similar observations can be made regarding the atomic bomb data EPA uses in its model. However, unlike the bomb data, the dial painter studies are the only epidemiological evidence on the actual health effects of human ingestion of low doses of radium-226 and radium-228 that was available at the time that EPA finalized the MCLs for these radium isotopes.[205]

Like the dial painter studies, the doses in the bomb survivor studies are estimated.[206] EPA acknowledged that the dose estimates in the bomb studies may be in error by as much as 25-45 percent.[207] In addition, the bomb survivors received very high doses through external

---

[203] 65 Fed Reg. at 76721; CRD-NODA at 3-5 to 3-6, 3-11 to 3-12 (Comments 3.A.1 and 3.B.3) (JA 938-939, 944-945).

[204] 65 Fed Reg. at 76721; CRD-NODA at 3-11, 7-6 (Comments 3.B.3 and 7.A.5) (JA 944, 1030).

[205] *See Chlorine Chemistry*, 206 F.3d at 1291 (best science is that available at time of rulemaking).

[206] CRD-NODA at 3-35 (Comment 3.B.33) (JA 968).

[207] FGR-13 at 173, D-25 (JA 110, 129).

exposure rather than ingestion.[208] The analysis of the doses was confounded because they also contained neutrons and gamma rays in addition to the alpha and beta particles released by radium-226 and radium-228.[209] Other confounding factors included the increased stress and nutritional deficiencies resulting from war-time conditions and the bomb devastation.[210] Furthermore, the bomb studies have limited value for extrapolation to low doses because the control group expected to show no effect was comprised of individuals exposed to low doses of radiation.[211]

Petitioners raised all these issues in comments, but EPA failed to deal with them.[212] EPA merely discussed access to the data and cross-referenced responses that address other issues.[213]

EPA relied heavily on the SAB's support for using the LNT assumption as a default in general and responded cursorily and cavalierly to a comment reminding EPA of the SAB's recommendation against using a model where specific epidemiological data exists on ingestion of radium-226 and radium-228. EPA asserts, without explanation, that the SAB recommendation regarding radium is outdated and that the SAB "has been consulted on the current risk assessment," thereby suggesting that the SAB rescinded its recommendation.[214]

---

[208] *Int'l Fabricare*, 972 F.2d at 393 (upholding risk assessment using ingestion and discounting inhalation data).

[209] CRD-NODA at 3-35 (Comment 3.B.33) (JA 968).

[210] *Id.*

[211] *Id.*

[212] *Id.* at 3-35 to 3-36 (JA 968-969).

[213] *Id.* at 3-36 (JA 969). The cross-referenced responses address the use of the LNT assumption and criticize the dial painter studies, a bone cancer study in Wisconsin, and ecological studies.

[214] *Id.* at 3-54 to 3-55 (Comment 3.B.56) (JA 987-988).

EPA's statement and suggestion are not supported by evidence in the record of such a consultation or by a report showing that the SAB changed its view.[215]

EPA prepared a table that attempts to show that the absence of cancers in dial painter populations below certain doses is consistent with the predictions of the FGR-13, but the comparison is flawed.[216] The agency did not show how it derived the number of cancers in the table predicted by its model[217] and used incorrect dose figures that distorted the model's actual predictions. If EPA had used the proper doses, EPA's comparison would have shown that its model predicts many more cancers than were observed in the dial painter studies.[218]

EPA's relies on an unsupported and speculative assertion about the similarities of radium isotopes in an attempt to reconcile the discrepancy between the dial painters that developed just two kinds of cancers from only high doses of radium-226 and radium-228 and the model that predicted low doses of those isotopes will cause cancers in those and many more organ sites.[219] EPA noted that leukemia[220] and cancers of the breast, liver, thyroid, bladder, and soft tissues

---

[215] *Id.*

[216] *Id.* at 7-8 (Comment 7.A.5) (JA 1032).

[217] *See State Farm*, 463 U.S. at 43 (agency reasoning must be discernable from record).

[218] Using the highest dose among the 52 people in the range of 5 to 10 gray (case 03-502) as EPA purported to do, the number of cancers predicted by the FGR-13 model in this dose range should be computed as 88.1 x 5 x (3.7×10^{4}) x (9.56×10^{-9}) x 52 = 8.1. Radium in Humans at 163 (JA 585); 56 Fed. Reg. at 33072; FGR-13 at 8, 83, 102 (JA 82, 103-104). In the dose range of 2.5 to 5 gray, 5.2 cancers are expected using the highest dose (case 03-489). Radium in Humans at 163 (JA 585). For the range from 1 to 2.5 gray, 5.3 cancers are expected at the highest dose (case 01-576). Radium in Humans at 154 (JA 584).

[219] *See Chemical Mfgs.*, 28 F.3d at 1266 (speculative factual assertion inadequate to support agency rulemaking).

[220] EPA acknowledged that "the evidence is inconclusive on the association between exposure to radium in drinking water and leukemia," CRD-Proposal at 3-16 (Comment 218ad) (JA 1106), and that "the relationship between radium and leukemia may not be proven." *Id.* at 3-6 to 3-7 (Comment 150aa) (JA 1103-1104).

were observed in patients injected with radium-224 for medical treatment[221] and said that "[g]iven our understanding of radium metabolism and the effects of alpha irradiation, it is expected that ingestion of any of the radium isotopes will increase the risks for various types of cancer other than bone."[222] This speculation is not supported by the dial painter studies and is contradicted by EPA's own statements that radionuclides affect human health differently depending on their half-life, forms of radioactive decay (alpha particles, beta particles, or photons) and level of energy (high or low LET).[223] The record showed that radium-224 has a half-life of 3.66 days.[224] The half-life for radium-228 is 5.75 years, and the half-life for radium-226 is 1600 years.[225] Radium-224 and radium-226 predominantly emit alpha particles while radium-228 is mostly a beta particle emitter.[226] Epidemiological studies confirm the disparate effects of these isotopes because head cancers were observed only in persons exposed to radium-226, and breast, soft tissue, liver, bladder, and thyroid cancers were seen only in persons exposed to radium-224.[227] Even if EPA could reasonably assume that all forms of radium cause the same types of cancer, that assumption would not reconcile the absence of data showing that any radium isotope causes cancer in the esophagus, stomach, colon, lung, skin, ovary or kidney . The

[221] 65 Fed. Reg. at 76722; 56 Fed. Reg. at 33072.

[222] 65 Fed. Reg. at 76722.

[223] 65 Fed. Reg. at 76720.

[224] 65 Fed. Reg. at 21586.

[225] 56 Fed. Reg. at 33072.

[226] 65 Fed. Reg. at 21586; 56 Fed. Reg. at 33064-65; BEIR IV at 180-81 (JA 1520).

[227] 65 Fed. Reg. at 76722; 56 Fed. Reg. at 33072-73.

SDWA requires MCLGs, and by extension MCLs, to be based on "known or anticipated" health effects and not merely "possible" health effects.[228]

EPA's disregard of the specific evidence on the health effects of radium-226 and radium-228 in favor of its general model on radionuclides was arbitrary and capricious[229] and contrary to the best science mandate of the SDWA.[230] The agency failed to demonstrate a rational relationship between the assumptions used in the FGR-13 model and the specific information in the record regarding the behavior of radium-226 and radium-228.[231] EPA did not demonstrate that it used the best available science on radium-226 and radium-228 or explain the methodology used to reasonably reconcile the inconsistencies in the scientific data.[232]

3. EPA Acted Arbitrarily And Capriciously By Failing To Explain In The Final Rulemaking Why It Was Reasonable In Its 1991 Proposal To Reconcile Inconsistencies Between Its Model And The Observed Data On Ingestion Of Radium-226 And Radium-228 But Not To Do So In 2000.

Before issuing its proposal in 1991, EPA modified the initial results of its RADRISK model to reconcile some of the inconsistencies between the model's predictions and the human epidemiological data involving radium-224, radium-226, and radium-228.[233] EPA's adjustments compensated for the over-prediction of leukemias and under prediction of head carcinomas in EPA's initial run of the RADRISK model, when compared to dial painter data and radium-224

---

[228] 42 U.S.C. § 300g-1(b)(4); *See NRDC v. EPA*, 812 F.2d 721, 725 (D.C. Cir. 1987) (holding early equivalent to MCLG called Recommended Maximum Contaminant Level could not be based on possible health effects).

[229] *Tex Tin Corp*, 992 F.2d at 355 (D.C. Cir. 1993) (agency cannot rely solely on generic studies and discount specific evidence); *Chemical Mfgs.*, 28 F.3d at 1265 (agency must show rational relationship of model to situation where applied in the face of specific evidence to the contrary).

[230] 42 U.S.C. § 300g-1(b)(3)(A).

[231] *Chemical Mfgs.*, 28 F.3d at 1265.

[232] 42 U.S.C. § 300g-1(b)(3)(B).

[233] 56 Fed. Reg. at 33056, 33073.

data.[234] EPA agreed with the SAB that the rate of leukemias predicted by its RADRISK model was not consistent with epidemiological data showing no substantial increase in leukemia among dial painters or patients injected with radium-224.[235]

To make the adjustments to the model, EPA replaced the risk coefficients in the RADRISK model with risk coefficients derived from the epidemiological studies.[236] EPA based the new risk coefficient for head carcinoma on the dial painter studies involving radium-226 and radium-228 and the risk-coefficient for leukemia on the radium-224 studies.[237]

EPA used the dial painter studies to adjust the model in 1991 despite its recognition that the data had limitations similar to those described by the agency in 2000. In 1991, EPA noted uncertainty in the studies because the doses were not measured at the time of ingestion but estimated after-the-fact.[238] EPA also identified uncertainty over the retention of radium in the body and potential bias in the way exposed workers were identified.[239]

The RADRISK model used assumptions similar to the FGR-13 model. RADRISK predicted cancer in all radiosensitive organs and added these risks together.[240] The model also assumed a linear dose-response curve.[241]

Nevertheless, when it faced essentially the same situation in 2000, the agency made no adjustments to its model based on the observed data and failed to explain why it was reasonable

---

[234] 56 Fed. Reg. at 33056, 33073; Radium Criteria Document at VIII-31 to VIII-34 (JA 1536-1539).

[235] 56 Fed. Reg. at 33056; Radium Criteria Document at VIII-31 (JA 1536).

[236] 56 Fed. Reg. at 33056, 33073; Radium Criteria Document at VIII-31 to VIII-34 (JA 1536-1539).

[237] Radium Criteria Document at VIII-31 to VIII-32 (JA 1536-1537).

[238] 56 Fed. Reg. at 33055.

[239] *Id.*

[240] Radium Criteria Document at VIII-29 to VIII-30, VIII-34 (JA 1534-1535).

[241] Radium Criteria Document at VIII-16 (JA 1521).

not to do so. In light of its past practice in this situation, it was incumbent upon EPA to explain its decision to ignore the dial painter studies in 2000. When an agency reverses a previous position, it must provide a reasoned explanation for the change to avoid acting in an arbitrary and capricious manner.[242]

4. EPA Violated The APA And The SDWA By Failing To Explain Why It Was Reasonable To Rely Solely On Its Model To Set MCLs For Ingestion Of Low Levels Of Radium-226 And Radium-228.

In its rush to finalize drinking water standards by the end of the year after the close of the comment period in June, EPA failed to explain why its methodology for setting those standards is reasonable. By contrast, EPA provided a reasoned explanation for its action when it proposed its drinking water standards in 1991.

In 1991 EPA undertook a comparative evaluation of the available data and methods that could be used to quantify the risk of ingesting radium-226 and radium-228 in drinking water. EPA discussed this evaluation in detail in the final Criteria Document for radium issued in 1991.[243] EPA considered the available data on the health effects of exposure to radium-224, radium-226, and radium-228 and two risk assessment methods: (1) fitting dose-response curves (linear, quadratic, or otherwise) to the observed data from the dial painter studies and extrapolating risks at low doses using the curves or (2) using the RADRISK dosimetric model that synthesized a variety of human epidemiological data on the carcinogenicity of radiation generally.[244]

EPA sought advice from the Radiation Assessment Committee of the EPA Science Advisory Board (SAB/RAC), which recommended that EPA rely on the epidemiological studies

[242] *Center for Science in the Public Interest v. Dept. of Treasury*, 797 F.2d 995, 999 (D.C. Cir. 1986).

[243] Radium Criteria Document at VIII-15 to VIII-37 (JA 1520-1542).

[244] 56 Fed. Reg. at 33071; Radium Criteria Document at VIII-15 (JA 1520).

rather than a model.[245] EPA conducted a risk assessment following that recommendation and determined that 12 pCi/L and 11 pCi/L for radium-226 and radium-228, respectively, would produce an acceptable level of risk using a linear dose-response curve.[246] Using a quadratic curve, EPA found 21 pCi/L and 250 pCi/L to be acceptable levels.[247]

The agency decided to use the RADRISK model but to adjust the results of the model to be consistent with observations in the epidemiological data. The agency explained that the modified RADRISK model approach provided the best estimate of cancer risk from low-level radium intake because of the added uncertainty resulting from deriving a linear risk coefficient from the non-linear dial painter data and the available alternative of using the linear data from the radium-224 studies in the model.[248] The bone cancer data from epidemiological studies of patients injected with radium-224 to treat spinal arthritis and tuberculosis of the bone best fit a linear dose-response curve.[249]

No such analysis or explanation was conducted or provided by EPA in 2000. Instead, EPA introduced a completely new model and epidemiological data set (the bomb survivor studies) without even acknowledging or addressing the prior deliberations over the most appropriate risk assessment method for radium-226 and radium-228.[250] Rather than adding FGR-13 to the discussion in the specific Criteria Document for radium, or updating that document, EPA issued a single, general Technical Support Document that focused in the health

---

[245] 56 Fed. Reg. at 33055; SAB Report, Cover Letter at 2 (JA 1575).

[246] Radium Criteria Document VIII-25 to VIII-26 (JA 1530-1531).

[247] *Id.*

[248] 56 Fed. Reg. at 33055; Radium Criteria Document at VIII-37 (JA 1542).

[249] Radium Criteria Document at I-3, VIII-16 (JA 1478, 1521).

[250] *See* 56 Fed. Reg. at 33055-56, 33071-72; Radium Criteria Document VIII-15 to VIII-37 (JA 1520-1542).

effects chapter (Chapter 3) on FGR-13 generally and only briefly discussed the application of this model to each radionuclide.[251]

In the Technical Support Document, NODA, and the Final Rule, EPA compares the magnitude of the risk projected by the FGR-13 model to the level of risk that EPA calculated using other methods in 1976 and 1991.[252] But EPA compares the risk numbers without comparing the merits of the underlying methods and science used to derive those numbers.

As to the merits of the new model, EPA explained that it selected the FGR-13 model because it was the newest model, the current model, and the one that EPA uses to predict risk from exposure to radionuclides.[253] EPA described FGR-13 as "[t]he Agency's current radionuclides health effects model"[254] and said that "[s]ince 1991, EPA has refined the way in which it estimates potential adverse health effects associated with the ingestion of radionuclides in drinking water"[255] EPA explained in summary fashion the nature of these refinements by pointing to specific new features of the model and the categories of new data that are incorporated in the model.[256] However, EPA does not explain why these refinements make the FGR-13 model the best available science or a reasonable method for assessing the health risks of radium-226 and radium-228.

Rather, EPA automatically and rigidly applied the FGR-13 model to identify risks from drinking water ingestion of radium-226 and radium-228, without explaining why the model is the

[251] Technical Support Document at III-16 to III-35 (JA 188-207).

[252] 65 Fed. Reg. at 76712; 65 Fed. Reg. at 21583-84, 21603; Technical Support Document at III-30 (JA 202).

[253] 65 Fed. Reg. at 21580, 21603; 65 Fed. Reg. at 76711-12; *see also* Technical Support Document at III-17 (JA 189).

[254] 65 Fed. Reg. at 21580.

[255] 65 Fed. Reg. at 21603; Technical Support Document at III-17 (JA 189).

[256] 65 Fed. Reg. at 21603; Technical Support Document at III-17 (JA 189).

best available science or a reasonable method for doing so. There is no discussion or comparison of the merits of other available methods for assessing this risk of these specific radium isotopes. EPA acted arbitrarily and capriciously when it failed to consider all the relevant factors and did not offer a satisfactory explanation for its choice to rely solely on its model.[257] EPA acted contrary to law by not showing that its science was the best available science on radium-226 and radium-228 health effects,[258] and not providing the public with the "comprehensive, informative, and understandable" document on health effects and risk assessments,[259] as Congress directed in 1996, to make the agency "do a better job explaining alternative interpretations of the scientific evidence" and describe "alternative risk estimates that put the regulation in a broader public health context."[260]

For the forgoing reasons, the MCL for radium-226 and radium-228 should be remanded to the agency.

B. EPA'S URANIUM MCLG AND MCL VIOLATE THE SDWA AND ARE ARBITRARY AND CAPRICIOUS.

In its uranium MCLG and MCL rulemaking, EPA failed to apply the best available science, and failed to follow the requirements of reasoned decision-making. The MCLG and MCL are therefore unlawful. The Court should vacate the standards and remand the rule.

In 1991, EPA proposed an MCL for natural uranium at 20 ug/L,[261] based, in part, on a proposed MCLG of zero. EPA came up with an MCLG of zero by "classif[ying] uranium in Group A as a human carcinogen (sufficient evidence of carcinogenicity in humans)," and relying

[257] *See State Farm*, 463 U.S. at 43.

[258] 42 U.S.C. § 300g-1(b)(3)(A).

[259] 42 U.S.C. § 300g-1(b)(3)(B).

[260] S. Rep. No. 104-169, at 29.

[261] 56 Fed. Reg. 33050 (JA 1368).

on the LNT default assumption.[262] EPA then determined that an MCL of 20 ug/L results in an acceptable risk using the RADRISK model. [263]

The 2000 NODA[264] reiterated EPA's position that the MCLG for uranium should be zero.[265] EPA also announced that, using the FGR-13 model, the estimated fatal cancer risks associated with the 1991 proposed MCL generally "exceed the agency's [acceptable] risk range."[266] EPA did not conclude that uranium poses a higher cancer risk based on FGR-13 and provided no discussion of the FGR-13 cancer risk estimate for uranium in drinking water.[267]

In November 2000, a month before the issuance of the Final Rule, EPA issued an Economic Analysis that, for the first time, considered an MCL of 30 ug/L.[268] In December 2000, the agency published its Final Rule establishing an MCLG of zero for uranium.[269] In the absence of "more direct information" regarding risks at low doses, EPA relied on data concerning effects at high levels of exposure to estimate what the effects "could be at lower exposures" to set the MCLG.[270] According to EPA, these data "demonstrate a higher incidence of cancer among exposed individuals and a greater probability of cancer as the exposure increases."[271] EPA ignores the lack of any data (human or animal) demonstrating carcinogenic effects from ingestion of natural uranium in drinking water.

---

[262] *Id*.

[263] *Id*.

[264] 65 Fed. Reg. at 21576 (JA 2).

[265] *Id.*

[266] 65 Fed. Reg. at 21579 (JA 5); 65 Fed. Reg. at 76710 (JA 877).

[267] *See* 65 Fed. Reg. at 76710 (JA 877).

[268] *See* Economic Analysis at 7-2 (JA 1262) ("The Agency had chosen 30 ug/L as the final MCL.").

[269] 65 Fed. Reg. at 76722 (JA 889).

[270] *Id*.

[271] *Id*.

In adopting a uranium MCL of 30 ug/L, EPA relied, for the first time, on its "new discretionary authority" to set the MCL at a level above the "feasible" level when the benefits of a stricter standard do not justify the benefits.[272] EPA "believes the feasible level [to be] . . . 20 ug/L,"[273] but promulgated a final MCL of 30 ug/L in part because: "in the agency's judgment, there is not a predictable difference in health effects due to exposure between . . . 20 ug/L and a level of 30 ug/L."[274] The agency admits that the "likelihood of any significant effect in population at 30 ug/L is very small" and the difference in kidney toxicity risk for exposures at 20 ug/L versus 30 ug/L is insignificant.[275]

1. EPA's MCLG Of Zero For Uranium Is Not Based On The Best Available Science.

In 1991, EPA proposed a zero MCLG for uranium based on EPA's reliance on the LNT assumption.[276] EPA relied on this default assumption again in the Final Rule.[277]

In *Chlorine Chemistry Council v. EPA*, this Court found EPA's application of a non-threshold assumption "openly overrode" the best available science, which suggested that chloroform is a threshold carcinogen.[278] *Chlorine Chemistry* instructs that where there is sufficient science to support a non-zero MCLG, EPA must use a non-linear, threshold model. For the uranium MCLG, EPA disregarded relevant scientific evidence and applied its default assumption, even though that assumption is contrary to the evidence in the record.

---

[272] *Id.* at 76712 (JA 879).

[273] *Id*.

[274] 65 Fed. Reg. at 76713 (JA 880).

[275] *Id.* at 76714 (JA 881).

[276] *See* 56 Fed. Reg. at 33050 (JA 1368).

[277] 65 Fed. Reg. at 76712 (JA 879).

[278] 206 F.3d at 1290.

a) The Best Available Science Does Not Support The Application Of The Default Assumption Of A Zero MCLG For Uranium.

EPA's guidance on risk assessments outlines various default assumptions and their application in regulatory actions.[279] EPA acted arbitrarily and capriciously in using the LNT assumption for uranium because there is no evidence in the record to support linearity and no evidence which detracts from the weight of the scientific evidence that supports the application of a non-linear model. EPA summarily concludes that "[s]ince uranium is radioactive and EPA uses a non-threshold linear risk model for ionizing radiation, today's rule sets the MCLG for this contaminant at zero."[280] A summary conclusion like this is an inadequate basis to conclude that natural uranium in drinking water causes cancer in humans.[281] It disregards the total lack of supporting data and is based on a model that "bears no rational relationship to the reality it purports to represent."[282]

EPA "retains a duty to examine key assumptions as part of its affirmative burden of promulgating and explaining a non-arbitrary, noncapricious rule."[283] Here, EPA applied its default model to uranium despite the lack of data supporting its use and in disregard of the lack of scientific data demonstrating carcinogenic effects from ingestion of uranium in drinking water

[279] *See* 61 Fed. Reg. at 17960.

[280] *Id.*

[281] *See Int'l Fabricare*, 972 F.2d at 392 ("A conclusory statement, of course, does not in itself provide the 'satisfactory explanation' required in rulemaking.") (quotation and citation omitted).

[282] *Am. Iron & Steel Inst. v. EPA*, 115 F.3d 979, 1005 (D.C. Cir. 1997) (citations omitted).

[283] *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 534 (D.C. Cir. 1983).

(*e.g.,* the ATSDR study discussed below). Accordingly, the promulgation of the zero MCLG based on the default LNT assumption is arbitrary and capricious.[284]

b) The MCLG For Uranium Is Inconsistent With EPA's Practice For Setting MCLGs.

To set an MCLG, EPA begins by classifying the contaminant. First, "each chemical is analyzed for the evidence of carcinogenicity via *ingestion*."[285] Each substance is placed into one of the following six categories: Group A, human carcinogens based on strong evidence of carcinogenicity from drinking water ingestion or sufficient evidence from epidemiological studies; Group B-1, probable human carcinogen based on at least limited evidence of carcinogenicity based on epidemiological studies in humans; Group B-2, probable human carcinogen based on sufficient evidence in animals and inadequate evidence or no data from epidemiological studies in humans; Group C, possible human carcinogen based on limited evidence of carcinogenicity in animals in the absence of human data; Group D, not classifiable based on lack of data or inadequate evidence of carcinogenicity from animal data; or Group E, *no* evidence of carcinogenicity.[286]

Once a contaminant has been classified, it is placed into one of three categories. Category I substances are those which "EPA has determined that there is strong evidence of carcinogenicity from *drinking water ingestion*."[287] EPA typically places "group A (based on sufficient human epidemiological data)" or group B1 or B2 substances in Category I.[288]

---

[284] *See, e.g., Chemical Mfrs. Ass'n v. EPA*, 28 F.3d 1259, 1265-66 (D.C. Cir. 1994) (EPA's use of analytical model was arbitrary and capricious when the evidence demonstrated that the model was a "poor fit.").

[285] 56 Fed. Reg. at 33070 (emphasis added) (JA 1388).

[286] *See* at 33071 (JA 1389).

[287] *Id.* at 33070 (JA 1388) (emphasis added).

[288] *Id.*

Category I substances are automatically assigned an MCLG of zero because "it is assumed, in the absence of other data, that there is no known threshold."[289]

Category II substances "include those contaminants for which EPA has determined there is "limited evidence of carcinogenicity *via drinking water ingestion* considering weight of evidence, pharmacokinetics, and exposure."[290] Category II substances are assigned an MCLG based on the reference dose ("RfD") with an additional safety factor up to 10, or by setting the goal based upon a nominal lifetime cancer risk calculation of 10^{-5} to 10^{-6}.[291] EPA places Group C substances into Category II.[292]

Finally, Category III substances are those "for which there is inadequate evidence of carcinogenicity in animals *via ingestion*."[293] The agency places Group D or E substances into Category III. The MCLG for Category III substances is based solely on the RfD. Thus, EPA's system for setting the MCLG under the SDWA relies upon the risk from *ingestion* of a regulated drinking water contaminant.

EPA has admitted that the estimated risk from ingestion of uranium in drinking water is not established by either human or animal evidence. According to EPA, "[a]nimal studies of exposure to natural uranium did not provide direct evidence of carcinogenic potential."[294] Moreover, "[e]xisting human epidemiological data are inadequate to assess the carcinogenicity

---

[289] *Id.*

[290] *Id.* (emphasis added).

[291] 56 Fed. Reg. at 33070 (JA 1388)

[292] *Id.*

[293] *Id*. (emphasis added).

[294] *Id.*

of uranium ingested in drinking water."[295] As a result, the agency relied on *inhalation* data for its conclusion.[296]

That is a fatal flaw. If EPA relies upon an analysis of an *ingestion* risk, uranium cannot be placed into the Group A, Category I classification because, by its own admission, there is not sufficient evidence from epidemiological studies evincing carcinogenic effect. Yet EPA has placed uranium in this category by using *inhalation* risk instead of *ingestion* risk and thereby, according to EPA's policy, automatically setting the MCLG at zero. EPA's use of inhalation data is inconsistent with the fact that the agency "has cautioned that inhalation data should not be relied upon in a risk assessment for oral exposure."[297] In *International Fabricare*, the agency argued that it need not rely on data offered by petitioners concerning inhalation, and the court

---

[295] *Id.*

[296] *See id.* ("[S]ome epidemiological data do suggest that inhalation exposure to uranium or direct exposure uranium deposits may be carcinogenic in humans."). The inhalation data referred to is limited to a study using the *inhalation* route in three species. (Only *two (2)* out of 72 test animals in one species had an adenoma from being exposed in the inhalation study *to uranium dioxide*. No tumors were observed in the other two species. Moreover, EPA acknowledged that the authors of the study state that the neoplasms in the two (2) test animals *should not be used to extrapolate carcinogenicity in humans*. EPA also acknowledges that there was no malignancy associated with the injection of natural uranium in mice. *See* EPA, Drinking Water Criteria Document for Uranium (June 1991) (III-D3-80) (JA 1553-1555). In addition, a study focusing on workers exposed to airborne uranium resulted in nonstatistically significant effects. EPA acknowledged as much. *See* 56 Fed. Reg. at 33070 (JA 1388). Thus, the evidence for carcinogenicity of uranium in animals is limited to *one study using the inhalation route,* which the authors say should not be used as evidence of carcinogenicity in humans.

[297] *See Int'l Fabricare*, 972 F.2d at 395 (citations omitted). To the extent the agency argues that it was not bound by this policy when it established the MCLG for natural uranium, it was "under an obligation to provide a rational explanation for [its] departure[ ]" from such policy. *Nat'l Conservative Political Action Comm. v. FEC*, 626 F.2d 953, 959 (D.C. Cir. 1980) ("Agencies are under an obligation to follow their own regulations, procedures, and precedents, or provide a rational explanation for their departures."). Nowhere in the record does EPA provide such an explanation.

deferred to this determination.[298] For the agency to now rely on inhalation data is arbitrary in light of its position in *International Fabricare*.[299]

There is no evidence supporting EPA's placement of natural uranium in drinking water in Category I. EPA acknowledges as much: "there is little direct evidence of U[ranium] carcinogenicity . . . . "[300] The studies relied on by the agency are based on exposure to enriched uranium and high activity isotopes of uranium, not natural uranium: "[s]tudies of enriched uranium and high activity isotopes of uranium have shown them to be carcinogenic in animal studies. Studies using natural uranium do not provide direct evidence of carcinogenic potential."[301]

Thus, the record lacks *any* human clinical data or animal data suggesting, let alone establishing, that natural uranium when *ingested* in drinking water has a carcinogenic effect. The evidence relied on by the agency in support of its zero MCLG relates to inhalation data, and somewhat disingenuously, enriched uranium or high activity uranium, not naturally occurring uranium, which is the subject of the Final Rule. EPA has not met the standards for any of the Category I substances (*i.e.,* Group A, B-l and B-2). As a result, EPA's placement of uranium in Category I and application of an MCLG of zero is not supported by the facts and should be reversed.[302]

---

[298] 972 F.2d at 395.

[299] *See Ctr. for Science in the Public Interest v. Dep't of Treasury*, 797 F.2d 995, 999 (D.C. Cir. 1986) (when agency reverses previous position, it must provide a reasoned explanation for the change to avoid acting arbitrarily and capriciously).

[300] 56 Fed. Reg. at 33072 (JA 1390).

[301] *Id.* at 33076 (JA 1394) (citation omitted, emphasis added).

[302] *See State Farm*, 463 U.S. at 29, *see also Baker v. Dep't of Agric.*, 928 F. Supp. 1513 (D. Idaho 1996) (reversing administrative decision because it had no basis in the facts found by the government). To the extent the agency defends its action based on application of FGR-13 to somehow model an inhalation dose from uranium in water, the use of FGR-13 is arbitrary because unlike radon, a gas in solution which

(continued)

For purposes of the SDWA, uranium should be placed into Category II or III, similar to EPA's approach in setting the MCLG for asbestos. Even though EPA classifies asbestos as a Group A, known human carcinogen, based on *inhalation* evidence, EPA did not propose "an MCLG for asbestos based upon this classification, since the evidence for the association between ingested asbestos and cancer is limited."[303] Instead, EPA proposed an MCLG for asbestos "considering the chemical for drinking water purposes as if it were in Group C, based on the limited evidence or carcinogenic effects via ingestion."[304]

In promulgating the final asbestos MCLG, EPA stated that

> EPA does not automatically place contaminants classified as Group A or B carcinogens in Category I. Additional scrutiny occurs to determine what evidence exists of the chemicals' carcinogenicity via ingestion considering pharmacokinetics, exposure, and weight of evidence. *If the additional evidence of carcinogenicity via ingestion is limited or inadequate, then the chemical will be placed in the appropriate category* and an MCLG is calculated accordingly.[305]

The scientific evidence for classifying uranium as other than a Category I, Group A carcinogen (*i.e.,* as a Group D substance, inadequate human and animal evidence of carcinogenicity, or no data available) is even stronger than the case for asbestos. For asbestos, EPA had some evidence of ingestion risk from a National Toxicology Program bioassay; there is however, no such evidence for uranium. Notably, EPA fails to address the categorization of

---

(continued)
can off-gas, Uranium in solution cannot be inhaled. Therefore, to the extent the agency relies on FGR-13, its reliance is misplaced and the decision is arbitrary and capricious.

[303] National Primary and Secondary Drinking Water Regulations, Proposed Rule, 54 Fed. Reg. 22062, 22072 (May 22, 1989) (JA 1464).

[304] *Id.* (emphasis added).

[305] National Primary Drinking Water Regulations; Final Rule, Synthetic Organic Chemicals and Inorganic Chemicals; Monitoring for Unregulated Contaminants; National Primary Drinking Water Regulations Implementation; National Secondary Drinking Water Regulations, 56 Fed. Reg. 3526, 3534 (Jan. 30, 1991) (JA 1468) (emphasis added).

uranium, rather it merely applies its default assumption to setting the MCLG of zero. Nowhere in the NODA or in the Final Rule does EPA address its assumption that *natural uranium* ingested in drinking water is a "known carcinogen."

Because EPA concedes that it has no evidence directly linking ingestion of natural uranium to carcinogenic effects and because EPA must "demonstrate[ ] a reasonable connection between the facts on the record and its decision" made pursuant to its statutory authority,[306] EPA acted unlawfully in setting the uranium MCLG and its decision should be set aside.[307] By relying on inhalation data, the agency acted arbitrarily and capriciously and its decision is entitled to little deference.[308] Finally, by placing natural uranium in Category I ("known carcinogen"), EPA's action conflicted with, or departed from, the plain meaning of its regulations concerning cancer classification. Accordingly, EPA's action should be vacated and remanded.

c) EPA Failed To Adequately Consider Relevant Scientific Data When Setting The Uranium MCLG And Failed To Adequately Respond To Comments Concerning The Data.

EPA failed to adequately consider relevant peer-reviewed scientific data when promulgating the uranium MCLG and, thus, failed to use the best available science. In addition, the agency failed to adequately respond to comments regarding such data.

---

[306] *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1064 (D.C. Cir. 1995).

[307] *See Michigan v. EPA*, 213 F.3d 663, 681 (D.C. Cir. 2000) (setting aside EPA's decision under APA because agency had "no record evidence" supporting its decision).

[308] *See United Transp. Union v. Lewis*, 711 F.2d 233, 242 (D.C. Cir. 1983) (less deference is accorded where agency is inconsistent in promulgating standards).

In September 1999, EPA's sister agency, the ATSDR, issued a detailed study addressing the health effects from exposure to uranium.[309] The conclusions of the ATSDR study are plain: "No evidence linking oral exposure to uranium to human cancer has been found." Perhaps most telling, ATSDR found that "[n]o studies were located that provided evidence that oral exposure of humans to uranium as an alpha-emitting radiation source causes cancer."[310] The study points out that "exposure to natural uranium is unlikely to be a significant health risk in the population and may well have no measurable effect."[311] The study concludes its analyses of the carcinogenic effects from uranium exposure by stating:

> The long-term feeding studies . . . *found no evidence of cancer induction* . . . . The available studies tested [using] extreme intakes of uranium corresponding to [high radioactive exposures] . . . .[312]

Petitioners have been unable to find even one reference to the ATSDR study in the NODA, the technical documents supporting the NODA, or in the Final Rule. EPA's only reference to the study is in its Certified List of Documents Comprising the Record filed with the Court in this matter, where it lists the study as "Other Health Documentation Not Cited." The ATSDR study is not even included in the record at EPA. EPA's failure to be "comprehensive" by including the study in the record, and its failure to adequately consider and address the ATSDR study (which "fails to support [the agency's] estimate of public health effects"),[313] is

---

[309] *See* Agency for Toxic Substances and Disease Registry, Toxicological Profile For Uranium, Atlanta, Ga. (Sept. 1999) ("ATSDR 1999 Study") (JA 1778-1790). Congress created ATSDR as the *principal* federal public health agency charged with the responsibility of evaluating the human health effects of exposure to hazardous substances. *See* Agency for Toxic Substances and Disease Registry, *Agency for Toxic Substances and Disease Registry Strategic Plan 2002-2007* (May 17, 2002) *available at* http://www.atsdr.cdc.gov/2002-2007strategicplan.html#overview (JA 1805).

[310] ATSDR 1999 Study at 137 (JA 1787)

[311] *Id.* at 138 (JA 1788)

[312] *Id.* (emphasis added).

[313] 42 U.S.C. § 300g-1(b)(3)(B).

particularly egregious here where it was raised by NMA and others in their comments on the NODA.[314] Rational decision-making requires that EPA "give reasoned responses to all significant comments in a rulemaking proceeding."[315] The agency cannot reply to comments in an unsupported and conclusory fashion when presented with specific and detailed scientific evidence contrary to its position.[316] EPA's failure to be "comprehensive" by including the 1999 study in the record, its failure to adequately consider and address the ATSDR study, much less to issue a document identifying the contradictory data and explaining the "methodology used to reconcile inconsistencies in the scientific data,"[317] and its failure to adequately respond to NMA's comments regarding the ATSDR study violates the SDWA and renders EPA's decision arbitrary and capricious.[318]

2. EPA Failed To Use The Best Available Science When Setting The Uranium MCL.

a) EPA's Uranium MCL Is Based, In Part, On An Invalid MCLG.

As discussed above, MCL's are to be promulgated as enforceable standards set as close to the MCLG as is "feasible."[319] As explained in *Halogenated Solvents Industry Alliance v. Thomas*,[320] MCLs should "closely track" MCLGs.

Because EPA ignored the mandate of the Act that the MCLG for uranium is to be based on the best available science, and because the uranium MCL "closely tracks" the faulty MCLG,

---

[314] *See, e.g.,* NMA Comments at 4-5 (DI I-I1-48) (JA 769-770).

[315] *Int'l Fabricare Inst.*, 972 F.2d at 389.

[316] *See Chemical Mfgs. Ass'n*, 28 F.3d at 1266.

[317] 42 U.S.C. § 300g-1(b)(3)(A)-(B).

[318] *See Appalachian Power Co. v. EPA*, 249 F.3d 1032, 1059 (D.C. Cir. 2001).

[319] 42 U.S.C. § 300g-1(b)(4)(B.

[320] 783 F.2d 1262, 1264 (5th Cir. 1986).

the MCL also violates of the Act's requirement that it be based on the "best available science." Had the agency properly set the MCLG, then the starting point for determining the "feasible" level would not have been zero. Instead, the starting point for determining "feasibility" (and then for conducting the cost benefit analysis under section 1412(b)(6)), would have been higher. Had the agency started its "feasibility" analysis for setting the MCL at 40 ug/L rather than at zero, the analysis would have produced a different numerical standard.

b) The Studies On Which EPA Relies Fail To Provide Evidence Of Adverse Impact From Uranium In Drinking Water.

According to the agency, the uranium MCL is based in part on "health effects endpoints of kidney toxicity."[321] Most of the studies concerning kidney toxicity, however, showed risks so small that EPA could not determine whether exposure resulted in an adverse impact. EPA disregarded this data when setting the MCL, and relied instead on "rat data" involving the ingestion of various concentrations of uranyl nitrate, which again, is not *natural* uranium.[322] In its final rulemaking document, EPA admits that the data show very little, if any, effect (let alone adverse effect) on renal function.[323]

Furthermore, the agency admits that its conclusions based on kidney toxicity are not based on the evidence of actual disease but rather "primarily on observed adverse effects at the cellular level, but which have not necessarily resulted in a recognized disease."[324] Moreover, EPA acknowledges that it has "some human data which demonstrates that *mild* proteinuria has

[321] 65 Fed. Reg. at 76712 (JA 879).

[322] *Id.* at 76713 (JA 880).

[323] *Id.* (emphasis added)

[324] *Id*.

been observed at drinking water levels between 20 and 100 ug/L."[325] Finally, in justifying why the agency adjusted the MCL upward from the "feasible" level of 20 ug/L to 30 ug/L, EPA admitted that its scientific basis for the standard was speculative: "[a]n MCL of 30 ug/L represents a relatively small increase [over the feasible level of 20 ug/L] . . . compared to the over-all *uncertainty* in the RfD and the *uncertainty* in the importance of the *mild* proteinuria observed for uranium exposures from high drinking water levels."[326]

Despite these admissions, EPA's calculations on which the final MCL is based take no account of these data. Rather, the agency's "best estimate" of risk is based solely on "rat data."[327] The studies, including human data, show limited, if any, adverse impact to kidney function (let alone disease) from drinking water levels up to 100 ug/L. The ignored data dictate a fundamentally different MCL value. EPA's failure to properly incorporate these data into its calculation violates the statutory requirement that it use the "best available science," and renders its decision arbitrary and capricious.[328]

For the foregoing reasons, EPA did not apply the best available science, and failed to adhere to the requirement of reasoned decisionmaking when promulgating the MCLG and MCL

---

[325] *Id.* (emphasis added) (JA 880).

[326] *Id*. at 76714 (JA 881).

[327] *Id*. at 76713 (JA 880).

[328] *See, e.g., Chemical Mfgs. Ass'n*, 859 F.2d at 989 (EPA must consider "all the evidence" and failure to do so renders the decision arbitrary and capricious). *See also, Appalachian Power Co. v. EPA*, 251 F.3d 1026, 1034 (D.C. Cir. 2001) (holding EPA's "failure to 'examine the relevant data and articulate a satisfactory explanation for its action' either is arbitrary decision making or at least prevents a court from finding it non-arbitrary." (citation omitted)).

for uranium. Accordingly, the Court should vacate the uranium standard, and remand the Final Rule to the agency.[329]

C. EPA'S BETA/PHOTON MCLS VIOLATE THE SDWA AND ARE ARBITRARY AND CAPRICIOUS.

1. The Beta/Photon MCLs Are Based On Obsolete Science.

EPA based its 1976 beta/photon MCLs on the 1959 "Publication 2" of the International Commission on Radiological Protection ("ICRP").[330] Even in 1976, this science was "old" and the data on which it was based, incomplete.[331] Nonetheless, in the 25 years since, EPA has never updated the 1976 MCLs. In the NODA, EPA reconsidered the beta/photon MCLs, invited public comment on them, and then readopted the 1976 MCLs in the Final Rule. In so doing, EPA violated the Act's mandate that the agency employ the best available science to update MCLs when conducting statutorily-required reviews.[332]

a) The 1976 MCLs

When it established the 1976 MCLs, EPA set a risk standard (*i.e.*, number of cancers per a given population) as a matter of policy: 56 per 1,000,000 (5.6×10^{-5}). EPA then turned to ICRP Publication 2 (1959) to translate that risk level into a dose of 4 millirem/year (*i.e.,* the

---

[329] The presumptive remedy for an invalid rulemaking has always been to vacate and remand. *See Camp v. Pitts*, 411 U.S. 138, 143 (1973) ("if [an agency] finding is not sustainable on the administrative record made, then the agency's decision must be vacated and remanded to it for further consideration.").

[330] 65 Fed. Reg. at 21603 (JA 29). The ICRP publishes periodic recommendations regarding radiation protection.

[331] When ICRP released Publication 2 in 1959, it recognized its guidance was based upon "very incomplete" information. ICRP, Report of the ICRP Committee II on Permissible Dose for Internal Radiation, at 2, 9 (1959) (DI III-D2c-33) ("ICRP 2") (JA 1563, 1564).

[332] *See, e.g.,* NEI Comments at 6-9 (JA 829-832); DOE Comments, Attachment at 3 (JA 780); NRC Comments, Letter at 1-2, Enclosure at 1-2 (DI I-I12-09) (JA 864-867).

amount of exposure that is estimated to produce that number of cancers), and to translate that dose into concentration limits[333] for each of the 168 beta/photon radionuclides.

The 1959 ICRP 2 methodology did not account for variability in cancer induction rates among different organs and tissues, which were unknown at that time. The ICRP 2 methodology therefore could not accurately determine an integrated "whole body" dose estimate.[334] Consequently, the 1976 Rule adopted a "critical organ" analysis. This approach effectively assumed (contrary to fact) that the cancer induction rates for all organs were equal to that of the most sensitive organ, and assumed that the risk to the whole body equated to the dose received by the most exposed organ, *i.e.,* the "critical organ." Even at the time, EPA realized that this "critical organ" analysis yielded an artificially low and unnecessarily conservative limit.[335]

b) Advances In Science

As EPA has acknowledged, radiation health science has advanced radically since 1959.[336] In 1977 and 1979, the ICRP noted dramatic scientific advances in its Publications 26/30.[337] ICRP 26/30 implemented, *inter alia*, a new "effective dose equivalent" or "EDE" standard, which integrated dose over the "whole body," using weighting factors to account for the specific

[333] Concentration limits, or MCLs, are the amount of radioactivity in a given volume, expressed as the number of picoCuries per liter.

[334] ICRP, Recommendations of the ICRP, ICRP Publication 26, at 9 (1977) (DI III-D3-22) ("ICRP 26") (JA 1570).

[335] EPA, Federal Guidance Report No. 11, at 201 (1988) ("FGR-11") (JA 1710) (Radiation Protection Guidance to Federal Agencies for Occupational Exposure, 52 Fed. Reg. 2822, 2827 (Jan. 27, 1987)).

[336] *See* FGR-11 at 13-16, 17, 18, 27, 30 (discussing advances) (JA 1697-1702, 1703, 1706).

[337] *See* ICRP, Limits for Intake of Radionuclides by Workers, ICRP Publication 30 (1979) (DI III-D3-23) ("ICRP 30"). ICRP Publications 26 and 30 reflected the same scientific knowledge, but ICRP Publication 26 was a policy document while ICRP Publication 30 described methodology. For convenience, this generation of radiation knowledge is referenced as "ICRP 26/30." The RADRISK model used by EPA in 1991 and discussed above incorporated ICRP 26/30 science.

sensitivity of each organ.[338] This approach expressly superseded the methodology in ICRP's prior publications.[339] By taking organ-specific and radionuclide-specific information into account, an "EDE" limit provides a more accurate picture of the risks associated with particular radionuclides than the "critical organ" approach.[340]

c) EPA's Response To Scientific Advances

EPA has touted the universal acceptance of, and indeed has repeatedly adopted, the advanced science of ICRP 26/30 over that of ICRP 2.[341] Even in 1976, EPA emphasized that it intended to update the MCLs to reflect these scientific advances.[342] Later, in 1986, EPA proposed updating the beta/photon MCLs using an "EDE" approach based on ICRP 26/30.[343] Since 1988, EPA has issued three iterations of its federal radiation guidance, all of which uniformly reject the outmoded "critical organ" approach in favor of an "EDE" approach.[344] Nevertheless, the 2000 rule re-promulgated standards based on discredited science, including the use of a "critical organ" dose that EPA has repeatedly rejected. Even EPA acknowledged that the rule employs "older" science, effectively ignoring "best available science."[345] This violates the SDWA's mandate and is arbitrary and capricious.

---

[338] *See, e.g.,* FGR-11 at 201 (JA 1710) (52 Fed. Reg. at 2827). *See also* ICRP 26 at 9 (JA 1570); ICRP 2 at xix (JA 1561).

[339] *See* ICRP 30 at cover page (JA 1573); ICRP 26 at 9, 15 (JA 1570, 1572); FGR-11 at 6 (JA 1696).

[340] In the 1980s and 1990s, the ICRP further revised its estimates of radiation effects to reflect improvements in biological information and modeling. *See, e.g.,* FGR-13 at 145-47 (JA 105-107).

[341] FGR-11 at 198 (noting ICRP Publications 26/30 recommendations were "in use, in whole or substantial part, in most" countries other than the United States), 203 (noting the "EDE" standard was in "general conformance with international recommendations and practice.") (JA 1707, 1712).

[342] *See* 41 Fed. Reg. at 28409 (JA 1453).

[343] 51 Fed. Reg. at 34843-44, 34849 (JA 1456-1457, 1461).

[344] *See generally* FGR-11, FGR-12, FGR-13.

[345] 65 Fed. Reg. at 21583, 21602-03 (JA 9, 28-29) (recognizing "the dose-based MCL of 4 mrem/year is based on older scientific models" and that EPA's 1991 proposed MCLs were based on scientific

(continued)

2. EPA's Outdated Beta/Photon MCLs Are Inconsistent With EPA's Own Radiation Protection Guidance and Regulations.

EPA develops radiation protection guidance for itself and other Federal agencies.[346] EPA has regularly updated those Federal Guidance Reports ("FGRs"). As long ago as 1987, EPA acknowledged the need to conform to recent advances including EDE dosimetry:

> We now have a *greatly improved ability to estimate risk* of harm due to irradiation of individual organs and tissues. As a result, some of the old numerical guides are now believed to be less and some more protective. . . . *These disparities and omissions should be corrected.* Drawing on this improved knowledge, the [ICRP] published, in 1977, new recommendations on radiation protection philosophy and limits for occupational exposure. . . . 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*[.] [347]

Since 1987, EPA's FGRs have (i) repeatedly acknowledged the obsolescence of the 1959 "critical organ" dosimetry; (ii) instructed regulators to incorporate more recent scientific advances; and (iii) relied on ICRP Publications 26/30 or later advances.[348] FGR-11 (1988) and FGR-12 (1993) incorporated the "effective dose equivalent" standards and methodologies of ICRP Publications 26/30 (1977/1979), and FGR-13 (1999) incorporated the "equivalent dose" standards and methodologies of ICRP Publications 60 (1990) and 72 (1995).

EPA also relies on EDE dosimetry from ICRP 26/30 in its own regulations, including its CERCLA reportable quantities rulemaking[349] and its radionuclide National Emissions Standards

---

(continued)
advances); 65 Fed. Reg. at 76716 (JA 883) (questioning whether EPA could update the MCLs in accordance with best available science given the anti-backsliding provisions).

[346] *See, e.g.,* 65 Fed. Reg. at 76711 (JA 878).

[347] FGR-11 at 198 (JA 1707) (emphasis added).

[348] *See, e.g.,* FGR-11 at 2, 3 (JA 1692-1693).

[349] 40 C.F.R. Part 302; s*ee* 54 Fed. Reg. 22524, 22530, 22533 (May 22, 1989).

for Hazardous Air Pollutants.[350] Other than with these MCLs, Petitioners are not aware of even one instance in the past fifteen years of a federal agency adopting radiation protection based on "critical organ" methodology.[351] EPA's inexplicable reversion to outdated science, including "critical organ" dosimetry, in its beta/photon MCLs is contrary to the SDWA's update and best available science provisions, is inconsistent with EPA's own regulations, radiation guidance and recommendations for the last fifteen years, defies the evidence before EPA, and is, therefore, unlawful.

3. The Beta/Photon MCLs Provide Inconsistent Protection.

In 1976, EPA believed (based on then-available science) that each of the 168 beta/photon MCLs it established corresponded to its targeted 4 millirem dose limit and 5.6 x 10^{-5} risk level. Current science demonstrates that those MCLs do *not* in fact comply with EPA's 1976 estimated dose or risk levels. Rather, the actual dose and the actual risk vary radically among the 168 beta/photon MCLs.[352] For example, the protection afforded by the MCL for I-134 is 625 times that afforded by the MCL for In-115.[353]

---

[350] 40 C.F.R. Part 61; National Emission Standards for Hazardous Air Pollutants; Radionuclides; Final Rule and Notice of Reconsideration; *see* 54 Fed. Reg. 51654, 51662 (Dec. 15, 1989) (JA 1466).

[351] Other agencies, including the NRC, have independently incorporated ICRP 26/30 dosimetry methods into their regulations. *See, e.g.,* Standards for Protection Against Radiation, Final Rule, 56 Fed. Reg. 23360, 23370 (May 21, 1991); Minor Revisions of Design Basis Accident Dose Limits for Independent Spent Fuel Storage and Monitored Retrievable Storage Installations, 63 Fed. Reg. 54559, 54560 (Oct. 13, 1998).

[352] EPA admits as much. 65 Fed. Reg. at 76176 (JA 883); 65 Fed. Reg. at 21582, 21605-14 (JA 8, 31, 40) (graph and table illustrating wide range of risk associated with the 1976 MCLs); *see also* NRC Comments, Letter at 1 (JA 864) (objecting to these MCLs because they yield "non-uniform risk levels" that "vary more than 1000 fold" and cautioning that the MCLs will "create confusion and unnecessary public alarm about the level of risk that is acceptable and attainable").

[353] *Compare* 65 Fed. Reg. at 21609 (JA 35) (In-115) *with id.* at 21610 (JA 36) (I-134).

EPA's own FGR-13 analysis reveals the inconsistent protection afforded by the 1976 MCLs.[354] In these graphs, the solid line depicts risks associated with each of the 1976 MCLs; the dotted line depicts risks associated with each of the 1991 proposed MCLs (based on EPA's reassessment of risk using FGR-13).[355] As these figures show, the 1976 estimated risk values vary so widely that many of them actually fall outside of EPA's risk range.[356] Rather than promulgating beta/photon MCLs reflecting a uniform risk, EPA effectively promulgated 168 different dose limits (corresponding to 168 different radiation risk limits), rendering the estimated risk to an individual dependent upon the particular radionuclide to which he or she is exposed.[357] EPA's repromulgation of obsolete beta/photon MCLs yielding radically varying risks violates the SDWA and is arbitrary and capricious.

4. EPA's Excuses Do Not Absolve The Agency Of Its Obligation To Update Beta/Photon MCLs.

EPA provides many reasons for not updating its beta/photon MCLs to reflect best available science: (i) it could not complete a new proposal before a purported November 2000

---

[354] *See* 65 Fed. Reg. at 21583 (JA 9); Attachment A. This graph depicts the same data as EPA's Figure 1 from the NODA (65 Fed. Reg. at 21582). Here that data is sorted by the 1991 re-estimated risks (instead of the 1976 re-estimated risks).

[355] The 1991 risk estimates exhibit less variability because they reflect the scientific advances between ICRP 2 and ICRP 26/30. *See* 65 Fed. Reg. at 21603 (JA 29); Attachment A. *See also* discussion in Section D.4.

[356] *See* 65 Fed. Reg. at 21582, 21605-14 (graph and table) (JA 8, 31-40); Attachment A. Some 1976 MCLs are too high, resulting in risks significantly above EPA's upper limit. *See* 65 Fed. Reg. at 21606, 21609, 21613 (JA 32, 35, 39) (Se-75 has a lifetime fatal cancer risk of 265 per 1,000,000; In-115 has risk of 450 per 1,000,000; Pt-193m has risk of 258 per 1,000,000). Arguably, this also violates the SDWA's "anti-backsliding" provision which requires that MCL updates must maintain levels of protection of human health. *See* 42 U.S.C. § 300g-1(b)(9). Other MCLs are set lower than needed to meet even EPA's "minimum" risk goal of 10^{-6}. 65 Fed. Reg. at 21605, 21610 (JA 31, 36) (Ca-45 has lifetime fatal cancer risk of 0.9 per 1,000,000; I-134 has a risk of 0.7 per 1,000,000 and Te-131 has a risk of 0.8 per 1,000,000).

[357] *See, e.g.,* Attachment A (straight line represents EPA's 1976 policy goal of a uniform 5.6×10^{-5} risk level).

consent decree deadline; (ii) it will be reviewing, and potentially revising, these MCLs soon; (iii) it relied upon FGR-13 to re-estimate risks; and (iv) risks under the 1976 Rule fell within EPA's risk range while the 1991 proposed MCL values did not. None of these arguments is persuasive.

a) EPA Is Not Excused From Revising The Beta/Photon MCLs Because It "ran out of time."

In the April 2000 NODA, EPA referenced a November 2000 deadline and proclaimed that it "has determined that there is no way to update the 4 mrem dose basis (1976) for the beta particle and photon radioactivity MCL without the extensive process of a new proposal."[358] EPA's proclamation refers to its consent decree commitments to take final action, or explain why it did not do so, by November 21, 2000.[359] EPA's claim that it is unable to "find the time" to update the MCLs rings hollow. It had been twenty-four years since the 1976 MCLs were first promulgated, nine years since EPA proposed the 1991 rule, and five years since the 1996 SDWA Amendments. More importantly, the consent decree did not require EPA to promulgate a new rule but alternatively allowed EPA simply to explain why it could not revise the rule by November 2000.[360] Thus, EPA's claim of a November 2000 deadline is disingenuous. EPA cannot simply repromulgate an existing, scientifically-discredited rule to avoid the procedural and substantive steps necessary to promulgate a final rule consistent with the SDWA.

An unlawful rule cannot serve as a stopgap until the agency issues a different, statutorily-compliant rule. In *Chlorine Chemistry*,[361] petitioners challenged EPA's decision not to update the chloroform maximum contaminant level goal ("MCLG") using new scientific evidence

[358] 65 Fed. Reg. at 21581 (JA 7).

[359] 65 Fed. Reg. at 21577, 21579 (JA 3, 5); 65 Fed. Reg. at 76732 (JA 899).

[360] *See* 65 Fed. Reg. at 21579 (JA 5).

[361] 206 F.3d at 1291

because such an update would have been "a major change in the substance of regulatory decisions related to chloroform," and EPA "could not complete . . . deliberations with the [Science Advisory Board] before the November 1998 deadline."[362] This Court rejected EPA's argument, vacating the rule as arbitrary and capricious and inconsistent with the SDWA.[363] Similarly, EPA here may not use a long-delayed, purported deadline to excuse statutory noncompliance.[364]

b) EPA Is Not Excused From Revising Its Beta/Photon MCLs Based On Its Promise To Review The MCLs Soon.

EPA defended its repromulgation of the 1976 MCLs in the 2000 Final Rule, claiming it would soon fulfill its statutory obligation to review and update the beta/photon MCLs.[365] Acknowledging the need to revamp the beta/photon MCLs,[366] EPA "committed to performing a review of the beta and photon emitters on an accelerated schedule."[367] EPA, however, may not ratify the discredited 1976 Rule based on promises of future review.[368]

Even if a promise to perform a review sometime in the future were sufficient, EPA's promises are suspect. To date, there is no evidence that EPA has conducted any periodic review since 1976, other than the proposed 1991 Rule that was only recently finalized. Under the former three-year review provision, EPA should have reviewed and updated the 1976 regulations

---

[362] *Id*. at 1290.

[363] *See id*. at 1291.

[364] *Id*. at 1290.

[365] 65 Fed. Reg. at 21583 (JA 9).

[366] *See* 65 Fed. Reg. at 76716 (JA 883) ("a near future review [of these MCLs] . . . is appropriate.").

[367] CRD-NODA at 6-7, 6-13 (Comments 6.C.10, 6.C.15) (JA 1018, 1024); 65 Fed. Reg. at 76716 (JA 883) (MCLs are to be reviewed "as expeditiously as possible (expected to be 2 to 3 years)")

[368] *Chlorine Chemistry*, 206 F.3d at 1291 (Congress requires EPA to take action "on the basis of the best available evidence *at the time* of the rulemaking").

at least in 1979, 1982, 1985, 1988, 1991 and 1994. EPA missed each deadline.[369] The 1986 SDWA amendments required EPA to publish the results of its reviews in the Federal Register by 1989. EPA was sued when it missed that deadline, leading to the November 2000 consent decree deadline that EPA now claims as its rationale to promulgate this Final Rule.

Moreover, EPA has now renounced its promise to update these MCLs.[370] In its recent Federal Register notice announcing a review of some radionuclides, EPA stated that the beta/photon MCLs will *not* be updated until 2008. Incredibly, EPA's excuse for not updating the MCLs is that those standards were "[r]eviewed/revised under December 7, 2000 Radionuclides Rule."[371] EPA cannot have it both ways. EPA cannot repromulgate an old rule, promising to review it on an "accelerated" basis in the "near future," and then offer the *post-hoc* rationalization that its earlier repromulgation was, in fact, a review and revision. EPA's Final Rule clearly violates the SDWA's mandate of review and revision based on best available science.[372]

---

[369] *See* S. Rep. No. 104-169, *reprinted in* 1995 WL 675317, at 41.

[370] *See* CRD-NODA at 6-11 (Comment 6.C.15) (JA 1022) ("The radionuclide MCL, for example, has been eliminated from the first 6 year review cycle, due to the fact that it is already being reviewed under the April 21, 2000 NODA[.]").

[371] National Primary Drinking Water Regulations; Announcement of Results of EPA's Review of Existing Drinking Water Standards and Request for Public Comment, 67 Fed. Reg. 19030, 19032-33, 19036 (April 17, 2002).

[372] EPA cannot retain the 1976 MCLs based on its claim that "there is no evidence of appreciable occurrence of man-made beta emitters in drinking water" and therefore the rule is unlikely to affect public drinking water suppliers. 65 Fed. Reg. at 21583 (JA 9); *see also* 65 Fed. Reg. at 76716 (JA 883). That position overlooks EPA's policy of enforcing these MCLs on the nuclear energy industry and NRC licensees under CERCLA. EPA is well aware of this application since it is the Agency imposing it. *See, e.g.,* 65 Fed. Reg. at 76716-17 (JA 883-884); NEI Comments at 11, 12 (JA 834-835).

c) EPA's Claim That An "Effective Dose Equivalent" Standard Is Not Better Science Contradicts More Than A Decade Of EPA Regulations, Policy, And Guidance Incorporating Updated Science.

In response to the NODA, NRC, DOE and others urged EPA to meet the best available science requirement by incorporating the effective dose equivalent basis for the MCL for beta and photon emitters.[373] In response to these comments, the agency asserted that the effective dose equivalent approach:

> is not inherently better science, in the Agency's view. It is simply a different approach using different dose units. . . . Furthermore, there is no uniform scientific consensus on the best units to use, several variations of the ede being used by different scientific bodies.[374]

EPA's assertions flatly contradict (i) the agency's prior position in SDWA rulemaking, (ii) three iterations of federal radiation guidance, and (iii) EPA's other regulations. Further, both the NODA and Final Rule concede that the 1976 MCLs are based on old science.[375] As discussed above, since 1987, EPA's regulations and federal radiation guidance have adopted an EDE approach.[376] In the NODA, EPA boasts that its most recent guidance, FGR-13, which incorporates EDE methodology, represents the "newest risk modeling" incorporating "state-of-

[373] NRC Comments, Attachment at 2 (JA 867); DOE Comments at 3 (JA 779); *see* NEI Comments at 5-9 (JA 828-832).

[374] CRD-NODA at 6-9 (JA 1020) (emphasis added).

[375] 65 Fed. Reg. at 21583, 21602-03 (JA 9, 28-29); 65 Fed. Reg. at 76716 (JA 883).

[376] *See* FGR-11 at 198 (JA 1707).

the-art methods."[377] Accordingly, EPA's statements in its response to comments[378] conflict with its policies of the past 15 years and therefore deserve no deference from this Court.[379]

d) EPA's Review Of The 1976 MCLs Using FGR-13 Does Not Remedy The Defects In The Science Underlying The Standards.

(1) EPA's use of FGR-13 does not meet the SDWA's "best available science" requirement.

EPA's assertion that its 2000 Rule is based on "newest science" because it used FGR-13 to reassess risk is fatuous.[380] FGR-13 distinctly was *not* used to update the MCLs. Rather, it was only used to re-estimate risks associated with (i) each of the 1976 MCLs (derived from 1959 "critical organ" dosimetry) and (ii) each of the 1991 MCLs (derived from more recent "effective dose equivalent" dosimetry). EPA re-estimated risk by multiplying each of the 1976 MCLs and the 1991 MCLs *by the same number* (derived from FGR-13).[381] The agency cannot mask a refusal to use improved science to set new MCLs by undertaking a very limited comparison of two previous sets of MCLs. Reevaluating those MCL sets and choosing one over the other certainly is not the equivalent of setting MCLs based on best available science.[382]

---

[377] 65 Fed. Reg. at 21579, 21580 (JA 5, 6).

[378] Any argument regarding some unexplained controversy over "different types" of "EDE" misses the more pressing issue – whether an EDE standard is better than the 1959 "critical organ" methodology. Petitioners are aware of no "controversy" in the scientific community regarding the latter point.

[379] *See INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987) (An agency is entitled to "considerably less deference" when its interpretations are inconsistent with prior positions.).

[380] 65 Fed. Reg. at 21580 (JA 6); 65 Fed. Reg. at 76711 (JA 878).

[381] This exercise has no utility. Because the purported comparison simply multiplies two different sets of MCL limits by a constant, the relationship between the 1976 and 1991 MCL values remains exactly the same.

[382] EPA's own analysis confirms NEI's position. The 1976 MCLs do not reflect their intended risk range of 5.6×10^{-5} nor is there any consistency among the risks associated with the 1976 MCLs. *See* Attachment A; 65 Fed. Reg. at 21582-83 (JA 8-9).

(2) EPA was not limited to choosing between the 1976 MCLs and 1991 MCLs, but should have employed best available science to establish a new set of MCLs corresponding to an acceptable risk.

EPA's ratification of the 1976 Rule arises in part from a false dichotomy posed by the agency. EPA was not limited to adopting either the 1976 existing rule or the 1991 proposed rule. Instead, to update the beta/photon MCLs based on current science, EPA should have started with the risk value or range it determined was appropriate[383] and then used recent radiation protection science to derive MCLs that accurately reflect that risk level. If EPA had taken that approach, its MCLs would have been consistent with "best available science." Indeed the Nuclear Regulatory Commission (an agency with at least equivalent expertise in radiation science) recommended this approach.[384] Even EPA has admitted that "[a] newly proposed MCL expressed in mrem-ede could result in a more consistent risk level within the Agency's target risk range."[385]

(3) EPA inappropriately mixed and matched different generations of science.

EPA's use of FGR-13 to reassess the 1976 and 1991 limits inappropriately mixed and matched different, incompatible generations of science and dosimetry. There are important differences between (i) the methodologies in the agency's 1999 FGR-13, (ii) those in the 1976 rule (using a critical organ approach), and (iii) those in the 1991 proposed rule (using ICRP

---

[383] For example, when EPA established the 1976 MCLs, it set them to correspond to a particular risk value (*i.e.*, 5.6 x 10^{-5}). Similarly, when EPA proposed the 1991 MCLs, it set them at 10^{-4} (*i.e.*, the upper limit of the risk range EPA announced in 2000 to be acceptable).

[384] *See* NRC Attachment at 2 (JA 867) ("A more appropriate approach would be to set the MCLs at a consistent risk level. . . . [A]n approach similar to that proposed in 1991 should be adopted, because it would provide a common technical and risk basis for . . . beta/photon emitters.").

[385] 65 Fed. Reg. at 76716 (JA 883). The 1991 Proposed Rule expanded the definition of beta/photon radionuclides and included limits for *over 230* different radionuclides, while the 1976 Rule included limits for only *168* radionuclides. 65 Fed. Reg. at 21581 (JA 7). EPA's fixation on choosing between the 1976 and 1991 MCLs completely ignored these additional radionuclides, producing, without explanation, a Final Rule that simply omits protection from those radionuclides.

26/30's "effective dose equivalent" approach). FGR-13 adopts an amalgam of methodological updates from ICRP 60 and 72 and other sources; applying FGR-13 to a critical organ approach and an effective dose equivalent approach cannot account for the differences between those two approaches. As such, when EPA applied FGR-13 to the 1976 "critical organ"-based MCLs it created a set of hybrid "risk levels." When EPA applied FGR-13 to the 1991 "effective dose equivalent"-based MCLs, it created an entirely different, incompatible set of hybrid risk levels.[386] Thus, EPA employed, without explanation, an analysis that combined and compared multiple, incompatible generations of science, which necessarily yielded inconsistent and incomparable results. Legally and logically, EPA should have used updated science to establish a uniform set of MCLs.

(4) EPA's reversion to the 1976 Rule based on "rounding" was unlawful.

Rationalizing its choice of the 1976 MCLs over the 1991 proposed MCLs, EPA contends that the reassessed risks associated with "most" of the 1976 MCLs fall somewhere within EPA's target risk range, or can be *rounded* to fall within that target risk range, which spans two orders of magnitude.[387] Promulgating a standard based on the notion that it is "close enough" to a particular risk range, however, cannot possibly meet any reasonable construction of the phrase "best available science."[388]

Even if EPA's decision to "round" values to enable them to fall within the risk range were appropriate, there is no principled, scientific justification for distinguishing between the

[386] *See, e.g.*, FGR-13 at 1-2 (JA 85-86).

[387] 65 Fed. Reg. at 21581 (JA 7).

[388] *See* NEI Comments at 10 (JA 833).

1976 and 1991 sets of concentration limits. EPA's Figure 1[389] and Attachment A demonstrate the artificiality of EPA's distinction. The re-estimated risk levels for the 1976 Rule MCLs are represented in Figure 1 and Attachment A by the solid line, those for the 1991 proposed MCLs are represented by the dotted line.[390] EPA purportedly discarded all of the 1991 MCLs because its mixed-generation analysis suggested that some of those MCLs fell above "the upper limit of the Agency's acceptable lifetime excess risk range."[391] When EPA reassessed the risks associated with the 1976 MCLs, it discovered that a number of those values also fell outside of that same risk range. Rather than discarding the 1976 Rule, however, EPA concluded that "while some are slightly above and some slightly below, all round to values within these orders of magnitude."[392] Any attempt to characterize this analysis as rational, let alone as best available science, would be frivolous.

EPA's distinction between the 1976 and 1991 MCLs does not provide a rational basis for rulemaking. EPA's Figure 1 shows that the highest point on the 1976 (solid) Line, In-115 with an estimated risk of 4.46×10^{-4}, is higher than *every single point* on the 1991 (dotted) Line except one.[393] Consequently, if *all* of the 1976 values (points along the solid line) round to 10^{-4}, then so do *all* of the 1991 values (points along dotted line) – except one. Accordingly, with the exception of Ge-71, the reassessed risks for each of the 1991 proposed MCLs round to within

---

[389] 65 Fed. Reg. at 21582 (JA 8).

[390] The lines are formed by connecting the values of the re-estimated risks for each of the 168 beta/photon MCLs. In other words, the horizontal axis displays the various individual radionuclides while the vertical axis displays the re-estimated risk associated with each individual radionuclide's concentration limit.

[391] 65 Fed. Reg. at 21580 (JA 6). In 1991, EPA acknowledged that its 4 mrem ede standard reflected a risk of approximately 10^{-4}, the upper limit of the risk range EPA later identified in 2000. 56 Fed. Reg. 33103 (JA 1421).

[392] 65 Fed. Reg. at 21581 (JA 7).

[393] Ge-71 has a 1991 risk of 8.19×10^{-4}. 65 Fed. Reg. at 21606 (JA 32).

EPA's acceptable risk range.[394] Given EPA's position that rounding is acceptable, there is no basis for EPA to distinguish between the 1976 and 1991 Rules based on risk.[395]

For each of the foregoing reasons, the Court should remand the beta/photon MCLs.

III. EPA VIOLATED THE ADMINISTRATIVE PROCEDURE ACT BY FAILING TO RESPOND TO COMMENTS THAT A LINEAR NON-THRESHOLD MODEL DOES NOT ACCURATELY ESTIMATE THE RISKS FROM EXPOSURE TO LOW DOSES OF IONIZING RADIATION.

EPA failed to respond adequately to the comments challenging EPA's use of a LNT model. Section 553(c) of the APA requires agencies to provide a concise and general statement of the rule's "basis and purpose."[396] The "basis and purpose statement is inextricably intertwined with the receipt of comments."[397] Indeed, "the opportunity to comment is meaningless unless the agency responds to significant points raised by the public."[398] While EPA is not required to refute every piece of evidence presented, EPA "must 'respond in a reasoned manner to the comments received, to explain how the agency resolved any significant problems raised by the comments, and to show how that resolution led the agency to the ultimate rule.'"[399] The detail required "depends on the subject of the regulation and the nature of the

---

[394] In contrast, three radionuclides on the 1976 Line (I-134, Te-131 and Ca-45) fall *below* EPA's de minimus risk target.

[395] Even if the average of the 1991 concentration limits is higher than the average of the 1976 limits, such a comparison is meaningless. Humans are not exposed to an "average" of these 168 radionuclides; they are exposed to individual radionuclides at particular doses.

[396] 5 U.S.C. § 553(c).

[397] *Action on Smoking & Health*, 699 F.2d at 1216 (quoting *Rodway v. United States Dep't of Agric.*, 514 F.2d 809, 817 (D.C. Cir. 1975)).

[398] *Am. Civil Liberties Union v. FCC*, 823 F.2d 1554, 1581 (D.C. Cir. 1987) (quoting *Alabama Power Co. v. Costle*, 636 F.2d 323, 384 (D.C. Cir. 1979)).

[399] *Action on Smoking & Health*, 699 F.2d at 1216 (quoting *Rodway*, 514 F.2d at 817).

comments received."[400] "[A]n agency decision may not be reasoned if the agency ignores vital comments regarding relevant factors, rather than providing an adequate rebuttal."[401]

EPA used the LNT default assumption to characterize the dose-response relationship for radionuclides to set the MCLG and in the FGR-13 model.[402] As described above, the LNT model characterizes health effects as having a linear relationship to dose all the way to zero exposure, based on the assumption that all exposures result in adverse health effects, and on epidemiological data from exposure to high doses of radiation.[403] EPA provides no direct support for its default assumption of linearity for low dose exposures to ionizing radiation, and concedes there is no confirmed human epidemiological data supporting the LNT based on low levels of exposure.[404]

In light of the statutory requirement that EPA use the "best available science" when establishing MCLs and MCLGs, various members of the public (including Waukesha, NMA, and RSH) commented on the inadequacy of the LNT model to support the drinking water standards. These comments provided evidence that EPA's assumptions of harmful effects of radiation at low doses are speculative and not based on the best available science, "cast[ing]

---

[400] *Id.*; *see also Cent. & S. W. Serv., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000), *cert. denied*, 532 U.S. 1065 (2001); *Reytblatt v. NRC*, 105 F.3d 715, 722 (D.C. Cir. 1997).

[401] *W. Coal Traffic League v. United States*, 677 F.2d 915, 927 (D.C. Cir. 1982) (citations omitted); *see, e.g., St. James Hosp. v. Heckler*, 579 F. Supp. 757, 765 (N.D. Ill. 1984), *aff'd*, 760 F.2d 1460, 1470 (7th Cir. 1985) ("[W]here apparently significant information has been brought to its attention . . . or substantial issues of policy or gaps in its reasoning raised, the statement of basis and purpose must indicate why the agency decided the criticisms were invalid.") (citation omitted).

[402] EPA also incorporates this LNT assumption in the FGR–13 model used to assess risks when calculating the MCLs.

[403] *See supra* at 5.

[404] *Id.* As discussed above, EPA guidance provides that the Agency will use the LNT model when (1) there is evidence of linearity, or (2) there is insufficient evidence of non-linearity. Here, EPA does not contend that there is evidence supporting linearity, only that there is insufficient evidence of non-linearity.

doubt on the reasonableness of the rule the agency adopt[ed]."[405] EPA was required to provide an adequate response to these comments because the comments went directly to EPA's reliance on a model it uses to support the standards promulgated, and challenge the lawfulness of the proposed rule.[406]

EPA, however, failed to respond adequately to the significant issues raised by these comments. In response to the Petitioners' significant comments providing peer-reviewed scientific data, EPA simply made general, blanket assertions about the perceived inadequacy of the data to support a non-linear dose-response, and reiterated its assumptions supporting the LNT. EPA's comments did not, therefore, provide a reasoned analysis of the issues raised, nor an explanation as to how it resolved those issues. In particular, EPA did not adequately respond to (1) comments criticizing the use of a linear model for low doses based on extrapolation of data from high dose exposures, (2) comments refuting EPA's assumption that any exposure to radionuclides results in adverse health effects, and (3) comments providing substantial evidence of beneficial effects to low-dose radiation exposures.

A. EPA DID NOT ADEQUATELY RESPOND TO COMMENTS DISPUTING THE USE OF THE LNT MODEL BY PROVIDING BLANKET STATEMENTS SUPPORTING ITS USE OF THE LNT MODEL.

EPA's responses to comments on the LNT were lumped into various general and generic statements that do not provide a reasoned analysis of significant issues raised by commenters.[407] For example, EPA provided blanket statements that information submitted "was familiar to the agency and . . . had already been considered," that "submissions cite anecdotal or case report

[405] *Baltimore Gas & Elec. Co. v. United States*, 817 F.2d 108, 116 (D.C. Cir. 1987) (citation omitted).

[406] *See, supra* n.79-82.

[407] *See, e.g., Abington Mem'l Hosp. v. Heckler*, 576 F. Supp. 1081, 1086 (E.D. Pa. 1983), *aff'd*, 750 F.2d 242 (3d Cir. 1984) (finding responses inadequate where agency addressed points raised by commenters in a highly conclusory fashion).

data," and that the "submissions do not provide the kind of data that EPA discusses in the remainder of this response and that the Agency considers to be necessary for determining environmental risk."[408] The "remainder of this response," however, merely reasserts EPA's speculative assumptions justifying its use of the LNT. For example, EPA restates its single "wild" cell assumption, which is based on the effects of irradiating isolated cells in a culture dish rather than studies of whole organisms, to support its assertion that "there can be no threshold for radiation induced mutations."[409] EPA then bootstraps this response by assuming its conclusion that the LNT model allows extrapolation of low-dose cancer risks from high-dose exposures.[410] Such comments do not provide a reasoned analysis explaining how the agency resolved the issues raised. Based on the detailed and numerous studies cited by commenters, EPA's blanket unsupported statements restating the agency's assumptions, do not rise to the scope and detail required under Section 553(c) of the APA, and the Final Rule is arbitrary and capricious.

B. EPA FAILED TO RESPOND ADEQUATELY TO COMMENTS REFUTING EPA'S ASSUMPTION THAT THE CARCINOGENIC MODEL FOR LOWER EXPOSURES TO RADIATION IS LINEAR BASED ON DATA FROM HIGH DOSE EXPOSURES.

Petitioners provided detailed comments refuting EPA's default assumption of linearity and its reliance on data for intermediate to high-dose exposures for atomic bomb survivors, and from the results of experiments on cells. Petitioners' comments on the LNT model demonstrate

[408] CRD-NODA at 3-5 (Comment 3.A.1) (JA 938). Indeed, EPA's response to NMA's detailed comments was to see the response to comment 3.A.1. *Id.* at 3-55 (Comments 3.B.56, 3.B.57) (JA 988). Comment 3.A.1 generally states that EPA's default assumptions are inapplicable where there is evidence of a non-zero threshold, and that the data indicates that a quadratic model should be used. NMA's comments, on the other hand, provide specific, detailed examples of actual data that establish the inapplicability of the LNT for low doses, directly refuting EPA's assumptions. EPA's generalized response is inadequate to explain why EPA chose to continue to rely on its assumptions in light of this contradictory evidence.

[409] CRD-NODA at 3-5 (Comment 3.A.1) (JA 938).

[410] CRD-NODA at 3-5 to 3-6 (Comment 3.A.1) (JA 938-939).

that the great weight of the scientific evidence for the actual health effects of exposures to whole organisms establishes that the LNT is inapplicable for low-dose exposures. For example, Petitioners' comments noted that various members of the scientific community have expressly stated that the "current mode of extrapolating high-dose to low-dose effects is erroneous for . . . radiation. Safe levels of exposure exist."[411] In response to comments, EPA generally referred back to its assumptions to support its use of the LNT. EPA simply disregarded direct evidence provided by the Petitioners in favor of its more speculative assumptions.[412]

Petitioners submitted comments supported by peer-reviewed studies that showed the LNT model does not adequately reflect the actual data on the effects of low-dose radiation exposures,[413] and that support a non-linear model.[414] The comments presented studies of data on the effects of low dose radiation exposures, which "show many clear instances where the relation is nonlinear and none in which linearity is unquestionably demonstrated," or indicate a non-linear threshold is more probable.[415] For example, one study cited in Petitioners' comments,

---

[411] CRD-NODA at 3-43 (Comment 3.B.42) (JA 976).

[412] *See, e.g., Leather Indus. of Am. Inc.*, 40 F.3d at 402-03 (finding EPA's reliance on assumptions arbitrary where record contained contradictory information); *Prof'l Pilots Fed'n v. FAA*, 118 F.3d 758, 771 (D.C. Cir. 1997) (in dissent) ("neither may a court sanction agency action when the agency merely offers conclusory and unsupported postulations in defense of its decisions or when it ignores contradictory evidence in the record and fails to justify seeming inconsistencies in its approach") (citations omitted).

[413] *See, e.g.,* CRD-NODA at 3-27 (Comment 3.B.24) (referring to Comments 3.A.1, 3.B.3, 3.B.5, and 3.B.23) (JA 960).

[414] In an analogous case, this Court reversed and remanded a regulation issued by the Occupational Safety and Health Administration ("OSHA") for failure to apply the best available science because OSHA rejected the use of a linear model despite the fact that the data available supported a linear model. *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. v. Pendergrass*, 878 F.2d 389 (D.C. Cir. 1989). In this case, EPA ignored evidence presented that indicates the data for low-dose exposures support a non-linear model. EPA, however, used the linear default assumption, despite having no scientific support for the model.

[415] Austin M. Brues, *Critique of the Linear Theory of Carcinogenesis*, Science, at 693, 698 (Sept. 1958) (contained in RSH Comments, Attachments) (DI I-I2-07) (JA 737); *see also* Radiation, Science & Health,

(continued)

which claimed to support the LNT, found that the LNT overestimated the cancer risk for low dose exposures.[416] The actual data reported in this study showed that there was a 33 percent reduction of cancer among the subjects exposed to a low level of ionizing radiation compared to the lowest dose group.[417]

Other studies provided in the comments similarly found no increased risk of cancer for low dose exposures.[418] This evidence directly refutes EPA's assumption that a linear dose relationship at high exposures can be extrapolated to lower exposures. In other words, EPA's model is not supported by empirical data.[419] EPA, however, never responds to these studies, other than with blanket statements supporting the LNT.

Similarly, Waukesha submitted evidence on radium that indicated, based on the data available, that the linear default assumption should be replaced with a non-linear, (quadratic) model with a threshold.[420] EPA's response to this comment, however, never addresses the applicability of a non-linear model, and EPA merely reiterates its default assumptions. EPA's

---

(continued)
Inc., Low Level Radiation Health Effects: Compiling the Data, § 1.2.1.1, at 4-6, § 1.2.2.1, at 5, § 1.2.3.2, at 1, § 1.2.6.3, at 4 (1998) ("Compiling the Data") (contained in RSH Comments, Attachments) (JA 691-693, 705, 711, 728).

[416] *See* CRD-NODA at 3-27 (Comment 3.B.24) (JA 960).

[417] *See id.* (JA 960). Applying the LNT, the study "predicted" an excess of breast cancer cases for a low-level exposure, contrary to its own data. *See id.* (JA 960).

[418] *See, e.g.,* Compiling the Data, § 1.2.1.1, at 4-6, § 1.2.2, at 1-2, 9, § 1.2.2.1, at 1, 5-7, § 1.2.2.2, at 1-2, § 1.2.3.2, at 1, § 1.2.6.3, at 4 (JA 691-693, 695-696, 699-700, 705-707, 709-711, 728); *see also* CRD-NODA at 3-21 (Comment 3.B.15) (JA 954) (a study of more than 100,000 female radiologic technicians found no association for breast cancer to experience in medical procedures using radiation, and "BEIR V reports that prostate cancer in radiologists with estimated lifetime exposures . . . showed no excess").

[419] *See Columbia Falls Aluminum Co.,* 139 F.3d at 923.

[420] CRD-NODA at 3-10 to 3-13 (Comment 3.B.3) (JA 943-946) (Waukesha). Other public comments similarly indicate that a non-linear model reflects the best available science for low dose exposures to radiation. *See id.* at 3-16 to 3-17, 3-52, 3-56, 3-58 (Comments 3.B.9, 3.B.54, 3.B.58, and 3.B.62) (JA 949-950, 985, 989, 991).

response does not provide the required analysis and reasoned explanation to support its regulation.

Petitioners also provided comments disputing EPA's reliance on data from Japanese atomic bomb survivors to support the default assumption of linearity. Because these individuals were directly exposed to the near-instantaneous radiation from an atomic bomb detonation with both neutron and gamma-ray components and because the war-time conditions caused uncertainty in attributing radiation exposure to health effects, Petitioners questioned the applicability of the Japanese atomic bomb survivors data.[421] Due to these stark differences and the substantial uncertainty regarding doses, Petitioners argued that this data should not be relied on to reflect the effects of low-dose, low-dose-rate, chronic exposures to ionizing radiation.[422] Although EPA acknowledges the uncertainties of using the LNT for low-dose exposures,[423] EPA fails to address these uncertainties or to provide any defense for its continued use of the LNT model.

Moreover, in its comments, RSH provided EPA with direct evidence that the atomic bomb survivor data does not reflect a linear relationship for low doses.[424] RSH also presented studies that applied the epidemiological data from atomic bomb survivors to estimate the effects of the 1986 Chernobyl accident, which demonstrated the "absurdity of the LNT."[425] These

---

[421] *See* RSH Comments at 28-29 (JA 660-661).

[422] *See* Zbigniew Jaworowski, *Radiation Risk and Ethics*, Physics Today, at 24, 27 (Sept. 1999) (contained in RSH Comments, Attachments) (JA 742).

[423] 65 Fed. Reg. at 21600.

[424] CRD-NODA at 3-35 to 3-36 (Comment 3.B.33) (JA 968-969); Compiling the Data, § 1.2.1, at 1, § 1.2.1.1, at 2-7 (JA 689-694); T.D. Luckey, *Radiation Hormesis in Cancer Mortality*, 3 Int'l J. of Occupational Med. & Toxicology 175, 192 (1994) (JA 762) (contained in RSH Comments, Attachments).

[425] Jaworowski, *supra*, at 27 (JA 742) (contained in RSH Comments, Attachments).

studies are in direct conflict with EPA's default assumption, but EPA never addresses them in response to comments.[426]

Instead, EPA simply refers back to several general responses to comments that merely make blanket statements or were made in response to unrelated studies. For example, one of EPA's most cited responses refers to radium dial painter studies, noting only that these studies, while "interesting" are of "limited value for the estimation of risk" because of uncertainties in the methodology,[427] which allegedly affect the development of a dose-response relationship.[428]

Nowhere does EPA respond to numerous comments that indicate that the LNT model is inappropriate with respect to effects of low doses of radiation, which are not based on the radium dial painter studies cited by EPA.[429] As an example, EPA's response to comment 3.B.5. refers to a study cited by Waukesha that was not relied upon by RSH and was based on data unrelated to studies cited by RSH.[430] Many of EPA's responses to RSH's comments similarly refer to this same response to an unrelated comment. In particular, none of these statements addresses the

---

[426] *See, e.g., Action on Smoking & Health*, 699 F.2d at 1217 ("to uphold the agency's action, it must be shown that the [agency] rationally considered the relevant evidence"); *see also Am. Mining Cong. v. EPA*, 907 F.2d 1179, 1189 (D.C. Cir. 1990) (finding EPA's failure to address criticisms of studies and reliance on conclusory statements to support agency action was inadequate).

[427] 65 Fed. Reg. at 76721; *see also* CRD-NODA at 3-11 to 3-12 (Comment 3.B.3) (JA 944-945). In the preamble to its proposed rule and in response to the Science Advisory Board's recommendations to apply the radium dial painter data, EPA recognized that "use of the dial painters data requires either deriving a linear risk coefficient from significantly non-linear exposure-response data, or abandoning EPA policy [to apply an LNT dose-response relationship]." 56 Fed. Reg. at 33055. *See* Section II.A.2.

[428] 65 Fed. Reg. at 76721. One of these alleged uncertainties is that the "dose estimates are speculative." CRD-NODA at 3-11 to 3-12 (Comment 3.B.3) (JA 944-945). RSH's submission addressed these concerns. RSH, Compiling the Data, DI I-I-1-29, § 1.2.4.1, at 1-9 (JA 716-724). For example, RSH provided updates to these early studies that refined the radium dial painter data, and further supported the assertion that there is a hard threshold. *Id.* Again, EPA does not provide any response to these data, and appears to have ignored these findings.

[429] *See, e.g.,* CRD-NODA at 3-20 to 3-21 (Comments 3.B.14, 3.B.15, referring to EPA Responses 3.A.1, 3.B.3, 3.B.5) (JA 953-954).

[430] CRD-NODA at 3-14 (Comment 3.B.5) (JA 947).

numerous studies of occupational exposures cited by RSH that have found no adverse risk to health at lower exposures of radiation.[431]

EPA also fails to respond to criticisms of the use of the LNT model found in documents EPA relied upon in support of its rulemaking. RSH cited to statements found in these documents that acknowledge that the LNT might be inapplicable at low-doses and the existence of data demonstrating the beneficial effects of low-dose radiation.[432] EPA merely states that it "disagrees" and refers to its famous litany of generalized responses.[433]

EPA purports that "[i]n the absence of more direct information" it is appropriate to use data at high exposures to estimate what the effects could be at lower exposures.[434] EPA then ignores the numerous studies that *do* provide more direct information, without providing a reasoned analysis or explanation of why it has ignored these studies, to support its reliance on its default assumption. EPA's failure to consider or provide a reasoned response to these comments is arbitrary and capricious.

---

[431] *See* CRD-NODA at 3-45 to 3-47 (Comment 3.B.45) (JA 978-980).

[432] *See* CRD-NODA at 3-41 (Comment 3.B.40) (JA 974). EPA notes, for example, that its application of the LNT is consistent with the recommendations of the National Academy of Sciences Committee on the Biological Effects of Ionizing Radiation ("BEIR") and the National Council on Radiation protection and Measurements ("NCRP"). 65 Fed. Reg. at 76721. RSH, as well as others, provided several criticisms of the conclusions of these organizations. *See, e.g.,* RSH Comments at 11-12, 29-30 (JA 643-644, 661-662); *see also* Compiling the Data, § 1.2.2.1, at 2-4, § 1.2.3.2, at 4-5 (JA 701-703, 714-715). As noted in RSH's comments, "[F]ew experimental studies, and essentially no human data, can be said to prove or even to provide direct support for the concept," at most "a linear non-threshold dose-response relationship cannot be excluded." RSH Comments at 1 (JA 633). EPA does not provide a response to these criticisms. CRD-NODA at 3-39, 3-41 (Comments 3.B.37, 3.B.39, 3.B.40) (JA 972-974).

[433] CRD-NODA at 3-41 (Comments 3.B.39, 3.B.40) (JA 974).

[434] 65 Fed. Reg. at 76720 (citation omitted).

C. EPA FAILED TO RESPOND TO COMMENTS PROVIDING EVIDENCE OF AN ACTUAL THRESHOLD FOR RADIONUCLIDES.

Petitioners also provided comments containing evidence of an actual threshold of risk for radionuclides, refuting EPA's speculative assumption that all radionuclides have a zero threshold. In response, EPA merely reiterates its assumption that any amount of radiation from any radionuclide can result in cancer.[435] Such a response is inadequate.[436]

EPA's assumption is based on the premise that, because radiation has been shown to induce transformations in cells in culture, damage to a single cell can lead to cancer.[437] EPA then concludes that "[w]hile much of this cellular damage is repaired by the body," an increased exposure to radiation leads to an increase in the risk of cancer or harmful genetic mutations.[438] EPA's claim that a single "hit" to a cell from radiation can lead to a cancer is contradicted by credible data in the record.

RSH provided extensive comment that studies based on cells in culture are not adequate to determine effects of radiation on a "whole organism." Carcinogenesis is a complex multi-step process involving tissue-level failures as a failure of cell society, not of an individual cell.[439] RSH's comments criticize the use of the LNT as a physics-based model to address biological effects.[440] EPA fails to address this important criticism.

---

[435] *See, e.g.,* CRD-NODA at 3-5 to 3-6, 3-18 to 3-20 (Comments 3.A.1, 3.B.12) (JA 938-939, 951-953).

[436] *See, e.g., Am. Forest & Paper Ass'n, Inc. v. EPA*, No. 93-CV-0694(RMU), 1996 U.S. Dist. LEXIS 13230, at *26 (D.D.C. Sept. 4, 1996) (finding EPA failed to adequately respond to comments because its "response" was "a mere restatement of EPA's assumption").

[437] *See* 65 Fed. Reg. at 76721; *see also* CRD-NODA at 3-5 to 3-6 (Comment 3.A.1) (JA 938-939).

[438] *See* 65 Fed. Reg. at 76720.

[439] *See* RSH Comments at 30-32 (JA 662-664); *see also* RSH Comments, Attachments at 14 (JA 677).

[440] *See* CRD-NODA at 3-34 (Comment 3.B.32) (JA 967).

In addition, EPA's analysis ignores scientific studies finding an actual threshold below which exposure to ionizing radiation does not adversely affect human health.[441] Petitioners provided evidence of studies that determined an actual threshold where radiation exposure would not lead to adverse health effects exists.[442] For example, RSH submitted extensive studies that found a threshold of 1,000 rad (50 million pCi) for radium,[443] and a study using more refined data on radium dial painters that reports an estimated threshold of 1,100 rad.[444] EPA responded to these various studies with the same blanket statements it made in reference to comments by Waukesha.[445] None of these statements addresses the use of this data to support a finding of an actual threshold. EPA simply failed to respond, and, seemingly, consider the results of these studies.[446]

EPA never responds directly to comments that the best available science supports an actual threshold below which no harm occurs. Instead, EPA attempts to sidestep the issue with a response to an unrelated theory of a practical threshold. In comparison to an actual threshold, a level below which no harm occurs, a practical threshold assumes harm occurs, but the latency

---

[441] *See* CRD-NODA at 3-10 to 3-13 (Comment 3.B.3) (JA 943-946) (citing to scientific findings, which are based on data from radium dial painters, that concluded "the threshold value below which the effect of ingesting radium does not adversely effect human health, should be some value greater than zero.").

[442] *See* CRD-NODA at 3-18 to 3-20 (Comment 3.B.12) (JA 951-953).

[443] *See id.* The fifty million pCi of internal radium, which is associated with ingestion of 250 million pCi of radium from drinking water, can be compared to EPA's limit of 5 pCi/L for radium, which is associated with ingestion of 2,000 pCi.

[444] *See id.* One thousand rad equates to a dose of 3-20 million millirem. This number can be compared to EPA's basis for dose limits of 4 millirem per year.

[445] *See* CRD-NODA at 3-20 (Comment 3.B.12, referring to EPA Responses 3.A.1, 3.B.3 and 3.B.5) (JA 953).

[446] *See, e.g., Action on Smoking & Health*, 699 F.2d at 1219 (finding failure to address proposal made in public comments "plainly disregards the agency's obligation to respond to the major comments received in rulemaking").

period for any cancer exceeds the normal human life span.[447] The practical threshold theory is a hypothesis that has been asserted to explain the lack of observed radiation health effects at low doses to be consistent with the LNT. RSH provided evidence that exposure to low doses of ionizing radiation does not cause harm (*i.e.*, there is an actual threshold).[448] EPA's only response rejects the theory of a practical threshold. EPA, therefore, never responds to RSH's comments that available scientific evidence supports a non-zero actual threshold. EPA's failure to provide any response to comments and data supporting the existence of an actual threshold is contrary to the requirements of Section 553(c) and is arbitrary and capricious.

D. EPA FAILED TO PROVIDE AN ADEQUATE RESPONSE TO COMMENTS THAT LOW DOSES OF RADIATION HAVE BEEN DEMONSTRATED TO PROVIDE MEDICAL BENEFITS.

RSH provided evidence of numerous studies of medical and occupational exposures that indicate low doses of radiation are not necessarily harmful, but can provide medical and health benefits.[449] Comments included studies that concluded these beneficial effects resulted from strengthening mechanisms by which organisms prevent and cure cancer, infections, and inflammation diseases.[450] These studies note that the demonstrable beneficial effects at low doses indicate that the use of the LNT to estimate risk for low-dose exposures to radiation is,

---

[447] 65 Fed. Reg. at 76721-22; *see also* CRD-NODA at 3-11 to 3-13 (Comment 3.B.3) (JA 944-946).

[448] EPA also asserts that these studies only relate to a practical threshold for bone cancer and not other risks, including nasal cancer. *See* CRD-NODA at 3-11 to 3-13 (Comment 3.B.3) (JA 944-946). The data provided by RSH, however, includes nasal cancers. Compiling the Data, § 1.2.4.1, at 1-9 (JA 716-724). In addition, other studies provided by RSH concluded that, except for a slight increase in breast cancers not associated with ingested radium, no such increase in other cancers were found among population of persons with internal body-burdens of radium-226 and radium-228. *See id.*, § 1.2.4.2, at 2 (JA 725). Again, EPA has apparently ignored the weight of the evidence provided by RSH.

[449] RSH Comments at 18-20, 27-28 (JA 650-652, 659-660); RSH Comments, Attachment at 1-8 (JA 665-671).

[450] RSH Comments, Attachment at 8-16 (JA 671-679).

"undoubtedly, wrong."[451] In response, EPA again provides only general statements that do not show a reasoned analysis of the evidence presented related to the potential "beneficial effects" of radiation.[452]

EPA characterizes these beneficial effects as "hormesis" – "small doses of radiation are good for you" – and "adaptive response" – "relatively small doses of radiation protect against large doses of radiation."[453] Rather than address the issues raised by these comments, EPA simply asserts that "based on available science, these phenomena are irrelevant to environmental radiation protection."[454] Frankly, this is a puzzling response. In this rulemaking, EPA establishes the MCLGs at zero based on an assumption that any non-zero exposure causes adverse health effects. Given this assumption, it is hard to imagine how the agency concludes that studies showing exposures to low doses in fact provide medical or health benefits are "irrelevant."

EPA never responds to studies provided in RSH's comments that found medical or health benefits related to low-dose exposures. For example, RSH cited to a study of medical patients exposed to low levels of ionizing radiation which found beneficial effects.[455] RSH provided other studies that show beneficial effects of low dose exposures of radiation related to *occupational* exposures.[456] In response to this evidence, EPA merely refers to a response

---

[451] Compiling the Data, § 1.4, at 6 (JA 729).

[452] *See, e.g.,* CRD-NODA at 3-22 to 3-23, 3-24, 3-26 (Comments 3.B.16, 3.B.17, 3.B.18, 3.B.22) (JA 955-957, 959).

[453] 65 Fed. Reg. at 76722.

[454] CRD-NODA at 3-22 (Comment 3.B.16) (JA 955); *see also* 65 Fed. Reg. at 76722.

[455] CRD-NODA at 3-31 to 3-32 (Comment 3.B.28) (JA 964-965).

[456] *See* CRD-NODA at 3-36 (Comment 3.B.34, "More recent studies that confirm successful treatment of cancer by [low dose radiation]") (JA 969); *Id.* at 3-37 (Comment 3.B.35, studies of nuclear workers showing "adaptive response") (JA 970).

addressing *ecological* studies and to general statements that do not address the conclusions reached by these studies.[457] Indeed, none of EPA's responses ever addresses the peer-reviewed studies that show that there is no adverse effect of radiation at low-dose occupational exposures. EPA then ignores the many studies that demonstrate that low dose exposure to radiation is beneficial.

EPA's failure to provide adequate reasoning (or any reasoning with respect to certain studies) to support its contrary conclusion with respect to the potential beneficial effects of low-dose occupational exposure to radiation violates the requirement of Section 553(c), and is arbitrary and capricious.

CONCLUSION AND RELIEF SOUGHT

For the foregoing reasons, the Court should remand the radium and beta/photon MCLs and vacate and remand the uranium MCLG and MCL.

[457] *See* CRD-NODA at 3-32 (Comment 3.B.28, referring to Comment 3.B.23) (JA 965); *Id*. at 3-36 to 3-37 (Comments 3.B.34 and 3.B.35, referring to Comments 3.A.1, 3.B.3, 3.B.5, and 3.B.23) (JA 969-970).

Dated: October 17, 2002

Respectfully submitted,

John N. Hanson, Esq.
Brian L. Doster, Esq.
Justin A. Savage, Esq.
Beveridge & Diamond, P.C.
1350 I Street, N.W., Suite 700
Washington D.C. 20005-3311
(202) 789-6000
Counsel for Petitioner, City of Waukesha

Curt R. Meitz, Esq., City Attorney
Vincent D. Moshcella, Esq., Asst. City Atty.
City of Waukesha
201 Delafield Street
Waukesha, WI 53188-3616

Donald P. Gallo, Esq.
Pamela Schaefer, Esq.
Reinhart, Boerner, Van Deuren, Norris & Rieselbach, S.C.
1000 North Water Street
Milwaukee, WI 53203-3400
Counsel for Petitioner, City of Waukesha and Bruce Zivney

David C. Lashway, Esq.
Shaw Pittman LLP
2300 N Street, N.W.
Washington, D.C. 20037
Counsel for National Mining Association

Katie Sweeney, Esq.
Associate General Counsel
National Mining Association
101 Constitution Ave., N.W., Suite 500
Washington, D.C. 20001

Anthony J. Thompson, Esq.
Law Offices of Anthony J. Thompson, P.C.
1225 19th Street, N.W., Suite 200
Washington, D.C. 20036
Counsel for National Mining Association

Michael B. Wigmore, Esq.
Swidler Berlin Shereff Friedman, LLP
3000 K Street, N.W., Suite 300
Washington D.C. 20007
Counsel for Radiation, Science & Health, Inc.

Jean V. MacHarg, Esq.
John C. Martin, Esq.
Susan M. Mathiascheck, Esq.
Patton Boggs LLP
2550 M Street, N.W.
Washington, D.C. 20037-1350
Counsel for Nuclear Energy Institute

Robert W. Bishop, Esq.
Ellen C. Ginsburg, Esq.
Nuclear Energy Institute
1776 I Street, N.W., Suite 400
Washington, DC 20006-3708

H. Stanley Riffle, Esq.
Arenz, Molter, Macy & Riffle
720 N. East Avenue
P.O. Box 1348
Waukesha, WI 53186-1348
Counsel for Intervenor for Petitioner, Village Of Sussex Water Commission

Phillip J. Eckert, Esq.
O'Meara Law Firm, LLP
622 Elm Street
West Bend, WI 53095-0348
Counsel for Intervenor, Village of Hustisford

Paul F. Reilly, Esq.
City Attorney
City of New Berlin
720 Clinton Street
Waukesha, WI 53187
Counsel for Intervenor, City of New Berlin

John S. Noble, Esq.
City Attorney
Weiler & Noble, P.C.
425 Williamsburg Avenue
Geneva, IL 60134
Counsel for Intervenor, City of Batavia, Illinois

Richard M. Glidden, Esq.
Law Office of Richard M. Glidden
522 Chief Street
P.O. Box 738
Benkelman, NE 69021
Counsel for Intervenor, City of Benkelman, Nebraska

Suzanne K. Schalig, Esq.
City Attorney
City of Brookfield
2000 North Calhoun Road
Brookfield, WI 53005
Counsel for Intervenor, City of Brookfield

Dennis M. Duffy, Esq.
Wieting, Calewarts, Duffy & Maxwell
716 Pine Street
Green Bay, WI 54305
Counsel for Intervenor for Petitioner, Village of Ashwaubenon

William Von Arx, Esq.
Von Arx Law Office
218 South Kingston Street,
Caledonia, MN 55921
Counsel for Intervenor, City of La Crescent

James B. Harvey, Esq.
McKeown, Fitzgerald, Zollner, Buck, Hutchison & Ruttle
2455 Glenwood Avenue
Joliet, IL 60435
Counsel for Intervenor, Village of Plainfield, Illinois

CERTIFICATE OF COMPLIANCE

Pursuant to Circuit Rule 28(d)(1), I hereby certify on this 17th day of October, 2002 that the foregoing "Joint Brief of Petitioners" contains 27,998 words, as counted by a computer word processing system.

_____
Brian L. Doster