Science in Regulation:
A Study of Agency Decisionmaking Approaches

APPENDICES

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Appendix A

The United States Nuclear Regulatory Commission's
Use of Scientific and Technical Advisory Committees

- Roland M. Frye, Jr.[1]

Advisory committees have played, and continue to play, a major role at the United States Nuclear Regulatory Commission's (NRC) analysis of scientific and technical issues. Even though the Commission[2] and the NRC staff do not always follow the recommendations of the agency's advisory committees, the Commission and its staff have never failed to at least consider a relevant advisory committee's recommendations.[3]

The Commission currently has only three active advisory committees chartered under the Federal Advisory Committee Act (FACA)[4] – the Advisory Committee on Reactor Safeguards (ASRS), the Advisory Committee on Medical Use of Isotopes (ACMUI), and the Licensing Support Network Advisory Review Panel (LSNARP).[5] The first two of these advisory committees are comprised of technical experts. The ACRS reports to and meets with both the Commission and the staff, while the ACMUI reports only

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[1] Senior Attorney, United States Nuclear Regulatory Commission, on detail to the Administrative Conference of the United States (ACUS). The contents of this paper do not necessarily reflect the views of either the NRC or ACUS. I would like to thank particularly Dr. Andrew Bates of the NRC's Office of the Secretary, Mr. Bradley Jones of the NRC's Office of the General Counsel, and Mr. Dan Glaser of the NRC's Atomic Safety and Licensing Board Panel for the wealth of knowledge that they generously shared with me during my preparation of this paper.

[2] For purposes of this paper, I follow the agency's own practice of using the word "Commission" when referring to the Commissioners in their collective capacity as agency head.

[3] Roland Frye's interview with Dr. Andrew Bates, Office of the Secretary, NRC (Oct. 27, 2011) (Bates interview). Dr. Bates is the NRC's Advisory Committee Management Officer and, in that capacity, manages all of the NRC's FACA advisory committees. An interview summary, approved by Dr. Bates, is included in "Attachment A" to this paper.

The only arguable exception occurred after the 9/11 terrorist attacks, when the Commission was considering significant security issues. The ACRS asked the Commission if it wished the committee's advice on reactor-related security issues. The Commission responded that it did want the ACRS's thoughts on those issues, but only to the extent those issues would affect reactor safety. The Commission was not, strictly speaking, refusing in that instance to use the ACRS in an area where it had expertise (nuclear reactor safety) but only where the committee lacked expertise (nuclear facility security). Bates interview.

[4] 5 U.S.C. app. I.

[5] Bates interview.

to the NRC staff and generally meets with the Commission once per year.[6] The third committee is not comprised of technical experts but instead includes representatives of various constituencies with interests in the High-Level Waste Repository adjudication.[7] I include it, however, because it addresses issues of computer science. This committee reports only to the staff.

Other advisory committees previously reported to the Commission but are now defunct, and still others report (or reported) to only the NRC staff. I also examine certain other advisory committees that either are defunct or were not chartered under FACA, because they shed at least some light on how the Commission uses or has used its expert scientific/engineering advisory committees. For purposes of completeness, I describe one now-defunct advisory committee (the Advisory Committee of State Officials) that addressed the transfer of materials regulation responsibilities to the states, even though the committee did not directly consider scientific or technical issues.[8] All but five of the committees described in this paper were comprised of technical or scientific experts; the membership of the remaining three was determined by constituency rather than expertise.[9] For each of the committees considered herein, I have included (where available) information regarding its lifespan, purposes, membership, whether it was chartered under FACA, the entity to whom it reports or reported, and its involvement (*vel non*) in rulemakings.

In the realm of reactor regulation, the Commission has for decades used the ACRS – a committee that, by its charter, reports directly to the Commission.[10] By contrast, the Commission's use of advisory committees in the field of materials regulation has either been for a shorter time period or imposed no obligation to report to the Commission itself. The Commission established the ACMUI in

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[6] E-mail from Andrew Bates to Roland Frye (Dec. 8, 2011 2:17 p.m.).

[7] *U.S. Department of Energy* (High-Level Waste Repository), NRC Docket No. 63-001-HLW (*Yucca Mountain*).

[8] I have limited my discussion to committees that, at least to some degree, focused their attention on scientific or technical issues. This has resulted my excluding a plethora of non-technical advisory committees. *E.g.*, Advisory Committee for African Americans, Advisory Committee for Employees with Disabilities, Asian/Pacific American Advisory Committee, Diversity Advisory Committee on Ageism, Federal Women's Program Advisory Committee, Hispanic Employment Program Advisory Committee, and Native American Advisory Committee.

[9] Those five committees were/are the LSNARP (*see* Part I.C, *infra*), the Advisory Panel for the Decontamination of Three Mile Island, Unit 2 (*see* Part II.B, *infra*), Pilot Program Evaluation Panel (*see* Part II.C, *infra*), the Reactor Oversight Process Initial Implementation Evaluation Panel (*see* Part II.D, *infra*), and the Advisory Committee of State Officials (*see* Part IV.A, *infra*).

[10] *See* Part I.A, *infra*. In the realm of reactor regulation, the Commission has also used the following FACA-chartered committees: the Advisory Panel for the Decontamination of Three Mile Island, Unit 2 (*see* Part II.B, *infra*), the Pilot Program Evaluation Panel (*see* Part II.C, *infra*), the Reactor Oversight Process Initial Implementation Evaluation Panel (*see* Part II.D, *infra*)

1958 and provided that it report to the NRC staff rather than directly to the Commission.[11] The Commission created the Advisory Committee on Nuclear Waste (ACNW) in 1988 to address the regulation of radioactive materials, but rescinded the ACNW's charter in 2008.[12] Subsequently, the Commission assigned the ACNW's duties to the ACRS.[13]

In addition to using these three advisory committees to address materials licensing issues, the Commission also uses "working groups" that can include outside experts (such as a medical advisor), the relevant NRC offices, and also the agreement states (i.e., those states that have signed agreements with the NRC to regulate materials licensees within their borders according to the Commission's own standards). These working groups do not include licensees or public interest groups, though the working groups may choose to hold public meetings to get comments in developing a rule, and may choose to share draft rule language with the public in order to facilitate public meetings.[14]

Further information on individual committees is available in the Commission's annual reports on each existing advisory committee, and may be found on the Commission's website (www.nrc.gov).[15] I have also included the specific URL for the webpage of each committee that has one.

I. EXISTING ADVISORY COMMITTEES CHARTERED UNDER FACA

A. Advisory Committee on Reactor Safeguards (ACRS)

Congress established the ACRS in section 29 of the Atomic Energy Act of 1954, as amended (AEA).[16] It is comprised of a maximum of 15 members who are selected solely on the basis of their expertise. In filling vacancies on the ACRS, the Commission looks for diversity of expertise in a wide

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[11] *See* Part I.B, *infra*. In the realm of materials regulation, the Commission has also used the following FACA-chartered committees: the Independent External Review Panel to Identify Vulnerabilities in the U.S. Nuclear Regulatory Commission's Material Licensing Program (*see* Part II.F, *infra*) and the Peer Review Committee for Source Term Modeling (*see* Part II.G, *infra*). *See also* Part IV.A, *infra*, describing the non-FACA-chartered Advisory Committee of State Officials.

[12] *See* Part II.A, *infra*.

[13] *See* Charter: Advisory Committee on Reactor Safeguards (Pursuant to Section 9 of the Federal Advisory Committee Act) at 2-3, ¶ 2(h) (Dec. 11, 2011) (available at ADAMS Accession No. ML083460423). "ADAMS" is the NRC's automated document retrieval system, available to the public at http://wba.nrc.gov:8080/ves/; information regarding its use is available at http://www.nrc.gov/reading-rm/adams.html. *See also* e-mail from Andrew Bates to Roland Frye (Dec. 8, 2011 2:17 p.m.).

[14] The source for all information in this paragraph is Roland Frye's interview with Bradley W. Jones and Geary Mizuno (Nov. 15, 2011) (Jones/Mizuno interview). Mr. Jones is the Assistant General Counsel for Reactor and Materials Rulemaking, and Mr. Mizuno is Special Counsel in Mr. Jones' office. A brief interview summary, approved by Messrs. Jones and Mizuno, is included in "Attachment A" to this paper.

[15] *See* 10 C.F.R. § 7.17(a).

[16] 42 U.S.C. § 2039.

range of relevant fields – e.g., fluid dynamics, heat and mass transfer, diesel generators, materials, civil engineering, chemical engineering, and health physics. The ACRS also looks for members with actual plant operational experience and with the technical skills noted above. Another form of diversity on the ACRS stems from the fact that its membership is drawn from academia, the national labs, and the regulated industry.[17]

According to Trip Rothschild (one of the NRC's two Associate General Counsels), the ACRS constitutes, in essence, a peer review body that examines the NRC staff's technical work.[18] Pursuant to Commission regulation, its responsibilities include:

> review[] and report[] on safety studies and applications for construction permits and facility operating licenses;[[19]]
>
> advise[] the Commission with regard to hazards of proposed or existing reactor facilities and the adequacy of proposed reactor safety standards;
>
> upon request of the Department of Energy (DOE), review[] and advise[] with regard to the hazards of DOE nuclear activities and facilities;
>
> review[] any generic issues or other matters referred to it by the Commission for advice; and
>
> conduct[] studies of reactor safety research and submit[] reports thereon to the U.S. Congress and the NRC as appropriate.[20]

Regarding the first of these responsibilities, the ACRS reviews and reports on "[e]ach application for a construction permit or an operating license for a facility which is of a type described in [10 C.F.R.] §

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[17] Bates interview, as subsequently revised by attachment to Dr. Bates's e-mail to Roland Frye (Dec. 6, 2011 @ 3:52 p.m.).

[18] Roland Frye's interview with Trip Rothschild (Oct. 26, 2011) (Rothschild interview). A brief interview summary, approved by Mr. Rothschild, is included in "Attachment A" to this paper.

[19] Although Dr. Bates does not believe that the committee's functions include the review of *research* reactor license applications, he is aware of no document providing a definitive answer one way or the other. Nor is he aware of any instances where the committee has actually undertaken such a review. He believes, however, that the ACRS could do so on its own initiative under Section 29 of the AEA as well as under 10 C.F.R. § 1.13, and that the Commission could ask it to do so under 10 C.F.R. § 2.102(b) & (c). Bates interview.

[20] 10 C.F.R. § 1.13. Although the ACRS's responsibilities are directed primarily at power reactors, the committee also reviews nuclear waste issues (as explained in text associated with note 13, *supra*). In addition, the committee considers the production of medical isotopes that are produced within a "power reactor" that was created solely to produce such isotopes. Jones/Mizuno interview.

50.21(b) or § 50.22, or for a testing facility."[21] The ACRS also examines and reports on the safety issues associated with applications for early approval of reactor site permits.[22] Along similar lines, the ACRS reviews and provides the Commission with a report on applications to renew operating licenses for nuclear power plants.[23] It likewise prepares reports for the Commission regarding (i) initial approval, or renewal, of a license to manufacture nuclear power plants,[24] and (ii) combined licenses (to both construct and operate a regulated facility).[25]

In performing each of the reviews mentioned in the preceding paragraph, the ACRS also examines the staff's documents that would approve, or would support a decision to approve, the application at issue. First, the staff presents its documentation, underlying reasoning, and conclusions to the advisory committee in subcommittee and/or full committee meetings.[26] The advisory committee then reviews the documentation and then sends its own report back to the staff or Commission.[27] If the ACRS agrees with the Staff's proposed approval of the licensing action, the ACRS will issue an approval letter to the NRC staff, though often with recommended licensing conditions.[28] The staff's current practice is to issue a written response to each of the advisory committee's recommendations (although this was not always the case).[29]

If a litigant seeks to challenge the application in a hearing before the Commission's trial-level adjudicatory body (the Atomic Safety and Licensing Board), the staff will submit the ACRS's letter to the Board.[30] Dr. Bates is aware of no instance where the ACRS has withheld its approval of an operating license application or construction permit application that was supported by the staff.[31] Conversely,

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[21] 10 C.F.R. § 50.58(a). Section 50.21(b) concerns the manufacture of nuclear power reactors, and section 50.22 concerns certain production or utilization facilities.

[22] 10 C.F.R. pt. 50, App. Q, § 3; 10 C.F.R. § 52.23.

[23] 10 C.F.R. § 54.25.

[24] 10 C.F.R. §§ 52.165, 52.177.

[25] 10 C.F.R. §§ 52.87.

[26] Bates interview.

[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] *See* 10 C.F.R. § 2.102(b) & (c).

[31] J. Samuel Walker, *Containing the Atom: Nuclear Regulation in a Changing Environment – 1963-1971,* at 80-81 (U. Cal. Press 1992) (Walker) (regarding the 1966 proposal to locate a power reactor in Burlington, NJ). *But compare id.* at 89 (same regarding a proposed site near Bodega Bay, CA) *with id.* at 97-98 (staff and ACRS later disagree regarding the same siting issue). To the extent the reader would like further background on the ACRS and other advisory committees, Dr. Walker's books on the NRC and

however, Dr. Bates reports several instances where staff did not adopt or agree with some of the ACRS's recommendations. These disagreements between the staff and the ACRS did not occur in the adjudicatory context but instead concerned proposed rules, draft regulatory guidance documents, and proposed staff actions.[32]

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its predecessor agency, the Atomic Energy Commission (AEC) are all good resources. Dr. Walker recently retired as the NRC's official resident historian after decades in that position. He is likely the single most knowledgeable individual on the history of the NRC and AEC.

[32] *See*, *e.g.*:

Memorandum to R. W. Borchardt, Executive Director for Operations, from Edwin M. Hackett, Executive Director, Advisory Committee on Reactor Safeguards, entitled "Topical Report NEDC-33173P-A, Supplement 2, Parts 1, 2, and 3, 'Analysis of Gamma Scan Data and Removal of Safety Limit Minimum Critical Power Ratio (SLMCPR) Margin'" (Nov. 14, 2011) (requesting that the staff delay issuance of its Safety Evaluation until it receives the ACRS's comments on that evaluation) (ML11318A024).

Letter from R. W. Borchardt, Executive Director for Operations, to Dr. Said Abdel-Khalik, Chairman, Advisory Committee on Reactor Safeguards (Nov. 3, 2011), entitled "Response to the Advisory Committee on Reactor Safeguards Report on the Proposed Rulemaking to Introduce a Site-Specific Performance Assessment and Human Intrusion Analysis Requirement to 10 CFR Part 61 (RIN-3150-AI92)" (expressing disagreement with the ACRS recommendation for changes to a staff proposal) (ADAMS Accession No. ML112730300).

Memorandum from Said Abdel-Khalik, ACRS Chairman, to Mr. R.W. Borchardt, Executive Director for Operations (Oct. 17, 2011), entitled "Draft Final Regulatory Guide (RG) 1.82, 'Water Sources for Long-Term Recirculation Cooling Following a Loss-of- Coolant Accident,' Revision 4," at 2-3 (recommending changes to a draft RG) (ML11284A157).

Memorandum from Said Abdel-Khalik, ACRS Chairman, to NRC Chairman Gregory B. Jaczko (Oct. 13, 2011), entitled "Initial ACRS Review of: (1) the NRC Near-Term Task Force Report on Fukushima and (2) Staff's Recommended Actions to be Taken Without Delay," at 2-10 (supplementing the staff report with ACRS' own recommendations) (ML11284A136).

Memorandum from Said Abdel-Khalik, ACRS Chairman, to NRC Chairman Gregory B. Jaczko (Sept. 22, 2011), entitled "Proposed Rulemaking to Introduce a Site-Specific Performance Assessment and Human Intrusion Analysis Requirement to 10 CFR Part 61" (disagreeing with staff recommendation) (ML11256A191).

Tension between the staff and the ACRS has been longstanding. For instance, in 1959, the ACRS adamantly opposed a staff recommendation regarding standards for locating nuclear power reactors in or near population centers.[33] Similarly, in 1965, the ACRS opposed a related recommendation by the regulatory staff to prohibit the location of power reactors in metropolitan areas.[34]

Although the ACRS often communicates with and offers recommendations to the NRC staff, the agency's regulations provide specifically that it report directly to the Commission (i.e., the Commissioners),[35] and indeed, pursuant to 10 C.F.R. § 1.11(c), the ACRS regularly makes oral presentations directly to the Commission.[36] The ACRS's final reports are generally directed to the Commission while interim reports and regulatory guidance reviews often go to the Executive Director for Operations.[37]

Memorandum from Said Abdel-Khalik, ACRS Chairman, to NRC Chairman Gregory B. Jaczko (Aug. 11, 2011), entitled "Response to the June 8, 2011, EDO Letter Regarding Draft Final Revision 3 of Regulatory Guide (RG) 1.152, 'Criteria for Use of Computers in Safety Systems of Nuclear Power Plants'" (disagreeing with the staff's position) (ML11199A149).

Memorandum from Said Abdel-Khalik, ACRS Chairman, to Mr. R.W. Borchardt, Executive Director for Operations (Aug. 11, 2011), entitled "Topical Report NEDC-33173p, Supplement 2, Part 1, 2 and 3, 'Analysis of Gamma Scan Data and Removal of Safety Limit Minimum Critical Power Ratio (SLMCR) Margin'" (offering recommendations that differ from those of the staff) (ML11199A114).

[33] Walker at 58.

[34] *Id.* at 76.

[35] 10 C.F.R. § 1.11(c); Bates interview. *See*, *e.g.*, NRC, Final Rule, Technical Specifications, 60 Fed. Reg. 36,953, 36,955 (July 19, 1995), 1995 WL 509924 (N.R.C.) (July 13, 1995), at *7; NRC, Final Rule, Protection Against Malevolent Use of Vehicles at Nuclear Power Plants, 59 Fed. Reg. 38,889, 38,890 (Aug. 1, 1994), 1994 WL 442849 (N.R.C.) (July 26, 1994), at *3; NRC, Advance Notice of Proposed Rulemaking, Acceptability of Plant Performance for Severe Accidents; Scope of Consideration in Safety Regulations, 57 Fed. Reg. 44,513, 44,515, 44,517 (Sept. 28, 1992), 1992 WL 288609 (N.R.C.), at *4, *9, *withdrawn*, 62 Fed. Reg. 53,250 (Oct. 14, 1997), 1997 WL 628100 (F.R.).

[36] *See* NRC, "Nuclear Energy Institute, Receipt of a Petition for Rulemaking," 60 Fed. Reg. 29,784, 29,784 (June 6, 1995), 1995 WL 358911 (N.R.C.) (May 31, 1995), at *3, *referring to* Nuclear Energy Institute, Petition for Rulemaking Regarding Amendments to 10 CFR 50.48 and Appendix R to 10 CFR Part 50, 1995 WL 360167 (N.R.C.) (February 2, 1995), at *4.

[37] Bates interview. The ACRS reviews every draft and final regulatory guide addressing reactor regulation. *Id.*

The Commission takes the recommendations of this advisory committee into account when that committee recommends a rule change. This is explained in section 2.809(a) of the Commission's regulations:

> In its advisory capacity to the Commission, the ACRS may recommend that the Commission initiate rulemaking in a particular area. The Commission will respond to such rulemaking recommendation in writing within 90 days, noting its intent to implement, study, or defer action on the recommendation. In the event the Commission decides not to accept or decides to defer action on the recommendation, it will give its reasons for doing so. Both the ACRS recommendation and the Commission's response will be made available at the NRC Web site, http://www.nrc.gov, following transmittal of the Commission's response to the ACRS.[38]

Section 2.809(b) provides that, when the staff is preparing a rule involving nuclear safety matters within the purview of the ACRS, "the Staff will ensure that the ACRS is given an opportunity to provide advice at appropriate stages and to identify issues to be considered during rulemaking hearings."[39] The ACRS used to review rules at both the proposed and final stages. But to promote efficiency, they are now given a second option of reviewing the proposed rule and are later sent the final rule for optional review. In instances where the proposed rule involves significant technical issues, the ACRS may choose to conduct a thorough review and provide detailed comments to the staff at the proposed stage; or it may instead indicate a desire to conduct its review only after the staff has received and considered public comment in the final rule stage.[40] Like all other advisory committees at the Commission, ACRS does not initiate rulemakings on its own; at most, it would recommend that the Commission initiate a rulemaking.[41] Given that the ACRS regularly reports to the Commission and holds annual meetings with the Commission, the committee has ample opportunity to propose rules and to comment on rules that already under development.[42]

Two more of the ACRS's responsibilities deserve at least brief mention. The Commission has indicated that it expects the ACRS to "play a significant role in reviewing proposed advanced reactor design concepts and supporting activities."[43] In this regard, the ACRS prepares a report for the

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[38] 10 C.F.R. § 2.809(a). *See also* Bates interview.

[39] NRC, Final Rule, ACRS Participation in NRC Rulemaking, 46 Fed. Reg. 22,358 (Apr. 17, 1981), 1981 WL 104254 (F.R.), *as amended*, NRC, Electronic Availability of NRC Public Records and Ending of NRC Local Public Document Room Program, 64 Fed. Reg. 48,948 (Sept. 9, 1999), 1999 WL 693470 (F.R.).

[40] Jones/Mizuno interview.

[41] Bates interview. *See also* 10 C.F.R. § 2.809(a), quoted *supra* in text associated with note 38.

[42] Jones/Mizuno interview.

[43] NRC, Final Policy Statement, Regulation of Advanced Nuclear Power Plants, 51 Fed. Reg. 24,643, 24,645 (July 8, 1986), 1986 WL 328107 (N.R.C.) (July 1, 1986), at *5. *See also* 10 C.F.R. §§ 52.53, 52.131, 52.141 (all regarding standard design certifications).

Commission on each application for initial approval, or renewal, of reactor design certifications.[44] Finally, the ACRS may, on its own initiative, "conduct reviews of specific generic matters or nuclear facility safety-related items."[45]

Further information about the ACRS is available at its website, http://www.internal.nrc.gov/ACRS.

B. Advisory Committee on Medical Uses of Isotopes (ACMUI)

The Atomic Energy Commission created this advisory committee in July 1958. Section 1.19(a) of the Commission's regulations provides that the committee consider medical questions that the Commission or the staff refers to the committee.[46] When requested, it offers expert opinions to the Commission on matters involving medical uses of radioisotopes, and likewise advises the NRC staff (specifically, the Office of Federal and State Materials and Environmental Management Programs (FSME)[47]) on policy issues regarding the "licensing of medical uses of radioisotopes."[48] The ACMUI does

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[44] 10 C.F.R. §§ 52.53, 52.54, 52.57.

[45] 10 C.F.R. § 1.13. This is in addition to its responsibility to examine these same kinds of issues when the Commission requests it to do so. *See id.*

[46] Early in its existence, the ACMUI served as a pool of individual advisors to NMSS. In the late 1980s, GSA nearly shut the ACMUI down for this reason. Bates interview.

[47] *Id.*

[48] 10 C.F.R. § 1.19(a). *See also* http://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html. Although most of ACMUI's responses are written, it will occasionally issue oral rather than written recommendations. Bates interview.

The ACMUI's charter makes no mention of the committee's responsibility to advise the Commission itself on these matters:

> The Committee provides advice, as requested by the Director, Division of Materials Safety and State Agreements (MSSA), Office of Federal and State Materials and Environmental Management Programs (FSME), on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. The Committee may provide consulting services as requested by the Director, MSSA.

http://www.nrc.gov/about-nrc/regulatory/advisory/acmui/charter.html. Despite this omission, the ACMUI does occasionally brief the Commission directly. The ACMUI generally meets with Commission once a year. Bates interview.

Regarding the medical administration of radioactive material and radiation from radioactive material, *see*, *e.g.*, NRC, Final Rule, Criteria for the Release of Individuals Administered Radioactive Material, 62 Fed. Reg. 4120, 4125, 4129 (Jan. 29, 1997), 1997 WL 57251 (N.R.C.) (Jan. 23, 1997), at *11, *19; NRC, Final Rule, Medical Administration of Radiation and Radioactive Materials, 60 Fed. Reg. 48,623, 48,623-

not, however, offer advice regarding the production aspect of medical isotopes – a responsibility that, as indicated *supra* in note 20, resides with the ACRS.[49] The ACMUI generally addresses its reports to the FSME Director, unless the Commission has directly asked the committee for input (which has happened).[50] Dr. Bates is, however, uncertain whether the ACMUI currently reviews all proposed and final rules that are relevant to its charter, or instead reviews only those that the staff sends the advisory committee.[51]

Like the ACRS, the ACMUI has a selection panel to recommend new members. At one time, the Commission itself made the appointments. But today, the Director of FSME makes the selection decisions, although the Director does notify the Commission before any appointments are final. All members of this committee come from outside the Commission and all are involved, directly or indirectly, in one facet or another of nuclear medicine.[52]

Although the Commission's regulations provide that the ACMUI is to be composed of physicians and scientists,[53] the committee's membership has actually spanned a far broader range of expertise. The current committee is composed of the following: "a nuclear medicine physician; a nuclear cardiologist; a medical physicist in nuclear medicine unsealed byproduct material; a medical physicist in radiation therapy; a radiation safety officer; a nuclear pharmacist; two radiation oncologists; a patients' rights advocate; a Food and Drug Administration representative; an Agreement State representative; a health care administrator; and a diagnostic radiologist."[54] This breadth of membership is hardly new. For instance, in 1994, the advisory committee was similarly comprised of "physicians (i.e., in nuclear medicine, cardiology, and radiation oncology), medical physicists, pharmacists, medical researchers, practicing technologists, hospital administrators, state medical regulators, Food and Drug Administration representatives, and a patient rights representative."[55]

The ACMUI's role has remained largely the same over the years. The following excerpt from a 1998 Notice of Proposed Rulemaking gives a sense of the kinds of issues addressed by the ACMUI:

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25 (Sept. 20, 1995), 1995 WL 654019 (N.R.C.) (Sept. 20, 1995), at *2, *4; NRC, Final Rule, Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use, 59 Fed. Reg. 61,767, 61,769 (Dec. 2, 1994), 1994 WL 740932 (N.R.C.) (Nov. 25, 1994), at *5; NRC, Proposed Rule, Medical Use of Byproduct Material; Proposed Revision, 63 Fed. Reg. 43,516, 43,550 (Aug. 13, 1998), 1998 WL 556336 (N.R.C.) (Aug. 5, 1998), at *75.

[49] Bates interview, as subsequently revised by e-mail dated Dec. 6, 2011; Jones/Mizuno interview.

[50] Bates interview; Jones/Mizuno interview.

[51] Bates interview.

[52] *Id.*

[53] 10 C.F.R. § 1.19(a).

[54] http://www.nrc.gov/about-nrc/regulatory/advisory/acmui/membership.html.

[55] NRC, Final Rule, Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use, 59 Fed. Reg. 61,767, 61,769 (Dec. 2, 1994), 1994 WL 740932 (N.R.C.) (Nov. 25, 1994), at *5.

> The ACMUI . . . discussed training and experience for authorized users, authorized medical physicists, authorized nuclear pharmacists, and Radiation Safety Officers . . . . The ACMUI agreed with the Commission's proposed general approach to training and experience, i.e., delete reference in the rule to the speciality boards names, require preceptor forms, and require that competency be demonstrated by successful completion of an examination . . . .
>
> The ACMUI unanimously recommended that the current training requirements for authorized users of sealed sources and devices for therapeutic applications . . . be maintained. Specifically, they recommended retaining the 3-year clinical training in an accredited program as an alternative to medical speciality board certification [as well as] . . . the current requirements for authorized users of brachytherapy and therapeutic medical devices. . . .
>
> The ACMUI unanimously recommended that the training requirements for authorized users of unsealed byproduct material for diagnostic uses . . . be reduced to the levels proposed by the NRC staff . . . . The ACMUI did not reach a consensus on the training requirements for authorized users of unsealed byproduct material for therapeutic uses. . . . Finally, they unanimously agreed with NRC staff's recommendation for training requirements for authorized nuclear pharmacists (700 hours in a structured educational program) and medical physicists (Masters of Science degree and 2 years).[56]

Like the ACRS, the ACMUI engages the staff in give-and-take exchanges of ideas regarding draft regulations that the staff has prepared.[57] The ACMUI receives from FSME an informational copy of a proposed rule within its purview, and also has an opportunity to comment on any final rule within its purview before the rule is forwarded to the Commission for promulgation.[58] Mr. Jones (Assistant General Counsel for Reactor and Materials Rulemaking) does not recall any instance where a rule involving medical treatment was not reviewed by the ACMUI.[59] In addition, the committee can recommend that the staff initiate a rulemaking.[60] If the ACMUI writes a letter regarding a proposed rulemaking, the letter would be addressed to FSME.[61] If FSME agrees with the ACMUI's comments, then FSME would send up a "SECY Paper" (an internal memorandum from the staff to the Commission)

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[56] NRC, Proposed Rule, Medical Use of Byproduct Material; Proposed Revision, 63 Fed. Reg. 43,516, 43,520 (Aug. 13, 1998), 1998 WL 556336 (N.R.C.) (Aug. 5, 1998), at *10 - *11.

[57] *See* NRC, Final Rule, Criteria for the Release of Individuals Administered Radioactive Material, 62 Fed. Reg. 4120, 4129 (Jan. 29, 1997), 1997 WL 57251 (N.R.C.) (Jan. 23, 1997), at *19 (describing the exchange of ideas).

[58] Jones/Mizuno interview.

[59] *Id.*

[60] *Id.*

[61] *Id.*

requesting that the Commission add the proposed rulemaking to the Commission's list of potential rules.[62]

Although the staff and ultimately the Commission often adopt the recommendations of the ACMUI,[63] they do not always do so. For instance, simultaneous with the issuance of the 1998 Notice of Proposed Rulemaking quoted in the text associated with note 56 *supra*, the staff issued a Draft Policy Statement rejecting the "regulation of the medical use of byproduct material on the basis of 'comparable risk,' as the ACMUI . . . ha[d] proposed."[64] The staff reasoned that ACMUI's "comparable risk" approach would not satisfy the requirement imposed by Section 161b of the Atomic Energy Act that the Commission regulates all uses of byproduct material "to protect health and minimize danger to life."[65] In another instance, the staff declined to follow the ACMUI's recommendation that the patient release criteria in 10 C.F.R. § 35.75 be expressed as a dose-based rather than an activity-based limit.[66] As a final example, despite the ACMUI's conclusion that standard medical practice rendered a particular kind of regulation unnecessary, the staff nonetheless sought public comment on that same issue.[67]

On occasion, the Commission staff will ask the ACMUI to look into a particular issue. One recent example involved the use of cesium to sterilize blood. The staff asked the ACMUI to look at the National

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[62] *Id.*

[63] *See*, *e.g.*, NRC, Final Rule, Criteria for the Release of Individuals Administered Radioactive Material, 62 Fed. Reg. 4120, 4125, 4130 (Jan. 29, 1997), 1997 WL 57251 (N.R.C.) (Jan. 23, 1997), at *12, *23; NRC, Final Rule, Quality Management Program and Misadministrations; NRC Override of OMB Disapproval of NRC Information Collection Request, 57 Fed. Reg. 41,376, 41,376 (Sept. 10, 1992), 1992 WL 225855 (N.R.C.) (Sept. 3, 1992), at *1 (responding in part to the ACMUI's recommendations, the Commission "reexamined its approach and published a second proposed rule"); NRC, Proposed Rule, Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use, 60 Fed. Reg. 322, 323 (Jan. 4, 1995), 1994 WL 740929 (N.R.C.) (Dec. 28, 1994), at *1. *Cf.* NRC, Proposed Rule, Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use, 58 Fed. Reg. 33,396, 33,405 (June 17, 1993), 1993 WL 270651 (N.R.C.) (June 10, 1993), at *21; NRC, Advance Notice of Proposed Rulemaking: Withdrawal, Medical Use of Byproduct Material; Training and Experience Criteria, 57 Fed. Reg. 46,522, 46,523 (Oct. 9, 1992), 1992 WL 311317 (N.R.C.) (Oct. 2, 1992), at *2.

[64] NRC, Draft Policy Statement, Medical Use of Byproduct Material, 63 Fed. Reg. 43,580, 43,583 (Aug. 13, 1998), 1998 WL 556325 (N.R.C.) (Aug. 5, 1998), at *7. *See also* NRC, Final Rule, Criteria for the Release of Individuals Administered Radioactive Material, 62 Fed. Reg. 4120, 4129 (Jan. 29, 1997), 1997 WL 57251 (N.R.C.) (Jan. 23, 1997), at *19 (staff accepts all but one of the ACMUI's comments).

[65] NRC, Draft Policy Statement, Medical Use of Byproduct Material, 63 Fed. Reg. 43,580, 43,583 (Aug. 13, 1998), 1998 WL 556325 (N.R.C.) (Aug. 5, 1998), at *7.

[66] NRC, Proposed Rule, Criteria for the Release of Patients Administered Radioactive Material, 59 Fed. Reg. 30,724, 30,728 (June 15, 1994), 1994 WL 362497 (N.R.C.) (June 9, 1994), at *8 - *9.

[67] NRC, Proposed Rule, Medical Administration of Radiation and Radioactive Materials, 60 Fed. Reg. 4872, 4875 (Jan. 25, 1995), 1995 WL 61647 (N.R.C.) (January 19, 1995), at *5 - *6.

Academy of Sciences study on that issue.[68] But it appears that, at least as far back as 2007, the Commission itself has not lodged direct requests with the ACMUI but instead has directed the staff to consult that committee.[69]

Further information on this committee is available at its website, http://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html.

As an aside, the NRC some years ago established a visiting medical fellows program that allows selected physicians or pharmacists to work for NRC for a period of one to two years.[70] Like the ACMUI, the visiting medical fellows program has yielded advice to the staff during rulemakings.[71] In at least one instance, the fellow's advice played a significant role in the Commission's decision to delete a medical recordkeeping requirement.[72] Although Commission documents alluded to the "visiting medical fellow" position as recently as 2010,[73] the last clear indication that the position still existed occurred in 1998, in a memorandum written by the person holding the fellowship.[74]

C. Licensing Support Network Advisory Review Panel (LSNARP or Panel)

Section 1.19(d) of the Commission's regulations explains that the Commission established the predecessor to this Panel[75] in 1989, pursuant to 10 C.F.R. § 2.1011(e); the predecessor was reconstituted

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[68] E-mail from Andrew Bates to Roland Frye (Dec. 8, 2011 3:42 p.m.) (referring to Dr. Bates's phone conversation with Ashley Cockerham).

[69] *Id.*

[70] NRC, Final Rule, Criteria for the Release of Individuals Administered Radioactive Material, 62 Fed. Reg. 4120, 4125 (Jan. 29, 1997), 1997 WL 57251 (N.R.C.) (Jan. 23, 1997), at *11; NRC, Final Rule, Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use, 59 Fed. Reg. 61,767, 61,769 (Dec. 2, 1994), 1994 WL 740932 (N.R.C.) (Nov. 25, 1994), at *5.

[71] *See* authority cited in note 70, *supra*.

[72] NRC Final Rule, Criteria for the Release of Individuals Administered Radioactive Material, 62 Fed. Reg. 4120, 4130 (Jan. 29, 1997), 1997 WL 57251 (N.R.C.) (Jan. 23, 1997), at *23 ("Upon reconsideration, based on public comments and consultation with the ACMUI, an NRC medical consultant, and the NRC Visiting Medical Fellow, the NRC has decided to delete this requirement").

[73] *See* "Comments received from NRC counsel concerning ACMUI Patient Release Report" (Draft, Dec. 20, 2010) (ML110600249).

[74] Memorandum to L. Joseph Callan, Executive Director for Operations, from Myron Pollycove, Visiting Medical Fellow, "Distribution of Potassium Iodide to Block Thyroid Uptake of Iodine-131 Accidental Release" (Sept. 3, 1998), appended to Letter from William D. Travers, Executive Director for Operations, to Peter G. Crane (Mar. 3, 2000) (ML003692456).

[75] The predecessor was the Licensing Support System Advisory Committee (LSSAC). *See* 10 C.F.R. § 2.1011(c)(2); NRC, Final Rule, Procedures Applicable to Proceedings for the Issuance of Licenses for the

and renamed in 1998.[76] Both the LSNARP and its predecessor stemmed from a negotiated rulemaking for 10 C.F.R. Part 2, Subpart J (regarding the *Yucca Mountain* proceeding) and originally focused on a licensing support network that would have been based on a mainframe computer; later, due to technological advances, the focus shifted to a web-based system.[77] Although a Commission advisory document states that the Commission directed that the LSNARP be absorbed into the ACRS around 2004-05,[78] Dr. Bates explains that the guidance document is incorrect, that the Panel is still alive (though in a coma) and, finally, that although the Panel was rechartered under FACA in 2010, it has held no meetings in the last six years.[79] It has, according to Dr. Bates, been kept on life-support simply to allow for the possibilities that DOE could either revive its petition for the Yucca Mountain high-level waste disposal repository or file with the Commission another petition for a different high-level waste disposal repository.[80]

The Panel is, in fact, an "advisory committee" chartered under FACA,[81] even though it was not talismanically so designated by the use those two specific words.[82] The Panel "provide[d] advice to the Commission on the design, development, and operation of the Licensing Support Network (LSN) -- an electronic information management system for use in the Commission's high-level radioactive waste (HLW) licensing proceeding."[83] More specifically, the Panel's purpose was to "arriv[e] at standards and

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Receipt of High–Level Radioactive Waste at a Geologic Repository, 63 Fed. Reg. 71,729, 71,739 (Dec. 30, 1998), 1998 WL 951712 (N.R.C.), at *22 (Dec. 22, 1998), promulgating 10 C.F.R. § 2.1011(d).

Although the current body has often been called the Licensing Support Network Advisory Review *Board*, its proper name ends instead in the word "Panel." 10 C.F.R. § 2.1011(c); Bates interview.

[76] 10 C.F.R. § 1.19(d).

[77] Bates interview. In 1998, a regulation changed Subpart J and also changed the computerized database system from a mainframe-based system to a web-based system. Roland Frye's interview with Dan Graser (Oct. 20, 2011) (Glaser interview).

[78] NRC, NUREG-1125, Volume 27, "A Compilation of Reports of the Advisory Committee on Reactor Safeguards: 2005 Annual," (June 2006), at 89 (ML061780504). (The NRC staff's NUREGs are guidance documents.)

[79] Bates interview; e-mail from Dr. Bates to Roland Frye (Nov. 1, 2011 4:39 p.m.).

[80] Bates interview.

[81] *Id.*; Glazer interview.

[82] *See* 10 C.F.R. §§ 2.1011(d) ("The Secretary of the Commission shall have the authority to appoint additional representatives to the LSN Advisory Review Panel consistent with the requirements of the Federal Advisory Committee Act").

[83] 10 C.F.R. § 1.19(d).

procedures to facilitate the electronic access to documentary material and to the electronic docket established for the HLW geologic repository licensing proceeding."[84]

In 1998, the Commission announced that it expected the Panel to "be very useful in discussing standards and procedures to ensure that all participants are able to access the electronic information."[85] It was comprised of members who represented the parties and potential parties to the NRC's high-level waste proceeding; it also included certain "Federal agencies with expertise in large-scale electronic information systems."[86] Given that the Yucca Mountain High-Level Waste Repository is currently on life support and given further that the Panel has not met for six years, its survival appears highly doubtful. Based on the comments of Dan Graser, the manager of the LSN, as summarized at length below, I would conclude that he agrees.[87]

The LSSAC, and later the LSNARP, differ from NRC's other two existing advisory committees in four respects. The Panel was created to address issues of computer science rather than pure science or engineering. It has a very narrow focus to oversee and implement a negotiated rulemaking – i.e., the building of a shared documentary database. It has been assigned a specific task/project rather than more general tasks. And its membership was selected on the basis of affiliation (constituency) rather than expertise.

When established in 1989 (at the time 10 C.F.R. Part 2, Subpart J was promulgated), "the public" was not really viewed as a constituency, because the public did not have a stake in the design and use of the database. In fact, most of the LSSAC members thought of public access as a mere side benefit. The LSSAC's membership reflected the interests of a very narrowly defined set of constituencies. Because the Committee was an outgrowth of the negotiated rulemaking process, some of the parties to the negotiated rulemaking (e.g., Nye County) were automatically assigned seats on the Committee. At first, a single county was designated to represent the interests of all Nevada counties other than Nye, but that was later changed to allow each county a representative. Other members included private attorneys who practiced before the NRC, Nevada county commissioners, a trained arbitrator, and a

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[84] NRC, Final Rule, Procedures Applicable to Proceedings for the Issuance of Licenses for the Receipt of High–Level Radioactive Waste at a Geologic Repository, 63 Fed. Reg. 71,729, 71,734 (Dec. 30, 1998), 1998 WL 951712 (N.R.C.), at *12 (Dec. 22, 1998), referring to 10 C.F.R. § 2.1011(d). The responsibilities of the advisory committee are set forth in greater detail in 10 C.F.R. § 2.1011(e).

[85] NRC, Final Rule, Procedures Applicable to Proceedings for the Issuance of Licenses for the Receipt of High–Level Radioactive Waste at a Geologic Repository, 63 Fed. Reg. 71,729, 71,734 (Dec. 30, 1998), 1998 WL 951712 (N.R.C.), at *12 (Dec. 22, 1998), referring to 10 C.F.R. § 2.1011(d).

[86] 10 C.F.R. § 1.19(d).

[87] Except for the text associated with notes 88-90, *infra*, the remainder of this section is derived entirely from my interview with Dan Graser. An interview summary approved by Mr. Graser is included in "Attachment B" to this paper.

litigation support expert. The Nevada Nuclear Waste Task Force (a public interest group) joined the LSSAC only in the 6th or 7th year of its life.[88]

As the description above suggests, LSSAC membership was assigned by affiliation, not computer expertise. Few people at the time understood large databases or, later, the worldwide web, and no one knew how to build huge litigation support databases. Members needing computer expertise would get it from within their own organizations or from sources other than the LSSAC or, later, the LSNARP.

Philosophically, the LSSAC reflected a distrust of both the DOE and the NRC -- many of its members thought that, unless a computerized document system were designed by an independent advisory committee, the DOE and the NRC would place other entities at a disadvantage. The environmentalists opted out of the negotiated rulemaking, but the other stakeholders stayed in the rulemaking and ultimately became members of the LSSAC when it was created by regulation in 1989.

The LSSAC members and, later, the Panel members were not at all involved in any subsequent rulemakings, including the 1998 rulemaking mentioned above.[89] And although some Panel members may have been involved in the 3.69 guidelines for review of the Yucca Mountain application,[90] the Panel itself was not.

During their active phase, the LSSAC and the Panel were useful in developing consensus. Specifically, they were effective in choosing member of the LSSAC's / Panel's smaller technical working groups that examined subsidiary issues. (The LSSSAC / Panel did not themselves directly address technical issues; those responsibilities fell to the working groups.) The full Committee or Panel (including all of its members) always adopted the technical working groups' recommendations in their entirety. The technical working groups (of which there were 3 or 4) would work on projects such as the bibliographical header design that formed the basis for searches. One such group created three different design approaches that were consistent with worldwide web (then new). The technical working groups formulated the functional requirements that, in effect, said: "this is [the kind of database and search engine] we intend to buy and these are the criteria that you, the contractor, must use in developing [this] product." The technical working groups were the foundation of all the accomplishments of the full Advisory Committee and, later, the Panel.

The Commission stopped using the Panel around 2004-05, effectively at the same time the NRC appointed the pre-adjudication presiding officer (PAPO). At that point, the administrator (Dan Graser) would report mainly to the PAPO and the construction authorization board (one of the Licensing Board's three-judge adjudicatory panels). The Panel became irrelevant because a PAPO order would trump anything that the Panel would recommend.

Prior to the appointment of the PAPO, the Commission and staff always followed the LSSAC's and Panel's recommendations. This was because the LSSAC and the Panel did exactly what they were

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[88] E-mail from Andrew Bates to Roland Frye (Dec. 8, 2011 2:34 p.m.).

[89] *See* notes 84-85, *supra*.

[90] *See* Regulatory Guide 3.69, Topical Guidelines for the Licensing Support Network (Rev. 1 June 2004) (ML041770135).

chartered to do. They gave statistics and recommendations to the Commission; the Commission would then tell Mr. Graser to make the recommendations happen; and Mr. Graser would give the Commission a request for the necessary resources to do so – resources which the Commission always authorized.

Finally, a few words regarding the meetings of the LSSAC and the Panel. During the Committee's / Panel's active phase, notices were published in *the Federal Register* announcing all public meetings. These meetings were always open to the public, with open microphones at end of each meeting. These meetings were held in either Washington DC or Nevada, plus one in Wisconsin. Little if anything was marked pre-deliberative.

To the extent anything was withheld from the public, it would have been associated with the awarding of the first contract in October 2000. This initial award was challenged and overturned; at the succeeding January 2001 meeting, Mr. Graser explained to the Panel why there would be a three-month delay in the project. He relayed some of this information to the Panel in only the most general terms. This was done because the contract was still new and was susceptible to another protest; so, given that the information was procurement-sensitive, Mr. Graser kept his remarks quite general in order to avoid a second protest. Mr. Graser, who was both the NRC's staffer and a voting member of the Panel, provided information that was available in the contract award document, but he would not put in the public domain any information that was commercially privileged (e.g., the percentage discount that the successful bidder was offering the NRC over other similar contracts). This was the only kind of information that he withheld from the Panel.

All meetings were transcribed and the transcripts were then placed in the NRC's public records system and Public Documents Room. At the time, this was the "state of practice" for governmental transparency. Ever since the Panel's inception in 1998, John Hoyle (the LSNARP Chairman) would write a two-page summary and provide it in-house and to all voting members of the Panel. The contents of the meetings were difficult for outsiders to follow because of the esoteric nature of the databases, the worldwide web and the administrative procedural rules -- so most of the public attendees would not have had any idea what the members were discussing.

II. DEFUNCT ADVISORY COMMITTEES CHARTERED UNDER FACA

A. Advisory Committee on Nuclear Waste (ACNW), a/k/a Advisory Committee on Nuclear Waste and Materials (ACNW&M).

This committee, which is now defunct, had a twenty-year lifespan – it was chartered under FACA in 1988, initially consisted of members who had been assigned from the ACRS, and was dissolved in 2008 when the Commission merged this committee back into the ACRS.[91] During its existence, the ACNW was required by regulation to report directly to the Commission,[92] although it also advised the NRC staff. Specifically, this advisory committee counseled the Commission on all aspects of nuclear waste management that fell within the NRC's regulatory responsibilities. The ACNW played "a significant

[91] http://www.nrc.gov/reading-rm/doc-collections/acnw/agenda/; http://www.nrc.gov/reading-rm/doc-collections/acnw/history.html; Bates interview.

[92] 10 C.F.R. § 1.11(c).

role in the review and resolution of key technical issues associated with the safe disposal of radioactive waste,"[93] and the Commission often followed the ACNW's recommendations.[94]

Although the ACNW's primary focus was on waste disposal, it also considered "other aspects of nuclear waste management such as handling, processing, transportation, storage, and safeguarding of nuclear wastes including spent fuel, nuclear wastes mixed with other hazardous substances, and uranium mill tailings."[95] The advisory committee "examine[d] and report[ed] on specific areas of concern referred to it by the Commission or designated representatives of the Commission, and undert[ook] studies and activities on its own initiative as appropriate to carry out its responsibilities."[96] Like the ACRS, the ACNW reviewed the agency's proposed and final rules that were relevant to its charter.[97] Finally, in fulfilling its responsibilities, "the committee interact[ed] with representatives of NRC, other Federal agencies, state and local governments, Indian Tribes, and private organizations."[98]

Further information about this committee is available on its website, http://www.nrc.gov/reading-rm/doc-collections/acnw.

B. Advisory Panel for the Decontamination of Three Mile Island, Unit 2.

The Commission established this committee in October 1980 under FACA, for the purposes of "obtain[ing] input and views from the residents of the Three Mile Island area[,] . . . afford[ing] Pennsylvania government officials an opportunity to participate in the Commission's decisional process regarding cleanup for Three Mile Island, Unit 2,"[99] and "provid[ing] independent advice from local officials, scientists and individuals in the area."[100] The Panel held its first meeting the following month[101]

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[93] http://www.nrc.gov/reading-rm/doc-collections/acnw/history.html.

[94] *See* NRC, Final Rule, Radiological Criteria for License Termination, 62 Fed. Reg. 39,058, 39,064 (July 21, 1997), 1997 WL 473269 (N.R.C.) (July 1, 1997), at *14.

[95] 10 C.F.R. § 1.18.

[96] *Id.*

[97] Bates interview.

[98] 10 C.F.R. § 1.18.

[99] 10 C.F.R. § 1.19(b).

[100] NRC, Statement of Policy, Programmatic Environmental Impact Statement of the Cleanup of Three Mile Island Unit 2, 46 Fed. Reg. 24,764, 24,764 (May 1, 1981), 1981 WL 120330 (F.R.).

[101] NRC, Office of Public Affairs, Fact Sheet, "The Accident at Three Mile Island" at p. 4 of 7 (Feb. 3, 2004) (ML012410303); Backgrounder on the Three Mile Island Accident at 4 (Jan. 28, 2004) (ML040280573), http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/3mile-isle.pdf.

and, during its lifetime, met at least once with the Commissioners.[102] Although section 1.19 of the Commission's current regulations still lists this as an active advisory committee, it in fact held its last meeting in September 1993.[103] Given the nature of its charter and the absence of any reference to it in the Commission's current website, it is safe to assume that it is now defunct.[104] Dr. Bates recently confirmed this conclusion.[105]

C. Pilot Program Evaluation Panel

This short-lived advisory committee existed only from 1999 to 2000.[106] The Commission established the Panel under FACA[107] to evaluate the success of the agency's new reactor oversight process improvement pilot program[108] during the six-month period from June through November

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[102] *See* NRC, Information Notice, Three Mile Island Unit 2 Cleanup; Progress Information, 50 Fed. Reg. 9143, 9144 (Mar. 6, 1985), 1985 WL 93257 (F.R.).

[103] NRC, Notice, Meeting of the Advisory Panel for the Decontamination of Three Mile Island, Unit 2, GPU Nuclear Corp., 58 Fed. Reg. 47,768, 47,768, 1993 WL 343065 (F.R.) (Sept. 10, 1993) (announcing that the Panel's final meeting would be held September 23, 1993).

[104] *See generally* 10 C.F.R. § 7.1(e) & (e)(1):

> (e) Except where otherwise required by law, an NRC advisory committee shall be terminated whenever the stated objectives of the committee have been accomplished, the subject matter or work of the committee has become obsolete. . . .
>
> (1) An advisory committee not required to be established by statute terminates no later than two years after its establishment or last renewed, unless renewed.

Accord 10 C.F.R. § 7.7(a). *See generally* 10 C.F.R. § 7.16(c).

[105] Bates interview.

[106] *Id.*

[107] Final Report of Pilot Program Evaluation Panel (n.d.), at 1, appended to Memorandum to Samuel J. Collins, Director, Office of Nuclear Reactor Regulation, from Frank P. Gillespie, Deputy Director, Division of Inspection Program Management Office of Nuclear Reactor Regulation, "Final Report of the Pilot Program Evaluation Panel" (Dec. 17, 1999), in turn appended to Memorandum from William D. Travers, Executive Director for Operations, to the Commissioners (Dec. 21, 1999) (ML993550449). *See also* Transcript of Meeting of the Pilot Program Evaluation Panel (July 28, 1999), at 23 (ML993260301); Draft "Pilot Program" at § 2.4.1, p. 7, appended as Attachment 6 to SECY-99-007A, "Recommendations for Reactor Oversight Process Improvements (Follow-Up to SECY-99-007)" (Mar. 22, 1999) (ML992740073).

[108] Draft "Objectives of the Regulatory Oversight Process Improvement Pilot Program" at 7 (Feb. 10, 1999), appended to Memorandum from August K. Spector to File, "Summary of the February 10, 1999 Meeting with the Nuclear Power Institute to Discuss the Continued Development of Performance

1999.[109] The Panel delivered its Final Report to the Commission in late December 1999.[110] The Panel was comprised of representatives from NRC, the Nuclear Energy Institute, the nuclear industry, the public, and the states.[111] These members were selected because of their affiliation rather than any particular technical expertise.[112]

D. Reactor Oversight Process Initial Implementation Evaluation Panel

This advisory committee was chartered under FACA[113] as a successor committee to the Pilot Program Evaluation Panel.[114] Its purpose was to serve "as a cross-disciplinary oversight group to independently monitor and evaluate the results of the first year of initial implementation of the ROP [reactor oversight process] and provide advice and recommendations to the Director of the Office of Nuclear Reactor Regulation on reforming and revising the ROP."[115] Its initial membership included an NRC resident inspector, a senior reactor analyst from the NRC, representatives from the NRC's Office of Enforcement, the NRC's regional offices, the Nuclear Energy Institute, public interest groups, state

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Assessment Process and Inspection Program Improvements" (Mar. 5, 1999) (ML003676345). The purpose of the pilot program was to test the Commission's new data reporting, inspection, assessment, and enforcement processes, "to identify process and procedure problems and make appropriate changes, and, to the extent possible, evaluate the effectiveness of the new process." SECY-99-007A, "Recommendations for Reactor Oversight Process Improvements (Follow-Up to SECY-99-007) (Mar. 22, 1999), at 6 (ML992740073). *See also* NRC Press Release 99-146, "Pilot Program Evaluation Panel to Meet in Rockville, Maryland" (July 13, 1999) (ML003696516).

[109] SECY-99-007A, "Recommendations for Reactor Oversight Process Improvements (Follow-Up to SECY-99-007) (Mar. 22, 1999), at 6 (ML992740073).

[110] Final Report of the Pilot Program Evaluation Panel, appended to Memorandum from William D. Travers (NRC Executive Director for Operations) to the Commissioners (Dec. 21, 1999) (ML993550449).

[111] SECY-99-007A, "Recommendations for Reactor Oversight Process Improvements (Follow-Up to SECY-99-007) (Mar. 22, 1999), at 7 (ML992740073).

[112] Transcript of Meeting of the Pilot Program Evaluation Panel (July 28, 1999), at 32, 34, 37 (ML993260301).

[113] NRC, Notice of Establishment of the Reactor Oversight Process Initial Implementation Evaluation Panel, 65 Fed. Reg. 58,831 (Oct. 2, 2000), 2000 WL 1450916 (F.R.); NRC, Charter: Reactor Oversight Process Initial Implementation Evaluation Panel (Oct. 17, 2000), at unnumbered page 1 (ML003760300).

[114] NRC, Meeting Notice, Reactor Oversight Process Initial Implementation Evaluation Panel, 65 Fed. Reg. 62,379 (Oct. 18, 2000), 2000 WL 1530810 (F.R.).

[115] NRC, Charter: Reactor Oversight Process Initial Implementation Evaluation Panel (Oct. 17, 2000), at unnumbered page 1 (ML003760300).

agencies, and companies operating nuclear power plants.[116] Thus, like the members of the Pilot Program Evaluation Panel, the members of this advisory committee appear to have been selected because of their affiliation rather than technical expertise. The advisory committee held its first meeting in November 2000[117] and issued its Final Report the following May.[118]

E. Nuclear Safety Research Review Committee (NSRRC)

The Commission established this FACA-chartered[119] committee in February 1988[120] and dissolved it in 1997.[121] During its lifetime, the NSRRC[122] or its Chairman[123] met often with the

[116] Memorandum to Samuel J. Collins, Director, Office of Nuclear Reactor Regulation, from Loren R. Plisco, Chairman, Initial Implementation Evaluation Panel, entitled "Summary of the Initial Implementation Evaluation Panel Meeting of November 1-2, 2000 (Dec. 5, 2000) (ML003774507); NRC, Notice of Establishment of the Reactor Oversight Process Initial Implementation Evaluation Panel, 65 Fed. Reg. 58,831 (Oct. 2, 2000), 2000 WL 1450916 (F.R.) ("The Panel membership will include participants from NRC headquarters and regional offices, a representative from the Nuclear Energy Institute, reactor licensee management representatives, a representative from the Union of Concerned Scientists (a public interest group), and representatives from State Governments"); NRC, Meeting Notice, Reactor Oversight Process Initial Implementation Evaluation Panel, 66 Fed. Reg. 19,804 (Apr. 17, 2001), 2001 WL 376102 (F.R.) (like all of this Committee's meeting notices, this one includes a list of members).

[117] Memorandum to Samuel J. Collins, Director, Office of Nuclear Reactor Regulation, from Loren R. Plisco, Chairman, Initial Implementation Evaluation Panel, entitled "Summary of the Initial Implementation Evaluation Panel Meeting of November 1-2, 2000 (Dec. 5, 2000) (ML003774507); NRC, Meeting Notice, Reactor Oversight Process Initial Implementation Evaluation Panel, 65 Fed. Reg. 62,379 (Oct. 18, 2000), 2000 WL 1530810 (F.R.).

[118] Memorandum to Samuel J. Collins, Director, Office of Nuclear Reactor Regulation, from Loren R. Plisco, Chairman, Reactor Oversight Process Initial Implementation Evaluation Panel, entitled "Final Report of the Reactor Oversight Process Initial Implementation Evaluation Panel" (May 10, 2001) (ML011290444).

[119] *See*, *e.g.*, NRC, Notice of Meeting, Nuclear Safety Research Review Committee, 62 Fed. Reg. 13,726, 13,726 (Mar. 21, 1997), 1997 WL 125401 (F.R.) (stating that the meeting will be conducted pursuant to FACA).

[120] 10 C.F.R. § 1.19(c). *See also* NRC, Nuclear Safety Research Review Committee; Meeting, 53 Fed. Reg. 4087 (Feb. 11, 1988), 1988 WL 264781 (F.R.) (first meeting on Feb. 17-18, 1988).

[121] SECY-01-0163, "Research Effectiveness Review Board" (Aug. 24, 2001), at 1 (ML011520471).

[122] *See*, *e.g.*, NRC, Sunshine Act Meeting, 62 Fed. Reg. 23,284 (Apr. 29, 1997), 1997 WL 205109 (F.R.), 62 Fed. Reg. 19,634 (Apr. 22, 1997), 1997 WL 190916 (F.R.), & 62 Fed. Reg. 18,374 (Apr. 15, 1997), 1997 WL 176246 (F.R.).

Commission. The committee's purpose was to "report[] to the Commission through the Director of the Office of Nuclear Regulatory Research on important management matters in the direction of the Commission's nuclear safety research program."[124] Its charter was broad, covering "all aspects of nuclear safety research including, but not limited to, accident management, plant aging, human factors and system reliability, earth science, waste disposal and seismic and structural engineering."[125] This committee

> Evaluat[ed] and report[ed] on the conformance of the nuclear safety research program to the NRC philosophy of nuclear regulatory research;
>
> Conduct[ed] specialized studies when requested by the Commission or Director of the Office of Nuclear Regulatory Research; and
>
> Interact[ed] with the Office of Research management staff and selected contractors in private industry, at national laboratories and universities.[126]

Its responsibilities also included the assessment of and recommendations concerning:

> a. Conformance of the NRC nuclear safety research program to the NRC Philosophy of Nuclear Regulatory Research, as stated in the Committee's Strategic Plan, and to specific Commission directions.
>
> b. Likelihood of the program meeting the needs of the users of research.
>
> c. Appropriateness of the longer range research programs and the correctness of their direction.
>
> d. Whether the best people are doing the work at the best places; whether there are other options, including cooperative programs, that would yield higher quality work, or otherwise improve program efficiency.
>
> e. Whether the program is free of obvious bias, and whether the research products have been given adequate, unbiased peer review.
>
> [f. . . . S]pecialized studies when requested by the Commission or the Director of the Office of Nuclear Regulatory Research. If appropriate, these studies will be published as reports.[127]

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[123] *See*, *e.g.*, NRC, Sunshine Act Meeting, 61 Fed. Reg. 66,337 (Dec. 17, 1996), 1996 WL 719355 (F.R.), 61 Fed. Reg. 65,247 (Dec. 11, 1996), 1996 WL 708088 (F.R.), & 61 Fed. Reg. 64,175 (Dec. 3, 1996), 1996 WL 687821 (F.R.).

[124] 10 C.F.R. § 1.19(c).

[125] *Id.*

[126] *Id.*

Its membership of 9-12 was selected "to ensure an appropriately balanced representation of the research management community, taking into account: (1) demonstrated experience in high-level management of programs in applied research; (2) demonstrated expertise in one or more disciplines of applied science and engineering;[[128]] (3) broad acquaintance with the public health and safety issues associated with the peaceful uses of atomic energy; and (4) a balance of experience in the academic, industrial, and national and not-for-profit laboratory environments."[129] More specifically, members were selected on the basis of their "expertise in nuclear engineering and nuclear safety, with emphasis on demonstrated capabilities in major portions of one of the following two areas[:]

> Advanced instrumentation and controls and human factors, including human-system interfaces.
>
> Broad experience in design and operation of nuclear power plants, nuclear engineering, and research related to nuclear power plants.[130]

F. Independent External Review Panel to Identify Vulnerabilities in the U.S. Nuclear Regulatory Commission's Material Licensing Program

The Commission created this FACA-chartered committee in October of 2007,[131] in response to a report from the NRC's Inspector General.[132] The Panel was charged with preparing "an assessment of the existing and potential security vulnerabilities related to NRC's specific, import, export and general license programs" and an "evaluat[ion of] the apparent good-faith presumption that pervades the NRC

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[127] NRC, Notice of Renewal of the Nuclear Safety Research Review Committee, 61 Fed. Reg. 6043 (Feb. 15, 1996), 1996 WL 62877 (F.R.).

[128] These disciplines included "applied physics, chemistry, radio-biology, health physics, human factors, digital and analog instrumentation and control systems, materials science and engineering and the classical engineering disciplines." NRC, Nuclear Safety Research Review Committee; Establishment, 53 Fed. Reg. 1423 (Jan. 19, 1988), 1988 WL 278412 (F.R.).

[129] NRC, Notice of Renewal of the Nuclear Safety Research Review Committee, 61 Fed. Reg. 6043 (Feb. 15, 1996), 1996 WL 62877 (F.R.). *See also* NRC, Nuclear Safety Research Review Committee; Establishment, 53 Fed. Reg. 1423 (Jan. 19, 1988), 1988 WL 278412 (F.R.) (Members were chosen "from industrial, national laboratory, university, and not-for-profit research organizations.").

[130] NRC, Call for Nominations for Nuclear Safety Research Review Committee, 60 Fed. Reg. 24,660, 1995 WL 263841 (F.R.).

[131] *See* Charter: Independent External Review Panel to Identify Vulnerabilities in the U.S. Nuclear Regulatory Commission's Material Licensing Program (Oct. 2, 2007) (ML072750491).

[132] Notice of Intent to Establish Independent External Review Panel to Identify Vulnerabilities in the U.S. Nuclear Regulatory Commission's Material Licensing Program, 72 Fed. Reg. 57,600 (Oct. 10, 2007), 2007 WL 2936548 (F.R.).

licensing process."[133] The Panel also performed an independent evaluation of the NRC's licensing policies and guidance.

The Panel was comprised of a former director of the NRC's Agreement State program and members from both the NRC's Advisory Committee on Nuclear Waste and Materials and the Defense Threat Reduction Agency.[134] During its six-month lifespan, the Panel received briefings from the NRC staff and an Agreement State representative; a licensee also briefed the Panel on issues related to the NRC's materials licensing program.[135] On March 18, 2008, the Panel in turn briefed the Commission on the Panel's Final Report.[136] Subsequently, the Chairman informed Senator Carl Levin that the Commission intended to implement the Panel's recommendations.[137]

Although the Panel's meetings were generally open to the public, portions were closed so that the NRC staff could brief the panel on classified material,[138] safeguards information and pre-decisional information.[139]

G. Peer Review Committee for Source Term Modeling

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[133] *Id.* at 57,600.

[134] Status of Recommendations from the U.S. Senate Permanent Subcommittee on Investigations Report, Dirty Bomb Vulnerabilities (n.d.), appended to letter from NRC Chairman Dale E. Klein to Sen. Carl Levin (June 6, 2008) (ML081350223).

[135] Audit Report: Audit of the NRC Byproduct Materials License Application and Review Process; OIG-06-A-11; Status of Recommendations (n.d.), at unnumbered page 5, appended to Memorandum to Luis A. Reyes, Executive Director for Operations, from Stephen D. Dingbaum, Assistant Inspector General for Audits, "Subject: Status of Recommendations: Audit of the NRC Byproduct Materials License Application and Review Process (OIG-06-A-11); and Summary Report and Perspectives on Byproduct Material Security and Control (OIG-07-A-12)" (May 1, 2008) (ML081220952).

[136] United States Nuclear Regulatory Commission, Briefing by the Independent External Review Panel to Identify Vulnerabilities in the U.S. NRC's Materials Licensing Program (Mar. 18, 2008) (ML080840367); "Final Report of the Independent External Review Panel to Identify Vulnerabilities in the U.S. Nuclear Regulatory Commission's Materials Licensing Program" (Mar. 11, 2008), appended to letter from Thomas E. Hill (Panel Chairman) to NRC Chairman Dale E. Klein (Mar. 11, 2008) (ML080700957).

[137] Status of Recommendations from the U.S. Senate Permanent Subcommittee on Investigations Report, Dirty Bomb Vulnerabilities (n.d.), appended to letter from NRC Chairman Dale E. Klein to Sen. Carl Levin (June 6, 2008), at 3 (ML081350223).

[138] Independent External Review Panel To Identify Vulnerabilities in the U.S. Nuclear Regulatory Commission's Materials Licensing Program; Meeting Notice, 73 Fed. Reg. 5235 (Jan. 29, 2008), 2008 WL 219866 (F.R.).

[139] Independent External Review Panel To Identify Vulnerabilities in the U.S. Nuclear Regulatory Commission's Materials Licensing Program; Meeting Notice, 72 FR 72,775 (Dec. 21, 2007), 2007 WL 4456289 (F.R.).

This advisory committee was chartered under FACA on October 10, 2002,[140] and, from the fact that the final *Federal Register* notice of the committee's meeting was published in June 2004,[141] it is safe to assume that the committee was dissolved around that time.[142] The membership was "composed of individuals with expertise in structural, nuclear, and thermal engineering, fuel performance and source term evaluations, consequence analyses, weapons and explosives, and transportation of radioactive material."[143]

The committee's purpose was to "[d]evelop guidance documents that will assist the NRC in evaluating the impact of specific terrorist activities targeted at a range of spent fuel storage casks and radioactive material . . . transport packages, including spent fuel."[144] The committee was instructed to develop these documents "from a literature search, appropriate code usage and an expert judgement [*sic*] process."[145] Given the subject it was chartered to address, it is not surprising that all of the committee's work was classified.[146] Consequently, its meetings were closed to the public to protect national security information.[147]

III. EXISTING ADVISORY COMMITTEE NOT CHARTERED UNDER FACA

A. The Committee To Review Generic Requirements (CRGR).

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[140] Charter, Peer Review Committee for Source Term Modeling (Oct. 10, 2002), appended to Letter from Andrew L. Bates to Mr. Richard Yarnal, Library of Congress (Oct. 10, 2002) (ML022830777); NRC, Notice of Establishment of the Peer Review Committee for Source Term Modeling, 67 Fed. Reg. 64,146 (Oct. 17, 2002), 2002 WL 31317081 (F.R.).

[141] NRC, Notice of Meeting, Peer Review Committee for Source Term Modeling, 69 Fed. Reg. 31,850 (June 7, 2004), 2004 WL 1236892 (F.R.).

[142] Neither Westlaw nor the Commission's database contain any document specifying the date, or even year, in which this committee was dissolved.

[143] Charter, Peer Review Committee for Source Term Modeling (Oct. 10, 2002), at 1, appended to Letter from Andrew L. Bates to Mr. Richard Yarnal, Library of Congress (Oct. 10, 2002) (ML022830777).

[144] *Id.*

[145] *Id.*

[146] Bates interview.

[147] *See*, *e.g.*, NRC, Notice of Meeting, Peer Review Committee for Source Term Modeling, 68 Fed. Reg. 14,266 (Mar. 24, 2003), 2003 WL 1442039 (F.R.); NRC, Notice of Meeting, Peer Review Committee for Source Term Modeling, 68 Fed. Reg. 2811 (Jan. 21, 2003), 2003 WL 137545 (F.R.).

As with other advisory committees that are comprised entirely of full-time NRC employees, the CRGR is not a FACA-chartered committee.[148] The CRGR once reviewed rulemakings but no longer does so.[149] It now reviews exclusively individual licensing issues.[150] Specifically, the CRGR reviews proposed generic "backfits"[151] that the NRC proposes to impose on all power reactors and/or selected nuclear materials facilities.[152] Specifically, its primary responsibilities are "to recommend either approval or disapproval of the staff's proposed backfits, and to guide and assist the NRC's program offices in implementing the Commission's backfit policy."[153] These reviews are intended to ensure that such backfits are consistent with the Commission's backfit policy and satisfy the backfit provisions in the NRC's regulations. The CRGR also provides the Commission with an annual report describing the committee's activities during the previous year and its recommendations regarding the issues reviewed during that period. Finally, the committee reviews the agency's "generic administrative backfit controls to ensure that they are sufficient and that the related staff guidance is comprehensive and clear."[154]

The committee is designated as an advisory committee to the NRC's Executive Director for Operations (EDO) rather than to the Commission itself. The EDO appoints the committee's chairman and members. The committee is comprised of the chairman and one representative from each of the following NRC offices:

- Office of Nuclear Regulatory Research
- Office of Nuclear Reactor Regulation
- Office of Nuclear Material Safety and Safeguards
- Office of Nuclear Security and Incident Response
- Office of New Reactors
- FSME

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[148] Bates interview. FACA-chartered advisory committees may, however, include *some* full-time governmental employees. *See*, *e.g.*, Reactor Oversight Process Initial Implementation Evaluation Panel, *supra*, at Section II.D.

[149] Jones/Mizuno interview.

[150] *Id.*

[151] 10 C.F.R. § 50.109 defines a "backfit" as "the modification of or addition to systems, structures, components, or design of a facility; or the design approval or manufacturing license for a facility; or the procedures or organization required to design, construct or operate a facility; any of which may result from a new or amended provision in the Commission's regulations or the imposition of a regulatory staff position interpreting the Commission's regulations that is either new or different from a previously applicable staff position. . . ."

[152] *See* Charter: Committee to Review Generic Requirements (Revision 8, March 2011) (ML110620618).

[153] http://www.nrc.gov/about-nrc/regulatory/crgr.html.

[154] http://www.nrc.gov/about-nrc/regulatory/crgr.html; http://pbadupws.nrc.gov/docs/ML1106/ML110620618.pdf.

- Office of the General Counsel
- One of the NRC's four Regional Offices[155]

Further information about this committee is available at its website, http://www.nrc.gov/about-nrc/regulatory/crgr.html. Also, the committee's charter is available at http://www.nrc.gov/about-nrc/regulatory/crgr/charter.html.

IV. DEFUNCT ADVISORY COMMITTEE NOT CHARTERED UNDER FACA

A. Advisory Committee of State Officials (ACSO)[156]

The AEC's Director of Operations formed the ACSO in late 1955,[157] and the committee first met in February 1956.[158] Its purpose was to advise the AEC on issues involving federal/state relations both prior to and after the 1959 enactment of Section 274 of the Atomic Energy Act.[159] Under Section 274, the NRC was authorized to transfer to "agreement states" its regulatory authority over byproduct, source and special nuclear materials.[160] To implement this section, the AEC consulted with the ACSO and other entities in 1960, and issued criteria the following year to evaluate the applications of those states seeking "agreement state" status.[161] By 1961, the committee was advising the AEC on issues involving the states' assumption of authority for the regulation of byproduct, source and special nuclear materials.[162] In 1962, it was reviewing and commenting to the AEC regarding proposed rules governing

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[155] http://www.nrc.gov/about-nrc/regulatory/crgr/membership.html.

[156] This advisory committee was chartered prior to the enactment of FACA in 1972. *See Miccosukee Tribe of Indians v. Southern Everglades Restoration Alliance*, 304 F.3d 1076, 1082 (11th Cir. 2002) (regarding the year of FACA's enactment).

[157] National Materials Program: Options and Recommendations, "Final Report of the Working Group, SECY-99-250, Vol. 1, at p. 1.3 (May 2001) (ML011590431); "Topical Discussion of the NRC/Agreement State Program" (1994) at 2 (referring to the "Director of Regulation (or equivalent)"), appended to Memorandum to Agreement State Program Directors from Ad-Hoc Committee to Update Topical Report (Dec. 10, 2001), entitled "Update to the OAS Topical Discussion" (ML020380420).

[158] "Topical Discussion of the NRC/Agreement State Program" (1994) at 2, appended to Memorandum to Agreement State Program Directors from Ad-Hoc Committee to Update Topical Report (Dec. 10, 2001), entitled "Update to the OAS Topical Discussion" (ML020380420).

[159] *Id.*

[160] *Id.* at 4.

[161] *Id.* at 5.

[162] Letter to Rad Ware from Richard P. Correia, Acting Chief, Materials Safety and Inspection Branch, Division of Industrial and Medical Nuclear Safety, NMSS, at 2 (Feb. 9, 2005) (ML050400249).

the transfer of authority to the states.[163] There appears to be no official record of the date on which the ACSO was disbanded, but the Organization of Agreement States commented in 1994 that it believed the dissolution occurred in the mid-to-late 1960s.[164]

[163] [Final Rule,] Part 150 – Exemptions and Continued Regulatory Authority in Agreement States under Section 274, 27 Fed. Reg. 1351, 1351 (Feb. 14, 1962).

[164] "Topical Discussion of the NRC/Agreement State Program" (Oct. 1994) at 2, appended to Memorandum to Agreement State Program Directors from Ad-Hoc Committee to Update Topical Report (Dec. 10, 2001), entitled "Update to the OAS Topical Discussion" (ML020380420); National Materials Program: Options and Recommendations, "Final Report of the Working Group, SECY-99-250, Vol. 1, at p. 1.3 (May 2001) (ML011590431).

Appendix B

Use of Expert Elicitation at the Nuclear Regulatory Commission - Roland M. Frye, Jr.[1] (EE Article -- 2/16/12)

Abstract

One way the Nuclear Regulatory Commission has resolved difficult technical problems has been through expert elicitation -- a formal, highly structured, and well-documented process for obtaining the judgments of multiple experts. Yet this useful and creative process has been almost completely ignored by scholars, judges, and even the NRC's own Commissioners. Only one law-related journal article has directly addressed the use of expert elicitation in the context of nuclear-related technical issues, and that article is now a decade old. Likewise, only one Federal court decision refers, even in passing, to this same topic.

Until last year, only occasionally did expert elicitation garner the attention of the NRC's Commissioners. For instance, the Commissioners have never referred to the expert elicitation process in their adjudicatory decisions. This changed in early 2011, when Commissioner George Apostolakis proposed that the agency reexamine its use of expert judgment and expert elicitation – placing the process squarely in the forefront of the agency's attention.

This article examines United States Nuclear Regulatory Commission's use of the "expert elicitation" process to address scientific and technical questions that are unanswerable when using more traditional data and modeling techniques. The article is intended to provide an overview of both the process and the history of expert elicitation at the NRC from 1996 forward -- including elicitation reports that the U.S. Department of Energy (DOE) submitted to the NRC in the *Yucca Mountain* application proceeding. To the extent possible, this article avoids delving into the scientific, technical and statistical details of individual NRC elicitations.

Contents

[1] Senior Attorney, United States Nuclear Regulatory Commission. This article was prepared as a research paper while the author was on detail from the NRC to the Administrative Conference of the United States (ACUS), in support of a proposed ACUS recommendation addressing the confluence of science and regulation. Its contents do not necessarily reflect the views of either agency. Because the research article was directed in part to an agency other than the NRC and because its current publication in this journal places it in the public domain, this article's citations are limited to publicly available documents. This approach is also consistent with ACUS' policy of openness and transparency. *See* http://www.acus.gov/foia/open-government/ (ACUS "is an independent federal agency that is committed to open government and is dedicated to achieving the goals of openness, transparency and accountability to the American public").

"Seldom is the development of an answer to a difficult problem the work of any single individual."[2]

This article examines United States Nuclear Regulatory Commission's (NRC) use of the "expert elicitation" process to address scientific and technical questions that are unanswerable when using more traditional data and modeling techniques.[3] The article is intended to provide an overview of both the process and the history of expert elicitation at the NRC from 1996 forward, including elicitation reports that the U.S. Department of Energy (DOE) submitted to the NRC in

[2] NUREG-1624, "Technical Basis and Implementation Guidelines for A Technique for Human Event Analysis (ATHEANA)," at xxix (Rev. 1, May 2000) (ADAMS Accession No. ML003719212). (An "ADAMS Accession Number" denotes the location of a document within the NRC's automated document management and retrieval system, available to the public at http://wba.nrc.gov:8080/wba/. Information regarding its use is available at http://www.nrc.gov/reading-rm/adams.html.)

NUREGs, such as the one cited immediately above, are guidance documents issued by the NRC staff (staff) and, as such, are not binding on either the Commission or licensees. *See Curators of the University of Missouri* (TRUMP-S Project), CLI-95-8, 41 NRC 386, 397 (1995), 1995 WL 395904 (N.R.C.), at *8; NUREG-1563, "Branch Technical Position on the Use of Expert Elicitation in the High-Level Radioactive Waste Program," at 9 (Nov. 1996) (NUREG-1563) (ML033500190) (branch technical positions "are not substitutes for regulations, and compliance with them is not required"). *See also International Uranium (USA) Corp.* (Request for Materials License Amendment), CLI-00-1, 51 NRC 9, 19 (2000), 2000 WL 558524 at *9 ("Like NRC NUREGs and Regulatory Guides, NRC Guidance documents are routine agency policy pronouncements that do not carry the binding effect of regulations"). Guidance documents are, however given "special weight" due to their implicit endorsement by the Commission. *Yankee Atomic Electric Co.* (Yankee Nuclear Power Station), CLI-05-15, 61 NRC 365, 375 n.26 (2005) ("guidance is at least implicitly endorsed by the Commission and therefore is entitled to correspondingly special weight"); *Private Fuel Storage, L.L.C.* (Independent Spent Fuel Storage Installation), CLI-01-22, 54 NRC 255, 264 (2001) ("Where the NRC develops a guidance document to assist in compliance with applicable regulations, it is entitled to special weight"), *pet. for review held in abeyance*, *Ohngo Gaudadeh Devia v. NRC*, 492 F.3d 421 (D.C. Cir. 2007).

[3] NUREG-1563, at A-1. *Accord id.* at 3.

the *Yucca Mountain* application proceeding.[4] To the extent possible, this article avoids delving into the scientific, technical and statistical details of individual NRC elicitations.[5]

I. INTRODUCTION

One way the NRC has resolved difficult technical problems has been through expert elicitation -- "a formal, highly structured, and well-documented process for obtaining the judgments of multiple experts."[6] Yet this useful and creative process has been almost completely ignored by scholars, judges, and even the NRC's own Commissioners. Only one law-related journal article has directly addressed the use of expert elicitation in the context of nuclear-related technical issues, and that article is now a decade old.[7] Likewise, only one Federal court decision refers, even in passing, to this same topic.[8] And until last year, only occasionally did expert elicitation garner the attention of the NRC's Commissioners. For instance, the Commissioners have never referred to the expert elicitation process in their adjudicatory decisions.

This changed in early 2011, when Commissioner George Apostolakis proposed that the agency reexamine its use of expert judgment and expert elicitation.[9] His stated objective was to ensure that expert elicitation "incorporates lessons learned from past major studies and is applied consistently in regulatory decision making throughout the Agency."[10] Specifically, he favored

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[4] Although this article cites or briefly discusses several pre-1996 elicitations or elicitation-related documents, the issuance of two documents in 1996 make that year a logical starting point for this examination of expert elicitation: (i) the completion of the first of DOE's voluminous elicitation reports and (ii) the NRC staff's issuance of its definitive guidance on elicitation. *See* Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS) , "Probabilistic Volcanic Hazard Analysis for Yucca Mountain, Nevada," (Rev. 0 June 1996) (Volcanology Expert Elicitation) (ML003743285, ML081560551), submitted by DOE in *U.S. Department of Energy* (High Level Waste Repository), NRC Docket No. 63-001-HLW (*Yucca Mountain*); NUREG-1563.

[5] For instance, this article describes the stage of the Yucca Mountain expert elicitation process in which the volcanology panel held a workshop on alternative hazard models. But the article does not describe, or discuss the relative merits of, the different models.

[6] NUREG-1563 at A-1. *Accord id.* at 3. *Cf.* NUREG-1804, "Final Report, Yucca Mountain Review Plan" (Rev. 2, July 2003), at p. 3-7 (NUREG-1804) (ML032030389) (defining expert elicitation as "[a] formal process through which expert judgment is obtained").

[7] Patricia Fleming, *Examining Recent Expert Elicitation Judgment Guidelines: Value Assumptions and the Prospects for Rationality*, 12 Risk: Issues in Health & Safety 107 (Spring 2001) (Fleming). Although other articles in law reviews and law-related journals have alluded to expert elicitation in contexts different from nuclear safety, those articles' references to elicitation were incidental to their focus on other topics.

[8] *Cook v. Rockwell Int'l Corp.*, 580 F. Supp. 2d 1071, 1093 (D. Colo. 2006).

[9] COMGEA-11-0001, Utilization of Expert Judgment in Regulatory Decision Making (Jan. 19, 2011) (COMGEA-11-0001) (ML110200139). For an explanation of the differences between the terms "expert judgment" and "expert elicitation," *see* text associated with notes 81-87, *infra*.

[10] *Id.* at 1.

the development of new "guidance to promote the consistent use of expert judgment in regulatory decision making throughout the Agency."[11] Commissioner Apostolakis explained that expert elicitation could, for instance, "play an important role in the resolution of difficult regulatory challenges including cyber security, digital instrumentation and control, small modular reactors, and material aging issues."[12] He listed the following advantages to using expert judgment/elicitation:

> This effort will promote a more consistent and transparent basis for regulatory decision making when expert judgment is required. It will also provide clear and consistent guidance to licensees and staff for both formally utilizing expert judgment and for reviewing licensing actions that are based, at least in part, on expert judgment. Finally, it is anticipated that this effort will improve the efficiency of Agency planning by identifying and prioritizing resources that are commensurate with the significance of the safety or security issue(s) and degree of reliance on expert judgment in the associated regulatory decision making.[13]

Yet he also pointed out that expert elicitation would be inappropriate for some cases, such as those requiring consultation with only a handful of subject-matter experts.[14]

With favorable comments, the other four Commissioners unanimously supported his request and the five Commissioners collectively issued a directive that the staff prepare a plan to develop such guidance.[15] In responding nine months later, the staff did not immediately comply

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[11] *Id.* at 2. *See also* SECY-11-0172, "Response to Staff Requirements Memorandum COMGEA-11-0001, "Utilization of Expert Judgment in Regulatory Decision Making," at 1 (Dec. 13, 2011) (SECY-11-0172) (ML112020602). "COM"s (such as COMGEA-11-0001) are Commission Action Memoranda to the staff. By contrast, "SECY Papers" (such as SECY-11-0172) are memoranda from the NRC staff to the Commissioners.

[12] COMGEA-11-0001 at 2.

[13] *Id.* at 3.

[14] *Id.* at 2-3. For a description of a DOE approach lying somewhere between the Commissioner's referenced non-use of elicitation when there are only a handful of experts and the more typical full-scale elicitation process, *see* text associated with note 321, *infra*.

[15] Staff Requirements – COMGEA-11-0001 – "Utilization of Expert Judgment in Regulatory Decision Making" (March 15, 2011) (ML110740304). Regarding favorable comments, *see* Commission Voting Record, VR-COMGEA-11-0001 (ML110740555):

> Chairman Gregory Jaczko: "I appreciate Commissioner Apostolakis making the Commission aware of the increasing importance of expert elicitation and phenomena identification and ranking table activities, and I agree that the development of guidance to ensure the consistent utilization of expert judgment by the staff is worthwhile."
>
> Commissioner Ostendorff: "I believe that major lessons learned from across the nuclear sector, if conveyed in a useful and practical manner, could improve the

with the Commissioners' directive but instead recommended that the Commission take no such action at this time, due to both the "relatively high resource implications" of such a project and the satisfactory nature of current NRC guidance regarding expert judgment.[16]

The Commissioners were not moved. They again offered quite favorable comments in support of the re-examination of the 1996 staff guidance document.[17] And Commissioner Apostolakis supplemented his earlier explanation as to why the revision of the 1996 guidelines was a wise idea:

> Although a number of different approaches have been used in several NRC-sponsored studies, structured, agency-wide process with corresponding implementation guidance is currently lacking. Its availability will formalize the utilization of expert judgment, incorporate lessons learned from past NRC studies, and ensure that elicitation processes are applied consistently in regulatory decision making throughout the Agency. . . . In cases of lack of experiential evidence, expert judgment methods are employed to produce information regarding the state of knowledge on particular issues. It is well known, however, that there is not one universally accepted way to elicit and process expert judgments. What the decision makers need to know is what methods have been used, what has not been done (thus imposing limitations on the results), and, as appropriate, the results of sensitivity studies using alternative methods.[18]

The only point of difference among the Commissioners was the issue of when to begin work on the revised guidance. Commissioner Ostendorff and Chairman Jaczko would instruct the staff to begin the revision as soon as possible, so long as it does not interfere with higher-priority

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> confidence level and consistency of future regulatory decision-making that rely heavily on expert judgment."

[16] SECY-11-0172 at 7.

[17] For instance, the Chairman commented that "improvements to the existing expert judgment approaches used by the NRC can be made, and . . . doing so is a worthwhile endeavor." Chairman Jaczko's vote sheet (Jan. 30, 2012) (ML120320315). Commissioner Magwood described the revision as "an important and timely initiative." Commissioner Magwood's vote sheet (Jan. 13, 2012). Commissioner Ostendorff observed that "this project has the potential to achieve [the] core research mission" of "further[ing] the state-of-knowledge in nuclear safety and provid[ing] the best available regulatory guidance." Commissioner Ostendorff's vote sheet (Jan. 13, 2012). By "synthesizing diverse practices in the use of expert opinion," the revised guidance would, according to Commissioner Ostendorff, "facilitate[e] knowledge management and [be] an "essential building block to sustain further advances in the discipline" of expert opinion." *Id.* Finally, Commissioner Svinicki opined that "the availability of [revised] guidance will ultimately save resources and has the potential to further advance the transparency of our application of expert judgment, further advancing the credibility of NRC's technical work." Commissioner Svinicki's vote sheet (Jan. 23, 2012). All five Commissioners' January 2012 vote sheets (including that of the Chairman, *supra*) are available at Commission Voting Record, VR-SECY-11-0172 (ML12038A164).

[18] Commissioner Apostolakis' vote sheet (Jan. 9, 2012).

projects[19] "such as implementation of the Fukushima Dai-ichi lessons learned recommendations, completion of fire protection NFPA 805 licensing amendment reviews, or resolution of generic issues."[20] Commissioner Magwood expressed similar concerns, but would have the staff report back to the Commission with a "revised plan, schedule, and resource estimate."[21] The Commissioners resolved their differences and on February 7, 2012, issued a Staff Requirements Memorandum rejecting the staff's recommendation and instructing it to proceed with the revision of the 1996 guidelines:

> The staff should pilot draft guidance [*sic*] in the Level 3 PRA [probabilistic risk assessment] project[[22]] that will require expert judgment elicitation in areas such as human reliability analysis and severe accident analysis. The pilot process will help inform the guidance and should identify areas for improvement. The staff should inform the Commission within 4 months how piloting the guidance has been integrated into a revised plan, schedule, and resource estimate with the expectation that the final guidance be completed within 18 months after the pilot. The staff should leverage their efforts by referencing the existing library of accepted expert elicitation guidance and information. Additionally, the staff should consult informally with organizations in the Federal family, national laboratory community, and Federally Funded Research and Development Centers (FFRDCs) to obtain a general understanding of the views of and practices in place within other organizations.[23]

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[19] Commissioner Ostendorff's vote sheet (Jan. 13, 2012) ("the staff should prioritize and resource this work in accordance with the Planning, Budgeting, and Performance Management process . . . ."); Chairman Jaczko's vote sheet (Jan. 30, 2012).

[20] Chairman Jaczko's vote sheet (Jan. 30, 2012).

[21] Commissioner Magwood's vote sheet (Jan. 13, 2012).

[22] In 2011, the Commission directed the staff to "plan for and perform a new full-scope comprehensive site Level 3 PRA for an operating plant." Staff Requirements Memorandum, "SECY-11-0089 – Options for Proceeding with Future Level 3 Probabilistic Risk Assessment (PRA) Activities" (Sep. 21, 2011) (ML112640419). A "full-scope comprehensive site Level 3 PRA" is defined as "a PRA that includes a quantitative assessment of the public risk from accidents involving all site reactor cores and spent nuclear fuel that can occur during any plant operating state, and that are caused by all initiating event hazards (internal events, fires, flooding, seismic events, and other site-specific external hazards)." SECY-11-0089, Options for Proceeding with Future Level 3 Probabilistic Risk Assessment Activities (July 7, 2011), at 1 n.2 (ML11090A041). Of the three different levels of PRA, a Level 3 PRA provides the "most complete representation of plant risk." Chairman Jaczko's vote sheet (Aug. 29, 2011), appended to VR-SECY-11-0089, Commission Voting Record, "SECY-11-0089 – Options for Proceeding with Future Level 3 Probabilistic Risk Assessment Activities" (Sep. 21, 2011) (ML11265A015). The NRC's most recent Level 3 PRA project resulted in the issuance of NUREG-1150 (published in 1990, and discussed briefly in text associated with notes 98-100, *infra*). *See* Commissioner Apostolakis' vote sheet (Aug. 9, 2011), appended to same.

[23] Staff Requirements – SECY-11-0172 – "Response to Staff Requirements Memorandum COMGEA-11-0001, 'Utilization of Expert Judgment in Regulatory Decision Making'" (Feb. 7, 2012) (ML120380251). *See also* Commissioner Magwood's vote sheet (Jan. 13, 2012) (Commissioner Magwood was the source of the instructions in the final quoted sentence).

One promising place for the staff to begin its research is the Environmental Protection Agency's (EPA) use of expert elicitation, and a good starting point for such EPA research would be the EPA's Expert Elicitation "White Paper"[24] and its underlying documents. EPA's White Paper discusses the potential utility of using expert elicitation to support EPA regulatory and non-regulatory analyses and decision-making, provides recommendations for expert elicitation 'good practices,' and describes steps for a broader application across EPA."[25] Also, a recent (January 26, 2011) search of the WestLaw's *Federal Register* library yielded 45 instances where the NRC used the term "expert elicitation,"[26] 41 instances for the EPA, [27] and 18 more instances for eight

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[24]EPA, Expert Elicitation Task Force White Paper (Aug. 2011), available at http://www.epa.gov/stpc/pdfs/ee-white-paper-final.pdf.

[25] EPA, Notice, EPA Science Advisory Board Office; Notification of Two Public Teleconferences of the Chartered Science Advisory Board, 74 Fed. Reg. 34,348 (July 15, 2009).

[26] In case the Commission instructs the staff to conduct further research into the NRC's and other Federal agencies' use of expert elicitation, this and the next two footnotes of this article provides short citations to all instances where a Federal agency has used the phrase "expert elicitation" in a *Federal Register* document. For the sake of brevity, and because the citations are not directly relevant to this article, the *Federal Register* citations associated with the textual paragraph above do not follow Blue Book citation format:

75 Fed. Reg. 13,
72 Fed. Reg. 61,189,
70 Fed. Reg. 67,598,
70 Fed. Reg. 57,901,
70 Fed. Reg. 25,622,
69 Fed. Reg. 68,411,
68 Fed. Reg. 45,086 at 45,100,
67 Fed. Reg. 79,168,
66 Fed. Reg. 32,074 at 32,101,
62 Fed. Reg. 24,670,
61 Fed. Reg. 36,399,
61 Fed. Reg. 7568,
60 Fed. Reg. 32,214,
60 Fed. Reg. 28,206,
58 Fed. Reg. 49,531,
& 54 Fed. Reg. 26,455.

74 Fed. Reg. 40,006,
72 Fed. Reg. 56,275,
70 Fed. Reg. 62,352,
70 Fed. Reg. 55,637,
70 Fed. Reg. 10,901,
69 Fed. Reg. 63,564,
68 Fed. Reg. 38,106,
66 Fed. Reg. 55,732,
65 Fed. Reg. 10,121,
61 Fed. Reg. 67,354,
61 Fed. Reg. 27,108,
61 Fed. Reg. 6867,
60 Fed. Reg. 31,185,
59 Fed. Reg. 23,084,
56 Fed. Reg. 24,848,

72 Fed. Reg. 65,358,
71 Fed. Reg. 38,906,
70 Fed. Reg. 60,859,
70 Fed. Reg. 53,639,
70 Fed. Reg. 8857,
68 Fed. Reg. 49,529,
68 Fed. Reg. 9098,

64 Fed. Reg. 8640,
61 Fed. Reg. 46,832,
61 Fed. Reg. 15,984,
60 Fed. Reg. 43,617
60 Fed. Reg. 29,911,
59 Fed. Reg. 9253,
56 Fed. Reg. 11,765,

[27] *See* 76 Fed. Reg. 74,854,
75 Fed. Reg. 25,324,
75 Fed. Reg. 9648,
74 Fed. Reg. 39,075,
74 Fed. Reg. 21,136,
74 Fed. Reg. 5157,
73 Fed. Reg. 35,838,
73 Fed. Reg. 3568,
72 Fed. Reg. 28,098,
72 Fed. Reg. 15,938,

76 Fed. Reg. 57,106,
75 Fed. Reg. 22,896,
74 Fed. Reg. 49,454,
74 Fed. Reg. 34,348,
74 Fed. Reg. 14,799,
73 Fed. Reg. 59,034,
73 Fed. Reg. 25,098,
72 Fed. Reg. 69,922,
72 Fed. Reg. 27,178,
72 Fed. Reg. 8428,

76 Fed. Reg. 55,673,
75 Fed. Reg. 14,670,
74 Fed. Reg. 44,442,
74 Fed. Reg. 24,904,
74 Fed. Reg. 9698,
73 Fed. Reg. 37,096,
73 Fed. Reg. 21,128,
72 Fed. Reg. 35,463,
72 Fed. Reg. 20,586,
71 Fed. Reg. 39,154,

other agencies or departments.[28] Finally, other promising avenues of research include elicitations by the private sector,[29] academia, [30] and the national laboratories.[31]

II. WHAT IS EXPERT ELICITATION

As noted above, the Commission staff has defined "expert elicitation" as "a formal, highly structured, and well-documented process for obtaining the judgments of multiple experts."[32]

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70 Fed. Reg. 61,283, 70 Fed. Reg. 17,766, 68 Fed. Reg. 7531,
67 Fed. Reg. 79,168, 66 Fed. Reg. 32,074, 64 Fed. Reg. 46,976,
63 Fed. Reg. 27,354, 62 Fed. Reg. 58,792, 61 Fed. Reg. 5224,
60 Fed. Reg. 5766, & 59 Fed. Reg. 31,238

[28] Department of Health and Human Services (Food and Drug Administration) (74 Fed. Reg. 15,293, 70 Fed. Reg. 23,813); Department of Transportation (National Highway Traffic Safety Administration) (76 Fed. Reg. 74,854, 76 Fed. Reg. 57,106, 75 Fed. Reg. 25,324, 74 Fed. Reg. 49,454) (all four overlapping with EPA); Department of Commerce (National Oceanic and Atmospheric Administration) (soliciting expert opinions derived from (inter alia) expert elicitation) (76 Fed. Reg. 41,217); Department of Agriculture (Food Safety and Inspection Service) (76 Fed. Reg. 80,873, 76 Fed. Reg. 19,952, 72 Fed. Reg. 16,327); Nuclear Waste Technical Review Board (62 Fed. Reg. 67,417, 62 Fed. Reg. 26,341); Department of Homeland Security (73 Fed. Reg. 18,384, 72 Fed. Reg. 69,819, 72 Fed. Reg. 35,088); Department of State (73 Fed. Reg. 18,384, 72 Fed. Reg. 35,088) (two overlapping with Department of Homeland Security); DOE (64 Fed. Reg. 67,054, regarding *Yucca Mountain*).

[29] *See*, *e.g.*, the Electric Power Research Institute (EPRI) Report No. 1006961, "Spurious Actuation of Electrical Circuits Due to Cable Fires: Results of an Expert Elicitation" (May 2002) (EPRI Report).

[30] *See*, *e.g.*, Monte N. Stewart & H. Dennis Tolley, *Investigating Possible Bias: the American Legal Academy's View of Religiously Affiliated Law Schools*, 54 J. Legal Educ. 136, 143-47 (2004); Emma Fauss et al., *Using Expert Elicitation to Prioritize Resource Allocation for Risk Identification for Nanosilver*, 37 J.L. Med. & Ethics 770, 771 (2009) (Fauss). The Fauss article presents an expert elicitation process quite different from the one used by the NRC and DOE. *Id.* at 774-79. Additional articles included in 37 J.L. Med. & Ethics likewise address the same expert elicitation process as Ms. Fauss, and are cited elsewhere in this article (notes 32, 40, 99, *supra*).

[31] *See*, *e.g.*, Bernreuter, D. L., J. B. Savy, R. W. Mensing, and J. C. Chen. 1989. Seismic Hazard Characterization of 69 Nuclear Plant Sites East of the Rocky Mountains. Report NUREG/CR-5250, vols. 1-8, prepared by Lawrence Livermore National Laboratory (LLNL) for NRC, cited in NUREG/CR-6372, Vol. 1, "Recommendations for Probabilistic Seismic Hazard Analysis: Guidance on the Uncertainty and Use of Experts" (Apr. 1997), at 2-3 (NUREG/CR-6372, Vol. 1) (ML080090003).

[32] NUREG-1563, at A-1. The staff has described expert elicitation as "a well-recognized technique for quantifying phenomenological knowledge when modeling approaches or data are insufficient." NUREG-1829, Vol. 2, "Estimating Loss-of-Coolant Accident (LOCA) Frequencies Through the Elicitation Process: Appendices A through M" (Apr. 2008) (NUREG-1829, Vol. 2) (ML081060300), at v. *Accord id.* at xv. *See also* NRC, Notice of Availability of Draft Report for Comment: "Estimating Loss-of-Coolant Accident (LOCA) Frequencies Through the Elicitation

The NRC has used this process in a variety of situations, such as rulemaking, adjudication, and technical analysis not associated with rulemaking or adjudication.[33] The staff's principle guidance document regarding expert elicitation is NUREG-1563, which specifically addresses DOE's use of the expert elicitation process to support the *Yucca Mountain* application but, according to the staff, would be equally applicable to any future DOE application for another high-level radioactive waste repository site.[34] In NUREG-1563, the staff states that the process is appropriate under any of the following circumstances:

Process," NUREG-1829, 70 Fed. Reg. 57,901, 57,902 (Oct. 4, 2005), 2005 WL 2427738 (F.R.) (describing expert elicitation as "well-recognized for quantifying phenomenological knowledge when data or modeling approaches are insufficient"); NUREG-1829, Vol. 2, at xv; NRC, Supplemental Proposed Rule, Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements, 74 Fed. Reg. 40,006 (Aug. 10, 2009), 2009 WL 2421533 (F.R.) (Supplemental Proposed Rule); NRC, Notice of Public Workshop on Draft Report for Comment: "Estimating Loss-of-Coolant Accident (LOCA) Frequencies Through the Elicitation Process," NUREG-1829, 70 Fed. Reg. 62,352, 62,352 (Oct. 31, 2005), 2005 WL 2835136 (F.R.); NUREG-1829, Vol. 1, "Estimating Loss-of-Coolant Accident (LOCA) Frequencies Through the Elicitation Process: Main Report" (Apr. 2008), at p. 1-10 (NUREG-1829, Vol. 1) (ML080630013):

> Expert elicitation is a formal process for providing quantitative estimates of the frequencies of physical phenomena when the required data is sparse and when the subject is too complex to adequately model. [Elicitation is particularly useful where] scientific uncertainty about [the issue under consideration] is so large that, in the absence of adequate data, validated models or computer codes cannot be developed.

See also Jennifer Kuzma, *et al.*, *Evaluating Oversight Systems for Emerging Technologies: A Case Study of Genetically Engineered Organisms*, 37 J.L. Med. & Ethics 546, 554 (2009) (Kuzma) ("Expert elicitation is an evidence gathering methodology in the face of high uncertainty and little information" (footnote omitted)).

[33] These are addressed in Part III of this article, *infra*. In addition, the Commission has twice cited an expert elicitation by EPRI in *Federal Register* notices seeking comments on generic communications addressing fire safety issues. NRC, Notice of Opportunity for Public Comment, Proposed Generic Communication; Post-Fire Safe-Shutdown Circuit Analysis Spurious Actuations, 70 Fed. Reg. 60,859, 60,859 (Oct. 19, 2005), 2005 WL 2656234 (F.R.) (referring to EPRI Report, *supra* note 29); NRC, Notice, Proposed Generic Communication; Clarification of Post-Fire Safe-Shutdown Circuit Regulatory Requirements, 70 Fed. Reg. 25,622, 25,623 (May 13, 2005), 2005 WL 1121559 (F.R.) (referring to EPRI Report).

[34] NUREG-1563 at D-6. Although expert elicitation had been used in several prior instances in the context of nuclear regulation (*see* Parts III.A and III.B, *supra*), NUREG-1563 was the first formal NRC guidance document on the subject. In drafting NUREG-1563, the staff drew upon those prior instances as well as various NRC resource documents to help formulate its position statements. *See* NRC, Notice, Availability of Final Branch Technical Position on the Use of Expert Elicitation in the High-Level Waste Program, 61 Fed. Reg. 67,354, 67,355 (Dec. 20, 1996), 1996 WL 728098 (F.R.). *See also* NRC, Notice, Availability of Draft Branch Technical Position on the Use of Expert Elicitation in the High-Level Waste Program, 61 Fed. Reg. 7568, 7569 (Feb. 28, 1996), 1996 WL 82126 (F.R.).

(a) Empirical data are not reasonably obtainable, or the analyses are not practical to perform;
(b) Uncertainties are large and significant to a demonstration of compliance;
(c) More than one conceptual model can explain, and be consistent with, the available data; or
(d) Technical judgments are required to assess whether bounding assumptions or calculations are appropriately conservative.[35]

The first of these appears most frequently in the NRC's and DOE's discussions of expert elicitation. The staff provides three examples of this circumstance: "(i) the site characteristics important to waste isolation would be irreversibly compromised by extensive data collection in such a way that could potentially disqualify the site; (ii) it is infeasible or impossible to collect data over the temporal or spatial scales appropriate to adequately address a particular issue; and (iii) the cost of collecting the comprehensive suite of data may be prohibitive."[36]

The staff emphasized that the customary modes of "acquisition and analysis of physical data should be the *primary* manner in which licensing information is collected,"[37] but acknowledged that "many considerations may preclude the collection of such information necessary for licensing."[38] When such considerations are present, expert elicitation or other forms of expert judgment[39] may be used "to complement or supplement the data obtained" through more traditional means.[40] In the same guidance document, the staff announced its expectation that

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[35] NUREG-1563 at 15. *See also* NUREG-1804 at p. 2.5-61.

[36] NUREG-1563 at 21. *See also id.* at 1. The staff discusses each of these four circumstances in *id.* at 20-22.

[37] *Id.* at 2 (emphasis added). *See also id.* at 1(expert elicitation should be used only "when other means of obtaining requisite data or information have been thoroughly considered and it has been concluded that such means are not[, without more,] practical to implement"), 19, 20.

[38] *Id.* at 2.

[39] For an explanation of the differences between these two terms, *see* text associated with notes 81-87, *infra*.

[40] *Id.* at 1. *See also* CRWMS, "Waste Form Degradation and Radionuclide Mobilization Expert Elicitation Project" at p. 2-2 (May 29, 1998) (Waste Form Expert Elicitation) (ML003757634) ("expert judgment is not a substitute for data; it is a process by which data are evaluated and interpreted"); CRWMS, "Saturated Zone Flow and Transport Expert Elicitation Project" (Oct. 1997), at p. 2-2 (1997 Saturated Zone Flow Expert Elicitation), available at http://www.osti.gov/bridge/servlets/purl/778912/ (same); CRWMS, "Probabilistic Seismic Hazard Analyses for Fault Displacement and Vibratory Ground Motion at Yucca Mountain, Nevada," Vol. 1, at p. 2-2 (Feb. 23, 1998) (Seismology Expert Elicitation) (ML032130141). The second and third volumes of this elicitation are available on ADAMS at, respectively, ML032450043 and ML031640256.

For examples of non-nuclear projects that use expert elicitation in conjunction with other modes of data collection, *see* Kuzma, 37 J.L. Med. & Ethics at 572 ("Through evaluation in three different ways (interviews, quantitative expert elicitation, and historical literature analysis), we were able to critically examine GEOs oversight and more broadly generate hypotheses about

DOE would consider "cost, schedule, resource availability, and other programmatic factors" when determining whether it could obtain the needed information through more preferable means than expert elicitation.[41]

The staff also emphasized the importance of transparency to the expert elicitation process, i.e., the ability of someone outside the process (i) to see all the relevant information that led to the elicitation's conclusions, (ii) to follow all communications amongst the panel members during their deliberations so that the outsider can understand the basis for the conclusions, (iii) to see how the panel used those same conclusions to reach the ultimate outcome of the elicitation, and (iv) to understand why the license applicant chose to use expert judgment rather than the more objective information-gathering methods.[42] Such transparency should, according to the staff, enhance both its own and the public's confidence in DOE's high-level waste program.[43]

The expert elicitation process, as outlined in NUREG-1563, is comprised of nine formal steps:

1. Definition of objectives
2. Selection of experts
3. Refinement of issues and problem definition
4. Assembly and dissemination of basic information
5. Pre-elicitation training
6. Elicitation of judgments
7. Post-elicitation feedback
8. Aggregation of judgments
9. Documentation[44]

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relationships among features and outcomes of oversight"); Jordan Paradise *et al.*, *Evaluating Oversight of Human Drugs and Medical Devices: A Case Study of the FDA and Implications for Nanobiotechnology*, J.L. Med. & Ethics 598, 598 (2009) (referring to the use of "a method of expert elicitation[, . . .] combined with the existing literature, case law, and regulations"); Jae-Young & Gurumurthy Ramachandran, Review of the OSHA Framework for Oversight of Occupational Environments, 37 J.L. Med. & Ethics 633, 635 (2009) (Choi) (referring to the "review of the relevant literature, historical analysis, group consensus, and quantitative expert and stakeholder elicitation"); Susan M. Wolf *et al.*, Gene Therapy Oversight: Lessons for Nanotechnology, 37 J.L. Med. & Ethics 659, 671 (2009) (referring to a combination of "expert elicitation with literature review").

[41] NUREG-1563 at 19. The staff lists three more preferable means: the gathering of additional field or laboratory data, the undertaking of additional theoretical analyses, and the alteration of the compliance demonstration strategy in order to lessen or remove the need to resolve the issue that would otherwise be a subject of expert elicitation. *Id.* at 20.

[42] *See id.* at 19.

[43] *Id.* at 20.

[44] *Id.* at 15-18 (including Fig. 1), 22-30. The staff's general description of its proposed expert elicitation protocol (*id.* at 15-18) is included as the Appendix to this article (exclusive of 16, Fig. 1). By contrast, this article considers the staff's detailed discussion of the protocol (*id.* at 22-30) only in passing.

The staff, however, did not consider these nine steps as carved in stone.[45] Rather, the staff intended that they constitute merely a "general framework" that could be "customized or revised" to suit the needs of the elicitation at issue.[46] The staff in fact expected that even the sequence of steps would be altered to fit those needs and that several of the steps would "proceed or . . . be initiated concurrently, subject to repeated iterations and opportunities for feedback from the subject-matter experts."[47]

The staff concluded that formal elicitation procedures could help to "ensure that expert judgments are *well-documented* and that the technical reasoning used to reach those judgments is *openly displayed for review*."[48] According to the staff, such documentation and

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More recently, the staff published two brief outlines of the nine steps in NUREG-1804 at pp. 2.5- 62 to 2.5-65. For a slight variation on the nine-step approach, *see* NUREG/CR-6372, Vol. 1, at 41-48 (seven steps), 70-78 (seven steps plus peer review), 106-14 (six steps). The staff describes the approaches of NUREG-1563 and NUREG/CR-6372 as "very similar" and "essentially the same." NUREG-2107, "Technical Evaluation Report on the Content of the U.S. Department of Energy's Yucca Mountain Repository License Application; Postclosure Volume: Repository Safety After Permanent Closure," § 2.5.4.2, at pp. 20-1, 20-2 (Aug. 2011) (NUREG-2107) (ML111990436).

In *Yucca Mountain*, DOE described how it implemented each of these nine steps in its expert elicitations regarding volcanology, seismology and hydrology. *See* DOE, Safety Analysis Report (SAR) § 5.4 (June 3, 2008) (ML081560572, ML090710110). Specifically, *see* the descriptions regarding those three expert elicitations in SAR §§ 5.4.1 (volcanology), 5.4.2 (seismology), 5.4.3 (hydrology). (The sections of the SAR cited in this article are found in three separate documents and therefore have three different ADAMS Accession Numbers. Therefore, to avoid confusion, this article diverges from standard citation format and instead includes the appropriate ADAMS Accession Number in each footnote where an SAR section is cited. The ADAMS Accession Number that is cited in a footnote will apply to all subsequent SAR citations in the same footnote, unless otherwise indicated.)

[45] *See* text associated with notes 200, 262, *infra* (staff's approval of DOE's expert elicitations despite their variations from the specific steps enunciated in NUREG-1563).

[46] NUREG-1563 at 22. For instance, an expert elicitation process used to address seismic source characterization would presumably differ from an elicitation process regarding ground motion. *See* NUREG/CR-6372, Vol. 1, at 69. And, indeed, DOE's expert elicitations regarding these two issues did differ somewhat. *See* text accompanying notes 219, 221-223, 228-229, *infra*. Moreover, the staff has observed that expert elicitation is not appropriate in all risk assessment contexts. NUREG-1829, Vol. 2, at p. v ("Because the alternative aggregation methods can lead to significantly different results, a particular set of LOCA frequency estimates is not recommended for all risk-informed applications. *The purposes and context of the application must be considered when determining the appropriateness of any set of elicitation results*.") (emphasis added); *id.* at xxii. *See also* text associated with note 14, *supra* (Commissioner Apostolakis).

[47] NUREG-1563 at 22.

[48] *Id.* at 8 (emphases added). The initial absence of sufficient documentation to support DOE's expert elicitations was of considerable concern to the staff. *Id.* at D-2.

openness offer numerous advantages. For instance, the staff observed that "[a] structured, *thoroughly documented procedure* allows reviewers to reconstruct the logic and events involved in the elicitation and use of expert judgment."[49] Presumably, the staff was referring to peer reviewers, the NRC administrative judges who conduct the prehearing and hearing stages of the *Yucca Mountain* adjudication, the NRC Commissioners, and any Federal judges or justices who sit on appeals of final NRC actions in *Yucca Mountain*. The staff also listed the following additional advantages: "(a) to improve decision-making associated with public policy; (b) to enhance communication; (c) to facilitate peer review, appraisal, and acceptance; (d) to recognize and minimize biases in expert judgment; (e) to indicate the current state of knowledge about important technical and scientific matters; and (f) to provide a basis for updating that knowledge."[50] Further, the staff explained that when properly conducted, "formal [expert] elicitation[[51]] can reveal a wide range of scientific and technical interpretations, thereby exposing (and possibly quantifying) the uncertainties in estimates concerning repository siting, design, and performance attributable to limitations in the state of technical knowledge."[52] According to the staff, expert elicitation can also assist groups of subject-matter experts in resolving "the

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[49] *Id.* at 22 (emphasis in original).

[50] *Id.* at 29-30.

[51] Occasionally, writers have used the terms "formal elicitation" and "informal elicitation." *See*, *e.g.*, *id.* at 7 ("the staff relied on informal elicitations"), 8 (The "staff believes that formal elicitation procedures . . . can help ensure that expert judgments are well-documented . . . ."); Volcanology Expert Elicitation § 2.1.1, at p. 2-4 ("formal expert elicitation"); "Issue Resolution Status Report; Key Technical Issue: Evolution of the Near-Field Environment " at 141, 169-70, 220, 223, 231, 234 (Rev. 3 Aug. 2000) (ML003746694) (all referring to "informal expert elicitation"). The addition of "formal" to the term "expert elicitation" is unnecessary because expert elicitation is, by its very nature a formal process. For the same reason, the addition of "informal" to the term is inaccurate. Presumably, the latter refers to expert judgment exclusive of elicitation. Finally, some writers have used the term "formal expert judgment," the meaning of which is unclear. *See*, *e.g.*, Volcanology Expert Elicitation § 2.1.1, at p. 2-4. *See generally* text associated with notes 81-87, *infra*, regarding the distinction between expert judgment and expert elicitation.

Likewise, as will be seen throughout this article, the nuclear community does not use uniform terminology when referring to the different players in an expert elicitation. For example, DOE uses the terms "evaluators," "panel members," "experts," and "subject-matter experts" when referring to the individuals who serve on an expert elicitation panel. *See*, *e.g.*, SAR § 5.4, at p. 5.4-1 (experts); Volcanology Expert Elicitation § 1.3, at p. 1-4 (subject matter experts), § 2.2.3, at p. 2-11 (evaluator); SAR § 5.4, at p. 5.4-3 (panel members). This article uses only the terms "subject-matter expert" and "panel member," both because those two terms are unambiguous ("expert" can also refer to resource experts, generalists, facilitators, and technical specialists (*see* text associated with notes 66-74 & 80 *infra*)) and because they are more comprehensible to people unfamiliar with expert elicitation. *See also* notes 75-78 and associated text, *infra* (three different terms for the support team that facilitates an expert elicitation), and text associated with note 72, *infra* (two different terms for a resource expert).

[52] NUREG-1563 at 8.

differences in their estimates by providing a common scale of measurement and a common vocabulary for expressing their judgments."[53]

But despite all these advantages, expert elicitation is hardly a panacea.[54] If not carefully structured and managed, the panel may be subject to dominance by a single outspoken member.[55] In addition, the process can be more expensive and time-consuming[56] because it involves more people than the solicitation of a single expert's judgment.[57] Moreover, it can be difficult to represent a panel's wide diversity of expert opinions about technical issues.[58] Furthermore, the results of expert elicitation may be less defensible in adjudications because no single expert "owns" the result.[59] As the NRC's Advisory Committee on Nuclear Waste (ACNW) pointed out, there may be difficulties in a licensing board admitting an expert elicitation report into evidence if not all subject matter experts are available to participate at an evidentiary hearing.[60] Exhibits such as expert reports have typically required an expert witness to "sponsor" them for admission into the administrative record.[61] Yet one subject-matter expert (or, for that matter, less than all subject-matter experts) may be deemed by a board to be insufficient "to represent, as his or her [or their] own, the full range of the technical arguments contained in the . . . elicitation."[62]

Pursuant to the guidance set forth in NUREG-1563, subject-matter experts in an expert elicitation panel should be individuals who:

(a) possess the necessary knowledge and expertise;
(b) have demonstrated their ability to apply their knowledge and expertise;

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[53] *Id.*

[54] For a critique of the Seismology Expert Elicitation, *see* NUREG/CR-6372, Vol. 2, App. H (NUREG/CR-6372, Vol. 2) (ML080090004).

[55] *Id.* at H-3.

[56] For instance, the expert elicitation associated with the Loss of Coolant Accident Rulemaking (described and discussed in Part III.D of this article, *infra*) lasted from February 2003 until April 2008. *See* NUREG-1829, Vol. 1, at p. 3-8 and second title page.

[57] *Id.*; NUREG-1829, Vol. 1, at p. 1-10. *Cf.* COMGEA-11-0001 at 2-3 (Commissioner Apostolakis, observing that expert elicitation will be inappropriate for some cases, such as those requiring consultation with only a handful of subject-matter experts).

[58] Volcanology Expert Elicitation § 2.1, at p. 2-1 (quoting the Senior Seismic Hazard Analysis Committee).

[59] NUREG/CR-6372, Vol. 2, at H-3.

[60] NUREG-1563 at F-4.

[61] *Id.*

[62] *Id.*

(c) represent a broad diversity of independent opinion and approaches for addressing the topic(s) in question;
(d) are willing to be identified publicly with their judgments; and
(e) are willing to publicly disclose all potential conflicts of interest.[63]

The staff's guidance document goes on to state a preference, though not a requirement, that the expert also have "at least some rudimentary knowledge of both decision-making theory and statistics."[64] The staff also recommends that the subject-matter experts be selected, at least in part, from a group of individuals nominated (i) by sources outside the NRC (e.g., professional and academic societies, national laboratories, private industry, representative public interest groups, knowledgeable federal agencies and international organizations), (ii) by recognized peers in the nominees' specialized field, and (iii) based on reviews of the scientific literature.[65]

The staff in NUREG-1563 proposed that expert elicitation participants include not only subject-matter experts but also four other kinds of "support team" participants. The first is the generalist, who "understands the context in which the results of the expert elicitation will be used, guides the structure of the elicitation to produce the needed results, provides relevant information and documentation to the subject-matter experts, and helps to train them."[66] The generalist also plays the role of translator amongst panel members from different disciplines or areas of expertise. In this regard, the generalist must "not only know enough of the language of

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[63] Id. at 15 (Step No. 2 of NUREG-1563's nine-step protocol) (footnote omitted). *Accord id.* at 23. *See also id.* at 22-25 (addressing the subject of panel member selection in detail); NUREG-1804 at pp. 2.5-62, 2.5-64.

In some instances, few experts will be available to serve on an expert elicitation panel. The sponsor of the elicitation may therefore need to turn to experts who are affiliated with the sponsor, either as employees or contractors. *See* Fleming, 12 Risk: Issues in Health & Safety at 113. In those circumstances, it is particularly important that the affiliated experts disclose their conflicts of interest.

[64] NUREG-1563 at 15 n.13 (Step No. 2).

[65] *Id.* at 23, 24. For a variation on this approach to selecting panel members, *see* Kuzma, 37 J.L. Med. & Ethics at 555.

[66] NUREG-1563 at 3. *See also id.* at 15 (Step No. 2), 23. The pre-elicitation training of the subject matter experts (Step 5) includes:

(a) Familiarization with the subject matter;
(b) Familiarization with the elicitation process;
(c) Education in uncertainty and probability encoding and the expression of expert judgment, using subjective probability;
(d) Practice in formally stating judgments and clearly identifying their associated assumptions and rationales; and
(e) Identification of biases that could unduly influence judgments.

NUREG-1804 at pp. 2.5-62, 2.5-64.

[the different experts'] cultures to act as an interpreter, but would also understand enough of their world-views or paradigms to encourage them" to exchange ideas.[67]

The second is the normative expert, who has "training and experience in statistics, decision analysis and probability encoding" and whose main function is to "structure the . . . elicitation and train the subject-matter experts in probability encoding."[68] Statistics is particularly important in scientific and technical expert elicitations because the issues that those panels address often involve the likelihood of a particular event occurring within a particular time period.[69] Other issues may include "the value of a parameter to be used in a model" and "the relative merits of alternative conceptual models."[70] The staff explains that generalists and normative experts are essential to a successful elicitation because the process "is not a 'do it yourself' activity" but instead "requires experienced practitioners to conduct the exercise."[71]

Third, an elicitation support team requires at least one "resource expert" or "implementer" who handles logistics and mailings, takes technical notes at the meetings, etc.[72] The resource expert can be a technical expert in his or her own right, but would not be a subject-matter expert for purposes of the elicitation.[73] Because of the technical nature of the elicitation's subject matter, the resource expert should be well-versed in the subject at issue.[74]

Regarding these first three support team participants, neither the terms nor the specific roles of "generalist," "normative expert" and "resource expert" are carved in stone. Some elicitations have combined the roles, others have not used one or more of the terms, and still others have used alternative terminology such as "Methodology Development Team,"[75] "facilitation team,"[76]

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[67] Fauss, 37 J.L. Med. & Ethics at 771.

[68] NUREG-1563 at 3. *See also id.* at 15 (Step No. 2), 23 (adding psychology to the list of the normative expert's areas of training and experience). For a detailed description of the normative expert's role, *see* NUREG/CR-6372, Vol. 1, at 29-31, 106, and Vol. 2, at H-5 to H-6 (all using the term "TFI" ("Technical Facilitator-Integrator") to include "normative expert"). Because few individuals would have all the different kinds of expertise needed to be the sole normative expert, an elicitation panel will likely include more than one normative expert. *See* NUREG/CR-6372, Vol. 1, at 106, and Vol. 2, at H-5. *See also* notes 78, 363, *infra*.

[69] NUREG-1563 at 4.

[70] *Id.*

[71] NUREG-1829, Vol. 2, at B-5.

[72] NUREG/CR-6372, Vol. 1, at 106.

[73] *Id.* Vol. 1, at 32, 73.

[74] *Id.* Vol. 1, at 106. *See also id.* Vol. 1, at 25.

[75] Volcanology Expert Elicitation § 1.3, at pp. 1-3 to 1-4. The members of the Volcanology Expert Elicitation's Methodology Development Team were responsible for "developing a strategic plan, facilitating workshops, eliciting members of the expert panel, performing calculations, . . . documenting methodology and results[,] . . . . reviewing the progress of the study[,] and recommending mid-course adjustments to ensure that the study met its objectives."

"Technical Integrator,"[77] or "Technical Facilitator/Integrator."[78] The important point here is that, for an expert elicitation to succeed, the members of its support team must collectively play all three roles.[79]

The fourth and final member of a support team is the "technical specialist" – an expert who presents data, interpretations or training to the subject-matter experts during workshops or field trips, but who is not a member of the elicitation panel.[80]

Before moving to an examination of the expert elicitation process, it is important to distinguish between expert elicitation and three related concepts -- "expert judgment," "peer review," and conventional consensus-building. Given the loose use of the terms, it is particularly important to distinguish between "expert elicitation" and "expert judgment."[81] The former is a subset of the latter, although the latter term is sometimes used in lieu of the former. The staff has defined

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Id. § 1.3, at p. 1.4. *See also* CRWMS, "Saturated Zone Flow and Transport Expert Elicitation Project" § 1.3, at p. 1-4 (Jan. 1998) (1998 Saturated Zone Flow Expert Elicitation) (ML031640590)).

[76] *See* Seismology Expert Elicitation at p. 2-1.

[77] Volcanology Expert Elicitation § 2.1.1, at pp. 2-4 to 2-5 (described as a single individual who "gathers and integrates information"). *Cf. id.* § 2.2.3, at p. 2-12 (quoted in note 78, *infra*).

[78] *Id.* § 2.2.3, at pp. 2-11 to 2-12:

> The role of technical facilitator/integrator . . . is key to facilitating the interactions among the experts, eliciting the expert judgments, and ultimately integrating the assessments into a single quantitative result. . . . The facilitator is a technical individual who is responsible for facilitating this interaction by: providing for proper preparation by the experts, ensuring that two-way communication occurs during discussions, promoting technical challenge of ideas, providing a hazard focus to the technical discussions, defusing tensions and personal confrontations, leading the elicitations, and ensuring complete documentation by the experts. The 'integrator' role . . . refers to the process of aggregating the assessments of the panel into an overall probability distribution.

See also id. § 2.1.1, at p. 2-5 (described as "facilitat[ing] the interactions of multiple experts and elicit[ing] their interpretations to represent the community distribution"),

[79] To avoid confusion, this article uses only the term "support team," except in quotations that use other terminology.

[80] *Id.* § 1.3, at p. 1.4, § 2.2.3, at p. 2-11. Resource experts may also serve as technical experts and make presentations to the subject-matter experts. NUREG/CR-6372, Vol. 1, at 73.

[81] For instance, the staff has criticized DOE for confusing these two terms. NUREG-1563 at E-1. As another example, Commissioner Apostolakis uses only the term "expert judgment" in his COMGEA-11-0001. But, when read as a whole, the document makes clear that he is referring to both expert judgment and expert elicitation. His subsequent communication regarding the COM explicitly uses both terms.

"expert judgment" as "information, provided by a technical expert, in his or her subject matter area of expertise, based on opinion, or on a belief based on reasoning."[82] The staff has also explained that "expert judgment does not create knowledge [but] rather . . . synthesizes disparate and often conflicting sources of information to produce an integrated picture."[83] Expert elicitation can be distinguished from "expert judgment" in two ways. First, the former is a formal approach while the latter is informal,[84] often implicit, and frequently undocumented.[85] Second, the former involves a panel of experts who specialize in a variety of fields while the latter generally involves only one subject-matter expert.[86]

Expert elicitation also has the following advantages over the judgment of a single subject-matter expert:

> "Expert elicitation is a structured process which enhances . . . accuracy, consistency, credibility, and thus acceptability compared to informal, less-structured processes. The emphasis on a structured decomposition of the issues improves accuracy and credibility, thus making the results more acceptable to the stakeholders. Expert elicitation reduces the likelihood of bias and enhances the consistency and comparability of the results. The emphasis on documentation leads to improved scrutiny and acceptance of the results.[87]

Expert elicitation is also distinguishable from "peer review." The latter has many of the same attributes as expert elicitation, such as disclosure of panelists' potential conflicts, documentation of the decision-making, and the use of expert judgment.[88] But it differs in one crucial respect. Elicitation leads or contributes to the creation of a scientific opinion or the solution to a problem, while peer review seeks expert judgment "regarding the soundness and quality" of an existing or proposed scientific opinion or solution.[89] In at least two instances, the NRC has obtained external peer review of a specific elicitation process.[90]

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[82] NUREG-1563 at 3 (footnote omitted).

[83] *Id.*, quoting S.C. Hora, "Acquisition of Expert Judgment: Examples from Risk Assessment," 118 J. of Energy Eng'g 136-148 (1993).

[84] NUREG-1563 at 3, A-1.

[85] Volcanology Expert Elicitation § 2.1.1, at p. 2-2.

[86] *Id.*

[87] NUREG-1829, Vol. 1, at p. 1-10.

[88] Some have characterized peer review as a kind of "formal application of expert judgment." Volcanology Expert Elicitation § 2.1.1, at p. 2-2. *See also* Fleming, 12 Risk: Issues in Health & Safety at 110.

[89] NUREG-1563 at 5.

[90] *See* NUREG-1829, Vol. 2, at xxv-xxvi (regarding risk-informed changes to loss-of-coolant accident technical requirements); Volcanology Expert Elicitation § 1.4, at p. 1-6 (Table 1-1), § 2.2.2, at p. 2-10, § 2.2.12, at p. 2-19 (regarding "participatory peer review" in the volcanology expert elicitation). In the latter instance, DOE drew a distinction between "participatory peer

Finally, expert elicitation differs from conventional consensus-building in several significant respects. Although both involve groups of experts who collectively address issues, the classic consensus-building processes are designed to achieve agreement amongst the experts,[91] while expert elicitation is designed to (i) aggregate the opinions of multiple subject-matter experts who represent diverse viewpoints of the scientific community as a whole[92] and, at least in the NRC, (ii) to obtain a range of "probability judgments that are to serve as input to a performance assessment."[93] For instance, DOE emphasized to its subject-matter experts throughout the entire elicitation process that disagreements among the members were both "expected and accepted"[94] – a position completely incompatible with the goal of consensus. Elicitation avoids the risk that a consensus is more the result of negotiation and strong personalities than it is the

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review," where the peer reviewer conducted an ongoing review throughout the elicitation, and "late-stage peer review," which occurs at or near the end of the elicitation, usually after submittal of the draft final report. Volcanology Expert Elicitation § 2.2.12, at p. 2-19.

[91] NUREG/CR-6372, Vol. 1, at 33.

[92] *Id.* Vol. 1, at 35:

> the primary objective . . . is not capturing the judgment of any individual expert . . ., nor even capturing the composite judgment of any specific subset of experts (including the panel), but rather, capturing as best possible the composite judgment of the overall scientific community of informed experts.

The aggregator can, but is not required to, assign equal "weight" to each participant in an expert elicitation. For the most part, DOE took this approach in the three elicitation upon which it relied in its Yucca Mountain application (discussed *infra*). By contrast, the aggregator may "weigh" the panel members' conclusions and choose to give disproportionately greater or lesser weight to some conclusions. The aggregator may choose to engage in this "weighing" (as opposed to "equal weighting," *supra*) in order to develop an assessment s/he "believes best captures the range of views and uncertainties" (Volcanology Expert Elicitation § 2.1.1, at p. 2-5; *accord id.* § 2.3.4.5, at p. 2-34) or to address any of the following problems:

> experts playing the role of a proponent and being unwilling to evaluate alternative interpretations; outlier experts whose interpretation is extreme relative to the larger technical community and may be overrepresented on a small expert panel; insufficient expert interaction such that experts misunderstand the hypotheses presented by others; uneven access to pertinent data sets such that the experts are relying on different data to arrive at their interpretations without knowledge of other data; and insufficient feedback such that the experts are not aware of the significant issues or the relative impact of each part of their assessments.

Id. § 2.2.11, at p. 2-18. *See also id.* § 2.3.4.5, at p. 2-34; note 248, *infra*, and associated text; and text associated with note 352, *infra*.

[93] NUREG-1563 at 26.

[94] SAR § 2.2.2.2.5, at p. 2.2-94 (ML090700908).

result of "diversity of education, experience and reasoning within a group."[95] Expert elicitation also avoids "the risk of understating the appropriate range of uncertainty by suppressing discussion of differences and focusing on points of agreement."[96]

III. INSTANCES WHERE THE NRC USED, OR REVIEWED AN APPLICANT'S USE OF, THE EXPERT ELICITATION PROCESS

A. Probabilistic Risk Assessment

The NRC's first use of expert elicitation began in the mid-1980s, when the agency was updating a 1975 assessment of the severe accident risk at five nuclear power plants.[97] Several years into the assessment (i.e., late 1980s), the staff applied "a formal protocol to elicit expert judgment in areas of the risk studies [of the five plants] where little or no operational data existed."[98] The elicitation involved seven panel members performing complete probabilistic risk assessments for each of the five plants.[99]

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[95] NUREG/CR-6372, Vol. 1, at 33.

[96] *Id.*

[97] NUREG-1563 at 5.

[98] *Id.* at 6 (referring to the elicitation that culminated in the issuance of NUREG-1150, Vol. 1, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants, Final Summary Report" (Dec. 1990) (NUREG-1150) (ML040140729).

[99] Volcanology Expert Elicitation § 2.1.2, at p. 2-6. Neither the NRC nor DOE appears to be concerned about panels with this number of subject-matter experts. *See* text associated with this note (probabilistic risk assessment – 7), and notes 101 (measurable atmospheric dispersion and deposition -- 16), 144 (volcanology -- 10), 209 (seismology – 18 seismic experts and 7 ground motion experts), **Error! Bookmark not defined.** (saturated zone flow -- 5), 303 (waste form – 6), 326 (unsaturated zone flow -- 7), and 364 (LOCA rulemaking -- 12), *infra*. It is, however, worth noting both that seventeen is a more typical number of panelists (*see* Kuzma 37 J.L. Med. & Ethics at 556), and that some authors who are experienced in expert elicitation consider fifteen subject-matter experts to be so small a number as to call the elicitation's conclusions into question. Susan Bartlett Foote, *Commentary: Evaluating Oversight of Human Drugs and Medical Devices*, 37 J.L. Med. & Ethics 629, 631 (2009). *See also* Jordan Paradise *et al*., *Developing U.S. Oversight Strategies for Nanobiotechnology: Learning from Past Oversight Experiences*, 37 J.L. Med. & Ethics 688, 697 (2009) (Paradise) ("Even in the case studies with the largest number of respondents [20 subject-matter experts], the sample size is still fairly small, although other studies in the literature using expert elicitation report similar sample sizes" (footnote omitted)).

DOE's Volcanology Expert Elicitation also offers brief descriptions of other nuclear-related expert elicitations: (i) an expert elicitation that "assess[ed] the long-term radionuclide releases from the Waste Isolation Pilot Plant, an underground radioactive waste repository in southeastern New Mexico;" (ii) an expert elicitation examining uncertainties associated with the earthquake potential of the Cascadia subduction zone and associated ground motion at a nuclear power plant site in western Washington; (iii) expert elicitations examining the seismic risks associated with the New Production Reactor Program for both the Idaho National

In the early 1990s, the staff reviewed and modified the expert elicitation process used in the late 1980s, to make it both more formal and more rigorous, by identifying nine discrete steps in the expert elicitation process[100] (steps that were eventually memorialized in NUREG-1563). Shortly thereafter, the Commission's Office of Nuclear Regulatory Research and the Commission of European Communities jointly used an expert elicitation panel of 16 international experts "to develop a library of uncertainty distributions for selected consequence parameters" regarding "measurable atmospheric dispersion and deposition."[101]

B. Probabilistic Seismic Hazards Assessment

In the mid-1980s, the NRC sponsored a study of seismic risk at 69 reactor sites.[102] The study was conducted by LLNL.[103] At roughly the same time, EPRI conducted a similar study of 37 sites in the same regions.[104] Although both studies used expert elicitation and the same sets of data, they arrived at significantly different results.[105]

A subsequent examination of these two studies suggested that the difference in results were attributable, at least in significant part, to "how the elicited information was aggregated in the respective elicitation processes."[106] The support team for the EPRI elicitation arranged the

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Engineering Laboratory and the Savannah River Site; (iv) an expert elicitation estimating the future climate in the Yucca Mountain area (DOE does not suggest, however, that the NRC conducted the elicitation); and (v) an elicitation study demonstrating a methodology for evaluating fault displacement at Yucca Mountain using expert elicitation. Volcanology Expert Elicitation § 2.1.2, at pp. 2-6 to 2-7.

[100] NUREG-1563 at 5-6 (referring to NUREG-1150).

[101] *Id.* at 6 (referring to "Harper, .T, et al., "Probabilistic Accident Consequence Uncertainty Analysis; A Joint Report Prepared by U.S. Nuclear Regulatory Commission and Commission of European Communities, U.S. Nuclear Regulatory Commission, NUREG/CR-6244, 3 vols., January 1995"). A WestLaw search indicates that NUREG/CR-6244 is the only expert elicitation to which the Federal courts have referred in their published decisions. *See Cook v. Rockwell Int'l Corp.*, 580 F. Supp. 2d 1071, 1093 (D. Colo. 2006).

[102] NUREG-1563 at 6.

[103] *Id.*; NUREG/CR-6372, Vol. 1, at 2-3 (referring to "Bernreuter, D. L., J. B. Savy, R. W. Mensing, and J. C. Chen. 1989. Seismic Hazard Characterization of 69 Nuclear Plant Sites East of the Rocky Mountains. Report NUREG/CR-5250, vols. 1-8, prepared by Lawrence Livermore National Laboratory for the U.S. Nuclear Regulatory Commission"); Volcanology Expert Elicitation § 2.1.2, at p. 2-6.

[104] NUREG-1563 at 6; NUREG/CR-6372, Vol. 1, at 2-3; Volcanology Expert Elicitation § 2.1.2, at p. 2-6; Seismology Expert Elicitation at p. 2-2. *See* EPRI, Seismic Hazard Methodology for the Central and Eastern United States, Vol. 1 (1986).

[105] NUREG-1563 at 6; NUREG/CR-6372, Vol. 1, at 3.

[106] NUREG-1563 at 6. *See also* NUREG/CR-6372, Vol. 1, at 3 ("there was a strong feeling in the PSHA [probabilistic seismic hazard analysis] community that procedural issues rather than

expert panel into six teams, each with a range of expertise.[107] It then conducted workshops on technical issues, and each team independently arrived at its own "consensus estimates of the uncertainties associated with seismic source characterizations and documented the technical basis for [each team's] assessments."[108] By contrast, the NRC-sponsored study elicited expert judgments from individual panel members rather than from teams, did not conduct workshops or other events at which the experts could interact, and did not document the technical basis for the conclusions of the individual panel members.[109]

Because these two studies yielded such different answers to the same seismological questions, the NRC, DOE and EPRI developed a detailed methodology for conducting such elicitations.[110] The resulting final guidance document was NUREG/CR-6372.

C. *Yucca Mountain* Adjudication

1. General Observations

The only adjudicatory proceeding where expert elicitation has played a significant role is the *Yucca Mountain* adjudication.[111] As the staff has explained, "[n]early every aspect of [the Yucca Mountain] site characterization and performance assessment will involve significant uncertainties."[112] As a result, DOE conducted eight expert elicitations in the *Yucca Mountain* proceeding. DOE relied upon three of these expert elicitations to support its application's conclusions regarding (i) volcanology,[113] (ii) seismology,[114] and (iii) saturated zone flow and

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technical earth-sciences issues *per se* were an important reason for the differences"); SAR § 5.4, at p. 5.4-2 (ML081560572, ML090710110) (the subsequent examination disclosed that "the process used to conduct an expert elicitation can have a significant effect on the results of the elicitation"). For a description of the differences between the two elicitations, *see* NUREG/CR-6372, Vol. 1, at 104.

[107] Volcanology Expert Elicitation § 2.1.2, at p. 2-6.

[108] *Id.*

[109] *Id.*

[110] SAR § 5.4, at p. 5.4-2 (ML081560572, ML090710110).

[111] In one other adjudication, a Licensing Board referred in passing to the process of expert elicitation, but the process did not appear to play a significant role in at least the adjudicatory portion of that proceeding. *See Duke Cogema Stone & Webster* (Savannah River Mixed Oxide Fuel Fabrication Facility), LBP-05-4, 61 NRC 71, 94-95, 2005 WL 5715830 (N.R.C.), at *16.

[112] NUREG-1563 at 1.

[113] Volcanology Expert Elicitation. *See also* SAR § 5.4.1 (lengthy description of this expert elicitation process) (ML081560572, ML090710110); *id.* § 2.2.2.2.1, at p. 2.2-91 (ML090700908) (citing Volcanology Expert Elicitation § 2.2.2.2.1.4, at pp. 2.2-93 to 2.2-94 (describing the expert elicitation process used by this particular panel), § 2.2.2.2.5, at pp. 2.2-100 to 2.2-101 (same), § 2.3.11.2.2.2, at p. 2.3.11-22 (same). *See also* Sandia Nat'l Lab. (for DOE), "Number of Waste Packages Hit By Igneous Events," ANL-MGR-GS-000003 REV 03, at p. 6-5, p. E-7 ("expert elicitation was used to estimate the annual frequency of intersection of the repository by an

transport.[115] (Each of these elicitations is discussed in Part III.C.3, *infra*.) DOE also conducted expert elicitations regarding (iv) waste package degradation,[116] (v) unsaturated zone flow,[117] (vi) near-field environment and altered zone coupled effects,[118] and (vii) waste form degradation and radionuclide mobilization.[119] Ultimately, however, DOE chose not to use these four elicitations in support of its application, though it did use indirectly the fifth (unsaturated zone flow) to

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igneous event (CRWMS M&O 1996 [DIRS 100116], Section 4.2) and summarized in *Characterize Framework for Igneous Activity at Yucca Mountain, Nevada* (BSC 2004 [DIRS 169989], Section 6.3)") (Sept. 2007) (ML090770278); *NRC Staff Answer to Intervention Petitions* at 844, 851 (Feb. 9, 2009) (ML090400554).

[114] Seismology Expert Elicitation. *See also* SAR § 2.2.2.1.1, at pp. 2.2-65 to 2.2-66, § 2.2.2.1.1.1, at pp. 2.2-66 to 2.2-67, § 2.2.2.1.5, at p. 2.2-90 (describing briefly the expert elicitation process used by this particular panel) (ML090700908), § 5.4.2 (ML081560572, ML090710110). *See also* Technical Evaluation Report on the Content of the U.S. Department of Energy's Yucca Mountain Repository License Application; Preclosure Volume: Repository Safety Before Permanent Closure (Sept. 2011) (TER), at pp. 1-23 to 1-26, 1-50 to 1-53 (ML112411460).

[115] 1997 Saturated Zone Flow Expert Elicitation; 1998 Saturated Zone Flow Expert Elicitation (*supra* note 75). *See also* SAR § 5.4.3 (ML081560572, ML090710110) (referring to 1998 Saturated Zone Flow Expert Elicitation). The NRC's "official record" copies of both the 1997 and 1998 versions of the Saturated Zone Flow Expert Elicitation report are, unfortunately, incomplete. The 1997 version contains only the odd-numbered pages of Chapters 1 and 2 – the two chapters relevant to this article. The 1998 version contains all of Chapter 1 ("Introduction") but omits Chapter 2 ("Process for Eliciting Expert Judgments") in its entirety. An examination of the older NRC records kept on microfiche, as well as the even-older hard-copy documents in the NRC's "Official Records" Archives, reveals that they too suffer from these same omissions. A complete version of the 1997 version was eventually located, is available at http://www.osti.gov/bridge/servlets/purl/778912/, and will be added to ADAMS shortly. But the author has been unable to find a complete copy of the 1998 version – at the NRC, DOE or the Nuclear Waste Technical Review Board. For these reasons, this article's citations (*infra*) to Chapter 2 of the Saturated Zone Flow Expert Elicitation are perforce limited to the 1997 version.

[116] *See* SAR § 2.3.6, at p. 2.3.6-2 (ML090710071) (referring to CRWMS, "Waste Package Degradation Expert Elicitation Project" (Rev. 1. 1998)). At least under this document name, Revision 1 is not available in ADAMS, but Revision 0 (Aug. 1997; the original report) can be found at ML003742155. However, a similarly-entitled document (Waste Form Expert Elicitation Project, *supra* note 40), with the correct date, could be the Revision 1 to which DOE refers. If so, then the fourth and seventh elicitations, *supra*, are the same.

[117] *See* SAR § 5.4, at p. 5.4-3 (ML081560572, ML090710110) (referring to CRWMS, "Unsaturated Zone Flow Model Expert Elicitation Project" (May 1997) (Unsaturated Zone Flow Expert Elicitation) (ML032200146)).

[118] *See id.* (referring to Near-Field/Altered Zone Coupled Effects Expert Elicitation (May 29, 1998)).

[119] *See id.* (referring to Waste Form Expert Elicitation).

confirm the reasonableness of the unsaturated zone percolation flux distribution.[120] Finally, DOE conducted an eighth elicitation, regarding human reliability[121] -- though this too appears not to have been used in support of DOE's *Yucca Mountain* application.[122]

Although the elicitations were prepared by DOE rather than the NRC staff, the latter took numerous opportunities during the pre-hearing phase of the proceeding to comment on the expert elicitation process generally and DOE's elicitations in particular.[123] The staff issued its

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[120] *Id.*

[121] *See* George Adams, Center for Nuclear Waste Regulatory Analyses (CNWRA), "Quantifying Low Probability Human Failure Events," at p. 1-2, pp. A-1, A-4 to A-6 (Sept. 2011) (ML112720213) (referring to a DOE expert elicitation, ATHEANA, based upon NUREG-1624, *supra* note 2). The CNWRA prepared the report for the NRC's Division of High-Level Waste Repository Safety. Even though DOE based its own expert elicitation on the NRC's ATHEANA document, the latter is not itself an expert elicitation report, does not claim to be so, refers to a "formal elicitation process" only once (NUREG-1624 at p. 1-11 n.1), and nowhere even cites NUREG-1563 -- the primary NRC guidance document regarding expert elicitation.

[122] It was also the only elicitation not mentioned in the SAR's section specifically addressing expert elicitations. *See* SAR § 5.4 (ML081560572, ML090710110).

[123] *See*, *e.g.*, NUREG-1563 (in 1996); NRC, Notice of Availability and Public Comments and Responses, Yucca Mountain Review Plan, NUREG-1804, Revision 2, Final Report, 68 Fed. Reg. 45,086, 45,100-01 (July 31, 2003), 2003 WL 21754503 (F.R.).

In addition to the staff, the ACNW has repeatedly considered the use of this process in the Yucca Mountain adjudication. *See* NRC, ACNW; Notice of Meeting, 71 Fed. Reg. 38,906, 38,906 (July 10, 2006), 2006 WL 1878285 (F.R.) ("A DOE representative will present an evaluation of the results of this drilling which has been done in support of the ongoing update of the 1996 expert elicitation on Probabilistic Volcanic Hazard Analysis"); NRC, ACNW; Notice of Meeting, 61 Fed. Reg. 46,832, 48,832 (Sep. 5, 1996), 1996 WL 497974 (F.R.) ("A continuation of discussions with the Department of Energy on Total System Performance Assessment will be held with emphasis on the use of expert elicitation panels"); NUREG-1563 at App. F, "Disposition of ACNW Comments" (setting forth the staff's response to the ACNW's comments on the staff's Feb. 1996 Draft Branch Technical Position (predecessor draft to NUREG-1563); NRC, ACNW; Notice of Meeting, 61 Fed. Reg. 36,399, 36,399 (July 10, 1996), 1996 WL 381676 (F.R.) ("The Committee will review the NRC staff's draft technical position on the use of expert elicitation in the licensing of a nuclear waste disposal facility"); NRC, Notice of Meeting, ACNW Joint Working Group on Expert Judgment and Human Intrusion in the Performance Assessment for Nuclear Waste Disposal; Meeting, 56 Fed. Reg. 24,848, 24,848 (May 31, 1991), 1991 WL 301374 (F.R.) ("The Working Group will focus on the mechanics of the expert elicitation process and the utilization of the results of that process. Participants will address the appropriate procedures for selection of experts and issues. . . . This is the second meeting addressing the role and the extent of expert judgment in the site characterization and licensing process with respect to the disposal of nuclear waste."); NRC, Advisory Committee on Reactor Safeguards (ACRS) and ACNW; Proposed Meetings, 56 Fed. Reg. 11,765, 11,767 (Mar. 20, 1991), 1991 WL 302024 (F.R.) ("ACNW Working Group on Expert Opinion . . . will continue the examination of methodologies of expert judgment, specifically on the methodology of an expert elicitation. The focus on the expert judgment reliance is the human intrusion scenario for the HLW repository.")

first set of observations in 1996, when it published its Branch Technical Position addressing expert elicitation (NUREG-1563), along with several other documents in the *Yucca Mountain* proceeding. In the NUREG, the staff set forth "specific technical positions that: (1) provide[d] general guidelines on those circumstances that may warrant the use of a formal process for obtaining the judgments of more than one expert (i.e., expert elicitation[[124]]); and (2) describe[d] acceptable procedures for conducting expert elicitation when formally elicited judgments are used to support a demonstration of compliance with NRC's geologic disposal regulation, currently set forth in 10 CFR Part 60."[125] The staff made clear, however, that an applicant's "adherence to a sound elicitation process" such as the one set forth in NUREG-1563 would not guarantee that the judgments arising from the elicitation would satisfy "the applicant's burden of proof regarding the substantive issues addressed by the elicitation."[126] Conversely, however, a flawed or poorly documented elicitation may undermine the credibility of the demonstrations of compliance that the elicitation was intended to support.[127]

In other 1996 *Yucca*-related documents, the staff similarly made clear that the final report of an expert elicitation panel would *not* be the final word on the subject of the panel's analysis. The staff explained that, although the agency had long considered different forms of expert judgment when "evaluat[ing] and interpret[ing] the factual bases of license applications," the agency had used the expert judgment merely "*to complement and supplement* other sources of scientific and technical information, such as data collection, analyses, and experimentation."[128]

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[124] *But see* Commissioner Apostolakis' comment, described in the text associated with note 14, *supra*.

[125] NRC, Notice, Availability of Final Branch Technical Position on the Use of Expert Elicitation in the High-Level Waste Program, 61 Fed. Reg. 67,354, 67,355 (Dec. 20, 1996), 1996 WL 728098 (F.R.). *Accord* NRC, Notice, Availability of Draft Branch Technical Position on the Use of Expert Elicitation in the High-Level Waste Program, 61 Fed. Reg. 7568, 7569 (Feb. 28, 1996), 1996 WL 82126 (F.R.).

[126] NUREG-1563 at 8. *See also id.* at 22, D-3, F-3 (comment of the ACNW); CRWMS, "Saturated Zone Flow and Transport Process Model Report," § 4.3, at p. 4-8 (Apr. 2000) (ML003724584) ("Even though the NRC indicate[s] that the expert elicitation was conducted and documented in acceptable way, they also caution . . . that the 'NRC staff is not bound by the conclusions of an elicitation *a priori* solely based on adherence to guidance provided by the staff'" (citing CRWMS, "'Geography and Demography,' Book 1 - Section 1 of Yucca Mountain Site Description" (1998)). *Accord* CRWMS, Saturated Zone Flow and Transport Process Model Report" § 4.3 at pp. 4-8 to 4-9 (Oct. 2000) (ML003774387).

[127] NUREG-1563 at 22.

[128] NRC, Notice, Availability of Final Branch Technical Position on the Use of Expert Elicitation in the High-Level Waste Program, 61 Fed. Reg. 67,354, 67,355 (Dec. 20, 1996), 1996 WL 728098 (F.R.) (emphasis added). *See also* NRC, Availability of Draft Branch Technical Position on the Use of Expert Elicitation in the High-Level Waste Program, 61 Fed. Reg. 7568, 7569 (Feb. 28, 1996), 1996 WL 82126 (F.R.); NUREG-1563 at iii, 8 ("the use of expert elicitation should not be considered as an acceptable substitute for traditional analyses based on adequate field or experimental data, when such data are reasonably available or obtainable, or the analyses are practicable to perform").

Seven years later, the staff issued a Notice of Availability of its 2003 Yucca Mountain Review Plan. There, the staff explained that it had incorporated into that Plan the expert elicitation standards set forth in NUREG-1563.[129]

Presumably because the *Yucca Mountain* adjudication never reached the evidentiary hearing stage, the Licensing Boards in that proceeding seldom mentioned DOE's various expert elicitations. A Westlaw search of the NRC library of adjudicatory decisions produced only two decisions referring to expert elicitation. The first, merely referred to a contention that DOE's description of the update to the volcanology elicitation "fail[ed] to comply with 10 C.F.R. §63.21(c)(19)[[130]] or the guidance of NUREG-1563, which DOE formally committed to follow."[131] Similarly, the second merely alluded, in an appendix and without discussion, to three of DOE's expert elicitations.[132]

2. Use of Expert Elicitation in Pre-Adjudicatory *Yucca Mountain* Activities in the early 1990s

In 1990, the NRC published a general study regarding expert elicitation and its potential application to performance assessments in the then-anticipated *Yucca Mountain* proceeding.[133] Three years later, the NRC published a study by the CNWRA applying expert elicitation specifically to the prediction of future climate at Yucca Mountain.[134] The following year, the NRC published a second study by the CNWRA, examining expert elicitation more broadly and identifying situations where the process might be useful in the NRC's high level waste

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[129] NRC, Notice of Availability and Public Comments and Responses, Yucca Mountain Review Plan, NUREG-1804, Revision 2, Final Report, 68 Fed. Reg. 45,086, 45,100-01 (July 31, 2003), 2003 WL 21754503 (F.R.) (quoting NUREG-1563 at 15).

[130] This regulation provides that an applicant must include in its Safety Analysis Report an explanation of how it used any expert elicitation. NUREG-2107 § 2.5.4.2, at p. 20-1.

[131] *U.S. Department of Energy* (High-Level Waste Repository), LBP-09-29, 70 NRC 1028, 1032, 2009 WL 8520129 (N.R.C.) at *3 (Licensing Board 2009) (footnote omitted).

[132] *U.S. Department of Energy* (High-Level Waste Repository), LBP-09-6, 69 N.R.C. 367, 496 (Appendix A: Admissible Contentions), 2009 WL 8484837 (N.R.C.) (2009) (WL pagination unavailable).

[133] NUREG-1563 at 7 (citing NUREG/CR-5411, "Elicitation and Use of Expert Judgment in Performance Assessment of High-Level Radioactive Waste Repositories" (May 1990) (prepared by the Sandia National Laboratories) (ML040150792)).

[134] *Id.* (citing CNWRA 93-016, "Expert Elicitation of Future Climate in the Yucca Mountain Vicinity -- Iterative Performance Assessment Phase 2.5" (Aug. 1993) (ML033630407)). *See*, particularly, *id.* at pp. B-1 to B-2 (describing the rationale of, and lessons learned from, the expert elicitation addressing the future climate at Yucca Mountain).

DOE did not file its application until June 3, 2008. *See* Letter to Michael F. Weber (NRC) from Edward F. Sproat, III (DOE), "Yucca Mountain Repository License Application (LA) for Construction Authorization" (June 3, 2008) (ML081560407), and attached application.

program.[135] Also, during the early 1990's, the staff used the expert elicitation process "to evaluate potential quantitative criteria to clarity the '. . . substantially complete containment requirements.'"[136]

3. Specific Elicitations Conducted for the *Yucca Mountain* Application

As noted above, the *Yucca Mountain* proceeding provides multiple examples of expert elicitation panels. Specifically, DOE relied upon expert elicitation to support its conclusions regarding volcanology, seismology, and saturated zone flow and transport (i.e., hydrology).[137] DOE's and the staff's descriptions of the process used to address these three topics provide good insights into how the expert elicitation process works. In addition, DOE's elicitations regarding "waste form degradation and radionuclide mobilization" and "unsaturated zone flow model" provide still further insights. All five elicitations are discussed below.

a. Volcanology

In 1995, DOE conducted its probabilistic volcanology hazards assessment using the expert elicitation process to address the uncertainties associated with the probability of a volcanic event affecting the Yucca Mountain high-level radioactive waste repository.[138] DOE published the expert elicitation panel's final report the following year.[139]

DOE acknowledged that one of the important objectives of a formal expert elicitation is "to ensure that the probability distribution developed during the study adequately represents the diversity of views in the larger informed technical community."[140] Accordingly, DOE selected for its expert elicitation panel ten subject-matter experts[141] who it considered to have, collectively, "a wide range of expertise and experience and who [were] associated with a variety of

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[135] NUREG-1563 at 7 (citing CNWRA 94-019, "Background Report on the Use and Elicitation of Expert Judgment" (Sep. 1994) (ML040230556)).

[136] *Id.* (citing CNWRA 92-016, "'Substantially Complete Containment' Elicitation Report" (Aug. 1992) (ML033640128)).

[137] SAR § 5.4, at p. 5.4-2 (ML081560572, ML090710110).

[138] SAR § 2.2.2.2.5, at p. 2.2-100 (ML090700908), § 5.4.1, at p. 5.4-4 (ML081560572, ML090710110); NUREG-2107 § 2.5.4.3, at p. 20-2. The SAR provides a brief technical description of the uncertainties that the expert elicitation panel addressed. SAR § 2.2.2.2.5, at pp. 2.2-100 to 2.2-101. For a description of how DOE implemented each of the nine expert elicitation steps set forth in NUREG-1563, *see* SAR § 5.4.1.

[139] Volcanology Expert Elicitation; NUREG-2107 § 2.5.4.3, at p. 20-2.

[140] SAR § 2.2.2.2.5, at p. 2.2-101 (ML090700908).

[141] SAR § 5.4.1, at p. 5.4-4 (ML081560572, ML090710110); NUREG-2107 § 2.5.4.3, at p. 20-2; Volcanology Expert Elicitation § 2.3.1, at p. 2-20.

institutions (e.g., universities[,] national laboratories),"[142] the federal and state governments, and private practice.[143] The panel's members were selected from among a group nominated by thirteen volcanologist (plus a few nominated by the elicitation support team),[144] and were all specialists "in physical volcanology, volcanic hazards, geophysics, and[/or] geochemistry."[145] The subject-matter experts were selected from more than seventy nominees.[146] The panel was

[142] SAR § 2.2.2.2.5, at p. 2.2-101 (ML090700908). *But see* text associated with note 192, *supra*. For a more detailed list of the selection criteria, *see* Volcanology Expert Elicitation § 2.3.2, at pp. 2-22 to 2-23.

[143] Volcanology Expert Elicitation § 2.3.2, at p. 2-23.

Allocation of spots on the panel to members of different professional communities (e.g., industry, government, academia, national laboratories) may raise both practical and credibility issues. *See* Paradise, 37 J.L. Med. & Ethics at 697 (commenting that one weakness of the authors' non-nuclear expert elicitation was, generally, the "uneven distribution of affiliation of respondents," and, more particularly, the overrepresentation of academics on the elicitation panels that made "comparisons by expert affiliation difficult"). The elicitation at issue in that article (and others like it that are examined in the same volume of J.L. Med. & Ethics) is, however, largely distinguishable from the nuclear-related elicitations discussed in this article.

The elicitations examined in 37 J.L. Med. & Ethics seek to evaluate the strengths and weaknesses of *existing* governmental oversight programs while the elicitations examined in this article relate, for the most part, to *proposed* entities (a rule, a repository). (The exceptions to the latter are the nuclear-related elicitations from the mid-1980s to mid-1990s concerning probabilistic risk assessment (Part III.A, *infra*) and probabilistic seismic hazards assessment (Part III.B, *infra*).) A determination of a program's strengths and weaknesses is, by its very nature, both subjective and (to a large extent) policy-oriented. Kuzma, 37 J.L. Med. & Ethics at 551 ("we hope our work contributes to a better understanding of how to both evaluate oversight from multiple perspectives and formulate good policies and systems for overseeing emerging technologies"). Its expert elicitation would therefore be more amenable to the inclusion of representative samples of various public interest groups, lobbyists or other agenda-driven constituencies. *See*, *e.g.*, *id.* (referring to "stakeholder interviews" as a source of information to supplement the results of an expert elicitation; referring to "quantitative expert and stakeholder elicitation;" and commenting that "[w]e blend literature analysis, expert and stakeholder interview data, and expert elicitation to strive for a holistic picture of how the oversight system for GEOs has performed in society"); Choi, 37 J.L. Med. & Ethics at 635 ("quantitative expert and stakeholder elicitation"). By contrast, a determination of the scientific or engineering acceptability of a proposal is technically oriented and, consequently, lends itself more to a representative sample of members of the *professional* community. Although no community (professional or otherwise) from which an elicitation panel draws its members can be said to be totally value-neutral, it would seem likely that professional scientists and engineers would have more of a proclivity in that direction than, say, members of an issue-driven public interest group or lobby, or employees of a governmental agency whose pet project could be affected by the results of an expert elicitation.

[144] Volcanology Expert Elicitation § 2.3.2, at p. 2-23.

[145] SAR § 5.4.1, at p. 5.4-4 (ML081560572, ML090710110).

[146] Volcanology Expert Elicitation § 2.3.1, at p. 2-20, § 2.3.2, at p. 2-23.

led by a Technical Facilitator-Integrator (which DOE also called a Methodology Development Team)[147] who, though not a panel member, shepherded the panel members through "carefully structured, intensive interactions among the panel members, including workshops and field trips."[148] Throughout the entire elicitation process, it was emphasized to the subject-matter experts that one of the key purposes of the expert elicitation was "to identify and understand uncertainty, not to eliminate it," and that disagreements among the members were both "expected and accepted."[149]

Before the first workshop, DOE assembled site-specific information and data and submitted them to each subject-matter expert.[150] Based on this information, each of the panel's subject-matter experts independently arrived at his or her own initial conclusion as to the probability distribution of a volcanic disruption,[151] e.g., 2×10^{-8} to 4×10^{-9}. (Distribution of relevant data and information also continued throughout the remainder of the elicitation.[152])

At the first workshop, the subject-matter experts received training in the expert elicitation process.[153] They also identified the significant issues, characterized the available data, and identified the data still needed to conduct the elicitation.[154] Immediately following the workshop, the support team culled the technical presentations given at the workshop and, from that information, compiled the available data sets that were specific to the Yucca Mountain repository.[155] The support team also compiled other relevant data sets from the technical presentations and other sources.[156] The support team then distributed lists of these data sets to the experts, to enable them to "choose the data they wanted to receive."[157] In addition, many of

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[147] *See* notes 14, 75-78, *supra*.

[148] SAR § 2.2.2.2.5, at p. 2.2-94 (ML090700908). *See also* NUREG-2107 § 2.5.4.3, at p. 20-2. Regarding nomenclature, *see* notes 75 & 78, *supra*.

[149] SAR § 2.2.2.2.5, at p. 2.2-94 (ML090700908).

[150] SAR § 5.4.1, at p. 5.4-5 (ML081560572, ML090710110); Volcanology Expert Elicitation § 2.3.1, at p. 2-20 ("Prior to the first workshop, the experts were sent a number of data sets and publications and were provided access by request to all Yucca Mountain data gathered as part of the volcanism project").

[151] SAR § 5.4.1, at p. 5.4-5 (ML081560572, ML090710110). *See also* NUREG-2107 § 2.5.4.3, at p. 20-2.

[152] Volcanology Expert Elicitation § 2.2.4, at p. 2-13, § 2.3.1, at p. 2-20.

[153] NUREG-2107 § 2.5.4.3, at p. 20-6.

[154] Volcanology Expert Elicitation § 2.3.1, at p. 2-20, § 2.3.3.1, at p. 2-25.

[155] *Id.* § 2.2.4, at p. 2-13, § 2.3.3.1, at p. 2-25.

[156] *Id.*

[157] *Id.*

the proponents who had made technical presentations to the panel offered to provide relevant unpublished data, upon request.[158]

The first workshop was followed by a field trip that provided the experts with field data and was led by "earth scientists with considerable experience in the area and from a variety of institutions and disciplines."[159]

At the second workshop, the subject-matter experts explored the different volcanic hazard models proposed for Yucca Mountain and other similar regions.[160] Technical experts (proponents) made presentations in support of the different models and were asked questions about them.[161] By the end of the second workshop, the subject-matter experts had begun to discuss how to modify or refine the models.[162]

Two elicitation events occurred between the second and third workshops. At the experts' request, the support team arranged for a second field trip -- this time to observe other similar geological areas.[163] Then, the support team sponsored a one-day informal meeting to enable panel members to discuss "various probabilistic methods available to model the spatial and temporal aspects of hazard analysis."[164]

The third workshop was divided (unlike Gaul[165]) into two parts. In the first part, the subject-matter experts were trained in the process of the elicitation interview (the step that would follow the third workshop).[166] The second part was a series of presentations by proponents on various technical issues.[167]

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[158] *Id.* § 2.2.4, at p. 2-13, § 2.3.3.1, at pp. 2-25 to 2-26.

[159] *Id.* § 2.3.1, at p. 2-20. For a description of the first field trip, *see id.* § 2.3.3.2, at p. 2-26.

[160] *Id.* § 2.3.1, at p. 2-20.

[161] *Id.* § 2.3.1, at pp. 2-20 to 2-21.

[162] *Id.* § 2.3.1, at p. 2-21. For a description of the second workshop, *see id.* § 2.3.3.3, at pp. 2-26 to 2-27.

[163] *Id.* § 2.2, at p. 2-8, § 2.3.1, at p. 2-21. For a description of the first field trip, *see id.* § 2.3.3.4, at p. 2-27. This second field trip, according to DOE, exemplified the importance of flexibility to make "mid-course corrections" in an elicitation. *Id.*

[164] *Id.* § 2.3.1, at p. 2-21. For a description of the informal meeting, *see id.* § 2.3.3.5, at p. 2-27.

[165] Julius Caesar, *De bello Gallico*, 1.1.1 ("Gallia est omnis divisa in partes tres"), translation available at Julius Caesar, *The Gallic Wars* (Translated by W. A. McDevitte and W. S. Bohn; n.d.) ("All Gaul is divided into three parts"), http://classics.mit.edu/Caesar/gallic.1.1.html.

[166] Volcanology Expert Elicitation § 2.3.1, at p. 2-21, § 2.3.4.1, at p. 2-30.

[167] *Id.* § 2.3.1, at p. 2-21. For a description of both parts of the third workshop, *see id.* § 2.3.3.6, at p. 2-28.

Six significant events occurred, in the following sequence, between the third and fourth workshops.

> Each panel member was given the same set of questions to facilitate the revision of their evaluations.[168]
>
> Using an innovation not reported in any of DOE's other elicitations, the support team conducted a trial (or mock) elicitation interview with a member of the support team who was himself an expert in many of the issues under consideration.[169] The mock elicitation's stated purpose was to enable the elicitation interview team "to gain insight into the structuring of the assessment, sequencing of questions, methods to capture uncertainties, data and maps to have available, and documentation procedures," and thereby to assist the team in refining its "framework for the actual elicitations of the experts."[170] It would logically follow that the panel members would likewise have benefited from the mock elicitation interview, in that they would have come away with a better understanding of the interview process and could therefore prepare for it more effectively.
>
> Each panel member engaged in a formal individual elicitation interview[171] in which s/he "provided . . . interpretations, expressed . . . uncertainties, and specified the technical basis for his [or her] assessments."[172]
>
> The elicitation team documented the elicitation during the interview and provided the panel member with a draft summary.[173]
>
> The panel member "reviewed, revised, and supplemented" the draft summary,[174] which the support team then reviewed for technical consistency and clarity.[175]
>
> The support team compiled and distributed to all panel members the written draft elicitation summaries for each panel member;[176] prepared preliminary

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[168] SAR § 5.4.1, at p. 5.4-5 (ML081560572, ML090710110). *See also* Volcanology Expert Elicitation § 2.3.4.1, at p. 2-30.

[169] Volcanology Expert Elicitation § 2.1.1, at p. 2-5, § 2.3.1, at p. 2-21.

[170] *Id.* § 2.3.1, at p. 2-21. *See also id.* § 2.3.4.1, at p. 2-30.

[171] SAR § 2.2.2.2.1.4, at p. 2.2-94 (ML090700908).

[172] Volcanology Expert Elicitation § 2.3.1, at p. 2-21. The interviews collectively took two days, supplemented by a few follow-up telephone calls. *Id.* § 2.3.4.2, at p. 2-31. For a description of the interview process, *see id.*

[173] *Id.* § 2.3.1, at p. 2-21, § 2.3.4.3, at p. 2-31.

[174] *Id.* § 2.3.1, at p. 2-21, § 2.3.4.3, at pp. 2-31 to 2-32.

[175] *Id.* § 2.3.4.3, at p. 2-32.

calculations which aggregated the then-current elicitation summaries;[177] and conducted sensitivity analyses and reviewed each elicitation summary for logical consistency.[178]

In the fourth and final workshop, the members reviewed each other's assessments and conclusions, and questioned each other's views.[179] At this workshop, the panel members confirmed that their collective interpretations provided a reasonable representation of the larger, informed technical community.[180] Following this workshop, the members further revised their initial elicitation summaries to reflect the feedback they had received,[181] independently arrived at their own revised conclusions as to the probability distribution,[182] and submitted a revised summary to the support team.

The support team then reviewed each panel member's draft elicitation summary for completeness and clarity, and provided the results of the review to each member.[183] This process was repeated several times.[184] Each panel member then conducted a final revision of the summary and submitted the document as his or her final elicitation report.[185] This concluded the subject-matter experts' involvement in the expert elicitation process.

In the final stage of the elicitation process, the support team prepared a collective final report, which provided the documentation of the elicitation process, the subject-matter experts' individual summaries, and the calculation methodologies and results.[186] To perform the

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[176] *Id.* § 2.3.3.7, at p. 2-29, § 2.3.4.3, at p. 2-32.

[177] *Id.* § 2.3.1, at p. 2-21.

[178] *Id.* § 2.3.1, at pp. 2-21 to 2-22.

[179] SAR § 2.2.2.2.1.4, at p. 2.2-94 (ML090700908); Volcanology Expert Elicitation § 2.2.7, at p. 2-15, § 2.3.1, at p. 2-22, § 2.3.3.7, at pp. 2-28, 2-29, § 2.3.4.3, at p. 2-32. For a description of the fourth workshop, *see* Volcanology Expert Elicitation § 2.3.3.7, at pp. 2-28 to 2-29.

[180] SAR § 2.2.2.2.5, at p. 2.2-101 (ML090700908).

[181] *Id.* § 2.2.2.2.1.4, at p. 2.2-94 (ML090700908); Volcanology Expert Elicitation § 2.3.1, at p. 2-22, § 2.3.4.3, at p. 2-32.

[182] SAR § 2.2.2.2.1.4, at p. 2.2-93, § 2.2.2.2.5, at p. 2.2-100 (ML090700908). *See also* NUREG-2107 § 2.5.4.3, at p. 20-2.

[183] Volcanology Expert Elicitation § 2.3.1, at p. 2-22, § 2.3.4.3, at p. 2-32.

[184] *Id.* § 2.3.4.3, at pp. 2-32 to 2-33.

[185] *Id.* § 2.3.1, at p. 2-22.

[186] *Id.* § 2.3.1, at p. 2-22.

calculations, the support team combined the subject-matter experts' distributions, assigning equal weight to each expert's conclusion, to arrive at the aggregate probability distribution.[187]

Although the staff ultimately concluded that this elicitation was conducted in a manner consistent with Commission guidance,[188] the staff did express four reservations.[189] The first involved DOE's use of insufficiently specific definitions of the terms "igneous event" and "event class."[190] The second (related) reservation concerned DOE's decision not to reconvene and seek the opinions of its expert elicitation panel once DOE had adjusted its data to reflect the more specific definitions of the two terms above.[191] The third reservation was "that a greater balance of panel experts would have encompassed a wider range of viewpoints."[192] The staff's fourth reservation was that DOE's documentation of the expert selection process and the potential sources of bias or conflict of interest could have been more thorough.[193]

Without specifically expressing reservations, the staff did observe that DOE had not followed two of the recommendations in NUREG-1563. The first of these had urged applicants to require subject-matter "experts to document revisions to their initial assessments."[194] DOE had instead followed the slightly different approach recommended in another NRC guidance document, NUREG/CR-6372.[195] DOE was specifically concerned that requiring documentation of such revisions could "anchor the experts to their initial evaluations, making them reluctant to revise

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[187] SAR § 2.2.2.2.5, at p. 2.2-93, p. 2.2-94, p. 2.2-100 (ML090700908); SAR § 5.4.1, at p. 5.4-6 (ML081560572, ML090710110); NUREG-2107 § 2.5.4.3, at p. 20-2, p. 20-7. Although DOE later updated its expert elicitation, DOE chose not to rely on the update in support of its application. NUREG-2107 § 2.5.4.3, at p. 20-7.

[188] NUREG-2107 § 2.5.4.4, at p. 20-7.

[189] *Id.* § 2.5.4.3, at pp. 20-4 to 20-5.

[190] *Id.* § 2.5.4.3, at p. 20-4. *See also* Volcanology Expert Elicitation § 2.3.4.5, at p. 2-34 ("each expert had a slightly different definition of a volcanic 'event'").

[191] NUREG-2107 § 2.5.4.3, at p. 20-4 ("Because separate probability estimates needed to be developed for the DOE Total System Performance Assessment, DOE developed . . . probability estimates subsequent to the 1996 [volcanology elicitation report] without re-engaging the experts to seek their opinions"). *But see id.* at p. 20-7 ("DOE did, however, reconvene the [volcanology] elicitation in 2004 to consider new information and to rely on a consistent set of event definitions and extrusive scenarios").

[192] *Id.* § 2.5.4.3, at p. 20-5. To the extent this observation was intended as a criticism, it was unfair – given that DOE offered panel positions to seventeen subject-matter experts, but only ten accepted the offers. Volcanology Expert Elicitation § 2.3.2, at p. 2-23.

[193] *Id.*

[194] SAR § 5.4.1, at p. 5.4-5 (ML081560572, ML090710110).

[195] *Id.* § 5.4.2, at pp. 5.4-5 to 5.4-6 (ML081560572, ML090710110); NUREG-2107 § 2.5.4.3, at p. 20-6, p. 20-7.

an evaluation after the feedback process."[196] The staff did not object to DOE's approach[197] and elsewhere stated in general terms that "DOE adequately explained how expert elicitation was used consistent with the applicable guidance in NUREG-1563 . . . ."[198] In the second recommendation from NUREG-1563, the staff had urged applicants to insist that their subject-matter experts disclose potential conflicts of interest – a mandate that DOE had not explicitly imposed upon its experts.[199] The staff observed, however, that the experts nonetheless provided enough information to satisfy the intent of this recommendation.[200]

The staff was not alone, however, in offering what were essentially a list of "lessons learned" from the volcanology expert elicitation. DOE compiled its own list:

> [1] All of the experts should be provided with, or have access to, a uniform data base.
>
> [2] Workshops or other meetings where interactions can take place are important to allow the experts to discuss data bases, clarify their interpretations, and challenge the interpretations of others.
>
> [3] The optimal number of experts for geologic hazard assessments is variable, but should be in the range of 4 to 12 individuals.
>
> [4] Workshops provide an opportunity to share and challenge interpretations; however, the best vehicle for the actual elicitation is individual interviews.
>
> [5] Interviews should include the technical expert, a normative expert (trained in probability), and a generalist to help translate between the two.
>
> [6] Each expert should have the opportunity to review the documentation of his or her assessments prior to actual calculations and aggregation of results across multiple experts.
>
> [7] The technical basis for the expert judgments should be documented in sufficient detail that a third party can understand the data, models, and thought processes used by the expert to arrive at the judgments.[201]

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[196] SAR § 5.4.2, at p. 5.4-6 (ML081560572, ML090710110). *See also* NUREG-2107 § 2.5.4.3, at p. 20-6.

[197] NUREG-2107 § 2.5.4.4, at p. 20-6.

[198] *Id.* § 2.5.4.4, at p. 20-7.

[199] SAR § 5.4.1, at p. 5.4-4 (ML081560572, ML090710110). *See also* NUREG-2107 § 2.5.4.3, at p. 20-5.

[200] NUREG-2107 § 2.5.4.3, at p. 20-5.

[201] Volcanology Expert Elicitation § 2.1.2, at pp. 2-7 to 2-8.

Regarding the seventh of these, DOE offered an additional, related "lessons learned:" "Documentation of the expert elicitations began with notes taken by the elicitation team during the course of the interviews. Experience on several other expert assessment projects has shown that other documentation methods are less effective (e.g., written questionnaires, experts writing their interpretations following the interview, etc.)."[202] DOE also observed that proper documentation not only "allows third parties to review and understand the thought processes followed by the experts" but also "can help the experts to organize their thoughts, consider the strengths and weaknesses of their arguments, and properly express their uncertainties."[203]

b. Seismology

i. Overview, General Comments, and Comparison of the Two Seismology Groups

In the late 1990s, DOE conducted an expert elicitation to determine how the Yucca Mountain site would respond to vibratory ground motions from an earthquake.[204] Unlike the other four *Yucca Mountain* expert elicitations addressed in this article, the seismology elicitation was performed by two groups of subject-matter experts.[205] The first group was comprised of six three-member teams of geologists and geophysicists (seismic source teams), and the second was comprised of seven seismology experts (ground motion experts).[206] Both of these groups "were supported by technical teams [also called "facilitation teams"[207]] from DOE, the U.S. Geological Survey, and Risk Engineering Inc. . . . which provided the [subject-matter] experts with relevant data and information; facilitated the formal elicitation, including a series of workshops designed to accomplish the elicitation process; and integrated the hazard results."[208] The seismic source teams also went on a field trip to Yucca Mountain.[209]

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[202] *Id.* § 2.3.4.2, at p. 2-31.

[203] *Id.* § 2.2.9, at p. 2-16.

[204] NUREG-2107 § 2.5.4.3, at p. 20-2 (citing Seismology Expert Elicitation (initiated in the late 1990s)); TER § 2.1.1.1.3.5.2, at p. 1-23. *See also* SAR § 5.4.2, at p. 5.4-6 (initiated in 1995) (ML081560572, ML090710110). For a technical description of the issues addressed in this expert elicitation, *see* TER § 2.1.1.1.3.5.2, at pp. 1-23 to 1-26. For a description of how DOE, in its Seismology Expert Elicitation, implemented each of the nine expert elicitation steps set forth in NUREG-1563, *see* SAR § 5.4.2.

[205] This article uses the term "group" to refer to either the ground motion experts collectively or the seismic source experts collectively. The article refers to all subject-matter experts in both groups as the "panel."

[206] Seismology Expert Elicitation at p. ES-2; TER § 2.1.1.1.3.5.2, at p. 1-24; NUREG-2107 § 2.5.4.2, at p. 20-3, p. 20-5. *See also* SAR § 5.4.2, at p. 5.4-7 (ML081560572, ML090710110). For a detailed history of this elicitation's selection process, *see* Seismology Expert Elicitation at pp. 2-7 to 2-9.

[207] *See* Seismology Expert Elicitation at p. 2-1.

[208] TER § 2.1.1.1.3.5.2, at p. 1-24. For a complete description of all the support teams, *see* Seismology Expert Elicitation at p. 1-7 to 1-9. For a list of the support team members, together

These panel members were experts in "regional and local earthquake and fault tectonics, earthquake physics, ground motion modeling, and seismic hazard analysis."[210] They were selected not only because of their subject-matter expertise, but also because of their (i) "willingness to participate in open workshops," (ii) willingness "to diligently prepare the required evaluations," (iii) willingness to "openly explain and defend technical positions," (iv) "strong communications skills," (v) "flexibility and impartiality" (including the willingness to "forsake the role of [a] proponent") (vi) "the ability to simplify and explain the basis for interpretations and technical positions," and (vii) availability and willingness to commit the time required to complete the project."[211]

DOE considered all but one of NUREG-1563's selection criteria -- the willingness to disclose publicly any conflicts of interest.[212] As with the volcanology panel,[213] DOE asserted that the experts themselves had expressed no objection to this obligation and in fact provided information that, in effect, satisfied this criteria.[214]

As in the volcanic elicitation, the seismic source teams and ground motion experts participated in a series of structured, facilitated workshops,[215] with each group having its own facilitator and generalists.[216] The two groups were, however, on different procedural tracks. The seismic teams' track was more elaborate and is described in "Seismic Group" subpart below. The ground motion experts' track involved half as many workshops (three, as compared to six), two working meetings, and no field trip.[217] This second track is described in the "Ground Motion Group" subpart, which immediately follows the description of the seismic group.

The seismic group initially identified the technical issues most significant to seismic hazards at Yucca Mountain, linked those issues to the most relevant data, specified the available relevant data, and identified the additional needed data.[218] To assist this group's teams, DOE provided

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with their affiliations, *see* Seismology Expert Elicitation at pp. 1-18 to 1-20 (Tables 1-1 through 1-3).

[209] Seismology Expert Elicitation at p. 1-7; NUREG-2107 § 2.5.4.3, at p. 20-6.

[210] SAR § 5.4.2, at p. 5.4-6 (ML081560572, ML090710110).

[211] *Id.* § 5.4.2, at p. 5.4-7 (ML081560572, ML090710110). *See also* Seismology Expert Elicitation at pp. 2-6 to 2-7.

[212] SAR § 5.4.2, at p. 5.4-7 (ML081560572, ML090710110); NUREG-2107 § 2.5.4.3, at p. 20-5.

[213] SAR § 5.4.2, at p. 5.4-4 (ML081560572, ML090710110).

[214] *Id. See also* NUREG-2107 § 2.5.4.3, at p. 20-5; Seismology Expert Elicitation at p. 2-9.

[215] SAR § 5.4.2, at p. 5.4-8 (ML081560572, ML090710110).

[216] NUREG-2107 § 2.5.4.3, at p. 20-5.

[217] Seismology Expert Elicitation at p. 3-14 (Fig. 3-1).

[218] SAR § 5.4.2, at p. 5.4-8 (ML081560572, ML090710110).

them with both data and lists of relevant sources of data relevant to their issues.[219] The ground motion experts likewise identified the principle issues relevant to their area of responsibility.[220] However, the ground motion experts may not have been provided their data until the first workshop.[221]

Once the workshops began, the two groups of experts went through essentially the same training and elicitation interviews as their counterparts on the volcanology panel.[222] The one exception was the interviews of the three-person seismic source teams. The support team interviewed each of the seismic teams as a unit rather than separately interviewing each individual on the team.[223]

Like the volcanology panel, the two seismic groups were encouraged to debate issues,[224] listened to proponents of various viewpoints relevant to the issues before the panels,[225] and had opportunities to revise their conclusions based on the discussions and feedback in the workshops.[226] And like the volcanology panel, the members of the seismology groups were not required by DOE to document the rationale underlying any change in their initial positions.[227] DOE's justification for this omission was the same as the one DOE offered for the volcanology panel, as was the staff's response to those justifications, *supra*.

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[219] *Id.*

[220] *Id.*

[221] *Compare* Seismology Expert Elicitation at p. 2-5 ("Before the first workshop, the [seismic] experts were sent a number of data sets and publications") *with* SAR § 5.4.2, at p. 5.4-8 (ML081560572, ML090710110) ("The ground motion [group] identified data and analyses required to resolve their technical issues in the first workshop") (ML081560572, ML090710110); Seismology Expert Elicitation at p. 5-2 ("copies of all presentation materials were made available during each meeting").

[222] SAR § 5.4.2, at pp. 5.4-8 to 5.4-9 (ML081560572, ML090710110); NUREG-2107 § 2.5.4.3, at p. 20-6.

[223] NUREG-2107 § 2.5.4.3, at p. 20-6. *See also* Seismology Expert Elicitation at p. 2-2 ("each expert team in the seismic source and fault displacement characterization was expected to function as a single 'virtual' expert and to express their [*sic*] assessments and uncertainties as an individual expert").

[224] Seismology Expert Elicitation at p. 2-5.

[225] *Id.*

[226] SAR § 5.4.2, at p. 5.4-9 (ML081560572, ML090710110); Seismology Expert Elicitation at p. 1-16; NUREG-2107 § 2.5.4.3, at p. 20-6.

[227] SAR § 5.4.2, at p. 5.4-9 (ML081560572, ML090710110); Seismology Expert Elicitation at p. 1-14, p. 1-16; NUREG-2107 § 2.5.4.3, at p. 20-6.

Also like the volcanology panel, the ground motion experts' views were given equal weight and then aggregated to arrive at a final probability distribution.[228] But again, the seismic source teams were the exception. Unlike the ground motion experts and the volcanology panel, the conclusions of the six seismic source teams – not their individual experts -- were given equal weight.[229]

ii. Seismic Group

Seismic group members attended a total of six workshops. At the first, they identified key technical issues, as well as the available and missing data; they also heard presentation from a series of technical experts.[230] The second workshop focused on "methods and approaches for characterizing seismic sources in the Yucca Mountain region."[231] As in the first workshop, a variety of technical experts presented the panel with their views on issues important to the elicitation.[232] In the third workshop, the group considered alternative models, hypotheses and interpretations, and were provided opportunities for structured debate on those subjects.[233] The third workshop also included a four-day field trip to the Yucca Mountain area.[234]

At the fourth workshop, the group members presented their preliminary interpretations and conclusions regarding key issues and received feedback from each other.[235] They were also trained in both the characterization of uncertainty and the elicitation process (in anticipation of the six teams' upcoming elicitation interviews).[236] In addition, the group was presented with, and discussed, further information and interpretations relevant to the elicitation.[237]

The elicitations were documented during the interviews, and afterwards, the subject-matter experts independently prepared their own documentation to support their conclusions.[238] At the same time as the subject-matter experts were preparing their documentation, the support team was providing each of the seismic expert teams with written documentation of its interview.[239]

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[228] SAR § 5.4.2, at p. 5.4-9 (ML081560572, ML090710110).

[229] *Id.*; NUREG-2107 § 2.5.4.3, at p. 20-3, p. 20-7.

[230] Seismology Expert Elicitation at p. 3-3.

[231] *Id.*

[232] *Id.*

[233] *Id.* at p. 3-4.

[234] *Id.*

[235] *Id.* at p. 3-5.

[236] *Id.* at p. 3-6.

[237] *Id.* at p. 3-5.

[238] *Id.* at p. 2-6. *See also id.* at p. 3-10.

[239] *Id.* at p. 3-10.

Next, the subject-matter experts attended their fifth workshop, where each expert's conclusions and underlying support were examined by colleagues in his or her group.[240] At the end of this workshop, the six seismic teams and the ground motion team (which had been on a separate procedural track[241]) held a joint session to discuss common issues.[242] Before the sixth and final workshop, the support team prepared and distributed "a 'white paper' summarizing the fault displacement evaluation approaches developed by the expert teams."[243]

The sixth workshop had three purposes: "(1) review and discuss alternative methods and models for assessing fault displacement, (2) discuss uncertainties in parameter values and models, and (3) facilitate the expert teams' discussion of the pros and cons of alternative approaches, models, and submodels."[244]

Following the final workshop (and also at many stages following the fourth workshop), the subject-matter experts from both groups and their support teams went through a series of revisions and technical reviews; and at the end of the last set of revisions, each subject-matter expert or team prepared a final conclusion, together with supporting technical bases.[245] The support team then aggregated the results, allotting equal weight to each ground motion expert and, separately, to each seismic team.[246] This equal weighing was not a foregone conclusion from the beginning of the elicitation, but merely a goal.[247] Had one of the subject-matter experts been unwilling to play the role of neutral evaluator, the support team could have given that expert's conclusions less weight, or even removed the expert from the panel.[248]

iii. Ground Motion Group

The pattern of the ground motion group's elicitation process was much the same as, though more abbreviated than, the pattern of the seismic group's process. The first ground motion workshop was devoted to identifying key issues and the unavailable data that was still needed

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[240] *Id.* at p. 3-6.

[241] *Id.* at p. 3-14 (Figure 3-1).

[242] *Id.* at pp. 3-7 to 3-8.

[243] *Id.* at p. 3-8.

[244] *Id.*

[245] *Id.* at p. 2-6, pp. 3-10 to 3-11.

[246] *Id.* at p. 3-12.

[247] *Id.*

[248] *Id.* at p. 3-13. *See also* Fleming, 12 Risk: Issues in Health & Safety at 118-120 (discussing how a Technical Facilitator-Integrator would "downweigh" the conclusions of an outlier, but observing that the NRC's use of equal weighing renders downweighing "irrelevant" (*id.* at 120)).

to evaluate them.[249] The second workshop addressed methods, models and preliminary interpretations, with technical presentations on several modeling issues.[250] In addition to these formal workshops, the subject-matter experts in this group also discussed the issues informally, often with one playing the role of proponent.[251] The two workshops were also supplemented with a working meeting in which the group members discussed various unresolved issues.[252]

The elicitation interviews of the individual group were conducted in the same way as in other elicitations (with the sole exception of the seismic group's team interviews). Each was asked the same set of questions and the support team documented the answers. In addition, each interviewee provided documentation to support his or her preferred model, and explained the reasons for preferring that model over other proposed models.[253] During or following the interviews, the support team identified inconsistencies to some of the subject-matter experts, who could then correct them.[254] In other instances, the support team pointed out that other subject-matter experts had considered only a limited number of proposed models; and as a result, those experts tended to expand the scope of models that they considered.[255]

Following the interviews, the support team conducted a third workshop, in which the group members examined each other's preliminary interpretations and conclusions and also looked in depth into a small number of technical issues.[256] This workshop also included a joint meeting with the seismic teams (described *supra*).[257] Shortly after the third workshop, the group held a working meeting.[258]

Next, the group members revised their conclusions based on the feedback received in the third workshop and the subsequent working meeting. These revisions began multiple cycles of the support team preparing revised models and the subject-matter experts revising their data or equations.[259] At the end of these cycles, each subject-matter expert documented the reasoning behind his or her conclusions, the support team reviewed the documentation for internal

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[249] Seismology Expert Elicitation at pp. 5-2 to 5-3.

[250] *Id.* at p. 5-3.

[251] *Id.*

[252] *Id.*

[253] *Id.* at pp. 5-3 to 5-4.

[254] *Id.* at p. 5-4.

[255] *Id.*

[256] *Id.* at p. 5-5.

[257] *Id.*

[258] *Id.*

[259] *Id.* at p. 5-6.

consistency and completeness, and the resulting documentation was reviewed by two other support team groups.[260]

iv. NRC Staff Review.

The staff reviewed and evaluated DOE's methodology, observed all of the groups' meetings, and reviewed all summary reports of those meetings.[261] Based on these reviews and observations, the staff concluded that the expert elicitation was consistent with the framework described in NUREG-1563[262] and that DOE had "reasonably developed the geological, geophysical, and seismological information necessary to support the expert elicitation."[263] The staff also observed that the two seismic groups represented an "appropriately broad spectrum of the larger seismology . . . communit[y]."[264] (In this respect, the staff's conclusion differed from that regarding the volcanology elicitation.[265])

Subsequently, although DOE chose not to update its seismology elicitation,[266] the staff reviewed additional geological, geophysical, and seismological information that had been unavailable to the panel, and concluded that the information would not have substantially altered the results of the expert elicitation.[267]

c. Saturated Zone Flow and Transport

In 1997, DOE conducted an expert elicitation to evaluate saturated zone groundwater flow and radionuclide transport.[268] The goals of this elicitation "were (1) to quantify uncertainties

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[260] *Id.* For a technical description of the issued addressed in each of the procedural steps above, see *id.* at pp. 5-6 to 5-23.

[261] TER § 2.1.1.1.3.5.2, at p. 1-25.

[262] *Id.*; NUREG-2107 § 2.5.4.3, at p. 20-7.

[263] TER § 2.1.1.1.3.5.2, at p. 1-25.

[264] NUREG-2107 § 2.5.4.3, at p. 20-5.

[265] *Id.*

[266] *Id.* § 2.5.4.3, at p. 20-7.

[267] *Id.*; TER § 2.1.1.1.3.5.2, at p. 1-26.

[268] SAR § 5.4.3, at p. 5.4-10 (ML081560572, ML090710110); SAR § 2.3.9.2.2.6, at p. 2.3.9-26 (ML081560543); NUREG-2107 § 2.5.4.3, at p. 20-4; CRWMS, Part 1, "Chapter 8, Total System Performance Assessment-Viability Assessment (TSPA-VA) Analyses Technical Basis Document Saturated Zone Flow and Transport" § 8.4.2, at p. 8-50 (Rev. 0 Aug. 14, 1998) (Chapter 8) (ML003758622). For brief technical descriptions of the scientific issues that the panel considered, *see* SAR § 5.4.3, at p. 5.4-10, p. 5.4-11 (ML081560572, ML090710110); SAR § 2.3.9.2.2.6, at p. 2.3.9-26 (ML081560543); NUREG-2107 § 2.5.4.3, at p. 20-5; Chapter 8 § 8.2.3.2, at pp. 8-25 to 8-26, § 8.2.3.4, at pp. 8-29 to 8-31. For a description of how, in this elicitation, DOE implemented each of the nine expert elicitation steps set forth in NUREG-1563, *see* SAR § 5.4.3.

associated with certain key issues . . ., and (2) to provide a perspective on modeling and data collection activities that may help characterize and reduce uncertainties."[269] The elicitation panel issued two "final" reports – the first in October 1997 and the second in January 1998.[270]

DOE selected a five-member elicitation panel to address saturated zone flow and transport.[271] DOE sought nominations from fifteen earth scientists and engineers, and received from them the names of 59 candidates.[272] In selecting the five panel members, DOE sought to ensure that they held diverse opinions, had the necessary technical expertise, and came from a variety of institutional and organizational backgrounds.[273] The panel's members came from academia, the private sector, and one of the national laboratories,[274] and had expertise in "methods for characterizing and/or methods for analyzing and modeling groundwater flow and radionuclide transport in saturated fractured rock."[275] DOE selected the members based on (*inter alia*) the following criteria: "knowledge and expertise in saturated zone flow and transport, technical competence, availability, willingness to participate, and a willingness to explain and defend their technical positions."[276] As with the volcanology and seismology elicitations, DOE considered all

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[269] 1998 Saturated Zone Flow Expert Elicitation § 1.2, at p. 1-2; 1997 Saturated Zone Flow Expert Elicitation § 1.2, at p. 1-2. *See also* SAR § 2.3.9.2.2.6, at p. 2.3.9-26 (ML081560543); SAR § 5.4.3, at p. 5.4-10 (ML081560572, ML090710110); NUREG-2107 § 2.5.4.3, at p. 20-4:

> The objective of [elicitation] was to quantify uncertainties associated with models and parameters key to modeling flow and transport in the saturated zone. A second objective was to reveal needed data collection and modeling that could reduce some of the more significant uncertainties. In this way, the expert elicitation was used to complement and guide data collection already underway, as well as to provide input to iterative performance assessment modeling by DOE.

[270] *See* 1997 and 1998 versions of the Saturated Zone Flow Expert Elicitation (*supra* notes 115 and 75, respectively). *See also* SAR § 5.4.3, at p. 5.4-10 (ML081560572, ML090710110).

[271] NUREG-2107 § 2.5.4.3, at p. 20-4; SAR § 5.4.3, at p. 5.4-10 (ML081560572, ML090710110); Chapter 8 § 8.1.3, at p. 8-4, § 8.2.3.2, at p. 8-25; PowerPoint Presentation by Geomatrix Consultants to Nuclear Waste Technical Review Board, "Saturated Zone Flow and Transport Expert Elicitation: Process and Summary of Results" (Jan. 20-21, 1998), at slide 4 (listing the panel members) (Process and Summary), available at http://www.nwtrb.gov/meetings/1998/jan/coppersmith.pdf.

[272] 1997 Saturated Zone Flow Expert Elicitation § 2.2.2, at p. 2-6.

[273] *Id.* § 2.2.2, at p. 2-7. The staff agreed with DOE that this panel "collectively represent[ed] an appropriately broad spectrum of the larger . . . hydrology communit[y]." NUREG-2107 § 2.5.4.3, at p. 20-5.

[274] 1998 Saturated Zone Flow Expert Elicitation § 1.4, at p. 1-6 (Table 1-2) 1997 Saturated Zone Flow Expert Elicitation § 1.4, at p. 1-6 (Table 1-2).

[275] SAR § 5.4.3, at p. 5.4-10 (ML081560572, ML090710110).

[276] 1997 Saturated Zone Flow Expert Elicitation § 2.2.2, at p. 2-7. *See also id.* § 2.2.2, at p. 2-6.

but one of NUREG-1563's criteria for selection of experts -- the willingness to disclose publicly any conflicts of interest -- and it offered the same justification (described above).[277] The staff later observed that the experts provided enough information to satisfy the intent of this recommendation.[278]

Again, similar to the volcanology and seismology expert elicitations, this elicitation panel participated in a series of workshops and one field trip to Yucca Mountain.[279] In the workshops, the experts broke the major issues down into more manageable subissues.[280] To enable the experts to examine the issues and subissues more effectively, DOE provided them with relevant literature and data sets.[281]

During the workshops, the experts received a variety of training to assist them in their responsibilities.[282] In the first workshop, the experts received training in the subject matter at issue, and included "discussion of available data and alternative models."[283] Prior to the second workshop, the subject-matter experts received a list of the specific topics to be covered in the elicitations interviews, and these topics were addressed in presentations during both the second and third workshops.[284] In the second workshop, the subject-matter experts were trained in "quantifying uncertainty for probability encoding, expressing alternative evaluations using subjective probability (weights), and understanding biases that might unduly influence expert evaluations."[285] The experts also "practiced articulating their judgments and the assumptions and rationales supporting their judgments."[286] The support team conducted the third and final workshop prior to the elicitation interviews.[287] In this workshop, the subject-matter experts

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[277] SAR § 5.4.3, at p. 5.4-10 (ML081560572, ML090710110).

[278] NUREG-2107 § 2.5.4.3, at p. 20-5.

[279] Process and Summary at slide 3. *See also* 1997 Saturated Zone Flow Expert Elicitation § 2.2.3.4, at p. 2-9; SAR § 5.4.3, at p. 5.4-10 (ML081560572, ML090710110); NUREG-2107 § 2.5.4.3, at p. 20-6.

[280] SAR § 5.4.3, at p. 5.4-10 (ML081560572, ML090710110).

[281] *Id.* at p. 5.4-11.

[282] *Id.*

[283] *Id. See also* 1997 Saturated Zone Flow Expert Elicitation § 2.2.3.1, at p. 2-8; Process and Summary at slide 3.

[284] 1997 Saturated Zone Flow Expert Elicitation § 2.2.4,1 at p. 2-10.

[285] SAR § 5.4.3, at p. 5.4-11 (ML081560572, ML090710110); 1997 Saturated Zone Flow Expert Elicitation § 2.2.3.2, at pp. 2-8, 2-9 to 2-10; Process and Summary at slide 3.

[286] SAR § 5.4.3, at p. 5.4-11 (ML081560572, ML090710110).

[287] 1997 Saturated Zone Flow Expert Elicitation § 2.2.2.3, at p. 2-9.

presented and discussed their preliminary interpretations and uncertainties regarding the key issues before the panel.[288]

The panel members' elicitation interviews were structured in essentially the same way as those for the volcanology and ground motion group's (seismology) elicitation interviews.[289] During the remainder of the elicitation process, the subject-matter experts received feedback from their fellow panel members.[290] In addition, each expert was "provided elicitation summaries from all [other] members of the . . . panel" in order to provide him or her "with the broader perspective on the range of interpretations being developed."[291] The support team reviewed the first draft of each panel member's elicitation summary, in order to ensure accuracy and completeness.[292] As with the volcanology and seismology elicitations, DOE did not require the elicitation panel members, during the feedback process, to document any revisions to their initial assessments.[293] DOE offered the same justification as it had in the other two elicitations, and the staff's response was likewise the same.

Once the subject-matter experts had reviewed the feedback information, *supra*, they prepared their final expert elicitation summaries.[294] These were then aggregated, giving equal weight to the conclusions of each panel member.[295] DOE chose not to update this elicitation.[296]

As in the seismology elicitation, the equal weighing was not a foregone conclusion from the beginning of the elicitation, but merely a goal.[297] If one of the panel members had been

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[288] 1997 Saturated Zone Flow Expert Elicitation § 2.2.2.3, at p. 2-9; Process and Summary at slide 3.

[289] *Compare* SAR § 5.4.3, at p. 5.4-11 (ML081560572, ML090710110) *with id.* at p. 5.4-5 (volcanic) and p. 5.4-9 (seismic) (ML081560572, ML090710110). *See also* 1997 Saturated Zone Flow Expert Elicitation § 2.2.4.2, at p. 2-10 (briefly describing the interview process).

[290] *Id.* § 5.4.3, at p. 5.4-11 (ML081560572, ML090710110); 1997 Saturated Zone Flow Expert Elicitation §§ 2.2.4.3 & 2.2.4.4, at p. 2-11.

[291] SAR § 5.4.3, at p. 5.4-11 (ML081560572, ML090710110). *See also* 1997 Saturated Zone Flow Expert Elicitation § 2.2.4.4, at p. 2-12.

[292] 1997 Saturated Zone Flow Expert Elicitation § 2.2.4.4, at p. 2-12.

[293] SAR § 5.4.3, at p. 5.4-11 (ML081560572, ML090710110); NUREG-2107 § 2.5.4.3, at p. 20-6.

[294] SAR § 5.4.3, at p. 5.4-11 (ML081560572, ML090710110).

[295] *Id.* at p. 5.4-12; NUREG-2107 § 2.5.4.3, at p. 20-7; 1997 Saturated Zone Flow Expert Elicitation § 2.3.4.5, at p. 2-12.

[296] NUREG-2107 § 2.5.4.3, at p. 20-7.

[297] 1997 Saturated Zone Flow Expert Elicitation § 2.3.4.5, at pp. 2-12 to 2-13.

unwilling to play the role of neutral evaluator, the support team could have given that expert's conclusions less weight, or even removed the expert from the panel.[298]

d. Waste Form Degradation and Radionuclide Mobilization

In its *Yucca Mountain* application, DOE did not rely upon its expert elicitation regarding Waste Form Degradation and Radionuclide Mobilization. The elicitation is, however, on the public record and, because it sheds at least some light on the elicitation process, a description is appropriate.

This elicitation's objective was "to characterize the processes of degradation of spent fuel and high level waste . . . glass following breach of the waste packages and mobilization of radionuclides within breached waste packages."[299] DOE selected a panel of six subject-matter experts and also provided technical experts to inform the subject-matter experts with data, interpretations and three workshop trainings.[300] The panel was comprised of experts from the national laboratories, industry, and the Atomic Energy Agency of Canada.[301] Ten experts were selected from a group of 35 nominees, recommended by seventeen "highly regarded scientists and engineers."[302] Six of the ten invited experts agreed to serve on the panel.[303] Each panel member submitted information on potential conflicts of interest.[304]

The support team provided the panelists with relevant data and publications throughout the elicitation process.[305] During the workshops, technical experts made presentations to the panel regarding "alternative data sets[,] . . . models and methods,"[306] and the panel member debated their different interpretations of the data and uncertainties.[307]

The first workshop was devoted to the identification of key technical issues and to presentations by thirteen technical specialists.[308] At the second workshop, the panel members reviewed "the key issues and uncertainties associated with waste form degradation and radionuclide

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[298] *Id.*

[299] Waste Form Expert Elicitation, *supra* note 40, at p. 1-1.

[300] *Id.* at p. 1-4.

[301] *Id.* at p. 1-6 (Table 1-2).

[302] *Id.* at p. 2-4. *See also id.* at p. 2-7 (number of nominators and nominees).

[303] *Id.* at p. 2-7.

[304] *Id.*

[305] *Id.* at p. 2-4, p. 2-8.

[306] *Id.* at p. 2-5.

[307] *Id.* at p. 2-4.

[308] *Id.* at p. 2-8.

mobilization," discussed "[a]lternative models, modeling results, and interpretations," and heard presentation from thirteen more technical experts.[309] At the third workshop, panel members presented and discussed their preliminary interpretations and uncertainties, and also received training in the elicitation interview process.[310]

Following the third workshop, the support team conducted elicitation interviews of each panel member, documenting the elicitation during the interview.[311] All the data that had been previously provided to the subject-matter experts were made available during the interview.[312] The support team then prepared summaries of each interview.[313] The subject-matter experts reviewed the summaries and then revised their earlier preliminary conclusions from the third workshop.[314] Upon receiving the revised conclusions, the support team prepared a draft report aggregating the elicitations and conclusions, and circulated it to all panel members so that they could review and comment on each other's conclusions and technical analyses.[315] Each panel member then reviewed the comments of his colleagues and, to the extent he saw fit, revised his conclusions still further.[316] After receiving those revisions, the support team posed to the panel members any last-minute requests for clarification, then finalized the elicitation summaries, and issued the final elicitation report.[317]

When aggregating the conclusions of the experts' judgments, the support team accorded equal weight to each expert's conclusions.[318] Just as with seismology and saturated zone flow expert elicitations discussed above, the equal weighing here was not a foregone conclusion from the beginning of the elicitation, but merely a goal.[319] If one of the panel members were unwilling to play the role of neutral evaluator, the support team could have given that expert's conclusions less weight, or even removed the expert from the panel.[320]

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[309] *Id.* at p. 2-9.

[310] *Id.*

[311] *Id.* at p. 1-5, p. 2-5, p. 2-10.

[312] *Id.* at p. 2-10.

[313] *Id.* at p. 1-5, p. 2-5.

[314] *Id.* at p. 1-5, p. 2-5, p. 2-11.

[315] *Id.* at p. 2-11.

[316] *Id.* at p. 2-5, p. 2-11.

[317] *Id.* at p. 2-5, p. 2-11.

[318] *Id.* at p. 2-3, p. 2-12.

[319] *Id.* at p. 2-12.

[320] *Id.* at p. 2-13.

One final point regarding this elicitation bears mentioning. It differed from the larger elicitations discussed in the previous three subparts in the following respect:

> In some cases, the [Waste Form Expert Elicitation] process followed approaches that were more appropriate for a relatively modest multi-expert study than a larger, resource-intensive study. For example, after the elicitation interviews, feedback to the experts was accomplished by providing each expert with a feedback package that summarized all of their assessments and the implications of those assessments to certain key issues. The experts then were given an opportunity to revise their assessments in light of the feedback, as suggested in the [NUREG/CR-6372] guidance. A more resource-intensive approach might have been to conduct a feedback workshop. Either process enables the experts to review the assessments of others on the panel and to examine the calculated implications of their assessments.[321]

e. Unsaturated Zone Flow Model

Just as with the Waste Form Expert Elicitation, DOE did not rely upon its expert elicitation regarding Unsaturated Zone Flow Model in support of its *Yucca Mountain* application. Still, this elicitation is on the public record and sheds at least some light on the elicitation process. So a description of it is appropriate.

The elicitation's purpose was "to identify and assess the uncertainties associated with certain key components of the unsaturated zone flow system at Yucca Mountain.[322] DOE selected seven subject-matter experts who had a broad range of experience and expertise[323] and who came from academia, private industry, national laboratories, and another government agency.[324] The standards for selection were the same as for the other elicitations discussed above.[325] Twenty-two nominators submitted the names of 75 candidates for the panel.[326] Nine candidates were offered positions on the panel, and seven accepted.[327] Each panel member submitted information regarding potential conflicts of interest.[328]

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[321] *Id.* at p. 2-3.

[322] Unsaturated Zone Flow Expert Elicitation, *supra* note 117, § 1.1, at p. 1-1.

[323] *Id.* § 1.1, at p. 1-1, § 1.4, at p. 1-8 (Table 1-2).

[324] *Id.* § 1.4, at p. 1-8 (Table 1-2).

[325] *Id.* § 2.2.2, at p. 2-6.

[326] *Id.*

[327] *Id.* § 2.2.2, at p. 2-7.

[328] *Id.*

The elicitation consisted of three workshops, one field trip and a series of interviews. The support team provided the subject-matter experts with relevant literature and technical data throughout the elicitation process.[329]

The goals of the first workshop were "to introduce the panel to the Yucca Mountain project, identify significant issues related to both the unsaturated zone site-scale modeling and the Total System Performance Assessment, and to present the various data sets related to the significant issues."[330] Regarding this last goal, "[t]welve technical specialists presented and discussed the data sets collected over the past several years to characterize unsaturated zone hydrology at Yucca Mountain."[331]

In the second workshop, the panel members considered and discussed "alternative methods and conceptual models for evaluating" the technical issues before them.[332] At this workshop, "e[i]ghteen technical specialists made presentations,"[333] and the support team provided elicitation training.[334]

At the third and final workshop, the subject-matter experts presented and discussed their own "preliminary interpretations and uncertainties regarding key issues in unsaturated zone flow processes."[335]

Following the third workshop, the support team "organized a one-day field trip to Yucca Mountain at the request of the expert panel members, who wanted to observe first-hand the general setting of Yucca Mountain."[336] "The field trip was led by earth scientists from the USGS and the U. S. Bureau of Reclamation" and enabled the subject-matter experts "to observe bedrock exposed in the Exploratory Studies Facility (ESF) and at the ground surface and to visit several data collection localities for the USGS infiltration studies."[337]

Prior to the elicitation interviews, the support team provided to each panel member a "Roadmap to the Elicitation,"[338] with a list of topics to be discussed.[339] The elicitation interviews followed

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[329] *Id.* § 2.2.2, at p. 2-8.

[330] *Id.* § 2.2.3.1, at p. 2-8.

[331] *Id.*

[332] *Id.*

[333] *Id.*

[334] *Id.* § 2.2.3.2, at p. 2-8, § 2.2.4.1, at p. 2-9.

[335] *Id.* § 2.2.3.3, at p. 2-9.

[336] *Id.* § 2.2.3.4, at p. 2-9.

[337] *Id.*

[338] *Id.* § 2.2.4, at p. 2-9.

[339] *Id.* § 2.2.4., at pp. 2-9 to 2-10.

the same pattern used in the other elicitations described above.[340] The support team took notes during each interview, thereby freeing the subject-matter expert "to focus on thinking through his answers and thoroughly expressing his interpretations."[341]

Following the interviews, the support team "provided each expert with written documentation of the interview."[342] The experts then reviewed and edited their preliminary assessments to reflect the expert's revised interpretations.[343] The revised assessment of each expert was then distributed to all panel members so that each could review the other experts' judgments and technical analysis, and then offer written feedback to his or her fellow panel members.[344]

After considering the feedback, each expert could make further revisions to his or her elicitation summary to reflect any resulting changes in analysis and/or conclusions.[345] The support team reviewed these revised summaries and made any necessary requests for clarification.[346] Once the support team received the clarifications, it finalized the summaries and compiled them into a single report.[347]

Although the support team assigned "equal weight" to each participant in an expert elicitation,[348] it was not required to do so. Rather, the "equal weight" approach was a goal, not a mandate.[349] The support team could instead have chosen to give disproportionately greater or lesser weight to some experts' conclusions.[350] The team was free to choose to use latter approach in order to develop an assessment it "believes best captures the range of views and uncertainties"[351] The elicitation provides two examples where such an approach might be appropriate:

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[340] *Id.* §§ 2.2.4 - 2.2.4.1, at pp. 2-9 to 2-10.

[341] *Id.* § 2.2.4.3, at p. 2-10.

[342] *Id.*

[343] *Id.* § 2.2.4.3, at p. 2-11.

[344] *Id.*

[345] *Id.*

[346] *Id.*

[347] *Id.*

[348] As explained *supra*, DOE generally took this "equal weight" approach in the volcanology, seismology and hydrology elicitations upon which it relied in its Yucca Mountain application, as well as in the Waste Form Expert Elicitation.

[349] *Id.* § 2.3.4.5, at p. 2-12. This subsection follows immediately after section 2.2.4.4, and therefore appears to have been misnumbered. The intended section number was likely 2.2.4.5.

[350] *Id.* § 2.1.1, at pp. 2-2 to 2-3.

[351] *Id.* § 2.1.1, at p. 2-3.

> For example, if a member of the expert panel had been unwilling to forsake the role of a proponent who advocates a singular viewpoint, for that of an evaluator who is able to consider multiple viewpoints, that expert may have been given less weight or removed from the panel entirely. Or the interpretations of a member of the panel would be given less weight if the rest of the panel declared him to have extreme, outlier views relative to both the views of the rest of the panel and the larger technical community. In this case, a weight of 1/7 (1 view in 7 on the panel) would be excessive relative to the true weight of his views when compared to the larger community (if, for instance, I in 100 might share the view).[352]

Finally, this elicitation used a more abbreviated approach to expert elicitation than did the larger elicitations addressed in Part III.C.1 through III.C.3 of this article.[353] In this respect, it was similar to the Waste Form Expert Elicitation.[354]

D. Rulemakings

Expert elicitation has played a significant role in only one NRC rulemaking proceeding.[355] In 2005, the NRC proposed "to amend its regulations to permit current power reactor licensees to implement a voluntary, risk-informed alternative to the current requirements for analyzing the performance of emergency core cooling systems (ECCS) during loss-of-coolant accidents (LOCAs) [and] . . . [to] establish procedures and criteria for requesting changes in plant design and procedures based upon the results of the new analyses of ECCS performance during LOCAs."[356] LOCAs can be caused by breaks in pipes, resulting in the loss of coolant to the

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[352] *Id.* § 2.3.4.5, at p. 2-13.

[353] *Id.* § 2.1.1, at p. 2-3.

[354] *See* text associated with note 321, *supra*.

[355] Expert elicitation has, however, been mentioned in passing in one other rulemaking proceeding. *See* NRC, Proposed Rule, Alternate Fracture Toughness Requirements for Protection Against Pressurized Thermal Shock Events, 72 Fed. Reg. 56,275, 56,276-77 (Oct. 3, 2007), 2007 WL 2850842 (F.R.) ("The technical basis [for this proposed rule] was developed using a flaw density, spatial distribution, and size distribution determined from a small amount of experimental data, as well as from physical models and expert elicitation").

[356] NRC, Proposed Rule, Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements, 70 Fed. Reg. 67,598, 67,598 (Nov. 7, 2005), 2005 WL 2921158 (F.R.) (Proposed Rule). The guidance document that supported this rulemaking provided an extensive description of the process used in the LOCA expert elicitation. *See* NUREG-1829, Vol. 2, at xv-xxvi. A reader interested in a detailed description of each phase of this elicitation will find it in NUREG-1829. The appendices to NUREG-1829 provide voluminous background information regarding the elicitation process and its participants. Particularly relevant is Appendix B, which sets forth the detailed minutes of the expert elicitation panel's meetings. Also, NUREG-1829's main report contains a detailed description of the particular approach the NRC used in this elicitation. NUREG-1829, Vol. 1, at pp. 3-1 to 3-35.

reactor. One of the key elements in analyzing LOCAs is the "transition break size" (TBS) – that is, the size of the break (hole or fracture) in a pipe.[357]

Two approaches have traditionally been used to estimate LOCA frequencies and their relationship to pipe size. However, the NRC concluded that "neither approach [was] particularly suited to evaluate LOCA event frequencies due to the rareness of these events and the modeling complexity."[358] Therefore, the NRC turned to expert elicitation.[359]

Prior to the initiation of the expert elicitation process, the staff performed its own "pilot" elicitation, to identify at least some of issues that the subject-matter experts would need to evaluate.[360]

The NRC used a twelve-expert panel[361] to help establish the TBS. This expert elicitation panel included a diverse group of subject matter experts,[362] plus nine members of the "facilitation

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[357] Proposed Rule, 70 Fed. Reg. at 67,602.

[358] *See* NUREG-1829, Vol. 2, at xv.

[359] *See id.*, Vol. 2, at xvi. It is also notable that the NRC's ACRS (note 123, *supra*) and its relevant subcommittees took considerable interest in this rule, meeting many times to discuss it. *See* NRC, ACRS; Meeting Notice, 72 Fed. Reg. 65,358, 65,358 (Nov. 20, 2007), 2007 WL 4103649 (F.R.) (considering Draft Final NUREG-1829); NRC, ACRS; Meeting of the ACRS Subcommittee on Reliability and Probabilistic Risk Assessment; Notice of Meeting, 72 Fed. Reg. 61,189, 61,190 (Oct. 29, 2007), 2007 WL 3128868 (F.R.) ("The Subcommittee will discuss the estimation of frequencies of occurrence of . . . LOCAs[] through the expert elicitation process"); NRC, ACRS; Meeting Notice, 70 Fed. Reg. 8857 (Feb. 23, 2005), 2005 WL 413022 (F.R.) (considering what would later become a Draft NUREG on expert elicitation); NRC, ACRS; Meeting Notice, 69 Fed. Reg. 68,411 (Nov. 24, 2004), 2004 WL 2671400 (F.R.) (same); NRC, ACRS, Meeting of the ACRS Subcommittee on Regulatory Policies and Practices; Notice of Meeting, 69 Fed. Reg. 63,564 (Nov. 2, 2004), 2004 WL 2430689 (F.R.) (same); NRC, ACRS; Meeting Notice, 68 Fed. Reg. 38,106, 38,106-07 (June 26, 2003), 2003 WL 21466621 (F.R.) ("The Committee will hear presentations by and hold discussions with representatives of the NRC staff with regard to conducting an expert elicitation as directed by the Commission in the March 31, 2003 Staff Requirements Memorandum related to risk-informing 10 CFR 50.46").

[360] *See* NUREG-1829, Vol. 2, at xvi.

[361] Proposed Rule, 70 Fed. Reg. at 67,603; NUREG-1829, Vol. 2, at xvi. Each subject-matter expert had "at least 25 years of relevant technical expertise." SECY-04-0060, "Loss-of-Coolant Accident Break Frequencies for the Option III Risk-Informed Reevaluation of 10 CFR 50.46, Appendix K to 10 CFR Part 50, and General Design Criteria (GDC) 35," (April 13, 2004), at unnumbered page 3 (SECY-04-0060) (ML040860129).

[362] NUREG-1829, Vol. 2, xxv. The group included individuals from Westinghouse Electric Co. LLC, OJV Consultancy Limited, Exelon Nuclear, the Idaho National Engineering Environmental Laboratory, the Swedish Nuclear Power Inspectorate, Engineering Mechanics Technology, Inc., ERIN® Engineering and Research, Inc., Structural Integrity Associates, Inc., Gesellschaft für Reaktorsicherheit (GRS) mbh, XGEN Engineering, the Pacific Northwest National Laboratory, and Engineering Mechanics Corporation of Columbus. *Id.* For detailed descriptions of each subject-matter expert's background, *see id.* App. A.

team"[363] (comprised of generalists, a normative expert, and two recorders[364]). The panel examined "degradation-related pipe breaks"[365] in typical reactors in order to "develop[] pipe break frequencies as a function of break size."[366] The panel's focus was limited to one narrow issue – "determining event frequencies that initiate by [certain kinds of] failures related to material degradation."[367] The panel estimated LOCA frequency "by consolidating service history data and insights from probabilistic fracture mechanics . . . studies with knowledge of plant design, operation, and material performance."[368]

The panel at its initial meeting discussed the staff's list of technical issues and developed a way of quantifying the effects of those issues.[369] This involved the lugubrious-sounding process of "decomposing" the complex technical issues into more manageable subissues.[370] The panel, together with the facilitation team, then developed the necessary background technical information and, with the help of the staff, drafted the elicitation questionnaire.[371]

At the second meeting, the panel reviewed and refined both the technical information and the questionnaire. The panel members then returned to their respective home institutions and prepared their own separate issues analyses in order to answer the questionnaire.[372]

Following these initial meetings, the facilitation team met separately with each panel member in a series of day-long elicitation interviews.[373] At these sessions, each subject-matter panel member "answered the elicitation questionnaire by providing quantitative estimates and a

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[363] *Id.* at xxv. The facilitation team in the LOCA elicitation played the same role as the "Technical Facilitator-Integrator" in the Yucca Mountain volcanology elicitation, and same role as the support teams in all the elicitations addressed in this article.

[364] *See id.*, Vol. 2, at xvii.

[365] Proposed Rule, 70 Fed. Reg. at 67,604.

[366] *Id.* at 67,603.

[367] *Id. See also* Supplemental Proposed Rule, 74 Fed. Reg. at 40,026.

[368] Notice of Availability of Draft Report for Comment: "Estimating Loss-of-Coolant Accident (LOCA) Frequencies Through the Elicitation Process," NUREG-1829, 70 Fed. Reg. 57,901, 57,901 (Oct. 4, 2005), 2005 WL 2427738 (F.R.). For a description of this expert elicitation, *see generally* NUREG-1829, Vols. 1 and 2, and *see specifically id.* Vol. 2, at xv-xxii. *See also* SECY-04-0060.

[369] NUREG-1829, Vol. 2, at xvii; SECY-04-0060 at unnumbered page 3.

[370] NUREG-1829, Vol. 2, at xvii.

[371] *Id.*; SECY-04-0060 at unnumbered pages 3-4.

[372] NUREG-1829, Vol. 2, at xvii; SECY-04-0060 at unnumbered page 3-4.

[373] SECY-04-0060 at unnumbered page 4; NUREG-1829, Vol. 2, at xvii.

qualitative rationale to support" the expert's conclusions regarding the questions he or she self-selected for discussion at the meeting.[374] Each subject-matter expert also specified the uncertainty associated with his or her conclusions.[375]

Following this series of individual meetings, the subject-matter experts again returned to their home institutions, where each revised his or her conclusions based on the feedback received during the interview.[376] The project staff, upon receiving the subject-matter experts' revised conclusions and rationales, "compiled the panel's [revised] responses and developed preliminary estimates of the LOCA frequencies."[377]

The staff presented these revised conclusions and rationales to the panel at a third meeting.[378] "Panel members were invited to fill in gaps in their questionnaire responses and, if desired, to modify their responses based on group discussion of important technical issues considered during individual elicitations."[379] Based on these further revisions, the project staff recalculated the earlier preliminary estimates of LOCA frequencies and provided the updated estimates to the subject-matter experts.[380]

Finally, at a fourth (video-conference) meeting, the subject-matter experts met yet again to discuss the most recent set of results.[381] The project staff then revised those results still further, to reflect the feedback during the fourth meeting.[382]

Following the computation of the LOCA frequencies after the fourth meeting, the staff initiated an external peer review of the expert elicitation and solicited public comment on the then-current draft report.[383] Once these two processes were completed, the staff revised the report one last time, to reflect the input from the peer review and public comments.[384] NUREG-1829 was the

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[374] SECY-04-0060 at unnumbered page 4. *See also* NUREG-1829, Vol. 2, at xvii.

[375] NUREG-1829, Vol. 2, at xvii; SECY-04-0060 at unnumbered page 4.

[376] NUREG-1829, Vol. 2, at xvii.

[377] *Id.*; SECY-04-0060 at unnumbered page 4.

[378] NUREG-1829, Vol. 2, at xvii; NUREG-1829, Vol. 1, at p. 3-1; SECY-04-0060 at unnumbered page 4.

[379] NUREG-1829, Vol. 2, at xvii-xviii (footnote omitted). *See also id.* Vol. 1, at p. 3-1; SECY-04-0060 at unnumbered page 4.

[380] *Id.* Vol. 2, at xviii.

[381] *Id.* Vol. 1, at p. 3-1.

[382] *Id. See id.* Vol. 1, at p. 3-2 for a flow chart depicting the entire LOCA elicitation process.

[383] *Id.* Vol. 1, at p. 3-1, pp. 3-34 to 3-35. Earlier studies had recommended, or at least hinted at, peer review of the expert elicitation process and results. NUREG-1563 at 6; NUREG/CR-6372, Vol. 1, at 48-50.

[384] NUREG-1829, Vol. 1, at p. 3-35.

end-product of the LOCA elicitation process, which lasted from February 2003[385] until April 2008.[386]

After the completion of the expert elicitation process, the staff used the panel's conclusions along with other information, to determine the TBS. The staff began this process by considering the results of the expert elicitation, but it then took a final step of adjusting those results to take into account the "uncertainty in the elicitation process, other potential mechanisms that could cause pipe failure that were not explicitly considered in the expert elicitation process, and the higher susceptibility to rupture/failure of specific piping in the RCS [reactor coolant system]."[387] The Proposed Rule offered this description of how, after the conclusion of the expert elicitation, the NRC took into account the uncertainties associated with each panel members' conclusions:

> The uncertainty associated with each expert's generic frequency estimates was . . . estimated. This uncertainty was associated with each expert's confidence in their generic estimates and frequency differences stemming from broad plant-specific factors, but did not consider factors specific to any individual plants. Thus, the uncertainty bounds of the expert elicitation do not represent LOCA frequency estimates for individual plants that deviate from the generic values. Variability among the various experts' results was also examined. A number of sensitivity analyses were conducted to examine the robustness of the LOCA frequency estimates to assumptions made during the analysis of the experts' responses.[388]
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> To address the uncertainty in the expert opinion elicitation estimates, the staff selected a pipe break frequency having approximately a 95th percentile probability of 10^{-5} per reactor-year. . . . However, this does not account for all failure mechanisms. In addition, the results of an expert opinion elicitation do not have the same weight as actual failure data. Therefore, choosing the 95th percentile values gathered from the expert opinion elicitation leaves additional margin for uncertainty than would be necessary if the mean frequency had

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[385] *Id.* at p. 3-8.

[386] *Id.* at second title page.

[387] Proposed Rule, 70 Fed. Reg. at 67,603. *See also id.* at 67,617; Supplemental Proposed Rule, 74 Fed. Reg. at 40,026, 40,028 ("The baseline TBS was adjusted upward to account for uncertainties and failure mechanisms leading to pipe rupture that were not considered in the expert elicitation process"). In this regard, the staff's action was analogous to DOE's approach, in its saturated zone flow expert elicitation, of "making sure that the [saturated zone] model has a specific discharge that is higher than that predicted by the expert elicitation committee." Calibration of the Site-Scale Saturated Zone Flow Model Draft (For Audit Purposes Only), at p. I-98 (Apr. 2000) (ML003724528).

[388] Proposed Rule, 70 Fed. Reg. at 67,603.

been calculated from actual failure data [*sic*].[389]

This final step was somewhat analogous to the staff's consideration of post-elicitation information in the Yucca Mountain elicitation because it reflects the staff's decision *not* to take the expert elicitation panel's conclusions as the final word. But the final step in this rulemaking process goes further by demonstrating the staff's willingness to actually refine those conclusions to suit the Commission's particular needs regarding the rulemaking.

IV. CONCLUSION AND RECOMMMENDATIONS

The NRC's last full-scale examination of expert elicitation process occurred in 1996. In that examination, the staff deconstructed the elicitation process into nine separate steps. The staff, however, wisely indicated that those nine steps were not carved irrevocably in stone but instead provided merely a general framework that could be customized or revised to suit the needs of the elicitation at issue. During the succeeding fifteen years, the NRC developed significant additional experience with the expert elicitation process in both the rulemaking and adjudicatory contexts. Yet during this period, the process flew largely -- perhaps entirely -- under the radar of the Commissioners themselves.

This changed in 2011, when Commissioner Apostolakis urged a reevaluation of the process, believing it could significantly help to resolve difficult regulatory challenges such as cyber security, digital instrumentation and control, small modular reactors, and material aging issues. Such a reevaluation, particularly as it is being initiated at the highest levels of the NRC, should enable the agency to determine how to take best advantage of expert elicitation's many positive attributes while minimizing the effects of its negative attributes.

The purpose of expert elicitation is to garner expert judgment for decision makers to use when resolving issues that do not lend themselves to other, more traditional and less formal evidentiary methods (e.g., data or modeling approaches). But however garnered, expert judgment is useless to a decision maker unless it is credible. As it happens, credibility is one of the expert elicitation process' most significant positive attributes – and is obtainable because of the process's transparency. Transparency provides credibility to the elicitation process because it allows someone outside that process (i) to see all the relevant information that led to the elicitation's conclusions, (ii) to follow all communications amongst the panel members during their deliberations so that the outsider can understand the basis for the conclusions, (iii) to see how the panel used those same conclusions to reach the ultimate outcome of the elicitation, and (iv) to understand why expert judgment was chosen over other less-formal, information-gathering methods. Such transparency should enhance the Commissioners', the NRC staff's and the public's confidence in any expert judgment arising from the elicitation.

Additional advantages include (a) improvement in NRC decision-making associated with public policy; (b) recognition and minimization of possible biases in expert judgment; (c) determination of the current state of knowledge about important technical and scientific matters and, perhaps, a basis for updating that knowledge; (d) revelation of the range of scientific and technical interpretations relevant to the issues at hand; (e) quantification of uncertainties associated with resolving those issues; and (f) resolution of differences in experts' estimates of uncertainty by providing a common vocabulary for expressing their judgments.

[389] *Id.* at 67,604.

Expert elicitation is, however, no panacea. For instance, an elicitation panel may be subject to dominance by a single outspoken member. In addition, the elicitation process can be more expensive and time-consuming than other forms of obtaining expert judgment, because it involves more people than the solicitation of a single expert's judgment or a handful of experts' collective judgment. Moreover, it can be difficult to empanel experts whose views actually represent the broad array of opinions within the professional community. Furthermore, the results of expert elicitation may be less defensible in adjudications because no single expert "owns" the result. One subject-matter expert (or, for that matter, less than all subject-matter experts) may be deemed by an NRC licensing board to be insufficient to represent the full range of the technical viewpoints contained in an expert elicitation report.

Any NRC reevaluation of the expert elicitation process should address the following dozen major issues that have surfaced subsequent (and, in some cases, prior) to the issuance of the staff's 1996 initial examination of expert elicitation:

> Should the staff's nine-step process for elicitation be revised?
>
> How should the complexity and number of issues to be addressed in an elicitation affect the number of workshops, informal working meetings, or field trips held during the elicitation process? (*Compare* the small Waste Form Expert Elicitation *with* the much larger Seismology Expert Elicitation.)
>
> How should the complexity and number of issues to be addressed in an elicitation affect the number of subject-matter experts selected for the panel? (*Compare* DOE's recommendation of a range between 4 and 12 subject-matter experts for geological hazard assessments *with* other elicitation experts' preference for much higher numbers outside the context of nuclear energy.)
>
> What are the best means of preventing or at least minimizing the empaneling of subject-matter experts with conflicts of interest? What are the best means of documenting conflicts of interest, and neutralizing the adverse effects if such conflicts are unavoidable?
>
> What are the best procedures for the selection of subject-matter experts, to assure that they are highly expert, are not invested in the outcome, and were not cherry-picked to produce a particular result in advance?
>
> What is the best way to ensure that the allocation of places on an elicitation panel is well balanced amongst different professional communities (e.g., industry, government, academia, national laboratories), so as to ensure a wide array of professional viewpoints?
>
> Should subject-matter experts be required to document revisions to their initial assessments during the process? Or would such a requirement "anchor" the subject-matter experts to their initial evaluations and make them reluctant to revise those evaluations during and after the feedback process?
>
> Should the NRC specify that the reports on individual elicitation interviews be based on notes taken during the interviews (as compared with post-interview written questionnaires, or experts writing their own interpretations following the interview)?

> Should the NRC use, or approve the use of, multi-member teams in lieu of individual subject matter experts (e.g., the seismic source teams in the seismology expert elicitation)? If so, should the members of each team be interviewed en mass or individually?
>
> Under what circumstances should the NRC or its licensees accord unequal weight to the conclusions of individual subject-matter experts (or teams of experts)? Under such circumstances, how should the support team determine the amount of weight to assign the expert or team? And how should those determinations be made transparent to the public.[390]
>
> Should elicitation panels be encouraged (or even required) to update their conclusions in light of new information that was unavailable during the panel's original deliberations? If not, should the Commission insist that the staff do so?
>
> How would the expert elicitation process generally, and the responses to the above eleven points in particular, differ if the subject of a nuclear-related elicitation were a policy determination rather than a scientific/technical evidentiary determination (as in the rulemaking and adjudicatory elicitations discussed in this article)?

The Commission should also evaluate or reevaluate the following six, less significant issues:

> If the NRC is an elicitation's sponsor, should the agency run a "pilot elicitation" prior to conducting the actual expert elicitation, in order to tune more finely the process to the issues before the expert panel?
>
> Who sets the agenda for the elicitation interview -- the subject-matter expert or the facilitator?
>
> Should the elicitation sponsor conduct peer review of the expert elicitation process? And, if so, should the review occur during or after the elicitation?
>
> Should the elicitation sponsor use videoconferences in lieu of face-to-face meetings?
>
> Should the sponsor conduct a post-elicitation survey of all participants to develop a "lessons learned" list?

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[390] *See*, particularly, Commissioner Apostolakis' vote sheet (Jan. 9, 2012):

> [T]he staff should provide guidance on whether and under what circumstances future elicitation exercises should implement corrections to expert judgments, or, even better, whether results with both corrected and uncorrected judgments should be reported.

The Commissioner was referring to the LOCA expert elicitation, where "a unique feature of this project was that the expert judgments were 'corrected' for potential biases, something that is not done routinely in such exercises." *Id.*

How should the NRC capture the knowledge accumulated by the NRC's own specialists in the expert elicitation process before those specialists retire?

In addition, the NRC should review any "lessons learned" that have already been compiled by the staff, DOE, or other nuclear-related entities (e.g., EPRI, LLNL) following previous expert elicitations. And finally, the NRC should investigate the use of the expert elicitation process by other agencies (especially EPA) and governmental entities, other scientific and technical disciplines, the private sector (including trade associations), academia, and national research laboratories.

APPENDIX

NUREG-1563, at 15, 17-18 ("Branch Technical Positions")

In view of the aforementioned policy considerations and statements of regulatory consideration underpinning 10 CFR Part 60, the staff has adopted the following technical positions concerning the use of expert elicitation in demonstrating compliance with the geologic repository disposal regulations. (As a supplement to the technical positions here, Appendix A provides definitions for certain key terms.)

(1) In matters important to the demonstration of compliance, the use of formal expert elicitation should be considered whenever one or more of the following conditions exist:

> (a) Empirical data are not reasonably obtainable, or the analyses are not practical to perform;
> (b) Uncertainties are large and significant to a demonstration of compliance;
> (c) More than one conceptual model can explain, and be consistent with, the available data; or
> (d) Technical judgments are required to assess whether bounding assumptions or calculations are appropriately conservative.

(2) (a) When formally eliciting expert judgment, the applicant should use a consistent and systematic procedure that will ensure that the results obtained accurately reflect what is known and not known about the topic in question. The components in an acceptable elicitation process are described below and are illustrated in Figure 1. Although written largely for the elicitation of individual subject-matter experts, the same approach can be applied to a *panel* (or a team) of subject-matter experts.

> *Step No. 1 - Definition of Objectives*
>
> The objectives of the elicitation should be defined explicitly and in a manner that reflects a clear understanding of how the judgments obtained will be used. The explication of these objectives should then guide the choice of experts, the information provided to them, and the form of the judgments that will be 'required.
>
> *Step No. 2- Selection of Experts*
>
> Before selection of the subject-matter experts, whose judgments will be elicited, two other types of experts should be recruited - the normative expert and the generalist. Because these types of experts may influence the outcome of the elicitation by the manner in which judgments are elicited, analyzed, or used, care should be taken in their selection to ensure that they can perform in an objective and impartial manner. Working together, the normative experts and generalists generate and apply specific criteria for the selection of the subject-matter experts. The subject-matter experts selected for elicitation should be individuals who: (a) possess the necessary knowledge and expertise; [fn 13] (b) have demonstrated their ability to apply their knowledge and expertise; (c) represent a broad diversity of independent opinion and approaches for addressing the topic(s) in question; (d) are willing to be identified publicly with their judgments; and (e) are willing to publicly disclose all potential conflicts of interest.

[fn 13] With regard to Item (a), it would be useful for members of the expert panel to possess at least some rudimentary knowledge of both decision-making theory and statistics. However, the possession or the lack of this knowledge should not be used as a selection criterion.

The criteria used to select the various experts of the elicitation team should be documented.

Step No. 3- Refinement of Issues and Problem Decomposition

The generalists and normative experts should work with the subject-matter experts to decompose the broad objectives of the elicitation by clearly and precisely specifying more focused and simpler sub-issues.

Step No. 4- Assembly and Dissemination of Basic Information

Assembly of background information should be initially conducted by the generalists and normative experts. As the elicitation process proceeds, the subject-matter experts may be able to recommend additional sources of information. Bias in the selection of this background material should be avoided such that a full range of views is represented and the necessary data and information are provided in a uniform, balanced, and timely fashion to all subject-matter experts.

Step No. 5 - Pre-Elicitation Training

Individual (or teams of) subject-matter experts should be provided training before the elicitations to: (a) familiarize them with the subject matter (including the necessary background information on why the elicitation is being performed and how the results will be used); (b) familiarize them with the elicitation process; (c) educate them in both' uncertainty and probability encoding and the expression of their judgments, using subjective probability; (d) provide them practice in formally articulating their judgments as well as explicitly identifying their associated assumptions and rationale; and (e) educate them with regard to possible biases that could be present and influence their judgments.

Step No. 6 - Elicitation of Judgments

The individual elicitation session with each subject-matter expert (or teams of subject-matter experts) should be held in a private setting conducive to uninterrupted discussion. The generalists and normative experts should be in attendance for the complete session with each subject-matter expert. At the start of the session for each subject-matter expert, the normative expert should summarize the issues to be covered and outline the logistics of the elicitation. All definitions and assumptions agreed to by the group during pre-elicitation meetings should be reviewed. All subject-matter experts should be queried in a uniform manner and asked to provide specific answers to questions about the issues considered and the reasoning behind their responses. Care should be taken to ensure that the required information is obtained and that it is internally consistent. Responses of all subject-matter experts should be documented thoroughly with one or more of the' following: written notes, transcription, and audio or video tape.

Step No. 7-Post-Elicitation Feedback

Each subject-matter expert (or teams of subject-matter experts) should be provided feedback from the elicitation team on the results of his or her elicitation as soon as practical after the elicitation sessions are completed. Each expert should be queried as to the need for revision or clarification of his or her respective judgments based on that feedback. As is the case for all the elicited judgments, the rationale for any revisions should be documented scrupulously.

Step No. 8 - Aggregation of Judgments (Including Treatment of Disparate Views)

Whatever aggregation method is employed, the individual expert's opinions must be preserved, documented, and provided to the NRC staff. Transparency in the aggregation process will render these judgments, including disparate views or outliers, [fn 14] useful for subsequent analyses. If disparate 'judgments are aggregated or combined, the applicant should: (a) provide some rationale for the specific aggregation techniques employed and provide documentation sufficient to trace the impact of the individual expert's judgment on the consolidated judgment; and (b) show what effect, if any, the disparate views would have on design and/or performance. When widely disparate opinions arise, extra effort should be taken to document thoroughly the bases for the differing views. Subject-matter experts with differing views should be asked to comment on opposing views during and/or after their individual elicitations. Should the disparity in views persist, then each of the significantly varying views should be provided as output of the elicitation so that it may be incorporated directly into technical analyses and performance assessments, or used to represent the extremes in a sensitivity analysis.

> [fn 14] As used in this guidance, outliers" refers to those opinions which lie apart from the views or expected (average) views of other experts.

Step No. 9-Documentation

Proper documentation of a formal expert elicitation should indicate what was done, why, and by whom. The resulting judgments should be clearly described along with the reasoning supporting these judgments. The specific issues addressed by the elicitation should be precisely defined. Unambiguous definitions of all specific terms should be provided and any assumptions used in the elicitation should be explicitly stated. The judgments, as they are stated by each subject-matter expert, should be provided, accompanied by the logic and information on which they are based. Any calculations that the experts considered important in determining judgments or models used should be recorded and all literature used, whether public or restricted, should be properly referenced. Proper documentation should clearly distinguish between that information provided directly by each subject-matter expert and any subsequent processing of that information, such as smoothing, interpolation, extrapolation, or aggregation of the judgments of different experts.

[(2])(b) The approach described above envisions that all of these process steps would be part of a procedure for an expert elicitation. If preferred, some of these steps can be combined as long as all of the elements of the process are addressed. If one or more of the process steps are omitted from the recommended procedure, the staff may need additional information for its consideration before accepting the results of an elicitation for its review and evaluation.

(3) If information from an expert elicitation is to be submitted in support of a license application, and if additional data or information becomes available, subsequent to the completion of the elicitation, which could change opinions or judgments obtained in the formal elicitation, the results of the elicitation should be re-examined and updated, as appropriate. In addition to the information requested above, documentation should include a detailed description of the updating process.

Appendix C

Excerpt from EPA, Policy Assessment for the Review of the Particulate Matter National Ambient Air Quality Standards at 2-104 to 2-110

(April 2011)

2.4 SUMMARY OF STAFF CONCLUSIONS ON PRIMARY FINE PARTICLE STANDARDS

In reaching conclusions on the adequacy of the current suite of $PM_{2.5}$ standards and potential alternative suites of standards to provide the appropriate protection for health effects associated with long- and short-term fine particle exposures, staff has considered these standards in terms of the basic elements of the NAAQS: indicator, averaging time, form, and level (sections 2.3.1 to 2.3.4). In considering the scientific and technical information, we reflect upon the information available in the last review integrated with information that is newly available as assessed and presented in the ISA and RA (US EPA, 2009a; US EPA, 2010a) and as summarized in sections 2.2 and 2.3. We also consider the issues raised by the court in its remand of the primary annual $PM_{2.5}$ standard as discussed in section 2.1.2.

As outlined in section 2.1.3, our approach to reaching conclusions about the adequacy of the current suite of $PM_{2.5}$ standards and potential alternative standards that are appropriate for consideration is broader and more integrative than approaches used in past reviews. Our approach integrates a much expanded body of health effects evidence, more extensive air quality data and analyses, and a more comprehensive quantitative risk assessment, and considers the combined protection against $PM_{2.5}$-related mortality and morbidity effects associated with both long- and short-term exposures afforded by the suite of annual and 24-hour standards.

We recognize that selecting from among alternative suites of standards will necessarily reflect consideration of the qualitative and quantitative uncertainties inherent in the relevant evidence and in the assumptions that underlie the quantitative risk assessment. In reaching staff conclusions on alternative suites of standards that are appropriate to consider, we are mindful that the CAA requires primary standards to be set that are requisite to protect public health with an adequate margin of safety, such that the standards are to be neither more nor less stringent than necessary. Thus, the CAA does not require that the NAAQS be set at zero-risk levels, but rather at levels that reduce risk sufficiently so as to protect public health with an adequate margin of safety (section 1.2.1).

Based on the currently available scientific evidence and other information, staff reaches the following conclusions regarding the primary fine particle standards:

(1) Consideration should be given to revising the current suite of primary $PM_{2.5}$ standards to provide increased public health protection from the effects of both long- and short-term exposures to fine particles in the ambient air. This conclusion is based, in general, on the evaluation in the ISA of the currently available epidemiological, toxicological, dosimetric, and exposure-related evidence, and on air quality information and analyses related to the epidemiological evidence, together with judgments as to the public health significance of the estimated incidence of effects remaining upon just meeting the current suite of standards.

(2) It is appropriate to retain $PM_{2.5}$ as the *indicator* for fine particles. Staff concludes that the available evidence does not provide a sufficient basis for replacing or supplementing the $PM_{2.5}$ indicator with any other indicator(s) defined in terms alternative size fractions (i.e., UFPs) or for any specific fine particle component or group of components associated with any source categories of fine particles, nor does it provide a basis for excluding any component or group of components associated with any source categories from the mix of particles included in the $PM_{2.5}$ indicator.

(3) With regard to *averaging times* for the $PM_{2.5}$ standards, it is appropriate to retain annual and 24-hour averaging times to provide protection against health effects associated with long- term (seasons to years) and short-term (hours to days) exposure periods. The available evidence does not provide a sufficient basis for consideration of other averaging times, including an averaging time less than 24 hours to address health effects associated with sub- daily exposures or an averaging time to address effects associated with seasonal exposures, given the relatively small amount of relevant information available.

(4) It is appropriate to consider revising the *form of the annual standard* to one based on the highest appropriate monitor in an area rather than a form that allows averaging across monitors (i.e., spatial averaging) to provide increased protection for susceptible populations. Further, it is appropriate to retain the 98^{th} percentile *form of the current 24-hour standard*.

(5) Consideration should be given to revising the suite of $PM_{2.5}$ standards to provide increased protection against effects associated with both long- and short-term exposures, taking into account both evidence-based and risk-based considerations, with a particular focus on revising the annual standard level to provide protection for effects associated with both exposure periods. An emphasis on the annual standard would be consistent with the policy approach of setting a "generally controlling" annual standard to provide protection for both long- and short-term $PM_{2.5}$ exposures in conjunction with a 24-hour standard that provides supplemental protection against days with high peak concentrations. This would limit peak concentrations in areas with high peak-to-mean ratios, possibly associated with strong local or seasonal sources. This would also provide supplemental protection for potential $PM_{2.5}$- related effects that may be associated with shorter-than-daily exposure periods. Staff concludes that this policy goal is the most effective and efficient way to reduce total population risk associated with

both long- and short-term exposures, and would provide relatively more uniform protection in areas across the country.

(a) Taken together, staff concludes that the currently available evidence and information from a quantitative risk assessment and air quality analyses provide support for considering revision of the level of the *annual standard* to within a range of 13 to 11 $\mu g/m^3$. Staff further concludes that the evidence most strongly supports consideration of an alternative annual standard level in the range of 12 to 11 $\mu g/m^3$.

(b) In conjunction with consideration of an annual standard level in the range of 12 to 11 $\mu g/m^3$, staff concludes it is appropriate to consider retaining the current *24- hour standard* level at 35 $\mu g/m^3$.

(c) In conjunction with consideration of an annual standard level of 13 $\mu g/m^3$, staff concludes that there is limited support to consider revising the 24-hour standard level to somewhat below 35 $\mu g/m^3$, such as down to 30 $\mu g/m^3$.

2.5 KEY UNCERTAINTIES AND AREAS FOR FUTURE RESEARCH AND DATA COLLECTION

The uncertainties and limitations that remain in the review of the primary fine particle standards are primarily related to understanding the range of ambient concentrations over which we continue to have confidence in the health effects observed in the epidemiological studies, as well as the extent to which the heterogeneity observed in the epidemiological evidence is related to differences in the ambient fine particle mixture and/or exposure-related factors. In addition, uncertainties remain in more fully understanding the role of $PM_{2.5}$ in relationship to the roles of gaseous co-pollutants within complex ambient mixtures.

In this section, we highlight areas for future health-related research, model development, and data collection activities to address these uncertainties and limitations in the current body of scientific evidence. These efforts, if undertaken, could provide important evidence for informing future PM NAAQS reviews and, in particular, consideration of possible alternative indicators, averaging times, and/or levels. In some cases, research in these areas can go beyond aiding standard setting to informing the development of more efficient and effective control strategies. We note, however, that a full set of research recommendations to meet standards implementation and strategy development needs is beyond the scope of this discussion.

As has been presented and discussed in the PM ISA, particularly in Chapters 4 through 8, the scientific body of evidence informing our understanding of health effects associated with long- and short-term exposures to fine particles has been broadened and

strengthened since the last review. In reviewing the adequacy of the current suite of primary $PM_{2.5}$ standards and in evaluating alternative health-based fine particle standards appropriate for consideration, we identify the following key uncertainties and areas for future research and data collection efforts that have been highlighted in this review. We recognize that some research could be available to inform the next PM NAAQS review, while other research may require longer-term efforts.

Interpretation of Epidemiological Evidence

Additional research focused on identifying the most important factors contributing to the observed heterogeneity in the epidemiological evidence could provide insights for interpreting these studies. We encourage research and data collection efforts directed at improving our understanding of the nature of the exposures contributing to the observed health effects, for example, the role of specific components, sources, and different size fractions (e.g., UFPs) within the current $PM_{2.5}$ mass-based indicator and the role of fine particles and co-pollutants within the broader ambient mixture, as well as improving our understanding of exposure-related factors that influence the magnitude and duration of fine particle exposures. Much of this research may depend on the availability of increased monitoring data, as discussed below.

- Components/Sources. The currently available scientific evidence continues to be largely indexed by aggregate $PM_{2.5}$ mass-based concentrations which vary in composition both regionally and seasonally. Source characterization, exposure, epidemiological, and toxicological research could focus on improving our understanding of the relative toxicity of different fine particle components, properties, and sources that may be more closely linked with various health effects. Critical to this better understanding of the impacts of $PM_{2.5}$ components and their associated sources are data that refines the temporal and spatial variability of the fine particle mixture. This research would reduce the uncertainties in estimating risks. It could also inform consideration of alternative indicators in future PM NAAQS reviews as well as aid in the development of efficient and effective source control strategies for reducing health risks.
- Ultrafine Particles (UFPs). Additional monitoring methods development work, health research, and ambient monitoring data collection efforts are needed to expand the currently available scientific data base for UFPs. UFP measurements should include surface area as well as number, mass and composition. It would be most useful for an UFPs monitoring network to be designed to inform our understanding of the spatial and temporal variability of these particles, including in near-roadway environments. This information would improve

  our ability to explore consideration of a separate indicator for UFPs in future PM NAAQS

reviews.

- Co-pollutant Exposures. Research focused on furthering our understanding of the extent to which an association between fine particles and specific health effects can be modified by one or more co-pollutants would inform our ability to discern the role of PM in the complex ambient mixture. For example, does the magnitude of a $PM_{2.5}$-related effect estimate differ on days when O_3 concentrations are higher compared to days when O_3 concentrations are lower?

- Factors Influencing Exposures. Additional research and analyses would be useful to provide insights on population exposures, specifically in improving our understanding of intra-city and inter-city differences related to various $PM_{2.5}$ components, source contributions and personal and building-related factors that may enhance our interpretation of the epidemiological evidence. This could include time-activity data to support probabilistic scenario-based exposure models, such as additional activity diary data to incorporate into the Consolidated Human Activity Database (CHAD); air conditioning use; residence near roadways; and penetration rates to better characterize ambient $PM_{2.5}$ impacts on indoor microenvironments. This research could focus on different size fractions in $PM_{2.5}$ (i.e., UFPs) as well as components. Coordination between exposure and health studies could advance our understanding of exposure-related factors. For example, epidemiological panel studies might use various exposure measurements to explore differences in personal exposures related to (1) indoor generated fine particles, (2) fine particle exposures measured
  by community monitors, and (3) fine particle exposures not captured by community monitors
  (i.e., personal exposures during commuting).

Health Outcomes, Exposure Durations of Concern, and Susceptible Populations

New information available in this review reinforces and expands the evidence of associations between long- and short-term $PM_{2.5}$ exposures and mortality and a number of cardiovascular and respiratory effects. Less evidence is available to understand other health effects (e.g., developmental/reproductive effects; central nervous system effects). Additional research could expand our understanding of the associations between $PM_{2.5}$ and a broader range of health outcomes; reduce uncertainties associated with our current understanding of concentration-response relationships; improve our understanding of exposure durations of concern; and improve our understanding of the potential public health impacts of fine particle exposures in susceptible populations. Toxicological studies could provide additional evidence of coherence and biological plausibility for the effects observed in epidemiological studies as well
as additional insights on possible mechanisms of action.

- Health Effects. Research on a broader range of cardiovascular and respiratory endpoints could improve our understanding of the mechanisms by which these effects occur. In addition, future research could expand the scientific data base for

health effects that are currently less understood including effects categorized within the ISA as having evidence suggestive of a causal relationship or for which currently available evidence is inadequate to support a quantitative risk analysis. To the extent that research supports a link between fine particles and adverse effects on the nervous system, reproduction, development, or other endpoints, such effects could play an increased role for informing future PM NAAQS reviews including expanding the health endpoints that could potentially be evaluated in future quantitative risk assessments.

- Concentration-Response Relationships. Research focused on improving our understanding of the shape of the C-R relationships, especially at lower ambient fine particle concentrations, as well as the confidence intervals around these C-R relationships, could reduce uncertainties associated with estimating and characterizing risks throughout the full range of air quality distributions. As more information becomes available on fine particle components and sources, it will be important to understand the C-R relationships for key constituents of the fine particle mixture, as well.

- Exposure Durations of Concern. Research should be directed at broadening the scientific data base to improve our understanding of health effects associated with short-term, peak exposures, such as those related to traffic-related sources, wildfires, agricultural burning, or other episodic events, as well as to improve our understanding of health effects associated with seasonal-length exposures, such as those related to wintertime wood-burning emissions. Additional quantitative measures of exposure might take into account factors including the magnitude and duration of sub-daily and seasonal length $PM_{2.5}$ exposures and the frequency of health impacts associated with repeated peak exposures. More research is needed to better understand effects that occur at longer lag times than have historically been studied (e.g., 0 to 2 day lags).

- Susceptible Populations. Improving our understanding of the populations that are more likely to experience adverse health effects related to fine particle exposures and the concentrations at which these effects may occur is important for informing future PM NAAQS reviews and for developing programs to reduce related public health risks. This evidence may also provide insights into the biologic modes of action for toxicity.

    - Pre-existing Health Conditions. While currently identified susceptible populations include persons with pre-existing cardiovascular and respiratory disease, evidence continues to emerge related to additional health conditions that may increase susceptibility to fine particle exposures (e.g., diabetes, obesity, neurological disorders). Research to replicate or extend these findings would enhance our understanding of these and other potentially susceptible populations.

    - Children. Epidemiological and toxicological studies provide evidence that children are more susceptible to PM exposures, primarily for respiratory-related effects. Evidence of developmental effects associated with PM

exposures continues to emerge. Additional research exploring issues to better understand key windows of development impacted by PM exposures could enhance our understanding of this important susceptible lifestage.

- Genetic Susceptibility. Research to expand our understanding of genetic susceptibility could inform our understanding of potentially susceptible populations and provide additional information for identifying the specific pathways and mechanisms of action by which PM initiates health effects.

Socioeconomic status (SES). Additional research is needed to identity what factors (e.g., general health status, diet, medication, stress, unmeasured pollution) cause SES differences in response to pollution measured in communities.

Data Collection Needs and Methods Development Activities

Additional research and data collection efforts focused on expanding current monitoring methods and networks as well as continued development of exposure models to expand data available for health studies could improve our understanding of potential alternative indicators, averaging times, and levels to consider in future PM NAAQS reviews. In particular, staff encourages work to enhance our understanding of the temporal and spatial variability of $PM_{2.5}$, $PM_{2.5}$ components, and different size fractions (e.g., UFPs).

- Monitoring Measurements. In order to improve our understanding of the association between fine particles and health effects, more frequent measurement data could be collected. This would provide information that could inform our understanding of alternative lags.
  - $PM_{2.5}$ Components. With respect to improving our understanding of the impacts of $PM_{2.5}$ components, enhancements to the CSN, including more frequent measurement schedules and the development and deployment of continuous monitoring methods for specific fine particle components (e.g., EC/OC, sulfates), could enhance our understanding of the temporal and spatial variability of specific components. Furthermore, identifying chemical species within the mix of organic aerosols would improve our understanding of the artifacts associated with semi-volatile PM components and aid in designing toxicological experiments.
  - Ultrafine Particles. In order to improve our understanding of the public health impacts of UFPs, consideration should be given to establishing an FRM for UFPs and establishing a national UFP monitoring network.
  - Source Apportionment. Composition data with better time resolution (e.g., 1 to 6 hour) and better size resolution (e.g., UFPs, accumulation mode particles, coarse particles in $PM_{2.5}$ and $PM_{10-2.5}$) could provide more precise and accurate information on sources of fine particles to inform health

research as well as development of more efficient and effective control strategies.

- Spatial Variability. Some portion of the required $PM_{2.5}$ monitoring network could be dedicated to improving our ability to characterize spatial variability across urban areas including both at localized and area-wide scales.

- Model Development. Continuing work to improve models for estimating $PM_{2.5}$ mass and composition in areas with only every third or sixth day measurements, and by space where measurements are not available could enhance our understanding of the temporal and spatial variability of fine particles. Refinement of these models to finer spatial scales may improve exposure estimates in epidemiological studies as well as in quantitative risk and exposure assessments.

- Air Quality Distributions Reported in Epidemiological Studies. Most epidemiological studies provide some information on the distribution of ambient measurement data evaluated, however, published information is often generally limited in scope and the descriptive statistics reported vary from one study to another. Understanding the air quality distributions at which effects have been observed is important for informing consideration of the adequacy of the current NAAQS as well as potential alternative indicators, averaging times, and levels to consider. Working with intramural and extramural research groups, we plan to encourage a more comprehensive and more consistent reporting of population-level and air quality data.

Appendix D

NRC FORM 757
NRC MD 10.158
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

NON-CONCURRENCE PROCESS

SECTION A - TO BE COMPLETED BY NON-CONCURRING INDIVIDUAL

TITLE OF DOCUMENT	ADAMS ACCESSION NO.
UPDATE ON THE YUCCA MOUNTAIN PROGRAM	**ML11180A265**
DOCUMENT SPONSOR	SPONSOR PHONE NO.
Catherine Haney	**301-492-3554**
NAME OF NON-CONCURRING INDIVIDUAL	PHONE NO.
King Stablein	**301-492-3199**

☑ DOCUMENT AUTHOR ☐ DOCUMENT CONTRIBUTOR ☐ DOCUMENT REVIEWER ☐ ON CONCURRENCE

TITLE	ORGANIZATION
Branch Chief	**NMSS/HLWRS**

REASONS FOR NON-CONCURRENCE

Please see attached document.

☐ CONTINUED IN SECTION D

SIGNATURE	DATE
King Stablein	**07/21/2011**

SUBMIT FORM TO DOCUMENT SPONSOR AND COPY TO YOUR IMMEDIATE SUPERVISOR AND DIFFERING VIEWS PROGRAM MANAGER

Reasons for King Stablein's Non-Concurrence on Memorandum to the Commission entitled "Update on the Yucca Mountain Program"
July 21, 2011

As the author of this memorandum, I have striven to provide the Commission with substantial information on, and appropriate context for, the important developments which have taken place in the Yucca Mountain Program since February 4, 2011, the date of the last such memorandum to the Commission. However, some of the most important, and most revealing, matters to have occurred in the last six months are almost imperceptible in the memorandum in its final form.

In particular, I refer to the discussion of the status of Technical Evaluation Reports (TERs). The staff completed the Postclosure TER volume on March 31, 2011, with an NLO from OGC, and was prepared to make it public upon approval by Catherine Haney, the NMSS Office Director. For over two months, the staff awaited action by her but received no feedback and no explanation as to why she was delaying issuance of the Postclosure TER volume. After over two months of silence, the Director informed Aby Mohseni, the acting Director of HLWRS, that she did not approve the document, as written, for publication, and provided direction on how she wanted the document modified. Mr. Mohseni responded by disagreeing with her decision in writing and asking either that she give permission for the Postclosure TER volume to be published immediately without changes or that the matter be referred to the Commission.

Ms. Haney did not pursue either course of action, so Mr. Mohseni felt compelled to take the highly unusual and very courageous step of writing a memorandum directly to the Commission on June 20, 2011, "to describe the environment in which the Division of High Level Waste Repository Safety (HLWRS) is working and to request Commission intervention." Among the interventions that Mr. Mohseni requested was for the Commission to determine the appropriateness of issuing the Postclosure TER volume. Other requested interventions were aimed primarily at assuring that the Commission had sufficient avenues to be fully and currently informed on the status of, and policy matters related to, the Yucca Mountain Program and that staff had the opportunity to complete its Yucca Mountain-related knowledge capture activities.

NMSS management took notice of Mr. Mohseni's memorandum and formulated a six-step Staff Action Plan. The first step was for HLWRS to make the changes directed by the NMSS Office Director to the Postclosure TER volume and to issue it promptly. Obviously, this direction runs counter to Mr. Mohseni's request to issue the document in an unaltered form. However, staff completed the changes as directed and made the Postclosure TER volume publicly available earlier today (July 21, 2011).

In the memorandum that is the subject of this non-concurrence, the discussion of the status of TERs contains virtually none of the above information and context. Buried near the end of the memorandum is a very short section entitled "Action Plan for Responding to Concerns Raised by NMSS Staff Members", which does not describe the staff concerns in Mr. Mohseni's memorandum but refers to them cryptically as "certain matters related to the Yucca Mountain

Program." The reader has no clue from this phrase that the concerns relate to the problems staff have encountered in trying to publish the staff version of the Postclosure TER volume and to the issues of "suppression and manipulation of programmatic and budgetary information to meet a politicized agenda, depriving the full Commission of the broad range of information, including programmatic options, needed by the Commission to fully discharge its responsibilities" (Mohseni memorandum to the Commission, June 20, 2011). Thus, the memo that is the subject of this non-concurrence serves as yet another glaring example of how information that is essential for the Commission to understand what is really happening in the Yucca Mountain Program--to the staff, to its products, and to its environment--is concealed or omitted in a document purporting to present the status of the Yucca Mountain Program to the Commission.

For these reasons, I respectfully decline to concur on this status update memorandum.

King Stablein 7/21/2011

King Stablein, Chief
Projects Management Branch B
Division of High-Level Waste Repository Safety
Office of Nuclear Material Safety and Safeguards

NRC FORM 757
NRC MD 10.158
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

NON-CONCURRENCE PROCESS

TITLE OF DOCUMENT	ADAMS ACCESSION NO.
UPDATE ON THE YUCCA MOUNTAIN PROGRAM	**ML11180A265**

SECTION B - TO BE COMPLETED BY NON-CONCURRING INDIVIDUAL'S SUPERVISOR
(THIS SECTION SHOULD ONLY BE COMPLETED IF SUPERVISOR IS DIFFERENT THAN DOCUMENT SPONSOR.)

NAME
Aby Mohseni

TITLE	PHONE NO.
Acting Division Director	**301-492-3181**

ORGANIZATION
HLWRS/NMSS

COMMENTS FOR THE DOCUMENT SPONSOR TO CONSIDER

☐ I HAVE NO COMMENTS

☑ I HAVE THE FOLLOWING COMMENTS

See attachment.

☐ CONTINUED IN SECTION D

SIGNATURE	DATE
	07/21/2011

SUBMIT THIS PAGE TO DOCUMENT SPONSOR

As Dr. Stablein's supervisor, I observe daily the subtle and not-so subtle pressures and intimidation he and his organization is subjected to. I have brought a few examples to the attention of the EDO and other senior managers to no avail. I have previously informed the Commission of manipulation and suppression of information regarding the Yucca Mountain Program. I informed the Commission of the politicization of our scientific products and licensing processes. While the OIG report shed some light on these issues at the highest level, it did not go far enough to capture the unhealthy impacts on the staff. Dr. Stablein's basis for his non-concurrence reflects yet another example of the same senior management attitude obsessed with controlling information that gets to the full Commission.

My comments would be incomplete without mentioning how well the staff has managed to stay focused on its mission despite the unbecoming behavior of senior management. The recent publication of the TER on Postclosure, albeit altered by direction from senior management, is an example. A few of the contributing staff were Tim McCartin, Chris Jacobs, Alicia Mullins, Jack Sulima. The Center for Nuclear Waste Regulatory Analyses provided critical support. Dr. Stablein, his staff, and the entire Division should be commended for their courage, professionalism, hard work, dedication, focus on the mission, scientific acumen, resilience, creativity to overcome obstacles, and adherence to our organizational values. They are truly the best assets of this Agency and for the country. I wish I could say the same for some of the senior managers who have posters of such values on the walls.

NRC FORM 757
NRC MD 10.158
(3-2009)

U.S. NUCLEAR REGULATORY COMMISSION

NON-CONCURRENCE PROCESS

TITLE OF DOCUMENT	ADAMS ACCESSION NO.
Update on the Yucca Mountain Program	**ML11180A265**

SECTION C - TO BE COMPLETED BY DOCUMENT SPONSOR

NAME
Catherine Haney

TITLE	PHONE NO.
Office Director	**301-492-3554**

ORGANIZATION
NMSS

ACTIONS TAKEN TO ADDRESS NON-CONCURRENCE (This section should be revised, as necessary, to reflect the final outcome of the non-concurrence process, including a complete discussion of how individual concerns were addressed.)

- see attached -

☐ CONTINUED IN SECTION D

SIGNATURE - DOCUMENT SPONSOR	DATE	SIGNATURE - DOCUMENT SIGNER	DATE
Catherine Haney	8-3-11	Catherine Haney	8-3-11

NON-CONCURRING INDIVIDUAL *(To be completed by document sponsor* when process is complete, i.e., after document is signed):

- ☐ CONCURS
- ☑ NON-CONCURS
- ☐ WITHDRAWS NON-CONCURRENCE (i.e., discontinues process)
- ☑ WANTS NCP FORM PUBLIC
- ☐ WANTS NCP FORM NON-PUBLIC

I have reviewed Dr. Stablein's written reasons for non-concurring on this memorandum and also met with him on July 21, 2011 to discuss his non-concurrence.

Dr. Stablein's primary concern, as I understand it, is that "some of the most important, and most revealing, matters to have occurred in the last six months are almost imperceptible in the memorandum in its final form." He wants to include a detailed discussion on the timing and development of my position with regards to the issuance of the Post Closure Technical Evaluation Report (TER) and to highlight Mr. Mohseni's June 20, 2011, memorandum to the Commission. He state that this information is needed for the Commission to understand the present status, products and environment of the Yucca Mountain Program.

I believe the current memorandum adequately describes the activities that have taken place in the Yucca Mountain Program since February 2011 and that no revisions to the final memorandum are needed. The Commission is also well aware of my direction with regards to the Postclosure TER as this matter is discussed in detail in Mr. Mohseni's memorandum to the Commission, "Request for Commission Intervention," dated June 20, 2011 (ML111940243). In addition, my position was discussed in my prepared testimony for the House Subcommittee on Environment and the Economy, in responses to questioning by the Subcommittee members and in a letter from Representatives, John Shimkus and Fred Upton to Chairman Jaczko dated, July 8, 2011. Therefore, I believe the Commission is well informed on this matter.

Appendix E

Figure 1: The original IRIS profile development process.

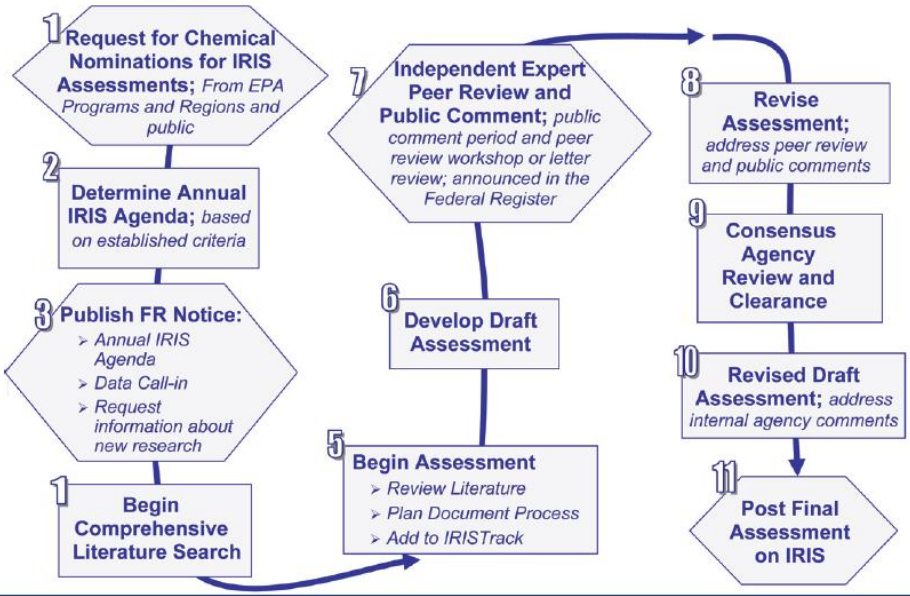

Figure 2: The process after the Bush Administration's first revisions.

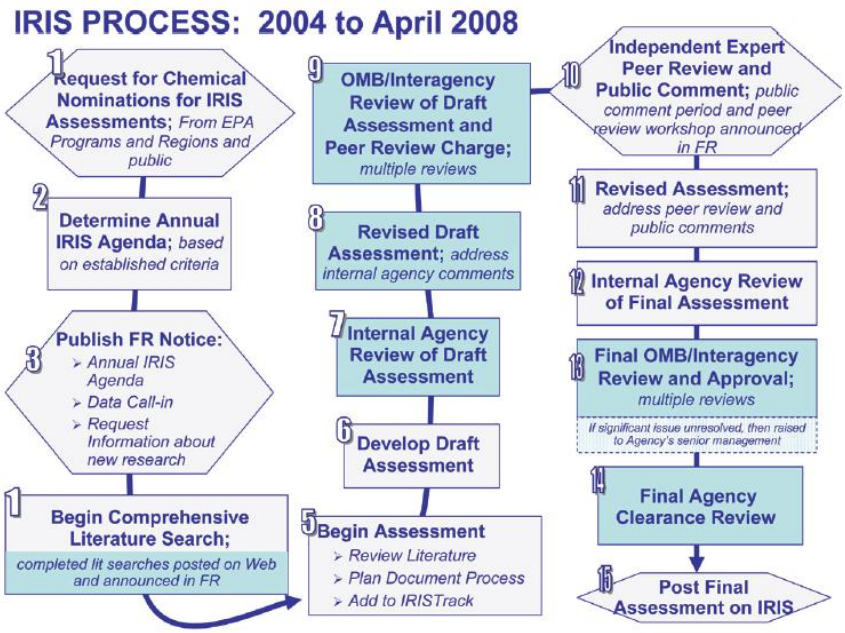

Figure 3: The process after the Bush Administration's second revisions.

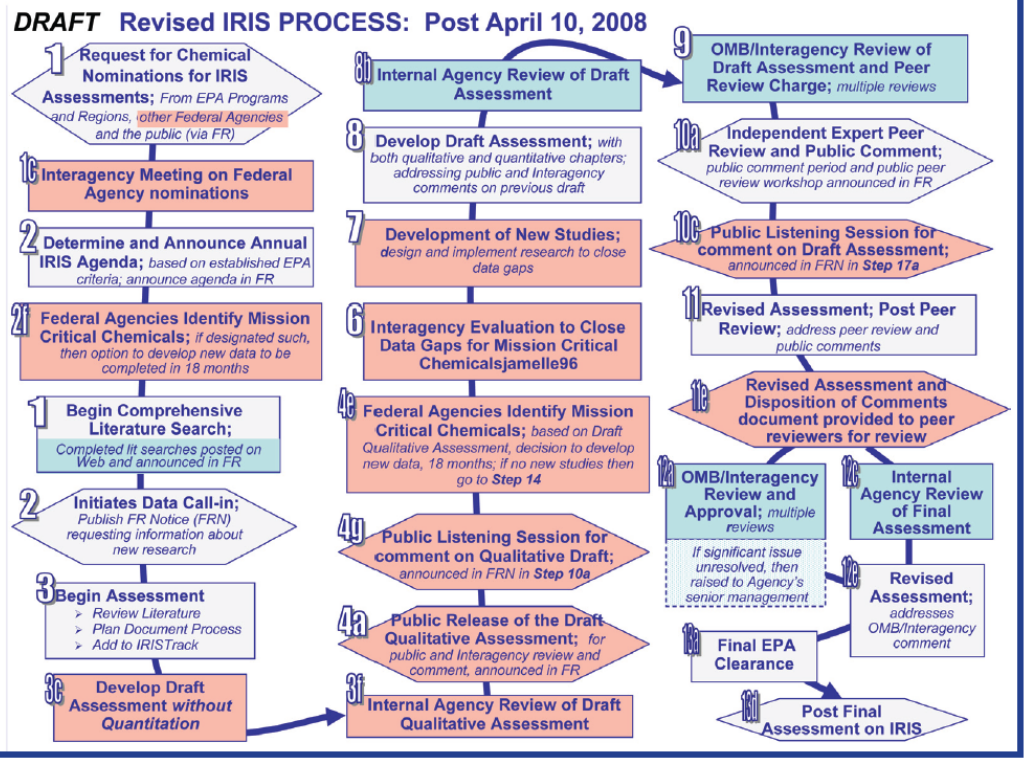

Figure 1,2, & 3: Hearing on Fixing EPA's Broken Integrated Risk Information System, Before the Subcomm. on Oversight and Investigations of the H. Comm. on Science and Technology (Jun. 11, 2009)."

Figure 4: The current process.

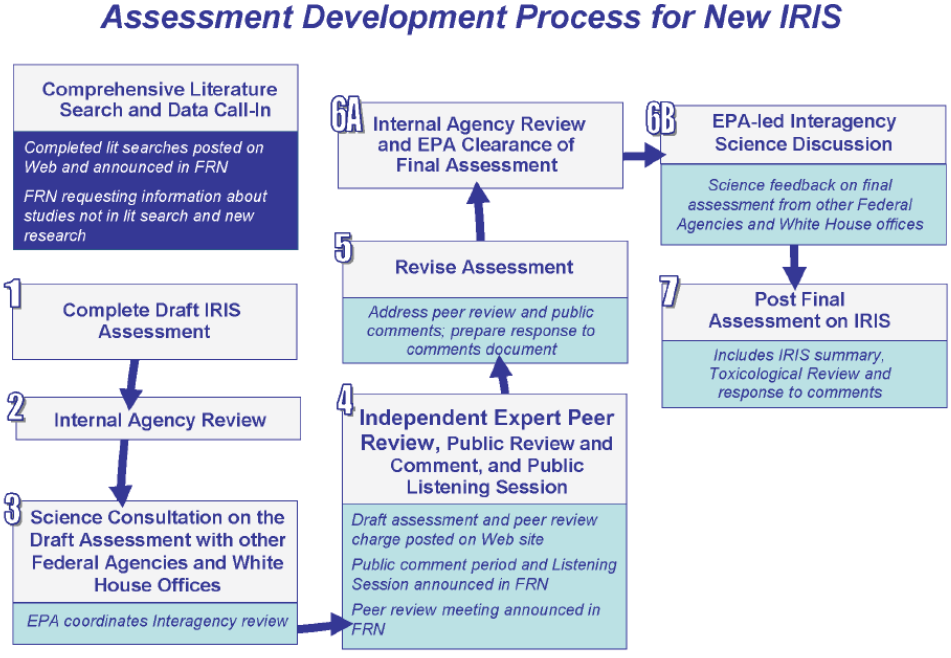

Figure 4: ENVIRONMENTAL PROTECTION AGENCY, NEW PROCESS FOR DEVELOPMENT OF INTEGRATED RISK INFORMATION SYSTEM (May 21, 2009), available at http://epa.gov/iris/process.htm.

Appendix F

OMB Staff Working Comments on EPA's Final Agency/Interagency Science Discussion draft Toxicological Review of Dichloromethane (DCM) and draft IRIS Summary (dated June 2011)

Aug 12, 2011

Due to the limited time provided for interagency science consultation, OMB focused only on EPA's response to the external peer review. Where EPA agrees with the comments, we suggest that appropriate conforming changes be made in the main text of the toxicological review and the IRIS summary.

General Science Comments:

- While we note that the peer review report is already final, for future assessments it would be helpful if the peer review report provided short summaries of the background of the expert reviewers. It may also be helpful if the peer review reports were to include information discussing any monetary funding (perhaps through a grant, cooperative agreement, sole-source agreement, or competitive contract) that the expert reviewer may have received from EPA's ORD. This would be consistent with generally-accepted disclosure practices for peer reviewers, particularly for reviews with significant public policy implications.
  - In 2009 ORD/NCEA signed a Memorandum of Understanding with CalEPA/OEHHA to cooperate on the development of risk assessment methods and toxicological assessments. It thus seems a bit awkward that one of the expert reviewers is from the OEHHA office. We wonder if this reviewer can truly provide an independent assessment of EPAs work as the two offices are collaborating on the development of toxicological assessments.

- We applaud EPA for having very specific questions regarding the pharmacokinetic modeling and for having multiple reviewers with this expertise. In fact, the expert panel has some of the US's best modelers. It is therefore surprising to see that in many cases EPA rejects their comments. Some specific cases are noted in the details below. It may be helpful for EPA to take a second look at the expert reviewer comments to see if they can be more receptive to their scientific suggestions.

- Similar to the comments above, we recognize that Dr. Kamendulis was likely on the panel due to her expertise in hepatoxicity. We note that she had significant concern with EPAs choice of study and endpoint for the RfD, but stated that "However, this reviewer would be satisfied if the limitations and deficiencies of this study and endpoint were sufficiently documented in the draft document."
  - EPA stated that such information was added to section 5.2.1 however we did not see this information in the redline provided. We suggest adding such a discussion and carrying it through to Section 6 as well as the IRIS summary.
  - Dr. Kamendulis (peer review report page 31) also noted that EPA "does not describe whether there is any biological significance for this endpoint." From her comments, it appears that she thinks it does not have a correlate to human exposure. EPA states that they have addressed this comment, but we note that section 5.2.1 states that "Hepatocyte vacuolation was considered a toxicologically relevant effect since the effect was characterized as correlating with fatty change (Burek et al., 1984) or as a vacuolation of

lipids in the hepatocyte (Nitschke et al., 1988a). It is not clear what is meant by 'toxicologically revant". Does EPA mean this is adverse or perhaps just a precursor to other effects? EPA notes that this could lead to more serious effects, thus it seems as though it is a precursor effect. Therefore, EPA should clarify in the toxicological review and IRIS summary that the endpoint used for the RfD is not an adverse effect but is a precursor effect. Such a change would likely move EPA in a direction that is more responsive to Dr. Kamendulis' comments on this topic.

- In light of these expert reviewer comments, we also suggest that EPA re-evaluate the confidence in the RfD derivation.

- Dr. Kamendulis also had concerns with the derivation of the Oral Slope Factor (OSF).
  - Regarding the OSF, Dr. Kamendulis stated: "The EPA's reanalysis used a different statistical approach and control groups than used by the authors, which lead to a very marginal statistical significant increase in the highest dose group. I do not agree with this approach and agree with the original interpretation by the authors who concluded that dichloromethane was negative for carcinogenicity by the oral route of exposure. Therefore, this study is inappropriate to use for the derivation of an OSF for dichloromethane." It is not clear that EPA has sufficiently addressed this concern and explained why EPA's different approach was taken. Although only Dr. Kamendulis and Dr. Bruckner opposed EPAs approach, considering their expertise, further rational is needed for why EPA has not made changes they suggested.

- Dr. Moore, in responding to the majority of questions (those relating to PBPK modeling, the RfD derivation and the RfC derivation) simply commented that the question was "outside my specific expertise." Dr. Moore is an expert in genotoxicity and that is likely why she was added to the panel. Of all the reviewers, she is the most qualified to answer the question regarding whether or not DCM induces cancer through a mutagenic mode of action. In response to this question (C2) she clearly states, after providing much background information: "Therefore, I do not believe that there is sufficient data to prove a mutagenic MOA for DCM. In looking at the alternative MOAs, there appears to be no evidence to strongly conclude that the MOA has a nonmutagenic MOA. So, unfortunately, one must conclude that while there is evidence to indicate that the MOA for DCM <u>might</u> be a mutagenic MOA, it is not possible to conclusively define a MOA for tumor induction. One then has to conclude that the MOA for DCM induced tumors is unknown."
  - It is surprising that EPA has not changed the conclusion based on this expert's opinion and notes that "EPA disagrees with one reviewer's determination." Rather than place this reviewer in the minority, we suggest that EPA, considering this reviewers expertise and reason for being on the panel, consider revising its conclusions regarding a mutagenic mode of action.

- In certain cases, in preparing Appendix A, EPA seems to overlook some important comments from the peer reviewers. It would be helpful if EPA acknowledged these comments, responded to them directly in Appendix A, and made appropriate changes in the tox review and IRIS summary. A few examples are provided below:
  - Page 9 of the external peer review report: Dr. Bruckner states: "The accounts of relevant scientific investigations are presented objectively, yet the summary sections and

rationales for decisions do not provide balanced overviews for the reader to consider in assessing the weight of scientific evidence on particular questions or subjects. Only findings/evidence in support of EPA's judgements and courses of action are presented."

- Page 12 of the external peer review report: Dr. Krishnan states, "Based on the arguments and simulations presented, it would appear that the model version D is the best. Such a conclusion should preferably be based on comparative simulations of dose metrics as well as some assessment of quantitative fitting analysis. In this regard, there does not appear to be a priori strategy of model averaging or a quantitative method for choosing the best model, it seems." He also states (page 13): "Whereas it is likely that some models in peer-reviewed literature just do not meet the requirements of an assessment, there has to be a strong case to significantly rework the model (or re-parameterize) during the evaluation and use in risk assessment, as is the case here."

- Page 14 of the external peer review report: Dr. Mehendale states, "No matter how sophisticated the PBTK model is for DCM, it is fraught with daunting errors, unless the inhibition of CYP2E1 by CO is fully taken into account."

- Page 20 of the external peer review report, Dr. Krishnan, in reiterating his comment that the scaling factor is not justified, provides two citations from the literature for supporting his argument. It is not clear where EPA discusses the studies he points to.

- Page 21 of the external peer review report, Dr Krishnan states: "While it is clear that that intent is to derive toxicity values that are protective of the most sensitive populations, it appears that the estimates may be overly conservative….. At least in the case of the RfD derivations, using the 1st percentile provides a HED value that is well below (~7-fold) that which would be derived if an uncertainty factor of 10 was applied (1.51 versus 0.216)."

- Page 26 of the external peer review report, Dr. Bruckner states, in referring to BMD modeling and PBPK modeling, "This approach and several assumptions result in a quite conservative RfD." (emphasis added by Dr. Bruckner)

- Page 35 of the external peer review report, Dr. Bruckner states, "I do not believe, however, that they have given a full account of pertinent information for and against their rationale for deriving an OSF, so readers are not given a balanced perspective." (emphasis added by Dr. Bruckner) At page 36, he states "Sound scientific judgment should be utilized in classifying potential human carcinogens and conducting cancer risk assessment, rather than consistently making worst case assumptions and reaching decisions based on entrenched policy. In light of knowledge available from the extensive human and animal database on DCM, I think it is a big "stretch" to classify DCM as a likely human carcinogen. Possible human carcinogen is much more appropriate for a chemical with limited evidence of animal carcinogenicity and largely negative epidemiology data." (emphasis added by Dr. Bruckner)

- Page 42 of the external peer review report, Dr. Moore states, in referring to mode of action "This MOA analysis framework should look at both "genotoxic" and nongenotoxic endpoints such as cell proliferation. Once this is done, issues of temporality and dose response concordance can be evaluated to assess the proposed and other possible MOAs. I would strongly encourage the authors to do this sort of MOA framework analysis in their revision."

- Page 44 of the external peer review report, Dr. Bruckner states: "The linear multistage extrapolation approach utilized here is based on a series of conservative assumptions. The net result (the cancer risk estimate) is much more health protective than necessary for DCM. This approach ignores protection and repair systems known to be operative in cells and organ systems, as well as the likelihood of minimal or negligible GST-mediated metabolism in humans at low/trace exposure levels."

- Page 46 of the external peer review report, Dr. Bruckner states: "Nevertheless, the use of such high vapor concentrations by NTP is troubling, considering the shift from the CYP to the GST pathway under such exposure conditions. This artificial experimental design certainly calls into question the validity of extrapolations to very low human vapor exposures in environmental settings."

- Page 48 of the external peer review report, Dr. Kishnan states: "Clarification is needed as to the validity and adequacy of this approach in light of the use of a probabilistic PBPK model that already accounts for the population distribution of parameters of relevance. Why is the slope factor determined for the most sensitive subpopulation and not for the entire population that also consists of this subpopulation (which would be more realistic)?..... Similarly, since the distributions of parameters representative of children of various ages are used in the PBPK model, the need to use additional adjustment factor for early life exposures should be more clearly presented."

- The majority of expert reviewers who commented on the database uncertainty factor for the RfD, suggested that a 3x factor was too high. Dr. Bruckner supported this with scientific information and Dr. Kamendulis referred to the extensive body of scientific literature when making his comment. Considering this feedback from the expert reviewers, it is surprising that EPA is not revising the uncertainty factor.
  - We additionally note that Dr. Krishnan provided a comment on EPAs confidence in the RfD (see external peer review report page 28) and noted that it is high. He noted that this seemed "somewhat inconsistent" considering the uncertainty factors applied. Appendix A should address the comment and appropriate changes in the toxicological review and IRIS summary should be made.

- Regarding the cancer classification, expert reviewers were split regarding whether or not it was appropriate (see external peer review report pages 35-39). The reviewers that did not support the classification provided very compelling discussion that shows they evaluated all the available information and the weight of the evidence. EPA's response to these comments does not seem to address their concerns but instead cites some default approaches (eg, EPA considers mouse liver tumors to be relevant to humans) and does not provide a clear

explanation, based on the weight of evidence, regarding why the Agency disagrees with these reviewers. It would be helpful if EPA provided a response, including scientific rational, to each of the critical reviewers comments.

- Last month, EPA announced improvements to the IRIS assessments that would lead to: "reducing volume and redundancy of assessments; fuller discussion of methods and concise statements of criteria used in studies for hazard evaluation; clearer articulation of the rationale and criteria for screening studies; implementing uniform approaches for choosing studies and evaluating their findings; and describing the determinants of weight that were used in synthesizing the evidence." Although we understand that such improvements will take time to implement and may not be possible for all the assessments currently underway, considering the importance of this assessment it would be helpful for EPA to transparently describe the changes that have been made to achieve the goals mentioned in the EPA announcement.

Specific Comments on Appendix A:

- Page A-2, EPA states: "Three reviewers supported the chosen model for rat PBPK toxicokinetics, and noted the clear presentation and discussion of the model assumptions, parameters, and uncertainties." However it is not clear from the external peer review report if this statement is supported by the peer reviewers' comments. Dr. Bruckner did make a similar positive statement, however we don't see any other positive reviewer comments. Dr. Salmon does not explicitly state support for the model although he does list some positive attributes as well as some concerns regarding uncertainties in the 2E1 pathway. Dr. Kamendulis states that the model "appears to have been applied appropriately" but recommends more information be added regarding justification for the many changes made, and requests more information on variability. Dr. Krishnan, stated that the model "would appear to be deficient,",and Dr. Mehendale provides detailed questions and comments expressing concern.

- Page A-4, considering Dr. Mehendale's expertise, and his strong comments regarding the need to consider the inhibitory effect of CO on 2E1 metabolism, it is rather surprising that EPA states that the "toxicological review was not revised to include a discussion of this issue." Even if EPA disagrees with a reviewers expertise, shouldn't the issue raised and EPA's rationale for not incorporating changes be incorporated into the toxicological review, considering its importance to the expert reviewer? If nothing else, it would clarify for readers why EPA did not consider the inhibitory effects of CO.

- Page A-7, EPA states: "Four reviewers noted agreement with the choice of the dose metric, and one reviewer did not comment directly on these questions." EPA should note that Dr. Krishnan noted that it "has been justified in a limited manner."

- Page A-7, EPA states: "An alternative derivation using an UF = 3 instead of the scaling factor is not presented because it is not a procedure that is supported by the available data." It seems the reviewer was suggesting the use of a default UF, rather than a scaling factor. It is unclear why EPA is saying that this is a procedure not supported by the data.

The reviewer (Dr. Kamendulis) also noted that the document lacked discussion of why such a scaling factor was used. In addition, Dr. Krishnan, also noted that the document did not clearly provide scientific support to justify the scaling factor. EPA should respond to these comments and add the appropriate discussion to the toxicological review.

- Page A-13, EPA states "Consistent with EPA's Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005a), the cancer assessment for dichloromethane is based on tumor data from the most sensitive species." We could not find any language in the Cancer Guideline which state that the assessment should be derived from tumor data of the most sensitive species. We suggest revising this sentence to track with language from the cancer guidelines. We believe that relevance and mode of action information would also help to inform the appropriate species for use in a cancer assessment.

- Page A-16, in response to a reviewers suggestion for adding a exposure-response array, EPA states that this was not done because data cannot be generated for all the endpoints. Acknowledging this, wouldn't it still be helpful to provide the recommended figure for those endpoints where data could be generated?

- Page A-23, the description of comments on B7 should also note that one reviewer thought it was a "conservative approach".

- Page A-26, EPA's characterization of the comments by reviewers who have concerns with EPAs cancer classification does not appear to capture the extent or significance of the comments. We suggest revising, perhaps by using direct quotes rather than paraphrasing concerns.

- Page A-30, EPA should acknowledge and respond to Dr. Bruckners comment which states: "It is also noteworthy that the tumor incidences in these DCM-treated mice and the F-344 rats were of marginal statistical significance."

Specific Comments on the IRIS summary:

- The IRIS summary should provide a link to the interagency comments associated with this final document. If an outsider were to go to IRIS to find an IRIS summary, they would have no way of knowing there were interagency comments available. We understand that EPA is working on this and we hope this change can be made in time for posting of this assessment.

Appendix G: How data was collected on OMB Review

A preliminary assessment was made of all the docketed communications between the agencies and OMB for each of the rules canvassed in the study, and the available red-lined documents for both the NAAQS and habitat designation rules were coded to determine the extent and nature of non-editorial changes and to assess whether any of them were technical in nature. This research was done quickly to provide reconnaissance information for further study. Thus the numbers are approximate and subject to change.

1. Compiling the Library of Relevant Documents

As the first step, the rules canvassed in this study that were subject to OMB review were identified through searches of the OMB website.[1] Using the RIN for each rule reviewed, the docket indices were then traced and accessed in regulations.gov. Once in each of the rulemaking documents, all documents referencing OMB were separated out with a second search.

The list of docketed exchanges is compiled in an excel, with hyperlinks to each document.[2] This inventory is available at /wewagner/Document Inventory of OMB review. Since the docket index was available for only one of the three FWS habitat designations, it is the only FWS document record that is available.

Each of documents posted at the hyperlinks in the docket were examined to extract the actual date the document was authored/sent. These actual dates were then compared against the dates listed on the OMB's site for its review of the rule to determine the number of exchanges that occurred outside the formal review process.

The table below is a compilation of these preliminary numbers. Since this is a reconnaissance study, the numbers are approximate and require further verification. Nevertheless the general trends – the large number of exchanges for some rules and the large number of exchanges occurring outside the formal review window for some rules – remain an interesting finding that seems likely to be robust to further investigation.

Docket Number	Documents regarding EPA-OMB Exchanges in the	Number of these documents that were authored/transmitted outside the formal OMB review window

[1] The primary terms in the type of rules (e.g., "ambient" for NAAQS and "habitat" for FWS habitat designations) were used to generate a longer list of OMB-reviewed documents. The relevant rules were then culled from this larger searching.

[2] Duplicate entries within the docket were not eliminated systematically. Thus, if the agency posted the same document multiple times, it may show up in the total document figures.

Docket		
EPA-HQ-OAR-2001-0017	64	33 (52%)
EPA-HQ-OAR-2005-0172	152	134 (88%)
EPA-HQ-OAR-2006-0735	127	119 (94%)
EPA-HQ-OAR-2006-0922	122	1 (1%)
EPA-HQ-OAR-2007-0352	93	24 (26%)
EPA-HQ-OAR-2007-1145	31	4 (13%)
EPA-HQ-OAR-2008-0338	8	0 (0%)

2. Evaluating the Nature of the Changes

From this document list, the red-lined documents were then identified and pulled out. Each red-lined documents was coded by me according to whether each change was a) purely editorial; b) non-editorial and non-technical; or c) non-editorial and technical in nature. The more specific criteria for this classification is provided in the text below. Since the coding was a preliminary effort (e.g., there is no reliability testing; the coding was done by the primary investigator rather than an independent analyst), it again must be treated as exploratory and the numbers viewed as approximate pending further investigation.

General Coding Conventions

Editorial changes were not counted. Editorial changes are those that simply move text to another part of the rule; correct grammar, spelling, or format; or otherwise appear to be purely non-substantive changes.

Substantive changes were classified as to whether they were technical or non-technical. All references to economic analysis or legal requirements were considered non-technical. Changes that altered the description of the scientific or technical evidence; that added or deleted technical sources; that changed the figures in tables not explained by changes in units; that altered technical requirements (e.g., reducing the number of ambient monitor stations or adding technical procedures); or that otherwise altered features of the rules that are not accessible to nonscientists or engineers were coded as technical.

It is important to note that the fact that there was a non-editorial change does not equate to a conclusion that the change was also material. It is possible that most or perhaps all of the many technical changes located in the red-lined documents are relatively trivial in their import; yet it is also possible that the changes are important and substantive. To make this determination, assistance from scientific and technical experts steeped in the rules is necessary and was not feasible in this reconnaissance exploration of OMB review.

All of the red-lined documents located for the NAAQS rules and habitat designation rules canvassed in this study are available here at /wewagner/upload for acus. The "re-created" red-lined for the proposed and final primary NAAQS nitrogen dioxide review is available at /wewagner/nitrogen dioxide change docs. The results of this exploratory coding are provided below. As noted in the text of the report, red-lined documents were not available for about 1/3 of the published rules canvassed in this study.

Title	Proposed/Final	# Non-editorial Changes	# Changes that were technical
Secondary	Proposed	44	35 (80%)
Secondary	Final	21	13 (62%)
Lead Monitoring	Proposed	24	15 (62%)
Ozone	Proposed	12	6 (50%)
Network Design	Proposed	5	0 (0%)
Sulfur Dioxide	Proposed	49	42 (86%)
Sulfur Dioxide	Final	16	10 (62%)
Monoxide	Proposed	26	13 (50%)
Monoxide	Final	14	10 (72%)

Appendix H:

Examples of Exchanges between OIRA and EPA on NAAQS Rules

FAX TRANSMITTAL

DATE: 4/24/05

TO: LYDIA WEGMAN

PHONE:

FAX: (919) 541-0804

FROM: HEIDI KING

PHONE:

FAX: (202) 395-7285

Number of pages (including transmittal sheet): 4 INC COVER

Remarks:

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HK

- The national-scale screen of surface water data initially identified some 42 sample locations of which 15 were then identified as unrelated to mining sites and having water column levels of dissolved Pb that were greater than hardness adjusted chronic criteria for the protection of aquatic life (with one location having a HQ of 15), indicating a potential for adverse effect if concentrations were persistent over chronic periods. Acute criteria were not exceeded at any of these locations. The extent to which air emissions of Pb have contributed to these surface water Pb concentrations is unclear.

- In the national-scale screen of sediment data associated with the 15 surface water sites described above, threshold effect concentration-based HQs at nine of these sites exceeded 1.0. Additionally, HQs based on probable effect concentrations exceeded 1.0 at five of the sites, indicating probable adverse effects to sediment dwelling organisms. Thus, sediment Pb concentrations at some sites are high enough that there is a likelihood that they would cause adverse effects to sediment dwelling organisms. However, the contribution of air emissions to these concentrations is unknown.

- In the primary Pb smelter case study, all three of the soil sampling clusters (including the "reference areas") had HQs that exceeded 1.0 for birds. Samples from one cluster also had HQs greater than 1.0 for plants and mammals. The surface water sampling clusters all had measurements below the detection limit of 3.0μg/L. However, three sediment sample clusters had HQs greater than 1.0. In summary, the concentrations of Pb in soil and sediments exceed screening values for these media indicating potential for adverse effects to terrestrial

organisms (plants, birds and mammals) and to sediment dwelling organisms. While the contribution to these Pb concentrations from air as compared to nonair sources is not quantified, air emissions from this facility are substantial (Appendix D, USEPA 2007b; ICF 2006).

BUT HISTORIC LOADING IS ALSO SUBSTANTIAL

- In the secondary Pb smelter case study, the soil concentrations, developed from soil data for similar locations, resulted in avian HQs greater than 1.0 for all distance intervals evaluated. The scaled soil concentrations within 1 km of the facility also showed HQs greater than 1.0 for plants, birds, and mammals. These estimates indicate a potential for adverse effect to those receptor groups.

MODELING EXERCISE?

CONTRIBUTIONS FROM AIR EMISSIONS (VIS A VIS LEGACY SOIL CONCENTRATIONS) IS UNKNOWN.

- In the nonurban, near roadway case study, HQs for birds and mammals were greater than 1.0 at all but one of the distances from the road. Plant HQs were greater than 1.0 at the closest distance. In summary, HQs above one were estimated for plants, birds and mammals, indicating potential for adverse effect to these receptor groups.

MODELING EXERCISE?

WHAT DOES A PLANT HQ>1 MEAN? (IF IT'S IN A FARM NOT GENERALLY AVAILABLE TO THEM?)

CONTRIBUTIONS FROM AIR EMISSIONS (VIS A VIS) LEGACY SOIL CONCENTRATIONS) IS UNKNOWN?

C. *The Secondary Standard*

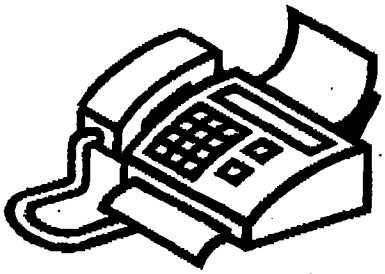
The NAAQS provisions of the Act require the Administrator to establish secondary standards that, in the judgment of the Administrator, are requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of the pollutant in the ambient air. In so doing, the Administrator seeks to establish standards that are neither more nor less stringent than necessary for this purpose. The Act does not require that secondary standards be set to eliminate all risk of

aquatic systems, as demonstrated by historical patterns in sediment cores from lakes and Pb measurements (section 2.8.1; CD, section AX7.2.2; Yohn et al., 2004; Boyle et al., 2005), as well as the comments of the CASAC Pb panel that a significant change to current air concentrations (e.g., via a significant change to the standard) is likely to have significant beneficial effects on the magnitude of Pb exposures in the environment and Pb toxicity impacts on natural and managed terrestrial and aquatic ecosystems in various regions of the U.S., the Great Lakes and also U.S. territorial waters of the Atlantic Ocean (Henderson, 2007a, Appendix E). We concur with CASAC's conclusion that the Agency lacks the relevant data to provide a clear, quantitative basis for setting a secondary Pb NAAQS that differs from the primary in indicator, averaging time, level or form. The Administrator concurs with CASAC's conclusion that the Agency lacks the relevant data to provide a clear, quantitative basis for setting a secondary Pb NAAQS that differs from the primary in indicator, averaging time, level or form.

Based on these considerations, and taking into account the observations, analyses, and recommendations discussed above, the Administrator proposes to revise the current secondary Pb standard by making it identical in all respects to the proposed primary Pb standard (described in section II.D.4 above).

IV. Proposed Appendix R – Interpretation of the NAAQS for Lead and Proposed Revisions to the Exceptional Events Rule

The EPA is proposing to add Appendix R, Interpretation of the National Ambient Air Quality Standards for Pb, to 40 CFR part 50 in order to provide data handling procedures for the proposed Pb standard. The proposed Appendix R would detail the computations necessary for determining when the proposed Pb NAAQS is met. The



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( ) Rich Theroux
( ) Edmond Toy

Comment(s):

In recognition of alternative views of the science and the appropriate policy response based on the currently available information, the Administrator also solicits comments on (1) alternative levels of the 24-hour $PM_{2.5}$ standard within the range of 35 to 30 $\mu g/m^3$, and alternative approaches for selecting the level of the 24-hour $PM_{2.5}$ standard, and related levels (such as approaches that suggest retaining the current level of 65 $\mu g/m^3$, setting a level no higher than 25 $\mu g/m^3$, or setting a level within the range of 65 down to 35 $\mu g/m^3$); (2) alternative levels of the annual $PM_{2.5}$ standard below 15 $\mu g/m^3$ down to 12 $\mu g/m^3$; and (3) an alternative form of the annual $PM_{2.5}$ standard based on the highest community-oriented monitor in an area. Based on the comments received and the accompanying rationale, the Administrator reserves the right to adopt other standards within the range of the alternatives identified above in lieu of the standards he is proposing today.

III. Rationale for Proposed Decisions on Primary PM_{10} Standards

This notice presents the Administrator's proposed decisions on revision to the primary NAAQS for PM_{10}. As discussed more fully below, the rationale for the proposed revisions of the primary PM_{10} NAAQS includes consideration of: (1) evidence of health effects related to short- and long-term exposures to thoracic coarse particles; (2) insights gained from a quantitative risk assessment prepared by EPA; and (3) specific conclusions regarding the need for revisions to the current standards and the elements of PM_{10} standards (i.e., indicator, averaging time, form, and level) that, taken together, would be requisite to protect public health with an adequate margin of safety.

In developing this rationale, EPA has taken into account the information available from a growing, but still limited, body of evidence on health effects associated with thoracic coarse particles from studies that use $PM_{10-2.5}$ as a measure of thoracic coarse particles. ~~EPA~~ has drawn upon an integrative synthesis of the body of evidence on associations between exposure to ambient thoracic coarse particles and a range of health endpoints (EPA, 2004, Chapter 9), focusing on those health endpoints for which ~~EPA concludes that~~ the associations ~~are likely~~ may be causal. In its policy assessment of the evidence judged to be most relevant to making decisions on elements of the standards, EPA has placed greater weight on U.S. and Canadian studies using

thoracic coarse particles measurements, since studies conducted in other countries may well reflect different demographic and air pollution characteristics.

As with virtually any policy-relevant scientific research, there is uncertainty in the characterization of health effects attributable to exposure to ambient thoracic coarse particles. As discussed below, however, there is a growing body of evidence available since the last review of the PM NAAQS, with important new information coming from epidemiologic, toxicologic, and dosimetric studies. Moreover, the newly available research studies have undergone intensive scrutiny through multiple layers of peer review and extended opportunities for public review and comment. While important uncertainties remain, the review of the health effects information has been extensive and deliberate. ~~In the judgment of the Administrator, this intensive evaluation of the scientific evidence has~~ provides an adequate basis for regulatory decision making at this time. This review also provides important input to EPA's research plan for improving our future understanding of the relationships between exposures to ambient thoracic coarse particles and health effects.

The Staff Paper concluded that

A. Evidence of Health Effects Related to Thoracic Coarse Particle Exposure

Evidence from dosimetric studies has been a key component in the rationale for previous PM NAAQS decisions. Such evidence led to a focus on particles less than or equal to 10 μm in diameter as being capable of penetrating to the thoracic regions of the respiratory tract and so of greatest concern to health (61 FR 65648). While considerable advances have been made, the available evidence continues to support the basic conclusions reached in the 1987 and 1997 reviews regarding penetration and deposition of size specific particles. An aerodynamic size of 10 μm remains a reasonable separation point for particles that penetrate and potentially deposit in the thoracic regions of the lungs, particularly for the more sensitive case of mouth breathing. As discussed in the Criteria Document, both fine and thoracic coarse particles penetrate to and deposit in the alveolar and tracheobronchial regions. For a range of typical ambient size distributions, the total deposition of thoracic coarse particles to the alveolar region can be comparable to or even larger than that for fine particles. For areas with appreciable coarse particle concentrations, thoracic coarse particles would tend to dominate particle deposition to the tracheobronchial region for mouth breathers (EPA, 2004, p. 6-16).

In the last review, little toxicologic evidence was available on potential effects of thoracic coarse particles and there were few epidemiologic studies that had included direct measurements of thoracic coarse particles. Evidence of associations between health outcomes and PM_{10} that were conducted in areas where PM_{10} was predominantly thoracic coarse particles was an important part of the basis for that review. The new studies available in this review include a number of epidemiologic studies that have reported associations with health effects using direct measurements of $PM_{10-2.5}$ as well as ~~a number of~~ new toxicologic studies.

a very limited set of.

This section outlines key information contained in the Criteria Document (Chapters 6-9 and the Staff Paper (Chapter 3) on known or potential effects associated with exposure to thoracic coarse particles and their major constituents. The information highlighted here summarizes: (1) new information available on potential mechanisms for health effects associated with exposure to thoracic coarse particles or their constituents; (2) the nature of the effects that have been associated with ambient thoracic coarse particles or their constituents; (3) an integrative assessment of the evidence on health effects related to thoracic coarse particles; (4) subpopulations that appear to be sensitive to effects of exposure to thoracic coarse particles; and (5) the public health impact of exposure to ambient thoracic coarse particles.

1. Mechanisms

As discussed above in section II.A, the results of numerous toxicologic and controlled human exposure studies have implicated a number of potential mechanisms or pathways for effects associated with PM. However, this evidence is generally more relevant to the effects of fine particles than to those of thoracic coarse particles. ~~Some~~ limited evidence ~~is available from~~ toxicologic ~~studies on~~ effects of $PM_{10-2.5}$ for either acute or chronic exposures (EPA, 2004, p. 9-55). As noted in past reviews (EPA, 1981b, 1996b), deposition of a variety of particle types in the tracheobronchial region, including resuspended urban dust and coarse-fraction organic materials, has the potential to affect lung function and aggravate symptoms, particularly in asthmatics. Of particular note are limited toxicologic studies that found urban road dust can produce cellular and immunological effects (e.g., Kleinman, et al., 1995; Steerenberg et al., 2003).

A few additional studies provide

This evidence includes results from several *in vitro* toxicologic studies that provide some insight into potential effects of thoracic coarse particles, particularly related to inflammatory or allergic effects. For example, two recent studies report inflammatory responses in cells exposed

to extracts of water-soluble and water-insoluble materials from thoracic coarse particles and fine particles collected in Chapel Hill, NC (Monn and Becker, 1999; Soukup and Becker, 2001). One study focused on water-soluble materials, and reported significant immune system effects with water-soluble extracts of ambient $PM_{10-2.5}$, in contrast to the lack of effects observed with extracts from ambient $PM_{2.5}$ as well as indoor-collected $PM_{10-2.5}$ and $PM_{2.5}$. The authors report that different components of $PM_{10-2.5}$ appeared to have different effects, with entoxin implicated in inflammatory effects, while metals appeared to have a role in the cytoxocity effects (Monn and Becker, 1999). Soukup and Becker (2001) used both soluble and insoluble components of thoracic coarse particles and fine particles, and report that the insoluble materials from thoracic coarse particles resulted in several effects on immune system cells.[34] In this extract of thoracic coarse particles, endotoxin appeared to be the most pro-inflammatory component, but "other moieties" (not endotoxin or metals) appeared to contribute to other effects. Using particles collected in two urban areas in the Netherlands, Becker et al. (2003) reported that thoracic coarse particles, but not fine or ultrafine particles, resulted in effects related to inflammation and decreased pulmonary defenses. This small group of studies thus suggests that exposure to thoracic coarse particles may cause pro-inflammatory effects, as well as cytotoxicity and oxidant generation (EPA, 2004, section 7.4.2). While few in number, these studies provide some insight into potential mechanisms for respiratory effects of thoracic coarse particles. The results also indicate that different health responses may be linked with different components of thoracic coarse particles.

However, two studies suggest that exposure to ambient thoracic coarse particles has only limited effects on blood cells or carcinogenic effects of thoracic coarse particle exposures. (Diociaiuti et al., 2001; Hornberg et al., 1998). This is consistent with the evidence from epidemiologic studies that provide only limited evidence for carcinogenicity or cardiovascular effects of thoracic coarse particles.

Road dust is a common source of thoracic coarse particles and can be considered as a PM sample that is representative of the components expected to be found in resuspended thoracic coarse particles. In the 1996 Staff Paper, results from one key toxicologic study were

[34] Examples of such effects include cytokine production, decreased phagocytic ability and oxidant generation.

highlighted in which immunological and cellular toxicity was observed in rats with exposure to road dust. Higher concentrations of road dust were needed to cause effects, compared with exposures to fine particle components (e.g., sulfates, nitrates), but it was observed that some of the apparent differential toxicity was due to differential penetration efficiencies of particles in the rat (EPA, 1996b, p. V-70). A recent study reported that road tunnel dust particles had greater adjuvant activity in two animal models of allergy than several other particle samples, including residual oil fly ash and diesel exhaust particles (Steerenberg et al., 2003). In contrast, a number of studies have reported that Mt. St. Helens volcanic ash, which is generally in the size range of thoracic coarse particles, has very little toxicity in animal or *in vitro* toxicologic studies (EPA, 2004, p. 7-216). The Criteria Document finds that the limited number of toxicologic studies using $PM_{10-2.5}$ provide some evidence that coarse fraction particle exposures can result in effects related to inflammation or oxidative stress mechanisms, as well as acting as allergic adjuvants. Thus, toxicologic studies have suggested potential pathways for effects from a few sources or components of thoracic coarse particles, such as road dust particles, metals or organic constituents. The need to better understand the relationship between different components or sources of thoracic coarse particles remains a key area of uncertainty with regard to the effects of thoracic coarse particles.

2. Nature of Effects

In the last review, EPA retained standards for thoracic coarse particles on the basis of a limited body of evidence indicating that short-term exposure to thoracic coarse particles was linked with respiratory morbidity effects, such as aggravation of asthma, increases in respiratory symptoms and respiratory infections (62 FR 38677). The few available epidemiologic studies did not provide conclusive evidence for associations between short-term exposure to $PM_{10-2.5}$ and mortality. In addition, there was no substantial evidence of mortality or morbidity effects related to long-term exposure to $PM_{10-2.5}$. However, EPA observed that toxicologic studies offered qualitative evidence for potential effects with long-term exposure to coarse particles or coarse particle constituents (62 FR 38678).

In this review, epidemiologic studies have continued to support a relationship between short-term exposure to thoracic coarse particles and respiratory morbidity, with effects ranging from increased respiratory symptoms to hospitalization for respiratory diseases. As discussed

below, the new studies also suggest associations with effects on the cardiovascular system and also with mortality. The evidence for such effects is summarized below.

a. Effects associated with short-term exposure to thoracic coarse particles

i. Mortality

In the few epidemiologic studies available for the last review, only one study evaluated the relationship between short-term exposure to $PM_{10-2.5}$ and mortality, using air quality data from the Six Cities study to do a time-series epidemiologic analysis. While short-term exposure to $PM_{10-2.5}$ was significantly associated with mortality in one of the six cities (Steubenville), it was not in the remaining five cities nor in the overall multi-city analysis (Schwartz, 2003a; Klemm and Mason, 2003; CD, p. 8-40 to 8-41).

Not in the analysis

The results of multi-city and single-city epidemiologic studies are presented in Figure 2; this figure includes results from U.S. and Canadian studies for associations between $PM_{10-2.5}$ and a range of mortality and morbidity health outcomes.[35] These new studies include a multi-city study that uses data from the eight largest Canadian cities. Associations were reported between total mortality and $PM_{2.5}$, PM_{10}, and $PM_{10-2.5}$, and the effect estimates were of similar magnitude for each PM indicator (Burnett et al., 2000; Burnett and Goldberg, 2003). However, the association with $PM_{10-2.5}$ did not reach statistical significance. Positive associations with $PM_{10-2.5}$ and mortality have also been reported for several individual cities in the U.S. (e.g., Coachella Valley, CA; Detroit, MI; Pittsburgh, PA; Phoenix, AZ; Philadelphia, PA) as well in Santiago, Chile (EPA, 2004, p. 8-61). As shown in Figure 1, among U.S. and Canadian studies, effect estimates for $PM_{10-2.5}$ are generally positive and similar in magnitude to those for $PM_{2.5}$ and PM_{10}, but for total mortality, none reach statistical significance. In general, effect estimates are somewhat larger for respiratory and cardiovascular mortality than for total mortality; for cardiovascular mortality, two of the five effect estimates for cardiovascular mortality with short-term $PM_{10-2.5}$ exposure are positive and statistically significant (Mar et al., 2003; Ostro et al., 2003). The magnitude of the effect estimates for $PM_{10-2.5}$ are similar to those for $PM_{2.5}$, generally

Focus on U.S. & Canada?

In 1-pollutant models

[35] Results are presented from time-series studies that did not use generalized additive models, or were reanalyzed using general linear models. Effect estimates are based on an increment of 25 $\mu g/m^3$ $PM_{2.5}$, and have been plotted in order of decreasing study power, using as an indicator the natural log of the product of the number of study days and number of health events per day.

particles are generally not distributed over broad areas, but rather reflect contributions from more localized sources, thus it is more difficult than for fine particles to generalize the results of these studies to areas with other types of sources. Based on the epidemiologic evidence, the Criteria Document concluded that the limited body of evidence provided suggestive evidence for associations between throacic coarse particles and various mortality and morbidity effects "in some locations" (EPA, 2004, p. 8-338).

the Criteria Document

Overall, EPA finds that evidence from health studies on associations between short-term exposure to $PM_{10-2.5}$ and mortality is "not as strong" as evidence for associations with $PM_{2.5}$ or PM_{10} but nonetheless is suggestive of associations with mortality (EPA, 2004, p. 9-32). As discussed briefly above, some epidemiologic evidence suggests that there are components of thoracic coarse particles (e.g., crustal material in non-urban areas) that are less likely to have adverse effects, at least at lower concentrations, than other components.

ii. Morbidity

(a) Effects on the respiratory system

Evidence available in the last review suggested that aggravation of asthma and respiratory infections and symptoms were associated with PM_{10} in areas where thoracic coarse particles were dominant, such as Anchorage, AK, and southeast Washington (62 FR 38679). Only one epidemiologic study had used $PM_{10-2.5}$ data; it reported significant associations between respiratory hospital admissions in Toronto with $PM_{2.5}$ but not $PM_{10-2.5}$, though the association with $PM_{10-2.5}$ was positive (Thurston et al., 1994).

Several recent studies have built upon that evidence, reporting associations between short-term exposure to $PM_{10-2.5}$ with hospital admissions for respiratory diseases in several U.S. and Canadian cities. As shown in Figure 2, the effect estimates for these associations are generally positive and the more precise estimates are statistically significant. In these associations with respiratory hospitalization, the risk estimates tend to fall in the range of 5 to 15% per 25 $\mu g/m^3$ $PM_{10-2.5}$ (EPA, 2004, p. 8-193).

1-pollutant models

As was true in the last review, EPA recognizes that information about the effects of thoracic coarse particles can also come from studies linking health effects with PM_{10} in areas where thoracic coarse particles are the dominant fraction of PM_{10}. This review includes studies that have been conducted in urban areas where thoracic coarse particles are the dominant fraction

of PM_{10}, such as Reno, NV and Anchorage, AK, and their findings support the evidence from the limited group of studies discussed above that have found associations between measured $PM_{10-2.5}$ and respiratory morbidity. In these areas, statistically significant associations have been reported between PM_{10} and hospitalization for respiratory diseases (Chen et al., 2000) and medical visits for asthma (Choudhury et al., 1997).

Several studies of respiratory symptoms and lung function have included both $PM_{2.5}$ and $PM_{10-2.5}$ data and these results suggest roles for both fine and thoracic coarse particles in reduced lung function and increased respiratory symptoms (EPA, 2004, p. 8-313). For example, in the Six Cities study, a statistically significant increase in lower respiratory symptoms for children was found with $PM_{2.5}$ but not with $PM_{10-2.5}$, while the reverse was true for cough. When both $PM_{2.5}$ and $PM_{10-2.5}$ were included in models, the effect estimates were reduced for each, but $PM_{2.5}$ retained significance in the association with lower respiratory symptoms and $PM_{10-2.5}$ retained significance in the association with cough (Schwartz and Neas, 2000). EPA finds that the new epidemiologic studies indicate that short-term $PM_{10-2.5}$ exposure is associated with respiratory morbidity, with outcomes ranging from respiratory symptoms to hospitalization for respiratory diseases (EPA, 2004, p. 8-312).

(b) Effects on the cardiovascular system

As discussed above, a number of recent epidemiologic studies have shown evidence of effects on the cardiovascular system with short-term exposures to PM, but for the most part, the newer studies have used $PM_{2.5}$ (and PM_{10}), not thoracic coarse particles. However, several studies have also reported associations between short-term exposure to $PM_{10-2.5}$ and hospital admissions for cardiovascular diseases. The results from U.S. and Canadian studies are shown in Figure 2, where it can be seen that the associations are positive and some are statistically significant. The excess risks for hospital admissions for cardiovascular diseases range from about 1 to 10% per 25 $\mu g/m^3$ $PM_{10-2.5}$ (EPA, 2004, p. 8-310). In addition, a statistically significant association was reported between PM_{10} and increased hospitalization for cardiovascular diseases in Tucson, AZ, an urban area where thoracic coarse particles are the dominant fraction of PM_{10} (Schwartz, 1997).

Epidemiologic studies have also reported associations between short-term exposures to ambient PM (often using PM_{10}) and more subtle cardiovascular health outcomes, such as cardiac arrhythmia, alterations in electrocardiogram (ECG) patterns, heart rate or heart rate variability

changes, and increases in blood components or biomarkers such as increased levels of C-reactive protein and fibrinogen (EPA, 2004, p. 8-169). However, the available evidence suggests that these effects are more strongly linked to fine particle than to thoracic coarse particle exposures. Several of these studies report significant associations between various cardiovascular endpoints and short-term $PM_{2.5}$ exposures; only one of the new set of studies included $PM_{10-2.5}$, in which no significant associations were reported between onset of myocardial infarction and short-term $PM_{10-2.5}$ exposures (EPA, 2005, p. 8-165; Peters et al., 2001). Thus, EPA finds that the new health evidence is limited, but suggestive of thoracic coarse particle effects on the cardiovascular system.

b. Effects related to long-term exposure to thoracic coarse particles

In the last review, the available prospective cohort study results had shown no evidence of associations between long-term exposure to thoracic coarse particles and either mortality (Dockery et al., 1993; Pope et al., 1995) or morbidity (Dockery et al., 1996; Raizenne et al., 1996). As discussed above for $PM_{2.5}$, new studies available in this review include the reanalyses and extended analyses for the Six Cities and ACS cohort studies of mortality, and new analyses from the southern California children's cohorts of morbidity effects.

In both the reanalyses and extended analyses of the ACS cohort study, long-term exposure to $PM_{10-2.5}$ was not significantly associated with mortality (CD, p. 8-105; Krewski et al., 2000; Pope et al., 2002). Based on evidence from reanalyses and extended analyses using ACS cohort data, EPA concludes that the long-term exposure studies find no associations between long-term exposure to thoracic coarse particles and mortality (EPA, 2004, p. 8-307).

In the earlier morbidity studies, associations between respiratory illness prevalence and decreased lung function in children were reported with fine particles or fine particle indicators, but not with the larger size fractions (Dockery et al., 1996; Raizenne et al., 1996). Several new studies have used data from the Southern California children's cohorts, one of which included $PM_{10-2.5}$ data. In this study, decreases in several measures of lung function growth were associated with long-term exposure to $PM_{10-2.5}$ (as well as PM_{10} and $PM_{2.5}$) though not all associations reached statistical significance (Gauderman et al., 2000). Taken together, the Criteria Document finds that only limited evidence is available on associations between long-term to exposure to $PM_{10-2.5}$ and respiratory morbidity (EPA, 2004, pp. 8-313, 8-314). Overall,

EPA finds that no conclusions can be drawn regarding long-term exposures to thoracic coarse particles and morbidity (EPA, 2004, p. 9-34).

3. Integration and Interpretation of the Health Evidence

As discussed in section II.A.3, the Criteria Document and Staff Paper focused on well-recognized criteria in evaluating the epidemiologic evidence, including the strength of associations; robustness of reported associations to the use of alternative model specifications, potential confounding by co-pollutants, and exposure misclassification related to measurement error; consistency of findings in multiple studies of adequate power, and in different persons, places, circumstances and times; and the nature of concentration-response relationships. These evaluations addressed key methodological issues that are relevant to interpretation of evidence from epidemiologic studies. Further, findings from epidemiologic studies were integrated with available experimental evidence (e.g., dosimetric and toxicologic), in considering the extent of coherence and biological plausibility of effects observed in epidemiologic studies. This integrative assessment formed the basis for the Criteria Document and Staff Paper to draw judgments about the extent to which causal inferences can be made about observed associations between health endpoints and thoracic coarse particles combination with other pollutants. Key elements of these evaluations are briefly summarized below.

(1) As was true for fine particles, associations between short-term exposures to thoracic coarse particles and various health outcomes are generally small in size. While fewer studies are available, the effect estimates from multi-city studies using thoracic coarse particles have greater precision due to the statistical power of the studies. Thus, these associations are strong relative to the precision of the studies; that is, the associations were strong enough to have been reliably measured by the studies such that many of the associations can be distinguished from the null hypothesis with statistical confidence (EPA, 2005, section 3.4.1).

(2) As discussed above in Section II.A.3, EPA has evaluated the robustness of epidemiologic associations in part by considering the effect of differences in statistical model specification, potential confounding by co-pollutants and exposure error on PM-health associations. With regard to sensitivity to model specification, the conclusions drawn for associations with $PM_{2.5}$ also apply to those with $PM_{10-2.5}$. In short, associations between short-term exposure to thoracic coarse particles and health outcomes are generally robust to the use of alternative modeling strategies (EPA, 2004, section 8.4.2).

Similarly, health effect associations with short-term exposures to $PM_{10-2.5}$ were found to be little changed in multi-pollutant models including one or more of the gaseous co-pollutants (EPA, 2004, section 8.4.3). Overall, EPA concludes that these studies indicate that effect estimates for associations between mortality and morbidity and various PM indices, including $PM_{10-2.5}$, are robust to confounding by co-pollutants, while recognizing that disentangling the effects attributable to various pollutants within an air pollution mixture is challenging (EPA, 2004, p. 9-37).

Not true ?

Recent epidemiologic studies have also evaluated the influence of exposure error on PM-health associations. This includes both consideration of error in measurements of PM, and the degree to which measurements from an individual monitor reflect exposures to the surrounding community. As discussed in section 8.4.5 of the Criteria Document, several studies have shown that fairly extreme conditions (e.g., very high correlation between pollutants and no measurement error in the "false" pollutant) are needed for complete "transfer of causality" of effects from one pollutant to another (EPA, 2004, p. 9-38). Exposure error is likely to be more important for associations with $PM_{10-2.5}$ than with $PM_{2.5}$, since there is generally greater error in $PM_{10-2.5}$ measurements, $PM_{10-2.5}$ concentrations are less evenly distributed across a community, and thoracic coarse particles are less likely to penetrate into buildings (EPA, 2004, p. 9-38). Thus, factors related to exposure error likely result in reduced precision for epidemiologic associations with $PM_{10-2.5}$. With increased error in $PM_{10-2.5}$ monitoring methods, any reported epidemiologic associations would be less likely to reach statistical significance (EPA, 2004, p. 5-126).

There are two key implications of this uncertainty for this review. First, for an individual epidemiologic association, the increased uncertainty in measurements would tend to increase the standard error about the effect estimate, possibly reducing statistical significance of the findings. This would mean that a set of positive but generally not statistically significant associations between $PM_{10-2.5}$ and a health outcome could be reflecting a true association that is measured with error.

Second, this uncertainty about measurements is an important consideration in evaluating the air quality concentrations with which a statistical association is reported. The air quality levels reported in these studies, as measured by ambient concentrations at monitoring sites within the study areas, are not necessarily good surrogates for the population exposures that are

changed somewhat but appeared to be independent.[38] EPA observes that, as was true for multi-pollutant models including the gaseous co-pollutants, colinearity between the concentrations of fine and thoracic coarse particles can make interpretation of the study results difficult. An additional uncertainty to be considered for thoracic coarse particles is the likelihood that measurement error is greater in $PM_{10-2.5}$ measurements than for $PM_{2.5}$. Thus, as discussed above, in analyses that include both $PM_{2.5}$ and $PM_{10-2.5}$ data, effect estimates for associations with $PM_{10-2.5}$ would tend to have larger confidence intervals and be less likely to achieve statistical significance. Taking these considerations into account, the little available evidence suggests that $PM_{2.5}$ and $PM_{10-2.5}$ are associated with effects and are generally independent of one another.

Overall, EPA concludes that associations reported between health outcomes and short-term exposure to $PM_{10-2.5}$ are generally robust to the use of alternative modeling strategies, to adjustment for the potential confounding effects of co-pollutants, and in terms of exposure error (EPA, 2004, p. 9-46). However, in interpreting the results of epidemiologic studies, EPA recognizes that it is difficult to determine how well $PM_{10-2.5}$ concentrations measured at ambient monitoring stations characterize the magnitude of population exposures to thoracic coarse particles.

Not true

(3) As discussed in section II.A, in assessing consistency in effect estimates, the results suggest that effect estimates differ from one geographic location to another, but the extent of variation is not clear. For example, in Canadian 8-city study, some limited evidence was reported in the reanalysis to address model specification issues that suggested some heterogeneity between cities for associations with $PM_{10-2.5}$, whereas there had been no evidence of heterogeneity in initial study findings (Burnett and Goldberg, 2003; EPA, 2004, p. 9-39). As was observed for fine particles, there are a number of factors that would be likely to cause variation in PM-health outcomes in different populations and geographic areas. Overall, EPA concludes that there is some consistency in effect estimates for hospitalization for cardiovascular

[38] These two studies were reanalyzed to address potential issues with statistical model specification, and these multi-pollutant model results were not included in the reanalysis reports. One study was the Canadian 8-city study, in which results for models including both $PM_{2.5}$ and $PM_{10-2.5}$ and gaseous co-pollutants showed little change in the effect estimate size for both PM indicators (Burnett et al., 2000). Moolgavkar (2003) presented results of two-pollutant models for $PM_{2.5}$ and $PM_{10-2.5}$ with COPD hospitalization in Los Angeles, and again, effect estimates for both pollutants were generally reduced somewhat in size, but not substantially.

and respiratory causes with short-term exposure to thoracic coarse particles, though fewer studies are available on which to make such an assessment (EPA, 2004, p. 9-47).

(4) As discussed above in section II.A, most new epidemiologic studies have been unable to detect threshold levels in the relationship between short-term PM exposure (generally using PM_{10}) and mortality, though a few analyses in individual cities have provided suggestions of some potential threshold levels, generally at fairly low ambient concentrations. One single-city study used $PM_{2.5}$ and $PM_{10-2.5}$ measurements in Phoenix and reported that there was no indication of a threshold in the association between $PM_{10-2.5}$ and mortality (Smith et al., 2000; EPA, 2004, p. 8-322). Thus, EPA concludes that the evidence did not support selecting any particular population threshold for $PM_{10-2.5}$, recognizing that there may be thresholds for specific health responses in individuals, and that it is possible that such thresholds exist toward the lower end of the range of air quality measurements in the health studies, but cannot be detected due to variability in susceptibility across a population. Even in those few studies with suggestive evidence of such thresholds, the potential thresholds are at fairly low concentrations (EPA, 2004, sections 8.4.7 and 9.2.2.5).

Given the inadequacy of the epi evidence how can we be this?

(5) Several issues related to fine particle exposure time periods were assessed in the Criteria Document, as summarized in section 3.6.5 of the Staff Paper. One key issue is the lag period between thoracic coarse particle exposure and health outcome in short-term exposure studies. As was true for fine particles, in many epidemiologic studies, the authors have reported a pattern of positive associations across several consecutive lag periods for thoracic coarse particles, such that an effect estimate for any individual lag day for thoracic coarse particles likely underestimates the magnitude of the PM-health response. A number of recent studies that have investigated associations with distributed lags provide effect estimates for health responses that persist over a period of time (days to weeks) after the exposure period and the effect estimates are often, but not always, larger in size that those for single-day lag periods; however, available studies have generally not included $PM_{10-2.5}$ (EPA, 2004, p. 8-281). As reported for fine particles, the Criteria Document concluded that it is likely that the most appropriate lag period for a study will vary, depending on the health outcome and the specific pollutant under study. (EPA, 2004, p. 8-279).

(6) In integrating evidence from across scientific disciplines, the Criteria Document and Staff Paper observed that the smaller body of evidence on thoracic coarse particles, especially

the limited evidence from toxicologic studies, provides only limited evidence of coherence for effects of thoracic coarse particles. Epidemiologic and dosimetric evidence, along with limited support from toxicologic studies, indicates that short-term exposure to $PM_{10-2.5}$ can affect the respiratory system. As has been observed in previous reviews, thoracic coarse fraction particles are "inhalable"; fractional deposition to the tracheobronchial region is greatest for thoracic coarse particles in the size range of 4 to 6 μm (EPA, 2004, p. 6-109). From the limited number of toxicologic studies using $PM_{10-2.5}$, as noted above in section III.A.1, there is some evidence that exposure to thoracic coarse particles results in effects such as inflammation or oxidative stress. In addition, allergic adjuvant effects were linked with road dust exposures, but exposure to one type of particles of geologic origin, Mt. St. Helens ash, has not been linked with effects in toxicologic studies. These findings are generally consistent with epidemiologic evidence linking $PM_{10-2.5}$ with respiratory morbidity, such as increased respiratory symptoms or risk of hospitalization for asthma. Based on an integrative assessment of the evidence, EPA concludes that this growing but still limited body of health evidence is suggestive of causality in associations between short-term (but not long-term) exposures to thoracic coarse particles and health effects, with stronger evidence for associations with morbidity (especially respiratory) than with mortality. The Criteria Document also recognizes that the reduced precision (i.e., larger confidence intervals) for associations with $PM_{10-2.5}$ may be influenced by exposure measurement error (EPA, 2004, pp. 9-79, 9-80).

(7) In summary, based on the available evidence and the evaluation of that evidence in the Criteria Document and Staff Paper, EPA concludes that the body of evidence on effects related to exposure to thoracic coarse particles is less strong than that for fine particles, but provides suggestive evidence of causality for short-term exposure to $PM_{10-2.5}$ and morbidity, including hospitalization for cardiopulmonary diseases, increased respiratory symptoms and decreased lung function, and possibly mortality. EPA recognizes, however, that the substantial uncertainties associated with this limited body of evidence suggest that it should interpreted with a high degree of caution.

IV. Sensitive Subgroups for Effects of Thoracic Coarse Particle Exposure

As described in section II.A.4, there are several population groups that may be susceptible or vulnerable to PM-related effects. These groups include those with preexisting heart and lung diseases, older adults and children. Emerging evidence indicates that people from

lower socioeconomic strata or who have particularly elevated exposures may be more vulnerable to PM-related effects. However, the available evidence does not generally allow distinctions to be drawn between the PM indicators, in terms of which groups might have greater susceptibility or vulnerability to $PM_{2.5}$ or $PM_{10-2.5}$ (EPA, 2005 pp. 3-35 to 36).

V. Impacts on Public Health from Thoracic Coarse Particle Exposure

Section II.A.5 above discusses the potential public health impact of exposure to $PM_{2.5}$, concluding that exposure to ambient fine particles can have substantial health impacts based on the evidence from epidemiologic studies and the magnitude of potentially susceptible population groups. While recognizing that the health evidence regarding effects of thoracic coarse particles is more limited, EPA has concluded that the evidence suggests causal associations between short-term exposure to thoracic coarse particles and morbidity effects, such as respiratory symptoms or hospital admissions for respiratory diseases, and possibly mortality. As observed above, the potentially susceptible populations for such effects include people with preexisting respiratory diseases, children and older adults. Considering the magnitude of these subpopulations and risks identified in health studies, EPA concludes that exposure to thoracic coarse particles can have an important public health impact.

B. Quantitative Risk Assessment

The general overview and discussion of key components of the risk assessment used to develop risk estimates for $PM_{2.5}$ presented in section II.B above is also applicable to the assessment done for $PM_{10-2.5}$ in this review. However, the scope of the risk assessment for $PM_{10-2.5}$ is much more limited than that for $PM_{2.5}$, reflecting the much more limited body of epidemiologic evidence and air quality information available for $PM_{10-2.5}$. As discussed in chapter 4 of the Staff Paper, the $PM_{10-2.5}$ risk assessment includes risk estimates for just three urban areas for two categories of health endpoints related to short-term exposure to $PM_{10-2.5}$: hospital admissions for cardiovascular and respiratory causes and respiratory symptoms.

Consistent with the approach used in the $PM_{2.5}$ risk assessment, discussed above in section II.B, $PM_{10-2.5}$-related health risks attributable to anthropogenic sources and activities (i.e., risk associated with concentrations above background or above various selected higher cutpoints intended as surrogates for alternative assumed population thresholds) were estimated by using the reported linear or log-linear concentration-response functions from epidemiologic studies and

available air quality data from the locations in which the studies had been conducted. A series of base case analyses were conducted, using the same assumed cutpoints as were used in the assessment of short-term exposures to $PM_{2.5}$.

Estimates of hospital admissions attributable to short-term exposure to $PM_{10-2.5}$ have been developed for Detroit (cardiovascular and respiratory admissions) and Seattle (respiratory admissions), and estimates of respiratory symptoms have been developed for St. Louis.[39] Base case estimates of respiratory-related hospital admissions under recent air quality levels in Detroit are on the order of several hundred admissions per year across the range of assumed cutpoints considered in this assessment. The Detroit estimates are roughly one to two orders of magnitude greater than the range of estimated asthma-related admissions in Seattle, which can be attributed in part to differences in baseline risks related to respiratory-related health endpoints as well as to differences in $PM_{10-2.5}$ air quality levels in these two areas. More specifically, recent (e.g., 2001-2003) $PM_{10-2.5}$ concentrations are substantially higher in Detroit, where the current 24-hour PM_{10} standard is not met, than they are in Seattle (where the 24-hour PM_{10} design value is well below the level of the current PM_{10} standard). In considering risk estimates for respiratory symptoms in St. Louis, the number of days of cough in children living in St. Louis associated with recent $PM_{10-2.5}$ levels range from approximately 27,000 days per year at the lowest assumed cutpoint to almost 3,000 days per year at the highest assumed cutpoint. For the same time period, $PM_{10-2.5}$ air quality levels in St. Louis are high, where, like Detroit, the current 24-hour PM_{10} standard is not met.

While one of the goals of the $PM_{10-2.5}$ risk assessment was to provide estimates of the risk reductions associated with just meeting alternative $PM_{10-2.5}$ standards, EPA concluded that the nature and magnitude of the uncertainties and concerns associated with this portion of the risk assessment weigh against use of these risk estimates as a basis for recommending specific standard levels (EPA, 2005, p. 5-69). These uncertainties and concerns include, but are not limited to the following:

(1) As noted above in section II.A and discussed more fully below in section III.G, the $PM_{10-2.5}$ levels measured at ambient monitoring sites in recent years may be quite different from

[39] Quantitative risk estimates associated with recent air quality levels for these three cities are presented in Figures 4-11 and 4-12 in Chapter 4 of the Staff Paper.

the total deposition of thoracic coarse particles to the alveolar region can be comparable to or even larger than that for fine particles (EPA, 2004, p. 6-16).

Beyond the dosimetric evidence, as noted in past reviews (EPA, 1981b, 1996b), toxicologic studies show that the deposition of a variety of particle types in the tracheobronchial region, including resuspended urban dust and coarse-fraction organic materials, has the potential to affect lung function and aggravate respiratory symptoms, particularly in asthmatics. Of particular note are limited toxicologic studies that found urban road dust can produce cellular and immunological effects (e.g., Kleinman, et al., 1995; Steerenberg et al., 2003). In addition, some very limited *in vitro* toxicologic studies show some evidence that coarse particles may elicit pro-inflammatory effects (EPA, 2004, section 7.4.4). Further, the Staff Paper assessment of the physicochemical properties and occurrence of ambient coarse particles suggests that both the chemical makeup and the spatial distribution of coarse particles are likely to be more heterogeneous than for fine particles (EPA, 2005, chapter 2). In particular, that assessment finds that coarse particles in urban areas can contain all of the components found in more rural areas, but be contaminated (i.e., "enriched") by a number of additional materials, from motor vehicle-related emissions to metals and transition elements associated with industrial operations. The Staff Paper concludes that the weight of the dosimetric, limited toxicologic, and atmospheric science evidence, taken together, lends support to the plausibility of the $PM_{10-2.5}$-related effects reported in urban epidemiologic studies, and provides support for retaining some standard for thoracic coarse particles so as to continue programs to protect public health from such effects (EPA, 2005, p. 5-49).

Is this based on empirical evidence? or is it a hypothesis? My understanding is it is an hypothesis.

The available epidemiologic evidence, discussed above in section III.A, includes studies of associations between short-term exposure to thoracic coarse particles, indexed by $PM_{10-2.5}$, and health endpoints, as well as evidence from PM_{10} studies conducted in areas in which the coarse fraction is dominant. More specifically, several U.S. and Canadian studies now provide evidence of associations between short-term exposure to $PM_{10-2.5}$ and various morbidity endpoints. Three such studies conducted in Toronto (Burnett et al., 1997), Seattle (Sheppard et al.,1999, 2003), and Detroit (Lippmann et al., 2000; Ito, 2003) report statistically significant associations between short-term $PM_{10-2.5}$ exposure and respiratory- and cardiac-related hospital admissions, and a fourth study (Schwartz and Neas, 2000) conducted in six U.S. cities including Boston, St. Louis, Knoxville, Topeka, Portage, and Steubenville reports statistically significant

Maybe these need to be explained.

associations with respiratory symptoms in children. These studies were mostly done in areas in which $PM_{2.5}$, rather than $PM_{10-2.5}$, is the predominant fraction of ambient PM_{10}, such that they are not representative of areas with relatively high levels of thoracic coarse particles (EPA, 2005, p.5-49).

In evaluating the epidemiologic evidence from health studies on associations between short-term exposure to $PM_{10-2.5}$ and mortality, the Criteria Document concluded that such evidence was "not as strong" as that for associations with $PM_{2.5}$ or PM_{10} but nonetheless was suggestive of associations with mortality (EPA, 2004, p. 9-32). Statistically significant mortality associations were reported in short-term exposure studies conducted in areas with relatively high $PM_{10-2.5}$ concentrations, including Phoenix (Mar et al., 2000, 2003), Coachella Valley, CA (Ostro et al., 2000, 2003), and Steubenville (as part of the Six Cities study, Schwartz et al., 1996; Klemm et al., 2003). In areas with lower $PM_{10-2.5}$ concentrations, no statistically significant associations were reported with mortality, though most were positive.

The Staff Paper also considers relevant epidemiologic studies indexed by PM_{10} that were conducted in areas where PM_{10} is typically dominated by the coarse fraction. Such studies include findings of associations between short-term exposure to PM_{10} and hospitalization for cardiovascular diseases in Tucson, AZ (Schwartz, 1997), hospitalization for COPD in Reno/Sparks, NV (Chen et al., 2000), and medical visits for asthma or respiratory diseases in Anchorage, AK (Gordian et al., 1996; Choudhury et al., 1997). In addition, a number of epidemiologic studies have reported significant associations with mortality, respiratory hospital admissions and respiratory symptoms in the Utah Valley area (e.g., Pope et al., 1989; 1991; 1992). This group of studies provides additional supportive evidence for associations between short-term exposure to thoracic coarse particles and health effects, particularly morbidity effects, generally in areas not meeting the PM_{10} standards (EPA, 2005, p.5-50).[42]

In contrast to the findings from the short-term exposure studies discussed above, available epidemiologic studies do not provide evidence that long-term exposure to thoracic coarse particles is associated with mortality or morbidity (EPA, 2005, p.3-25). More specifically, no association is found between long-term exposure to thoracic coarse particles and

[42] Based on recent air quality data, as well as the summary information provided for PM concentrations used in the studies, the existing PM_{10} standards are not met in any of these study cities except Tucson, AZ.

with current levels of air quality, and the related limitations and uncertainties, the Staff Paper concludes that this information supports (1) revising the current PM_{10} standards in part by revising the indicator for thoracic coarse particles, and (2) consideration of a standard that will continue to provide public health protection from short-term exposure to thoracic coarse particles of concern that have been associated with morbidity effects and possibly mortality at current levels in some urban areas (EPA, 2005, p.5-52).

In CASAC's review of these Staff Paper recommendations, there was general concurrence among CASAC Panel members that there is a need to revise the current PM_{10} standards and establish a primary standard specifically targeted to address particles in the size range of 2.5 to 10 μm (Henderson, 2005b). In making this recommendation, CASAC indicated its agreement with the summary of the scientific data regarding the potential adverse health effects from exposures to thoracic coarse particles in section 5.4 of the Staff Paper upon which the EPA staff recommendations were based.

In considering whether the primary PM_{10} standards should be revised, the Administrator has carefully considered the rationale and recommendations contained in the Staff Paper, the advice and recommendations of CASAC, and public comments to date on this issue. The Administrator concludes that the health evidence, including dosimetric, toxicologic and epidemiologic study findings, supports retaining a standard to protect against effects associated with short-term exposure to thoracic coarse particles. Further, the Administrator finds that the new evidence on health effects from studies that use $PM_{10-2.5}$ as a measure of thoracic coarse particles, together with the much more extensive data now available to characterize air quality in terms of $PM_{10-2.5}$, provide an appropriate basis for revising the current PM_{10} standards in part by revising the indicator to focus more narrowly on particles between 2.5 and 10 μm. The Administrator also notes that the need for a standard for thoracic coarse particles has already been upheld based upon evidence of health effects considerably more limited than now available. *American Trucking Associations v. EPA*, 175 F. 3d at 1054. Based on these considerations, the Administrator concludes that the current suite of PM_{10} standards should be revised to provide more targeted protection from short-term exposure to those thoracic coarse particles that are of concern to public health.

D. Indicator of Thoracic Coarse Particles

comparing the potential health effects associated with thoracic coarse particles in urban and rural settings, as discussed below.

Atmospheric science and monitoring information indicates that exposures to thoracic coarse particles tend to be higher in urban areas than in nearby rural locations. Further, the mix of thoracic coarse particles typically found in urban areas is notably enriched by a number of contaminants, whereas such enrichment is not commonly found in the mix of natural crustal particles that is typical of rural areas. The elevation of $PM_{10-2.5}$ levels in urban locations as compared to those at nearby rural sites indicates that sources located within urban areas are generally the cause of elevated urban concentrations; conversely, $PM_{10-2.5}$ concentrations in such urban areas are not largely composed of particles blown in from more distant regions. Important sources of thoracic coarse particles in urban areas include dense traffic that suspends significant quantities of dust from paved roads, as well as industrial and combustion sources that contribute to ambient coarse particles both directly and through deposition to soils and roads (EPA, 2005, Table 2-2). It follows that the mix of thoracic coarse particles in urban areas would differ in composition from that in rural areas, being relatively enriched in components from urban mobile and stationary source emissions.

Basis?

Basis?

While detailed composition data are more limited for $PM_{10-2.5}$ than for $PM_{2.5}$, available measurements from some areas as well as studies of road dust components do show a significant influence of urban sources on both the composition and mass of thoracic coarse particles generally found in urban areas. Although crustal elements and natural biological materials represent a significant fraction of thoracic coarse particles in urban areas, both their relative quantity and character may be altered by urban sources. For example, in industrial cities, primary particle emissions from industrial sources and resuspended road dust can increase the relative amount of iron, one of the metals that has been noted as being of some interest in the studies of mechanisms of toxicity for PM, as well as other industrial process-related and potentially toxic materials such as nickel, cadmium, and chromium (EPA, 2005, p. 5-54). Traffic-related activities can also grind and resuspend vegetative materials into forms not as common in more natural areas (Rogge et al., 1993). Studies of urban road dusts find that levels of a variety of components are increased from traffic as well as from other anthropogenic urban sources, including products of incomplete combustion (e.g. polycyclic aromatic hydrocarbons) from motor vehicle emissions and other sources, brake and tire wear, rust, salt and biological

What does this mean?

as coarse fraction? Basis?

recently, a set of toxicologic and controlled human exposure studies have used particles extracted from filters from ambient PM_{10} monitors from periods when the plant did and did not operate. In both human volunteers and animals, greater lung inflammatory responses were reported with particles collected when the source was operating, as compared to the period when the plant was closed (EPA, 2004, p. 9-73). In addition, in some studies it was suggested that the metal content of the particles was most closely related to the effects reported (EPA, 2004, p. 9-74). While peak days in the Utah Valley occur in conditions that enhance fine particle concentrations, over the long run, over half of the PM_{10} was in the coarse fraction. The aggregation of particles collected on the filters during the study period reflect this long-term composition and represent the kinds of industrial components that would be incorporated in road dusts in the area.

Epidemiologic studies that examine exposures to thoracic coarse particles generally found in urban environments or exposures to natural crustal materials typical of rural areas, taken together, support the view that the mix of thoracic coarse particles generally found in urban areas is of concern to public health, in contrast to natural crustal dusts of geologic origin that are not enriched with contaminants. With respect to the urban results, several recent studies have shown associations between $PM_{10-2.5}$ and health outcomes in a number of sites across the U.S. Associations have been consistently reported with morbidity in urban areas, some of which had relatively low $PM_{10-2.5}$ concentrations. For mortality, statistically significant associations have been reported only for urban areas that have notably higher ambient $PM_{10-2.5}$ concentrations. These associations are with short-term exposures to aggregated $PM_{10-2.5}$ mass, and no epidemiologic evidence is available on associations with different components or sources of $PM_{10-2.5}$. However, these studies have all been conducted in urban areas of the U.S., and thus reflect effects associated with the ambient mix of thoracic coarse particles generally present in urban environments.

In contrast, recent evidence from epidemiologic studies has suggested that mortality and possibly other health effects are not associated with thoracic coarse particles from dust storms or other such wind-related events that result in suspension of natural crustal materials of geologic origin. The clearest example is provided by a study in Spokane, WA, which specifically assessed whether mortality was increased on dust-storm days using case-control analysis methods. The average PM_{10} level was more than 200 $\mu g/m^3$ higher on dust storm days than on

In considering an appropriate indicator for a standard intended to afford protection from health effects associated with exposure to thoracic coarse particles of concern, the Administrator has carefully considered the rationale and recommendations contained in the Staff Paper, the advice and recommendations from CASAC, and public comments to date on this issue. In so doing, the Administrator is persuaded, despite the substantial limitations and uncertainties in the relevant information available, that it is appropriate to establish a new indicator for such particles at this time. The Administrator recognizes that any such indicator should be defined not only by particle size, to generally include those particles between 2.5 and 10 μm in diameter, but also by qualifications that narrow the scope of the indicator. In considering an indicator that is intended to focus on the mix of thoracic coarse particles generally present in urban environments and commonly derived from sources typically found in urban environments, consistent with Staff Paper and CASAC recommendations, the Administrator notes that identifying it as an "urban" thoracic coarse particle indicator could be misconstrued as meaning that the standard is limited to certain geographic locations and, thus, not a national standard. To avoid this semantic problem, the Administrator has sought to define the indicator in a way that more clearly focuses on the nature of the mix of thoracic coarse particles intended to be included, rather than just where they are found, and that also explicitly focuses on what would be excluded from such an indicator. In so doing, the Administrator intends the indicator to be equivalent to the one recommended in the Staff Paper and endorsed by CASAC, but to do so in a manner that will be more clearly understood and less likely to be misinterpreted.

Taking into account the considerations discussed above, the Administrator proposes to establish a new indicator for thoracic coarse particles in terms of $PM_{10-2.5}$, the definition of which includes qualifications that identify both the mix of such particles that are of concern to public health, and are thus included in the indicator, and those for which currently available information is not sufficient to infer a public health concern, and are thus excluded. More specifically, the proposed $PM_{10-2.5}$ indicator is qualified so as to include any ambient mix of $PM_{10-2.5}$ that is dominated by sources typically found in urban environments, such as resuspended dust from high-density traffic on paved roads, industrial sources, and construction activities, and to exclude any ambient mix of particles that is dominated by rural windblown dust and soils and

What is it about construction dust and soil that makes it different from ag and mining dust?

agricultural and mining sources, ~~that is not enriched with contaminants typical of urban sources,~~[45] In short, the indicator is not defined by nor limited to any specific geographic area, but includes the mix of $PM_{10-2.5}$ in any location that is dominated by the noted sources of concern.

With the indicator as defined above, each area in the country would fall into one or the other of these two categories – either the majority of the ambient mix in an area is from sources typically found in urban environments, such as resuspended dust from high-density traffic on paved roads, industrial sources, and construction activities, or the majority of the ambient mix is from rural windblown dust and soils and agricultural and mining sources that is not enriched with contaminants typical of urban sources. EPA recognizes that in many cases it will be clear which of these two categories applies, while in other cases it may be difficult to determine the appropriate category. As described in more detail in the preamble to EPA's proposed monitor network design rule, published elsewhere in today's Federal Register, the proposed minimum monitor siting criteria would provide guidance on distinguishing between areas where the mix of $PM_{10-2.5}$ would likely be dominated by the noted sources of concern and those areas where it would not. Consequently, all $PM_{10-2.5}$ captured by a monitor that is properly sited in light of the indicator described above, as discussed in the proposed monitoring rule, would be considered in applying the standard, since the monitor would be capturing the mix of ambient $PM_{10-2.5}$ covered by the proposed indicator. As such, the proposed indicator does not present the type of over-inclusion or under-inclusion problems noted by the court with respect to a PM_{10} indicator (see *American Trucking Associations v. EPA*, 175 F. 3d at 1054), since the application of the proposed indicator would result in compliance being based on measurement of the mix of ambient $PM_{10-2.5}$ at which the standard is directed.

The Administrator recognizes that the proposed indicator, which includes considerations beyond particle size in its definition, represents a shift in the way in which the particulate matter indicator has been defined historically, and thus poses new challenges in ensuring a common understanding of how it can be appropriately and consistently implemented in areas across the

[45] As noted in the Criteria Document, resuspended dusts and soils, comprised of natural geologic crustal materials, can become contaminated from a variety of typically urban sources, including motor vehicle traffic (e.g., brake and tire wear, vehicle exhaust), and industrial process emissions (e.g., metals) (EPA, 2004, p. 8-344). Resuspended dusts and soils contaminated from such typically urban sources would be included in the indicator without consideration of where the dust or soil originally came from, except where otherwise provided for in the natural events policy which will be proposed in the near future. The focus is on the current source of the ambient coarse particles and not on what might be thought of as the original source.

in Detroit and Seattle.[47] In looking also at the mortality studies that report statistically significant and generally robust associations with short-term exposures to $PM_{10-2.5}$ in Phoenix (Mar et al., 2000, 2003) and Coachella Valley, CA (Ostro et al., 2000, 2003), the reported 98th percentile values were approximately 70 and 107 $\mu g/m^3$, respectively. These studies were conducted in areas with air quality levels that did not meet the current PM_{10} standards. In addition, a statistically significant association was reported between $PM_{10-2.5}$ and mortality in Steubenville as part of the Six Cities study (Schwartz et al., 1996; Klemm et al., 2003), where the $PM_{10-2.5}$ concentrations in this eastern city were fairly high, with a reported 98th percentile value of 53 $\mu g/m^3$. In contrast to the statistically significant mortality associations with $PM_{10-2.5}$ reported in these studies, the Staff Paper notes that no such associations were reported in a number of other studies, including those in the five other cities that were part of the Six Cities study (Boston, St. Louis, Knoxville, Topeka, and Portage), San Jose, Detroit, Philadelphia, and Pittsburgh. With the exception of Pittsburgh, these cities had much lower 98th percentile $PM_{10-2.5}$ values, ranging from 18 to 49 $\mu g/m^3$. Thus, in mortality studies that reported statistically significant associations, the reported 98th percentile $PM_{10-2.5}$ values were all above 50 $\mu g/m^3$, whereas in the mortality studies that reported no statistically significant associations, the reported 98th percentile $PM_{10-2.5}$ values were generally below 50 $\mu g/m^3$.

In looking more closely at air quality data used in the morbidity and mortality studies discussed above, however, the Staff Paper recognizes that the uncertainty related to exposure measurement error associated with using ambient concentrations to represent area-wide population exposure levels can be potentially quite large. For example, in looking specifically at the Detroit study, the Staff Paper notes that the $PM_{10-2.5}$ air quality values were based on air quality monitors located in Windsor, Canada. While the study authors concluded that these monitors were appropriate for use in exploring the association between air quality and hospital admissions in Detroit, a close examination of air quality levels at Detroit and Windsor sites in recent years led to the conclusion that the statistically significant, generally robust association with hospital admissions in Detroit likely reflects population exposures that may be appreciably

[47] As shown in air quality data trends reports: for Seattle, *1997 Air Quality Annual Report for Washington State*, p. 17, at http://www.ecy.wa.gov/pubs/97208.pdf; for Detroit, *Michigan's 2003 Annual Air Quality Report*, p. 46, at http://www.deq.state.mi.us/documents/deq-aqd-air-reports-03AQReport.pdf.

allowed by the current standards, but have not been associated with air quality levels that would generally meet the current standards, and morbidity effects have been associated with air quality levels that exceeded the current standards only a few times. Further, the Staff Paper finds little basis for concluding that a greater degree of protection is warranted in light of the very high degree of uncertainty in the relevant population exposures implied by the morbidity studies. The Staff Paper concludes, therefore, that it is reasonable to interpret the available evidence as supporting consideration of a short-term standard for thoracic coarse particles, so as to provide generally "equivalent" protection to that afforded by the current PM_{10} standards, recognizing that no one $PM_{10-2.5}$ level will be strictly equivalent to a specific PM_{10} level in all areas (EPA, 2005, p.5-67). Such a standard would likely provide protection against morbidity effects especially in urban areas where, unlike the study areas, PM_{10} is generally dominated by coarse-fraction rather than fine-fraction particles. Such a standard would also likely provide protection against the more serious, but more uncertain, $PM_{10-2.5}$-related mortality effects generally observed at somewhat higher air quality levels.

To identify a range of levels for consideration for a 24-hour $PM_{10-2.5}$ standard, based on the indicator proposed above and set so as to afford generally "equivalent" protection as the current PM_{10} standards, the Staff Paper presents the results of analyses of relevant data on $PM_{10-2.5}$ and PM_{10} 24-hour average concentrations.[48] In one such analysis of 205 monitoring sites (Schmidt et al., 2005),[49] a $PM_{10-2.5}$ level of approximately 60 $\mu g/m^3$, in terms of a 98th percentile form, would be roughly equivalent on average across the U.S. to the current PM_{10} standard level of 150 $\mu g/m^3$, in terms of the current one-expected-exceedance form.[50] While noting appreciable variability in the estimated point of equivalence across individual sites, these levels of approximate average equivalence are quite consistent across each of the five regions in which all

Provide this analysis

[48] Consistent with $PM_{10-2.5}$ monitoring network design criteria discussed in section 5.4.2.2 of the Staff Paper, monitors included in this analysis are those in CBSAs with at least 100,000 population and in census block groups with a population density of at least 500, and that also had 3 years of complete data in each quarter for both PM_{10} and $PM_{10-2.5}$ (EPA, 2005, p.5-67).

[49] These analyses were based on collocated PM_{10} and $PM_{10-2.5}$ data, and used linear regression methods to predict $PM_{10-2.5}$ concentrations (98th percentile form) equivalent to the 24-hour PM_{10} standard level of 150 $\mu g/m^3$ (one expected exceedence form) at a national and at regional levels.

[50] Across the U.S., the 95% confidence intervals around these point estimates are approximately $\pm$ 3 $\mu g/m^3$, while region-specific intervals are approximately $\pm$ 10 $\mu g/m^3$ in the five regions in which all of the areas that do not meet the current PM_{10} standards are located (EPA, 2005, p.5-68).

of the areas that do not meet the current PM_{10} standards are located (including the southern California, southwest, northwest, upper mid-west, and southeast regions). Notably different average equivalence levels were observed in the other two regions, i.e., approximately 40 $\mu g/m^3$ in the northeast and over 70 $\mu g/m^3$ in the industrial mid-west.

Another such analysis was based on comparing the number of areas, and the population in those areas, that would likely not meet a specific $PM_{10-2.5}$ standard, set at a given level and form, with the same measures in areas that do not meet the current PM_{10} standards. This analysis, based on 2001 to 2003 data, provides some rough indication of the breadth of protection potentially afforded by alternative standards. The results of this analysis indicate that a $PM_{10-2.5}$ standard of about 70 or 65 $\mu g/m^3$, 98th percentile form, would impact approximately the same number of counties or number of people, respectively, as would the current PM_{10} standards.[51]

Provide this analysis?

In considering the relevant dosimetric, toxicologic, and epidemiologic evidence, related limitations and uncertainties, and analyses of relevant air quality information, the Staff Paper concludes that it is appropriate to consider a 24-hour $PM_{10-2.5}$ standard in the range of 50 to 70 $\mu g/m^3$, with a 98th percentile form.[52] The lower end of this range is based on a close examination of the air quality patterns related to the limited number of relevant epidemiologic studies. The upper part of this range is based on a more cautious approach to interpreting the available information and reflects a generally "equivalent" degree of protection to that afforded by the current PM_{10} standards. Consideration of a generally "equivalent" $PM_{10-2.5}$ standard would reflect a judgment that while the epidemiologic evidence supports establishing a short-term standard for urban thoracic coarse particles at such a generally "equivalent" level, the evidence concerning

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[51] As shown in Tables 5B-2(a) and (b) of the Staff Paper, there are 585 counties with PM_{10} monitoring sites used in determining compliance with the PM_{10} standards, whereas only 309 of those counties have monitor sites that would be included in the monitoring network design criteria discussed in section 5.4.2.2 of the Staff Paper. Of these 309 counties, 259 have PM_{10} and $PM_{10-2.5}$ air quality data that meet the data completeness criteria defined for this analysis, which are somewhat less restrictive that the criteria that were applied in the regression analysis described above.

[52] Beyond looking directly at the relevant epidemiologic evidence and related air quality information, the Staff Paper also considers the extent to which the $PM_{10-2.5}$ risk assessment, discussed above in section III.B, can help inform consideration of alternative 24-hour $PM_{10-2.5}$ standards. The Staff Paper concludes that the nature and magnitude of the uncertainties and concerns associated with this portion of the risk assessment weigh against use of these risk estimates as a basis for recommending specific standard levels (EPA, 2005, p. 5-69).

air quality levels of thoracic coarse particles in the studies is not strong enough to provide a basis for changing the level of protection generally afforded by the current PM_{10} standards.

Based on its review of the Staff Paper, there was general agreement among the CASAC Panel members that the Staff Paper-recommended range of 50 to 70 $\mu g/m^3$, with a 98th percentile form, for a 24-hour $PM_{10-2.5}$ standard was reasonably justified. Most CASAC Panel members favored levels at the upper end of that range, while several members supported the lower end of the range (Henderson, 2005b). Because of the significant uncertainties resulting from the limited number of studies to date in which $PM_{10-2.5}$ has been measured and the potentially large exposure measurement errors in such studies, the CASAC Panel did not generally support a level below the Staff Paper-recommended range.

In considering an appropriate level for a 24-hour $PM_{10-2.5}$ standard intended to afford protection from health effects associated with exposure to thoracic coarse particles of concern, the Administrator has carefully considered the rationale and recommendations contained in the Staff Paper, the advice and recommendations of CASAC, and public comments to date on this issue. Taking these considerations into account, the Administrator proposes to set the level of the primary 24-hour $PM_{10-2.5}$ standard at 70 $\mu g/m^3$. In the Administrator's judgment, based on the currently available evidence, a standard set at this level would protect public health with an adequate margin of safety from the morbidity and possibly mortality effects that have been associated with short-term exposures to thoracic coarse particles of concern. This proposed standard is expected to have the most impact in areas that do not meet the current 24-hour PM_{10} standard.

In reaching this judgment, the Administrator recognizes that the epidemiologic evidence on morbidity and possible mortality effects related to $PM_{10-2.5}$ exposure is very limited at this time, and that there are potentially quite large uncertainties inherent in interpreting the available evidence for $PM_{10-2.5}$ as compared with the evidence related to fine particles. For example, $PM_{10-2.5}$ concentrations can vary substantially across a metropolitan area and thoracic coarse particles are less able to penetrate into buildings than fine particles; thus, the ambient concentrations reported in epidemiologic studies may not well represent area-wide population exposure levels. Further, the Administrator is mindful that considering what standard is requisite to protect public health with an adequate margin of safety requires judgments that neither overstate nor understate the strength and limitations of the evidence or the appropriate inferences to be drawn from the

evidence. Thus, the Administrator concludes that the selection of a level that provides generally equivalent protection to that provided by the current PM_{10} standards is an appropriate policy response to the very limited body of evidence that is available at this time. EPA intends to address the considerable uncertainties in the currently available information on thoracic coarse particles as part of the Agency's ongoing particulate matter research program.

Having reached this decision based on the approach to interpreting the available information described above, the Administrator recognizes another view that would place greater weight on the available epidemiologic evidence as a basis for selecting a level down to 50 $\mu g/m^3$ or below and/or for selecting an unqualified $PM_{10-2.5}$ indicator. While recognizing that important uncertainties are present in the available evidence, this view would support incorporating a larger margin of safety consistent with a more highly precautionary policy response. In soliciting comments on a wide array of views, the Administrator solicits comment on this view and on standard levels that are consistent with this view.

The Administrator also recognizes that there is no one level for a $PM_{10-2.5}$ standard that would be equivalent to the current PM_{10} standards in every area across the country, and that there are likely additional approaches to identifying a generally equivalent standard level beyond those approaches considered in the Staff Paper upon which the proposed level is based. Thus, the Administrator also solicits comment on alternative approaches to identifying a generally "equivalent" standard level.

The Administrator is also aware of other views that focus strongly on the limitations and uncertainties in the body of information that underlies the proposed indicator and on the substantial challenges associated with implementing a standard based on the proposed indicator. Such views would support approaches based on retaining the current 24-hour PM_{10} standard until such time as relevant new research on thoracic coarse particles and air quality monitoring data become available. Consistent with the goal of soliciting comments on a broad array of views, the Administrator seeks comment on retaining the current 24-hour PM_{10} standard either with or without new rules related to adjustments to mass measurements of PM_{10} to achieve a more narrow focus, especially with regard to legal questions and technical issues that would be raised by such approaches.

The Administrator also recognizes that some commenters may hold the view that the uncertainties that exist at the present time are so great that no standards for thoracic coarse

particles are warranted at this time. To solicit comments on the full array of views that have been expressed to date, the Administrator also solicits comment on revoking the current 24-hour PM_{10} standard at this time (as well as the current annual PM_{10} standard, as proposed above), not adopting a thoracic coarse particle standard at this time, and taking into account any new relevant research that becomes available as a basis for considering a more targeted standard for thoracic coarse particles in the next periodic review of the PM NAAQS.

H. Proposed Decisions on Primary $PM_{10-2.5}$ Standard

For the reasons discussed above, and taking into account the information and assessments presented in the Criteria Document and Staff Paper, the advice and recommendations of CASAC, and public comments to date, the Administrator proposes to revise the current primary PM_{10} standards to provide more targeted protection from thoracic coarse particles that are of concern to public health. In particular, the Administrator proposes to establish a new indicator for thoracic coarse particles in terms of $PM_{10-2.5}$, the definition of which includes qualifications that identify both the mix of such particles that are of concern to public health, and are thus included in the indicator, and those for which currently available information is not sufficient to infer a public health concern, and are thus excluded. More specifically, the proposed $PM_{10-2.5}$ indicator is qualified so as to include any ambient mix of $PM_{10-2.5}$ that is dominated by sources typically found in urban environments, such as resuspended dust from high-density traffic on paved roads, industrial sources, and construction activities, and to exclude any ambient mix of particles dominated by rural windblown dust and soils and agricultural and mining sources ~~that is not enriched with contaminants typical of urban sources~~. The Administrator proposes to replace the current primary 24-hour PM_{10} standard with a 24-hour standard defined in terms of this new $PM_{10-2.5}$ indicator and set at a level of 70 $\mu g/m^3$ so as to generally maintain the degree of public health protection afforded by the current PM_{10} standards from short-term exposure to thoracic coarse particles of concern. The proposed new standard would be met at an ambient air quality monitoring site[53] when the 3-year average of the annual 98th percentile 24-hour average $PM_{10-2.5}$

[53] Monitoring sites that are appropriate for determining compliance with this standard are those that are consistent with the proposed indicator. Guidance on this can be found in the proposed monitoring network design criteria published elsewhere in today's Federal Register.

concentration is less than or equal to 70 $\mu g/m^3$.[54] The Administrator also proposes to revoke and not replace the annual PM_{10} standard.

To address issues related to the transition from the current PM_{10} standards to a new $PM_{10-2.5}$ standard, the Administrator intends to propose for public comment EPA's plans for assuring an effective transition as part of an implementation policy notice that will be published in a future Federal Register. In addition, and consistent with the more targeted nature of the proposed new $PM_{10-2.5}$ indicator, the Administrator proposes that the current 24-hour PM_{10} standard be revoked for an area upon a determination by the Administrator that (1) the area meets the current 24-hour PM_{10} standard, or (2) the ambient mix of thoracic coarse particles in the area is dominated by rural windblown dust and soils and agricultural and mining sources, ~~that is not enriched with contaminants typical of urban sources, and is not dominated by sources typically found in urban environments, such as resuspended dust from high density traffic on paved roads, industrial sources, and construction activities.~~ In all other areas, the Administrator intends that the timing of the revocation of the current 24-hour PM_{10} standard be linked to the implementation of the proposed 24-hour $PM_{10-2.5}$ standard. In addition, as noted earlier, the Administrator is proposing to revoke the current annual PM_{10} standard immediately should EPA finalize the primary standards for $PM_{10-2.5}$ proposed in this notice.

How do you determine this? Region 7? Missoula, Gillette, Who? Got list of current NA areas for PM_{10}?

In recognition of alternative views of the currently available scientific information and the appropriate policy response to this information, the Administrator also solicits comments on (1) alternative approaches to selecting the level of a 24-hour $PM_{10-2.5}$ standard or to selecting an unqualified $PM_{10-2.5}$ indicator, and (2) alternative approaches to providing continued protection from thoracic coarse particles based on retaining the current 24-hour PM_{10} standard. Alternatively, the Administrator also solicits comment on revoking and not replacing the 24-hour PM_{10} standard. Based on the comments received and the accompanying rationale, the Administrator reserves the right to adopt other standards within the range of the alternatives identified above in lieu of the standard he is proposing today.

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[54] Data handling conventions are specified in a new proposed Appendix P, as discussed in Section V below, and the reference method for monitoring PM as $PM_{10-2.5}$ is specified in a new proposed Appendix L, as discussed in Section VI below. The proposed data handling conventions also reflect the proposed rules for the treatment of air quality data influenced by exceptional events, published elsewhere in today's Federal Register

Appendix I:

Examples of Possible Best Practice Models for Agency Compliance with Section (E)(ii) of Executive Order 12866

FEDERAL AVIATION ADMINISTRATION
COMPLIANCE WITH E.O. 12866

Section 6(a)(3)(E) of E.O. 12866 requires agencies to identify for the public, in a complete, clear, and simple manner, those changes in a regulatory action made at the suggestion or recommendation of the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget.

Title of Rulemaking:

Regulatory Identification Number:

_____ OIRA did not review the rulemaking document.

_____ OIRA reviewed the rulemaking document, but did not suggest or recommend any changes.

__X__ OIRA reviewed the rulemaking document, and we have documented the changes we made at OIRA's suggestion or recommendation in an attachment to this sheet.

Signature of Analyst

11/8/10
Date

Attachment

Changes to NPRM preamble:

- Made minor editorial changes throughout preamble.
- Added hyperlinks and footnotes to preamble to aid finding referenced documents.
- Added International Civil Aviation Organization (ICAO) Annex 6, Operation of Aircraft to docket.
- Clarified preamble language including:
    - Expanding discussion of Flight Operational Quality Assurance (FOQA) program.
    - Some rewording of accident descriptions to better explain how a safety management system (SMS) may have prevented or mitigated.
    - Revision of SMS Pilot Program description.
    - Invitation for comments on how to include air carriers' existing systems and processes into an SMS.
    - Incorporation of OIRA suggestions to better describe and determine impacts of new information collection requirements by this proposed rule.

Changes to Regulatory Evaluation

- Made minor editorial changes throughout the Regulatory Evaluation
- Added hyperlinks and footnotes to the Regulatory Evaluation to aid finding referenced documents.
- Clarified some math computations on page 18 in the description of SMS staffing estimates and analysis.
- In "Total Cost" page 19 revised 20 year cost estimate to $710 million over 20 years ($375.5 million present value).
- Potential benefits revised to $1,143.1 million ($500.8 million present value) over 20 years.

Memorandum

U.S. Department
of Transportation

**Federal Railroad
Administration**

Date: January 5, 2012

To: Rulemaking Docket No. FRA-2008-0059, Notice No. 4

From: Anna N. Winkle Anna N. Winkle
Trial Attorney, Office of Chief Counsel

Subject: Memorandum Pursuant to Executive Order 12866 Regarding OIRA's Suggested Edits to the Final Rule on Adjacent-Track On-Track Safety for Roadway Workers

Pursuant to paragraph (a)(3)(E) of section 6 of Executive Order 12866, FRA is posting to the rulemaking docket redlines of the changes made to the draft final rule and regulatory impact analysis (RIA) submitted to the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget.

While there were no substantive changes to the rule text, at OIRA's request, FRA increased the data period on which it based its estimate of fatalities, from a four-year period to a ten-year period, 1999-2008. This change reduced the expected number of fatalities avoidable, which were used in calculating the benefits. See, particularly, pages 16 and 24-26 of the redlined RIA. Accordingly, throughout the RIA, FRA adjusted its calculations to take this reduction into account. FRA also revised the RIA to include an additional benefit resulting from the general portion of the job briefing requirement that FRA had not accounted for in the notice of proposed rulemaking (NPRM), and to account for the new value of a statistical life (VSL) recommended by DOT, as the VSL had increased after the issuance of the NPRM. FRA revised the discussion of the RIA in the final rule document to reflect these revisions to the RIA.

In response to questions raised by OIRA, FRA also made some clarifying changes to the preamble of the final rule document and to the RIA. Finally, FRA made minor edits to both the RIA and final rule document to correct typographical and formatting errors.

All of the changes made to the draft final rule and RIA submitted to OIRA and incorporated into the final rule signed by the FRA Administrator are reflected in the attached redlined documents.

Attachments

Form for Compliance with E.O. 12866 Docket Requirements

Title of Regulation: *Water Quality Standards for the State of Florida's Streams and Downstream Protection Values for Lakes: Remanded Provisions*

Contact person: Mario Sengco

Phone number: 202-566-2676

Was this regulation reviewed by OMB under **Executive Order 12866 - Regulatory Planning and Review**?

X Yes No

If you checked "no", you are done with this form. Simply place it in the docket for your regulation. If you checked "yes", please fill out the remainder of the form before placing it in the docket. Also docket any relevant documents referenced in the form.

For regulations that are checked "Yes" above:

This regulation was reviewed by OMB under *Executive Order 12866 - Regulatory Planning and Review*.

Attached is the draft regulation and any other documents sent to OMB for review, such as analyses and assessments. E.O. 12866 requires agencies to make these publicly available.

E.O. 12866 also requires agencies to identify the **substantive changes** between the draft regulation sent to OMB for review and the regulation subsequently announced [*Please check the appropriate box below:*]

_X_ **EPA made substantive changes to this regulation (includes changes initiated by EPA or OMB).**
Attached is a document which: (1) identifies all the substantive changes made, and (2) notes those changes OMB suggested or recommended.

____ **No substantive changes were made to this regulation**
Therefore, no further attachments are required.

If you have questions about this regulation, please call the EPA contact person listed above.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
WATER

MEMORANDUM

SUBJECT: Proposed Rule: *Water Quality Standards for the State of Florida's Streams and Downstream Protection Values for Lakes: Remanded Provisions* - Executive Order 12866 Docket Requirements Compliance

FROM: Mario Sengco, Regulation Manager
Office of Water

TO: Docket EPA-HQ-OW-2009-0596

Overview
On November 14, 2012, the proposed rule titled: *Water Quality Standards for the State of Florida's Streams and Downstream Protection Values for Lakes: Remanded Provisions* was submitted to the Office of Management and Budget for review under E.O. 12866. On November 30, 2012, OMB concluded review of the proposed rule.

This review resulted in a number of changes being made to the proposed rule as a result of recommendations from OMB or other agencies. In-text edits from OMB and EPA's responses and actions are provided in the attached redline strikeout version of the preamble.

Background
On January 14, 2009, EPA determined under CWA section 303(c)(4)(B) that new or revised water quality standards in the form of numeric nutrient water quality criteria for nitrogen and phosphorus pollution are necessary to protect the designated uses that Florida has set for its Class I, Class II, and Class III waters. Subsequently, EPA entered into a Consent Decree, effective on December 30, 2009 (and further revised on several occasions), which established a schedule for EPA to propose and promulgate numeric nutrient criteria for Florida's lakes, springs, flowing waters, estuaries, and coastal waters. The Consent Decree provided that if Florida submitted and EPA approved numeric nutrient criteria for the relevant waterbodies before the dates outlined in the schedule, EPA would no longer be obligated to propose or promulgate criteria for those waterbodies.

On December 6, 2010, EPA published a rule finalizing numeric nutrient criteria for Florida's lakes, springs, and flowing waters outside of the South Florida Nutrient Watershed Region (40 CFR 131.43). Following publication of the "inland waters rule", challenges were filed in the U.S. District Court for the Northern District of Florida alleging that EPA's determination and final rule were arbitrary, capricious, an abuse of discretion, and not in accordance with the law for a variety of reasons. On February 18, 2012, the court issued its ruling. While upholding EPA's

determination and much of its rule, the court invalidated EPA's numeric nutrient criteria for Florida's streams because it found that EPA had either "aimed for the wrong target" or not sufficiently explained what it did in aiming for the right target. For similar reasons, the court also invalidated EPA's default downstream protection values (DPVs) for streams where the downstream lake is attaining its lake numeric nutrient criteria.

Hence, the court ordered EPA to either "sign for publication a proposed rule, or sign for publication a final rule, that sets numeric nutrient criteria for Florida streams" by May 21, 2012. As to the DPV where a lake is attaining its lake numeric criteria, the same order applies unless EPA files a notice by May 21, 2012 that it has decided not to propose or adopt such DPV, with an explanation of that decision. On May 30, 2012, the court granted EPA's request to extend the deadline for signing a proposed rule to November 30, 2012. The court also ordered that the final rule must be signed for publication by August 31, 2013.

Summary of Key Changes

In summary, EPA accepted most of OMB's edits and comments and made changes in response to the comments. The most significant point was with regard to the recommendation of an alternative where the narrative criteria for Florida would be suitable for waters not covered by the State's rule that EPA approved on November 30, 2012. EPA did not agree with this recommendation. Relying on the narrative as an option would violate the determination and consent decree. EPA's determination addressed the need for numeric nutrient criteria and EPA remains focused on this approach. As a compromise to the additional text proposed by OMB, EPA agreed to acknowledge the possibility of other approaches that are similarly protective of designated uses and requested comment on the matter.

6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 131

[EPA-HQ-OW-2009-0596; FRL#9678-6]

RIN 2040-AF39

Water Quality Standards for the State of Florida's Streams and Downstream Protective Values for Lakes: Remanded Provisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is proposing a rule that addresses an order by the U.S. District Court for the Northern District of Florida from February 18, 2012, which remanded to EPA two portions of its numeric water quality standards for nutrients in Florida that were promulgated and published on December 6, 2010. For this proposal, EPA is re-proposing the same numeric nutrient criteria for total nitrogen (TN) and total phosphorus (TP) for Florida streams not covered by EPA-approved State rulemaking, as included in EPA's final rule, with further explanation of how the proposed numeric streams criteria will ensure the protection of the Florida's Class I and III designated uses. EPA is also proposing default approaches available for use when modeling cannot be performed to derive downstream protection values (DPVs) that will ensure the attainment and maintenance of the numeric nutrient criteria that protect Florida's lakes. The default approaches would be applicable to streams that flow into unimpaired lakes, but could also be used for streams that flow into

Comment [MS1]: EPA will use the term, "streams criteria" consistently in this document.

impaired lakes.

DATES: EPA will accept public comments on this proposed rule until [Insert date 45 days from date of publication in the **Federal Register**]. Because of EPA's obligation to sign a notice of final rulemaking on or before August 31, 2013 under Consent Decree, the Agency regrets that it will be unable to grant any requests to extend this deadline.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-OW-2009-0596, by one of the following methods:

1. www.regulations.gov: Follow the on-line instructions for submitting comments.
2. Email: ow-docket@epa.gov
3. Mail to: Water Docket, U.S. Environmental Protection Agency, Mail code: 2822T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460, Attention: Docket ID No. EPA-HQ-OW-2009-0596.
4. Hand Delivery: EPA Docket Center, EPA West Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004, Attention Docket ID No. EPA-HQ-OW-2009-0596. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-HQ-OW-2009-0596. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is

restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at http://www.epa.gov/epahome/dockets.htm.

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at a docket facility. The Office of Water (OW) Docket Center is open from 8:30 a.m. until 4:30 p.m., Monday through Friday, excluding legal holidays. The OW Docket Center telephone number is (202) 566-2426, and the Docket address is OW Docket, EPA West, Room 3334, 1301 Constitution Avenue, NW, Washington, DC 20004. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744.

FOR FURTHER INFORMATION CONTACT: For information concerning this rulemaking, contact Mario Sengco, U.S. EPA Headquarters, Office of Water, Mailcode: 4305T, 1200 Pennsylvania Avenue, NW, Washington, DC 20460; telephone numbers: 202-566-2676 or 202-564-1649; fax number: 202-566-9981; email address: sengco.mario@epa.gov.

SUPPLEMENTARY INFORMATION: This supplementary information section is organized as follows:

Table of Contents

H. Executive Order 13211 (Actions That Significantly Affect Energy Supply, Distribution, or Use)

I. National Technology Transfer Advancement Act of 1995

J. Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations)

I. General Information

A. Executive Summary

Florida is known for its abundant and aesthetically beautiful natural resources, in particular its water resources. Florida's water resources are very important to its economy, for example, its $6.5 billion freshwater fishing industry.[1] However, nitrogen and phosphorus pollution has contributed to severe water quality degradation in the State of Florida. In the most recent Florida Department of Environmental Protection (FDEP) water quality assessment report, the *Integrated Water Quality Assessment for Florida: 2012 305(b) Report and 303(d) List Update*[2], FDEP describes widespread water quality impairment in Florida due to nitrogen and phosphorus pollution. FDEP's 2012 report identifies approximately 1,918 miles of rivers and streams (about 14 percent of assessed river and stream miles), 378,435 acres of lakes (about 31 percent of assessed lake acres), 754 square miles (482,560 acres) of estuaries (about 14 percent of assessed estuarine area) and 102 square miles (65,280 acres) of coastal waters (about 1.6 percent of assessed

[1] Florida Fish and Wildlife Conservation Commission. 2010. *The economic impact of freshwater fishing in Florida*. <http://www.myfwc.com/CONSERVATION/Conservation_ValueofConservation_EconFreshwaterImpact.htm.>. Accessed August 2010.
[2] FDEP. 2012. *Integrated Water Quality Assessment for Florida: 2012 305(b) Report and 303(d) List Update.* (May 2012). Florida Department of Environmental Protection, Division of Environmental Assessment and Restoration, Tallahassee, FL. <http://www.dep.state.fl.us/water/docs/2012_integrated_report.pdf>. Accessed August 2012.

coastal waters) as impaired by nutrients. Despite FDEP's intensive efforts to diagnose, evaluate and address nitrogen and phosphorus pollution, substantial and widespread water quality degradation from nitrogen and phosphorus pollution has continued and remains a significant problem.

On January 14, 2009, EPA determined under Clean Water Act (CWA) section 303(c)(4)(B) that new or revised water quality standards (WQS) in the form of numeric water quality criteria are necessary to protect the designated uses from nitrogen and phosphorus pollution that Florida has set for its Class I and Class III waters.[3] The Agency considered 1) the State's documented unique and threatened ecosystems, 2) the large number of impaired waters due to existing nitrogen and phosphorus pollution, and 3) the challenge associated with growing nitrogen and phosphorus pollution associated with expanding urbanization, continued agricultural development, and a significantly increasing population that the U.S. Census estimates is expected to grow over 75% between 2000 and 2030.[4] EPA also reviewed the State's regulatory accountability system, which represents a synthesis of both technology-based standards and point source control authority, as well as authority to establish enforceable controls for nonpoint source activities.

In December 2009, EPA entered into a Consent Decree with Florida Wildlife Federation, Sierra Club, Conservancy of Southwest Florida, Environmental Confederation of Southwest Florida, and St. Johns Riverkeeper, which established a schedule for EPA to propose and promulgate numeric nutrient criteria for Florida's lakes,

[3] Class I is designated for potable water supplies. Class III is designated for recreation, propagation and maintenance of a healthy, well-balanced population of fish and wildlife. F.A.C. Section 62-302.400
[4] U.S. Census Bureau, Population Division, Interim State Population Projections, 2005. <http://www.census.gov/population/projections/SummaryTabA1.pdf>.

springs, flowing waters, estuaries, and coastal waters, as well as downstream protection values (DPVs) to protect downstream lakes and estuaries. The Consent Decree provided that if Florida submitted and EPA approved numeric nutrient criteria for the relevant water bodies before the dates outlined in the schedule, EPA would no longer be obligated to propose or promulgate criteria for those water bodies.

On December 6, 2010 (75 FR 75762), EPA's final rule[5] was published in the Federal Register and codified at 40 CFR §131.43. The final rule established numeric nutrient criteria, or numeric limits on the amount of nitrogen and phosphorus allowed in Florida's waters (i.e., lakes, streams and springs) while still protecting applicable designated uses.

Comment [MS2]: See additional preceding paragraph that provides more information.

Following the rule's publication, EPA soon received 12 challenges from a range of plaintiffs that included environmental groups, the State Department of Agriculture, the South Florida Water Management District and several industry/discharger groups. The challenges alleged that EPA's determination and final rule were arbitrary, capricious, an abuse of discretion, and not in accordance with the law. The U.S. District Court for the Northern District of Florida consolidated the suits and held oral argument on January 9, 2012.

On February 18, 2012, the court issued its ruling.[6] While upholding EPA's determination and much of its rule, the court invalidated EPA's numeric nutrient criteria for Florida's streams because it found that EPA had either "aimed for the wrong target" or not sufficiently explained what it did in aiming for the right target. The court observed

[5] Federal Register, Vol. 75, No. 233, 75762, December 6, 2010. Water Quality Standards for the State of Florida's Lakes and Flowing Waters.
[6] Florida Wildlife Federation, Inc., et. al. v. Jackson, Case 4:08-cv-00324-RH-WCS, Doc. 351 (N.D.Fla. February 18, 2012).

that Florida's existing narrative criterion states, in relevant part, that "nutrient concentrations of a body of water [must not] be altered so as to cause an imbalance in natural populations of aquatic flora or fauna." Fla. Admin. Code r. 62-302.530(47)(b). Based on that narrative criterion, as implemented by FDEP, the court found that the correct target would be to avoid any *harmful* increase in nutrient levels, as opposed to *any* increase in nutrient levels. The court found that EPA had apparently derived stream numeric nutrient criteria to prevent *any* increase in nutrient levels, and had thus aimed at the wrong target. If EPA had derived stream numeric nutrient criteria to prevent any harmful increase, the court found that EPA had not provided a sufficient explanation for its action. For similar reasons, the court also invalidated EPA's default DPV for streams where the downstream lake is attaining its lake numeric nutrient criteria. Hence, the court ordered EPA to either "sign for publication a proposed rule, or sign for publication a final rule, that sets numeric nutrient criteria for Florida streams" by May 21, 2012. As to the DPV where a lake is attaining its lake numeric criteria, the same order applies unless EPA files a notice by May 21, 2012 that it has decided not to propose or adopt such DPV, with an explanation of that decision.

On May 30, 2012, the court granted EPA's request to extend the deadline for signing a proposed rule to November 30, 2012. The court also ordered that the final rule must be signed for publication by August 31, 2013.

For this proposal, EPA is re-proposing the same numeric nutrient criteria for TN and TP published in EPA's final rule on December 6, 2010 (75 FR 75762), with further explanation on how the proposed streams criteria will ensure the protection of Florida's Class I and III designated uses and how the criteria are an appropriate translation of

Comment [MS3]: See comment MS4

Comment [MS4]: Regarding the comments received from the USDA, EPA reviewed and considered them, but respectfully disagrees. EPA firmly believes in the use of the reference condition approach and its selection of the 90th percentile values (75th percentile in the West Central region) as the appropriate total nitrogen and total phosphorus criteria that protect the applicable designated uses and translate Florida's narrative nutrient criterion for the purposes of the CWA. The use of the reference condition approach was evaluated and upheld by the U.S. District Court for Northern District of Florida. The choice of the percentile values were supported by multiple lines of evidence, including the peer-reviewed scientific literature and a review of data from Florida showing harmful adverse impacts at higher concentrations provided by the Florida Department of Environmental Protection. Given EPA's analysis, the Agency is confident that it has met the court's order and the requirement of the CWA.

Comment [MS5]: Removed highlight.

Florida's narrative nutrient criterion. This proposal also is consistent with the objective and requirements of the CWA and EPA's implementing regulations at 40 CFR part 131. EPA is also proposing default approaches available for use when modeling cannot be performed to derive DPVs that will ensure the attainment and maintenance of the numeric nutrient criteria that protect the designated uses of Florida's downstream lakes. These default approaches are applicable to streams that flow downstream into unimpaired lakes, but could also be used for streams that flow downstream into impaired lakes.

On June 13, 2012, FDEP submitted new and revised water quality standards for review by the EPA pursuant to section 303(c) of the CWA. These new and revised water quality standards are set out primarily in Rule 62-302 of the Florida Administrative Code (F.A.C.) [Surface Water Quality Standards]. FDEP also submitted amendments to Rule 62-303, F.A.C. [Identification of Impaired Surface Waters], which sets out Florida's methodology for assessing whether waters are attaining State water quality standards. On November 30, 2012, EPA approved the provisions of these rules submitted for review that constitute new or revised water quality standards (hereafter referred to as the "newly-approved state water quality standards").

Among the newly-approved state water quality standards are numeric criteria for nutrients that apply to a set of streams, as that term is specifically defined in the newly-approved state water quality standards. Under the Consent Decree, EPA is relieved of its obligation to propose numeric criteria for nutrients for any waters for which FDEP submits and EPA approves new or revised water quality standards before EPA proposes. Thus, under normal circumstances, EPA would be clearly relieved of its obligation to

propose numeric criteria for nutrients in streams Florida covered in its newly-approved state water quality standards.

However, another provision included in Florida's Rule, specifically subsection 62-302.531(9), F.A.C., casts some doubt as to whether the newly approved state water quality standards will go into effect if EPA proposes and promulgates numeric nutrient criteria for streams not covered by the newly-approved State water quality standards. Therefore, it is unclear whether an EPA proposal to "gap fill", or establish numeric criteria for nutrients for Florida streams that FDEP does not cover in its Rule, would trigger 62-302.531(9), F.A.C. and result in Florida's streams criteria not taking effect.

In addition, due to a recent administrative challenged filed in the State of Florida Department of Administrative Hearings, there is uncertainty as to whether FDEP will be able to implement its newly approved state water quality standards consistent with FDEP's "Implementation of Florida's Numeric Nutrient Standards" (Implementation Document). ~~EPA approved Florida's new or revised water quality standards based on the Agency's understanding that FDEP will implement the streams criteria as provided in its Implementation Document~~. Thus, EPA approved portions of Florida's new or revised water quality standards subject to the State being able to implement them as provided in its Implementation Document. If, as a result of legal challenge, FDEP is unable to implement its Rule as provided in its Implementation Document, EPA would intend to revisit ~~portions of~~ its November 30, 2012 approval of Florida's new or revised water quality standards. EPA has therefore reserved its authority to withdraw or modify ~~portions of~~ that approval.

Comment [MS6]: Corrected throughout.

Comment [MS7]: Accepted comments and edits.

Comment [MS8]: Accepted strikeout

Comment [MS9]: Accepted strikeout.

In light of the above, EPA seeks comment on finalizing a rule that applies EPA's streams criteria to streams meeting EPA's definition of "stream" that are not covered under Florida's numeric interpretation of narrative nutrient criteria at 62-302.531(2)(c), F.A.C. This would serve to fill gaps in coverage if Florida's streams criteria are in effect, or apply to all streams if Florida's streams criteria are not in effect for any reason, including those mentioned above.

Finally, as described in EPA's November 30, 2012 approval of Florida's new or revised water quality standards, while EPA believes that the provisions addressing downstream protection will provide for quantitative approaches to ensure the attainment and maintenance of downstream waters consistent with 40 CFR 131.10(b), the provisions themselves, however, do not consist of numeric values. Because EPA is currently subject to a Consent Decree deadline to sign a rule proposing numeric downstream protection values (DPVs) for Florida by November 30, 2012, EPA is proposing numeric DPVs to comply with the Consent Decree. However, EPA has amended its January 2009 determination to specify that numeric criteria for downstream protection are not necessary and that quantitative approaches designed to ensure the attainment and maintenance of downstream water quality standards, such as those established by Florida, are sufficient to meet CWA requirements. As such, EPA will ask the court to modify the Consent Decree consistent with the Agency's amended determination, i.e., to not require EPA to promulgate numeric DPVs for Florida. Accordingly, EPA approved the State's downstream protection provisions subject to the district court modifying the Consent Decree to not require EPA to promulgate numeric DPVs for Florida. If the district court agrees to so modify the Consent Decree, EPA will not promulgate numeric DPVs for

Florida. However, if the district court declines to so modify the Consent Decree, EPA would intend to promulgate numeric DPVs for Florida and would also expect to revisit its November 30, 2012 approval of the State Rule's downstream protection provisions to modify or withdraw its approval. Therefore, EPA has also reserved its authority to do so in its approval document.

A full description of all of EPA's recent actions on Florida numeric nutrient criteria and related implications for EPA's own rules can be found at http://water.epa.gov/lawsregs/rulesregs/florida_index.cfm.

B. Which Water Bodies Are Affected By This Rule?

The criteria in this proposed rulemaking apply to a group of inland waters of the United States within Florida. Specifically, these criteria apply to flowing waters (i.e., streams) located outside of the South Florida Region that are designated as either Class I or Class III not covered by the State of Florida's Rule.[7] EPA notes if Florida's Rule will not take effect due to subsection 62-302.531(9), F.A.C., EPA would expect to finalize the criteria in this proposed rulemaking for all flowing waters (i.e., streams) located outside of the South Florida Region that are designated as either Class I or Class III. EPA solicits comment on this potential outcome.

Class I and Class III streams share water quality criteria established to "protect recreation and the propagation and maintenance of a healthy, well-balanced population of fish and wildlife" pursuant to Subsection 62-302.400(4), F.A.C.[8] "Stream", as defined at

[7] For purposes of this rule, EPA has distinguished South Florida as those areas south of Lake Okeechobee and the Caloosahatchee River watershed to the west of Lake Okeechobee and the St. Lucie watershed to the east of Lake Okeechobee, hereinafter referred to as the South Florida Region.
[8] Class I waters also include an applicable nitrate limit of 10 mg/L and nitrite limit of 1 mg/L for the

40 CFR §131.43(b)(12) means a free-flowing, predominantly fresh surface water in a defined channel, and includes rivers, creeks, branches, canals, freshwater sloughs, and other similar water bodies. EPA notes that as defined at 40 CFR § 131.43(b)(8) and consistent with Section 62-302.200, F.A.C., "predominantly fresh waters" means surface waters in which the chloride concentration at the surface is less than 1,500 milligrams per liter (mg/L).

The definition of stream in the approved water quality standards for purposes of applying the numeric interpretation of the narrative nutrient criterion to streams is less inclusive than as defined at 40 CFR §131.43(b)(12). Florida's stream definition for purposes of applying the numeric interpretation of the narrative nutrient criterion (see Subsection 62-302.200(36), F.A.C) specifically excludes non-perennial water segments; tidally influenced segments; and ditches, canals and other conveyances that are man-made or predominantly channelized or physically altered, are used primarily for water management purposes, and have marginal or poor stream habitat components. Inland flowing waters that meet EPA's definition of stream yet do not meet Florida's definition of stream for purposes of applying the numeric interpretation of the narrative nutrient criterion are designated Class I or Class III waters in Florida water quality standards. If they are not Class I or Class III waters, then this proposed rule would not apply. This rule does not apply to wetlands, including non-perennial stream segments that function as wetlands because of fluctuating hydrologic conditions that typically result in the dominance of wetland taxa.

protection of human health in drinking water supplies. The nitrate limit applies at the entry point to the distribution system (i.e., after any treatment); see Chapter 62-550, F.A.C., for additional details.

C. What Entities May Be Affected By This Rule?

Citizens concerned with water quality in Florida may be interested in this rulemaking. Entities discharging nitrogen or phosphorus to flowing waters of Florida could be indirectly affected by this rulemaking because WQS are used in determining National Pollutant Discharge Elimination System (NPDES) permit limits. Categories and entities that may ultimately be affected include:

Category	Examples of potentially affected entities
Industry	Industries discharging nitrogen and phosphorus to flowing waters in the State of Florida.
Municipalities	Publicly-owned treatment works discharging nitrogen and phosphorus to flowing waters in the State of Florida.
Stormwater Management Districts	Entities responsible for managing stormwater runoff in Florida.

Comment [MS10]: No change made. EPA only regulates point-sources under the CWA.

This table is not intended to be exhaustive, but rather provides a guide for entities that may be directly or indirectly affected by this action. This table lists the types of entities of which EPA is now aware that potentially could be affected by this action. Other types of entities not listed in the table, such as nonpoint source contributors to nitrogen and phosphorus pollution in Florida's waters may be affected through implementation of Florida's water quality standards program (i.e., through Basin Management Action Plans (BMAPs)). Any parties or entities conducting activities within watersheds of the Florida waters covered by this rule, or who rely on, depend upon, influence, or contribute to the water quality of flowing waters of Florida, may be affected by this rule. To determine whether your facility or activities may be affected by this action, you should carefully examine the language in this proposal. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

D. How Can I Get Copies of This Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under Docket Id. No. EPA-HQ-OW-2009-0596. The official public docket consists of the document specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the OW Docket, EPA West, Room 3334, 1301 Constitution Ave., NW, Washington, DC 20004. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The OW Docket telephone number is 202-566-2426. A reasonable fee will be charged for copies.

2. *Electronic Access*. You may access this Federal Register document electronically through the EPA Internet under the "Federal Register" listings at http://www.regulations.gov. An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.regulations.gov to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. For additional information about EPA's public docket, visit the EPA Docket Center homepage at http://www.epa.gov/epahome/dockets.htm. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the Docket Facility identified earlier.

II. Background

A. Nitrogen and Phosphorus Pollution in the United States and the State of Florida

Excess loading of nitrogen and phosphorus compounds[9] is one of the most prevalent causes of water quality impairment in the United States. Nitrogen and phosphorus pollution problems have been recognized for decades in the U.S. For example, a 1969 report by the National Academy of Sciences noted that "*[t]he pollution problem is critical because of increased population, industrial growth, intensification of agricultural production, river-basin development, recreational use of waters, and domestic and industrial exploitation of shore properties. Accelerated eutrophication causes negative changes in plant and animal life – harmful, adverse changes that often interfere with use of water, detract from natural beauty, and reduce property values."* [10] Inputs of nitrogen and phosphorus lead to over-enrichment in many of the Nation's waters and constitute a widespread, persistent, and growing problem.[11] Nitrogen and phosphorus pollution in fresh water systems can significantly negatively impact aquatic life and long-term ecosystem health, diversity, and balance.[12] More specifically, high nitrogen and

[9] To be used by living organisms, nitrogen gas must be fixed into its reactive forms; for plants, either nitrate or ammonia (Boyd, C.E. 1979. *Water Quality in Warmwater Fish Ponds*. Auburn University: Alabama Agricultural Experiment Station, Auburn, AL). Eutrophication is defined as the natural or artificial addition of nitrogen and phosphorus to bodies of water and to the effects of added nitrogen and phosphorus (National Academy of Sciences (U.S). 1969. *Eutrophication: Causes, Consequences, Correctives*. National Academy of Sciences, Washington, DC.)

[10] National Academy of Sciences (U.S). 1969. *Eutrophication: Causes, Consequences, Correctives*. National Academy of Sciences, Washington, DC.

[11] GulfBase. 2009. *Bays and Estuaries.* http://www.gulfbase.org/bay/. Accessed April, 2009.; NSTC. 2003. *An Assessment of Coastal Hypoxia and Eutrophication in U.S. Waters*. National Science and Technology Council, Committee on Environment and Natural Resources, Washington, DC. http://coastalscience.noaa.gov/documents/hypoxia.pdf. Accessed July, 2009; USEPA, 2009. National Summary of State Information. U.S. Environmental Protection Agency, Washington, D.C., http://iaspub.epa.gov/waters10/attains_nation_cy.control. Accessed June, 2009.

[12]USEPA, 2006. USEPA. 2006b. *Wadeable Streams Assessment*. EPA 841-B-06-002. U.S. Environmental Protection Agency, Washington, DC; Chesapeake Bay Program, 2009. *Underwater Bay Grasses*.

phosphorus loadings can result in harmful algal blooms (HABs), reduced spawning grounds and nursery habitats, fish kills, and oxygen-starved hypoxic or "dead" zones.[13] Public health concerns related to nitrogen and phosphorus pollution include methanoglobanemia due to impaired drinking water sources from high levels of nitrates, increase in bladder cancer due to possible formation of disinfection byproducts in drinking water, and neurotoxicity and kidney damage due to increased exposure to cyanotoxins produced by harmful algae and cyanobacteria.[14,15] Degradation of water bodies from nitrogen and phosphorus pollution can result in economic costs. For example, given that freshwater fishing in Florida is a significant recreational and tourist attraction generating over six billion dollars annually,[16] degradation of water quality in Florida to the point that sport fishing populations are negatively affected will also negatively affect this important part of Florida's economy. Elevated nitrogen and phosphorus levels can occur locally in a stream or ground water, or can accumulate downstream leading to degraded lakes, reservoirs, and estuaries where fish and aquatic

Comment [MS11]: This paragraph is all about general effects. The next two paragraphs that follow talks about effects specific to Florida. EPAs justification on the 90th is presented in Section III. Also, the portions of this rule that were not remanded, allows for the development of site-specific alternative criteria that can be established where conditions warrant and it is appropriate.

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http://www.chesapeakebay.net/baygrasses.aspx?menuitem=14621. Accessed July, 2009.

[13] NOAA, 2009. *Harmful Algal Blooms.* National Oceanic and Atmospheric Administration, Silver Spring, MD. http://oceanservice.noaa.gov/topics/coasts/hab/. Accessed April, 2009; Tomasko et al., 2005. Spatial and temporal variation in seagrass coverage in Southwest Florida: assessing the relative effects of anthropogenic nutrient load reductions and rainfall in four contiguous estuaries. *Marine Pollution Bulletin* 50: 797-805.; Selman et al., 2008. *Eutrophication and Hypoxia in Coastal Areas: A Global Assessment of the State of Knowledge*. WRI Policy Note No. 1 World Resources Institute, Washington D.C.; Mississippi Rive/Gulf of Mexico Watershed Nutrient Task Force, 2008. *Gulf Hypoxia Action Plan 2008 for Reducing, Mitigating and Controlling Hypoxia in the Northern Gulf of Mexico and Improving Water Quality in the Mississippi River Basin*. Washington, D.C.

[14] Villanueva, C.M. et al., 2006. Bladder Cancer and Exposure to Water Disinfection By-Products through Ingestion, Bathing, Showering, and Swimming in Pools. *American Journal of Epidemiology* 165(2):148-156.

[15] USEPA. 2009. *What is in Our Drinking Water?*. United States Environmental Protection Agency, Office of Research and Development. < http://www.epa.gov/extrmurl/research/process/drinkingwater.html>. Accessed December 2009.

[16] Florida Fish and Wildlife Conservation Commission. 2010. *The economic impact of freshwater fishing in Florida*. <http://www.myfwc.com/CONSERVATION/Conservation_ValueofConservation_EconFreshwaterImpact.htm>. Accessed August 2010.

life can no longer survive or spawn and the designated use is no longer supported. For additional information on the sources, impacts (e.g., human health, aquatic life, environmental) and economic implications of nitrogen and phosphorus pollution, please refer to the December 6, 2010 final rule.[17]

Comment [MS12]: See comment MS4

Florida's flat topography causes water to move slowly over the landscape, allowing ample opportunity for nitrogen and phosphorus to be transported offsite and result in eutrophication. Florida's warm and wet, yet sunny, climate further contributes to increased run-off and ideal temperatures for subsequent eutrophication responses.[18] As outlined in EPA's January 2009 determination, water quality degradation resulting from excess nitrogen and phosphorus loadings is a documented and significant environmental issue in Florida. For example, the Florida Department of Environmental Protection (FDEP) *2008 Integrated Water Quality Assessment* notes: "the close connection between surface and ground water, in combination with the pressures of continued population growth, accompanying development, and extensive agricultural operations, present Florida with a unique set of challenges for managing both water quality and quantity in the future. After trending downward for 20 years, phosphorus levels again began moving upward in 2000, likely due to the cumulative impacts of nonpoint source pollution associated with increased population and development. Increasing pollution from urban stormwater and agricultural activities is having other significant effects. In many springs across the State, for example, nitrate levels have increased dramatically (two-fold to three-fold) over the past 20 years, reflecting the close link between surface and ground

Comment [MS13]: See comment MS4

[17] 75 FR 75762, December 6, 2010. Water Quality Standards for the State of Florida's Lakes and Flowing Waters.
[18] Perry, W. B. 2008. Everglades restoration and water quality challenges in south Florida. *Ecotoxicology* 17:569-578.

water."[19] To clarify current nitrogen and phosphorus pollution conditions in Florida, EPA analyzed recent STORET (STOrage and RETrieval) data pulled from Florida's Impaired Waters Rule (IWR),[20] which are the data Florida uses to create its integrated reports, and found increasing levels of nitrogen and phosphorus compounds in Florida waters over 12 years (1996-2008). Florida's IWR STORET data indicates that levels of total nitrogen (i.e., State-wide average) have increased by 20% from 1996 to 2008, and total phosphorus levels (i.e., State-wide average) have increased by 40% over the same time period.

The combination of the factors reported by FDEP and listed earlier (including population increase, climate, stormwater runoff, agriculture, and topography) has contributed to significant harmful, adverse effects from nitrogen and phosphorus pollution (nutrient pollution) to Florida's waters.[21] In the most recent Florida Department of Environmental Protection (FDEP) water quality assessment report, the *Integrated Water Quality Assessment for Florida: 2012 305(b) Report and 303(d) List Update*, FDEP describes widespread water quality impairment in Florida due to nitrogen and phosphorus pollution. FDEP's 2012 report[22] identifies approximately 1,918 miles of rivers and streams (about 14 percent of assessed river and stream miles), 378,435 acres of lakes (about 31 percent of assessed lake acres), 754 square miles (482,560 acres) of estuaries (about 14 percent of assessed estuarine area) and 102 square miles (65,280

[19] FDEP. 2008. Integrated Water Quality Assessment for Florida: 2008 305(b) Report and 303(d) List Update.
[20] IWR Run 40. Updated through February 2010.
[21] FDEP. 2008. Integrated Water Quality Assessment for Florida: 2008 305(b) Report and 303(d) List Update.
[22] FDEP. 2012. Integrated Water Quality Assessment for Florida: 2012 305(b) Report and 303(d) List Update. (May 2012). Florida Department of Environmental Protection, Division of Environmental Assessment and Restoration, Tallahassee, FL. <http://www.dep.state.fl.us/water/docs/2012_integrated_report.pdf>. Accessed August 2012

acres) of coastal waters (about 1.6 percent of assessed coastal waters) as impaired by nutrients. In addition, the same report indicates that 1,108 miles of rivers and streams (about 8 percent of assessed river and stream miles) and 107 square miles (68,480 acres) of lakes (about 5 percent of assessed lake square miles) are impaired due to nutrient pollution.

For additional information regarding the prevalence of nutrient pollution in various water bodies in Florida and negative implications of nutrient pollution in State waters, please refer to the December 6, 2010 final rule.[23]

B. Statutory and Regulatory Background

Section 303(c) of the CWA (33 U.S.C. 1313(c)) directs states to adopt WQS for their navigable waters. Section 303(c)(2)(A) and EPA's implementing regulations at 40 CFR part 131 require, among other things, that state WQS include the designated use or uses to be made of the waters and criteria that protect those uses. EPA regulations at 40 CFR §131.11(a)(1) provide that states shall "adopt those water quality criteria that protect the designated use" and that such criteria "must be based on sound scientific rationale and must contain sufficient parameters or constituents to protect the designated use." In addition, 40 CFR §131.10(b) provides that "[i]n designating uses of a waterbody and the appropriate criteria for those uses, the state shall take into consideration the water quality standards of downstream waters and ensure that its water quality standards provide for the attainment and maintenance of the water quality standards of downstream waters."

[23] 75 FR 75762, December 6, 2010. Water Quality Standards for the State of Florida's Lakes and Flowing Waters.

States are required to review their WQS at least once every three years and, if appropriate, revise or adopt new standards. (*See* CWA section 303(c)(1)). Any new or revised WQS must be submitted to EPA for review and approval or disapproval. (*See* CWA section 303(c)(2)(A) and (c)(3)). In addition, CWA section 303(c)(4)(B) authorizes the Administrator to determine, even in the absence of a state submission, that a new or revised standard is needed to meet CWA requirements. The EPA approved the State of Florida's rules ~~for streams~~ on November 30, 2012. The criteria proposed in this rulemaking protect the uses designated by the State of Florida and implement Florida's narrative nutrient provision at Subsection 62-302-530(47)(b), F.A.C. for the purposes of the CWA, into numeric values that apply to flowing waters not covered by the State's Rule outside of the South Florida Region and DPVs to ensure the attainment and maintenance of the water quality standards of downstream lakes.[24] For a thorough review of the statutory and regulatory background for this proposed rule, refer to the December 6, 2010 final rule.

Comment [MS14]: Accepted comment and edits

Comment [MS15]: Accepted strikeout

C. Water Quality Criteria

Under CWA section 304(a), EPA periodically publishes criteria recommendations (guidance) for use by states in setting water quality criteria for particular parameters to protect recreational and aquatic life uses of waters. Where EPA has published recommended criteria, states have the option of adopting water quality criteria based on EPA's CWA section 304(a) criteria guidance, section 304(a) criteria guidance modified to reflect site-specific conditions, or other scientifically defensible

[24] The criteria finalized in this rulemaking do not address or implement Florida's narrative nutrient provision at Subsection 62-302.530(47)(a), F.A.C. Subsection 62-302.530(47)(a), F.A.C., remains in place as an applicable WQS for CWA purposes.

methods. (*See* 40 CFR §131.11(b)(1)). For nutrient pollution, EPA has published under CWA section 304(a) a series of peer-reviewed, national technical approaches and methods regarding the development of numeric nutrient criteria for lakes and reservoirs,[25] rivers and streams,[26] and estuarine and coastal marine waters.[27] For an overview of EPA's recommended approaches for deriving numeric nutrient criteria in Florida lakes and flowing waters, please refer to the December 6, 2010 final rule.[28] EPA believes that numeric nutrient criteria will expedite and facilitate the effective implementation of Florida's existing point and non-point source water quality programs under the CWA in terms of timely water quality assessments, TMDL development, NPDES permit issuance and, where needed, Basin Management Action Plans (BMAPs) to address nitrogen and phosphorus pollution.

D. EPA Determination Regarding Florida and EPA's Rulemaking

On January 14, 2009, EPA determined under Clean Water Act (CWA) section 303(c)(4)(B) that new or revised water quality standards (WQS) in the form of numeric water quality criteria are necessary to protect the designated uses from nitrogen and phosphorus pollution that Florida has set for its Class I and Class III waters. EPA's determination is available at the following website:

http://www.epa.gov/waterscience/standards/rules/fl-determination.htm

[25] USEPA. 2000a. *Nutrient Criteria Technical Guidance Manual: Lakes and Reservoirs.* EPA-822-B-00-001. U.S. Environmental Protection Agency, Office of Water, Washington, DC.
[26] USEPA. 2000b. *Nutrient Criteria Technical Guidance Manual:Rivers and Streams.* EPA-822-B-00-002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.
[27] USEPA. 2001. *Nutrient Criteria Technical Manual: Estuarine and Coastal Marine Waters*. EPA-822-B-01-003. U.S. Environmental Protection Agency, Office of Water, Washington, DC.
[28] 75 FR, 75762, December 6, 2010. Water Quality Standards for the State of Florida's Lakes and Flowing Waters.

On August 19, 2009, EPA entered into a Consent Decree with Florida Wildlife Federation, Sierra Club, Conservancy of Southwest Florida, Environmental Confederation of Southwest Florida, and St. Johns Riverkeeper, committing to the schedule stated in EPA's January 14, 2009 determination to propose numeric nutrient criteria for lakes and flowing waters in Florida by January 14, 2010, and for Florida's estuarine and coastal waters by January 14, 2011, unless the State submits and EPA approves new or revised water quality standards pursuant to section 303(c)(3).[29] The Consent Decree also required that EPA sign a notice of final rulemaking for the respective proposals by October 15, 2010, for lakes and flowing waters, and by October 15, 2011, for estuarine and coastal waters, unless the State submits and EPA approves new or revised water quality standards pursuant to section 303(c)(3). The Consent Decree, which became effective on December 30, 2009, also included a commitment to develop numeric DPVs to protect downstream lakes and estuaries. To review the bases for EPA's determination, and the information it considered in making its determination, please see the December 6, 2010 final rule.

Comment [MS16]: Accepted addition

Comment [MS17]: Accepted addition

Comment [MS18]: This sentence added in response to OMB comment to provide more information.

Comment [MS19]: See additional sentence above.

E. EPA Promulgation of the Final Rule and Subsequent Litigation

In accordance with the January 14, 2009 determination, the August 19, 2009 Consent Decree, and subsequent revisions to that Consent Decree, EPA signed a notice of final rulemaking establishing numeric nutrient criteria for streams, lakes, and springs in the State of Florida[30] on November 14, 2010. As stated in the final rule at 40 CFR

[29] Florida Wildlife Federation, Inc., et. al. v. Jackson, Case 4:08-cv-00324-RH-WCS, Doc. 90-2 (N.D.Fla. August 25, 2009).
[30] For purposes of this rule, EPA has distinguished South Florida as those areas south of Lake Okeechobee and the Caloosahatchee River watershed to the west of Lake Okeechobee and the St. Lucie watershed to the

§131.43(f), the rule was scheduled to take effect on March 6, 2012, except for the site-specific alternative criteria (SSAC) provision at 40 CFR §131.43(e), which took effect on February 4, 2011. EPA selected the March 6, 2012 effective date for the criteria part of the rule to allow time for EPA to work with stakeholders and the Florida Department of Environmental Protection (FDEP) on important implementation issues, to help the public and all affected parties better understand the final numeric nutrient criteria and the basis for those criteria, and for EPA to engage and support, in full partnership with FDEP, the general public, stakeholders, local governments, and sectors of the regulated community across the State in a process of public outreach education, discussion, and constructive planning. 75 FR 75787. The effective date was subsequently extended (77 FR 13497 and 77 FR 39949) such that the current effective date of the rule is January 6, 2013. In addition to this proposal, EPA has proposed to stay the December 6, 2010 final rule (75 FR 75762) to November 15, 2013 (See http://water.epa.gov/lawsregs/rulesregs/florida_inland.cfm)

Following the publication of the rule in the Federal Register on December 6, 2010, 12 cases were filed in the U.S. District Court for the Northern District of Florida challenging the rule. The cases, consolidated before Judge Robert Hinkle in the Tallahassee Division of the Northern District, were filed by environmental groups, Florida's State Department of Agriculture, the South Florida Water Management District, and various industry/discharger groups. The challenges alleged that EPA's determination and final rule were arbitrary, capricious, an abuse of discretion, and not in accordance

east of Lake Okeechobee, hereinafter referred to as the South Florida Region. Numeric criteria applicable to flowing waters in the South Florida Region will be addressed in the second phase of EPA's rulemaking regarding the establishment of estuarine and coastal numeric criteria. (Please refer to Section I.B for a discussion of the water bodies affected by this rule).

with the law for a variety of reasons. Oral argument in the case was held on January 9, 2012 before Judge Hinkle.

On February 18, 2012, the Court upheld EPA's January 2009 determination and the final numeric nutrient criteria for Florida's lakes and springs, as well as the site-specific alternative criteria (SSAC) provisions and the provisions for calculating DPVs using either modeling or a default option for an impaired lake that is not attaining its numeric nutrient criteria. See February 18, 2012 Court Order. For EPA's numeric nutrient criteria for flowing waters (i.e., streams) and the default option to calculate DPVs for unimpaired lakes based on ambient stream nutrient concentrations at the point of entry to the lake, the Court found that EPA had not provided sufficient information in its final rule explaining why or how the criteria or DPV protect against harmful increases, as opposed to any increase, in nutrients. The Court observed that EPA's scientific approach to deriving streams criteria (i.e., the reference condition approach), including the criteria's duration and frequency components, "are matters of scientific judgment on which the rule would survive arbitrary-or-capricious review." Order at 63. The Court also found, however, that EPA had not explained in sufficient detail how the streams criteria would prevent a "harmful increase in a nutrient level". Order at 63. In addition, the Court found that EPA had not explained in sufficient detail how exceedances of the default DPV for unimpaired lakes would lead to "harmful effects" in the downstream lake. Order at 63. Thus, the Court invalidated these two aspects of EPA's final rule and remanded them to the Agency for further action.

Comment [MS20]: See comment MS4

The Court ordered that the upheld portions of EPA's final rule be codified at 40 CFR §131.43 with the exceptions of the streams criteria and the default DPV for

unimpaired lakes. Order at 85. For the exceptions, the Court ordered: "By May 21, 2012, the Administrator must sign for publication a proposed rule, or sign for publication a final rule, that sets numeric nutrient criteria for Florida streams that are not in the South Florida region. By May 21, 2012, the Administrator must sign for publication a proposed rule, or sign for publication a final rule, that sets default downstream-protection criteria for unimpaired lakes, unless by that date the Administrator has filed a notice that she has decided not to propose or adopt such criteria, together with an explanation of the decision." Order at 85. After the May 21, 2012 deadline was jointly extended by the parties to June 4, 2012, on May 30, 2012, the court granted EPA's request to further extend the deadline for signing a proposed rule to November 30, 2012. The court also ordered that EPA must sign a notice of final rulemaking by August 31, 2013. In accordance with the Court's Order, EPA is proposing numeric nutrient criteria for Florida's streams and three default approaches for deriving DPVs for unimpaired lakes (and impaired lakes) with this proposed rule.

F. Florida Adoption of Numeric Nutrient Criteria and EPA Approval

On June 13, 2012, the Florida Department of Environmental Protection (FDEP) submitted new and revised water quality standards for review by the EPA pursuant to section 303(c) of the CWA. These new and revised water quality standards are set out primarily in Rule 62-302 of the Florida Administrative Code (F.A.C.) [Surface Water Quality Standards]. FDEP also submitted amendments to Rule 62-303, F.A.C. [Identification of Impaired Surface Waters], which sets out Florida's methodology for assessing whether waters are attaining State water quality standards. On November 30,

2012, EPA approved the provisions of these rules submitted for review that constitute new or revised water quality standards (referred to in this preamble as the "newly approved state water quality standards"). These newly-approved state water quality standards include provisions that set forth numeric interpretations of the narrative nutrient criterion in paragraph 62-302.530(47)(b), F.A.C. for streams (Subsection 62-302.531(2)(c), F.A.C) that meet a specific definition (Section 62-302.200(36), F.A.C.).

The numeric interpretation for stream protection in Florida's newly approved water quality standards uses biological information in combination with nutrient thresholds. Stream protection is achieved if (1) various measures of aquatic plant growth (e.g., "floral metrics") indicate "no imbalances" and EITHER (2) measures of the faunal stream community health called the Stream Condition Index (SCI) is above a certain threshold OR (3) the nutrient thresholds for total phosphorus (TP) and total nitrogen (TN) for the relevant region are met. The nutrient thresholds in Florida's newly approved water quality standards are identical to the "stand-alone" streams criteria in this proposed rule. EPA's approval document is included in the set of materials provided in the docket for this proposed rule (Docket number EPA-HQ-OW-2009-0596, www.regulations.gov).

Comment [MS21]: See comment MS4

III. Numeric Criteria for Flowing Waters and Downstream Protection of Lakes in the State of Florida

A. Introduction

In the December 2010 final rule, using the reference condition approach, EPA promulgated numeric nutrient criteria for Florida's streams based on the concentrations of total nitrogen (TN) and total phosphorus (TP) observed in a sample of least-disturbed

streams. EPA set the numeric nutrient criteria so that the annual average concentrations of TN and TP most often observed in reference sites that are known to support the designated uses would not exceed the criteria. The court, however, found that EPA failed to explain "how the 90% mark correlates with a *harmful* increase in nutrients" (as opposed to *any* increase in nutrients). Order at 65. The court noted that it "may well be that there is a sufficient correlation" that above the criteria concentrations "harmful change is likely." Order at 66. However, the court found that EPA had not adequately explained its decision and remanded to EPA for further action.[31]

In response to the court's remand, EPA has conducted a comprehensive review of available scientific data and information to more fully document the likelihood of harmful change occurring in the natural populations of aquatic flora and fauna of Florida streams at TN and TP concentrations above the proposed numeric nutrient criteria in today's proposal. EPA conducted this review to confirm whether its proposed numeric nutrient criteria are established at TN and TP concentrations sufficient (i.e., necessary) to protect against "harmful" change in the biota.

EPA's review confirmed its original decision that the criteria the Agency published in December 2010 were set at the appropriate levels to protect the applicable designated uses and translate Florida's narrative nutrient criterion for the purposes of the CWA. EPA has re-selected the upper percentile of annual average TN and TP

[31] As set out more fully in a subsequent section, EPA set criteria concentrations at the 90th percentile of the reference condition distribution in four of the five nutrient watershed regions defined in Florida. In the fifth region, known as the West Central region, EPA set criteria concentrations at the 75th percentile of the reference distribution. For ease of reference, where EPA refers to the "upper percentile" or the "90th percentile" in this preamble, unless the reference relates specifically to the basis for the criteria in the four nutrient watershed regions where EPA selected the 90th percentile, EPA is referring to both the 90th percentile that was applied in four regions and the 75th percentile that was applied in the West Central region.

concentrations from its sample of reference sites as the level that the Agency is confident will avoid "harmful" increases in TN and TP, and thus a level at which designated uses are protected in Florida's streams. The reference sites (described more fully in the following sections) are least-disturbed and more closely represent minimally-impacted conditions associated with a natural population of flora and fauna. By selecting a criterion-magnitude that was exceeded only 10% of the time[32] on an annual average basis in the reference sites that were determined to support designated uses, EPA is confident that other streams attaining and maintaining those levels of TN and TP would also support applicable designated uses and not experience harmful change in the biota. EPA is, therefore, proposing TN and TP criteria at the same levels as EPA promulgated in the December 2010 final rule.

Comment [MS22]: See comment MS4

In its decision, the court, in discussing numeric criteria translating Florida's narrative criterion, stated that "the right target was a criterion that would identify a *harmful* increase in a nutrient level – an increase that, in the language of Florida's narrative criterion, would create an 'imbalance' in flora and fauna." Order at 63. That language could be read as requiring identification of the exact point where harmful change, or imbalance of flora or fauna, occurs as the appropriate level for numeric nutrient criteria. EPA evaluated whether available data allow derivation of criteria with such precision to set the criteria at a level where any increase at all would result in an imbalance of flora and fauna, and therefore impairment of Florida's designated uses. As set out more fully in subsequent sections, EPA concluded the data did not allow derivation of criteria with such precision. In order to derive criteria with such precision, it

Comment [MS23]: See comment MS4

[32] In the West Central Region, EPA selected a criterion-magnitude that was exceeded only 25% of the time on an annual average basis across all sites.

would be necessary to have sufficient data to precisely model (either statistically or mechanistically) the stressor- response relationship in each stream reach within the State, due to the various confounding factors that introduce variability into that relationship within a given stream reach. Because EPA did not have such data available, EPA was not able to pinpoint the exact level at which any increase in nitrogen and phosphorus concentrations at all would result in such imbalance and designated use impairment.

Comment [MS24]: See comment MS4

In determining appropriately protective criteria, EPA must ensure that such criteria comply with the CWA. The CWA envisions that water quality standards will be developed, based on available scientific knowledge and information, at levels that are sufficient to protect designated uses. See CWA section 303(c)(2)(A). 40 CFR §131.11(a)(1). The record supports EPA's conclusion that its proposed numeric streams criteria are based on sound scientific rationale and will protect Florida's designated uses. If commenters are aware of available data and/or information demonstrating that setting criteria at less stringent levels than those in this proposed rule would be protective of designated uses and protect against harmful increases of TN and TP, or that criteria must be set at more stringent levels in order to protect designated uses and protect against harmful increases of TN and TP, commenters should submit such scientific information and analyses to EPA during the comment period for EPA's consideration.

Finally, EPA's approach to deriving numeric nutrient criteria is consistent with FDEP's approach to interpreting its narrative nutrient criterion and deriving numeric thresholds at the State level. FDEP recently established numeric interpretations of the State's narrative nutrient criterion.[33] FDEP has approached the derivation of numeric TN

[33] See FDEP's Rule 62-302.531, F.A.C. at:

and TP threshold values for streams in much the same way as EPA by aiming to prevent adverse effects to natural populations of aquatic flora and fauna.[34] To set protective numeric threshold values for streams for TN and TP where the data were not available to ascertain an accurate quantifiable stressor-response relationship for streams, FDEP utilized a reference condition approach similar to the reference condition approach that EPA utilized in the December 2010 final rule. In the absence of a positive showing that some higher level of nutrients still protects designated uses and against harmful change in the biota in a particular stream, or a showing that some lower level of nutrients is needed to protect designated uses and natural populations of biota in a particular stream, both FDEP and EPA have determined that the upper percentile of reference streams is an appropriate and protective level of nutrients to properly protect designated uses and avoid any adverse change in natural populations of aquatic flora or fauna. In addition, EPA included a Site Specific Alternative Criteria ("SSAC") provision in its December 2010 final rule for adoption of alternative criteria if a demonstration could be made that more or less stringent criteria are warranted for individual waters. Similarly, FDEP included a provision in its rule for adoption of SSAC, as well as a provision for adoption of other site-specific interpretations for individual waters.

Comment [MS25]: Information specific to the effect of nutrients in Florida streams is located in Section II.A. See also the discussion on harmful effects specific to Florida streams in Section III.C.3. Also, the portions of this rule that were not remanded, allows for the development of site-specific alternative criteria that can be established where conditions warrant and it is appropriate

Along with this proposed rule, EPA is providing a technical support document that discusses in more detail the scientific basis for the proposed criteria for streams and the

http://www.dep.state.fl.us/water/wqssp/nutrients/docs/meetings/62_302_final.pdf, accessed on April 27, 2012.

[34] *State of Florida Numeric Nutrient Criteria Development Plan*, Prepared by: Bureau of Assessment and Restoration Support, Division of Environmental Assessment and Restoration, Florida Department of Environmental Protection Tallahassee, FL, March 2009; *Technical Support Document: Development of Numeric Nutrient Criteria for Florida Lakes and Streams*. Florida Department of Environmental Protection, Standards and Assessment Section, June 2009; *Technical Support Document: Development of Numeric Nutrient Criteria for Florida Lakes, Spring Vents and Streams*. Florida Department of Environmental Protection, Standards and Assessment Section, 2012.

default options to determine DPVs for unimpaired lakes. The technical support document helps explain how EPA's proposed numeric streams criteria would prevent harmful increases in TN and TP concentrations, which was specifically discussed by the Court in its decision invalidating EPA's numeric streams criteria and default DPV for unimpaired lakes.[35]

B. EPA Derivation of Numeric Nutrient Criteria for Streams

1. Components of Water Quality Criteria

Water quality criteria include three components. The first component is "magnitude," the concentration of a pollutant that can be maintained over time in the ambient receiving water without adversely affecting the designated use that the criteria is intended to support. The second component is "duration," or the time period over which exposure is averaged (i.e., the averaging period) to limit the duration of exposure to elevated concentrations. This accounts for the variability in the quality of the ambient water due to variations of constituent inputs, stream flow, and other factors. The third component is "frequency," or how often the magnitude/duration condition may be exceeded and still protect the designated use. Combining the criterion-magnitude with the duration and frequency prevents the allowance of harmful effects by ensuring compensating periods of time during which the concentration is below the criterion-magnitude. Where criterion-magnitudes are exceeded for short periods of time or infrequently, water bodies can typically recover; that is, designated uses are typically protected. Designated uses are typically not protected when criteria-magnitudes are

[35] "Technical Support Document for EPA's Proposed Rule for Numeric Nutrient Criteria to Protect Florida's Streams and the Downstream Protection of Unimpaired Lakes" ("EPA Proposed Rule TSD for Florida's Streams and DPV for Unimpaired Lakes").

exceeded for longer periods of time (i.e., for longer than the specified duration) or more frequently (i.e., more often than the allowed frequency). [36]

Use of this magnitude-duration-frequency format allows for some exceedances of the criteria-magnitude concentrations while still protecting applicable designated uses, which is important for pollutants such as nitrogen and phosphorus because their concentrations can vary naturally in the environment. The duration and frequency values associated with the numeric streams criteria EPA is proposing today are the same as those associated with the numeric criteria in EPA's December 2010 rule. For more information on the basis for these duration and frequency components, see 75 Fed. Reg. 75776-77.

2. Selection of Target for Numeric Nutrient Criteria

In evaluating the appropriate endpoint for deriving numeric nutrient criteria, EPA first looked at Florida's applicable designated uses since, as mentioned in the previous sections, water quality criteria must be sufficient to protect the designated uses. CWA 303(c)(2)(A); 40 CFR § 131.11(a)(1). The designated uses established by Florida for its streams include Class I (for potable water supply) and Class III (recreation, propagation and maintenance of a healthy, well-balanced population of fish and wildlife). Fla. Admin. Code 62-302.400. EPA next looked to Florida's narrative nutrient criterion, which represents Florida's determination of what is protective of the Class I and III designated uses.[37] That criterion provides that "in no case shall nutrient concentrations of a body of

[36] Water Quality Standards Handbook: Second Edition, Chapter 3 – Water Quality Criteria. EPA-823-B-94-005a. USEPA. 1994; Technical Support Document for Water Quality-based Toxics Control. Appendix D – Duration and Frequency. EPA/505/2-90-001. USEPA 1991.

[37] Florida's narrative nutrient criterion also serves to protect their Class II waters for propagation and harvesting of shellfish, which will be covered under EPA's forthcoming rulemaking efforts for estuarine and coastal waters.

water be altered so as to cause an imbalance of natural populations of aquatic flora and fauna". Fla. Admin. Code 62-302.530(47)(b). As set out more fully in subsequent sections, in deriving the numeric nutrient criteria to protect against concentrations of TN and TP that will create an imbalance of natural populations of aquatic flora and fauna and, thus, ensure the protection of the designated uses in Florida's streams, EPA used the reference condition approach.

Comment [MS26]: See comment MS4.

Unlike for streams, for Florida's lakes the Agency was able to accurately quantify a stressor-response relationship between TN and TP concentrations and harmful, adverse effects in those waters. EPA used that stressor-response information to derive numeric nutrient criteria, promulgated in the December 2010 final rule, to protect designated uses for Florida's lakes. EPA did not establish the numeric lake criteria exactly at the point where nutrient pollution is demonstrated to adversely affect all lakes at all times, as that would not be protective of all lakes. Rather, EPA established the numeric lake criteria at concentrations that were known to protect against harmful, adverse effects by protecting and maintaining the expected trophic state[38] (by meeting protective chlorophyll-*a* concentrations for either oligotrophic or mesotrophic conditions) for the majority of lakes. At the same time, EPA allows higher concentrations within a given range if there is a positive showing that some higher concentrations of TN and TP still maintain the protective chlorophyll-*a* concentrations, and thus still protect the designated uses in a particular lake.[39] The court upheld EPA's numeric nutrient criteria for Florida's lakes in its February 18, 2012 Order.

[38] Tropic state describes the nitrogen and phosphorus levels and algal state of an aquatic system: oligotrophic (low nitrogen/phosphorus and algal productivity), mesotrophic (moderate nitrogen/phosphorus and algal productivity), and eutrophic (high nitrogen/phosphorus and algal productivity).
[39] Additionally, the SSAC provision at §131.43(e) is also available if it determined that concentrations

For Florida's streams, as stated in the previous section, EPA determined that the scientific data and information available were insufficient to establish accurate quantifiable relationships between TN and TP concentrations and harmful, adverse effects in streams due to confounding factors that affect the chemical and biological responses to nutrient pollution in streams, such as shading from canopy and stream velocity. Thus, in spite of the substantial data collected over many years, EPA could not use the stressor-response approach to establish the numeric streams criteria at concentrations that protect against harmful adverse effects by protecting and maintaining a given biological response at a protective level measured in streams. Therefore, EPA relied upon the reference condition approach as described in more detail in Section III.C of this preamble to identify TN and TP concentrations that protect the designated uses, and above which harmful, adverse effects are likely to occur in the majority of Florida streams. At the same time, EPA allows alternative criteria be set at higher or lower concentrations through the use of the SSAC provision, if there is a positive showing that higher or lower concentrations of TN and TP are sufficient or necessary to protect the designated uses in a particular stream. The following sections set forth how EPA determined that the numeric streams criteria in today's proposal are set at the appropriate level to protect against a harmful, adverse effects due to increased TN and TP concentrations.

Comment [MS27]: See comment MS4

C. Reference Condition Approach for Developing Numeric Nutrient Criteria for Streams

outside of the range are necessary to protect the designated uses in a particular lake.

The reference condition approach, a long-standing peer-reviewed methodology published by EPA, was designed to develop protective numeric nutrient criteria where reference conditions can be confidently defined. [40] The reference condition approach, which has been well documented, peer reviewed, and developed in a number of different contexts,[41,42,43,44,45,46] is used to derive numeric nutrient criteria that are protective of applicable designated uses by identifying TN and TP concentrations occurring in least-disturbed, healthy streams that are supporting designated uses. The core scientific basis for EPA's use of the reference condition approach to derive the proposed numeric nutrient criteria for Florida's streams is outlined in EPA's December 2010 final rule[47] and final December 2010 rule TSD.[48] Briefly, EPA screened and evaluated water chemistry data from more than 11,000 samples from over 6,000 sites Statewide. EPA also evaluated biological data consisting of more than 2,000 samples from over 1,100 Florida streams. EPA then selected a reference set of streams where the Agency was confident

[40] USEPA. 2000. Nutrient Criteria Technical Guidance Manual: Rivers and Streams. EPA–822–B–00–002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.; USEPA-SAB. 2011. *Review of EPA's draft Approaches for Deriving Numeric Nutrient Criteria for Florida's Estuaries, Coastal Waters, and Southern Inland Flowing Waters*. U.S. Environmental Protection Agency, Science Advisory Board, Washington, DC.
[41] USEPA. 2000a. *Nutrient Criteria Technical Guidance Manual: Lakes and Reservoirs.* EPA-822-B-00-001. U.S. Environmental Protection Agency, Office of Water, Washington, DC.
[42] USEPA. 2000b. *Nutrient Criteria Technical Guidance Manual: Rivers and Streams.* EPA-822-B-00-002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.
[43] Stoddard, J. L., D. P. Larsen, C. P. Hawkins, R. K. Johnson, and R. H. Norris. 2006. Setting expectations for the ecological condition of streams: the concept of reference condition. *Ecological Applications* 16:1267 – 1276.
[44] Herlihy, A. T., S. G. Paulsen, J. Van Sickle, J. L. Stoddard, C. P. Hawkins, L. L. Yuan. 2008. Striving for consistency in a national assessment: the challenges of applying a reference-condition approach at a continental scale. *Journal of the North American Benthological Society* 27:860 – 877.
[45] U.S. EPA. 2001. Nutrient Criteria Technical Manual: Estuarine and Coastal Marine Waters. Office of Water, Washington, DC. EPA-822-B-01-003.
[46] USEPA-SAB. 2011. *Review of EPA's draft Approaches for Deriving Numeric Nutrient Criteria for Florida's Estuaries, Coastal Waters, and Southern Inland Flowing Waters*. U.S. Environmental Protection Agency, Science Advisory Board, Washington, DC.
[47] Final rule can be found at: http://edocket.access.gpo.gov/2010/pdf/2010-29943.pdf or 75 Federal Register 75762 (December 6, 2010).
[48] Final rule TSD can be found at: www.regulations.gov, Docket # EPA-HQ-OW-2009-0596.

that designated uses are protected. Finally, EPA selected an upper percentile of the data distribution associated with those reference streams as the stream criterion-magnitude. While developing the December 2010 final rule, EPA met and consulted with FDEP expert scientific and technical staff on numerous occasions as part of an ongoing collaborative process. EPA carefully considered and evaluated the technical approaches and scientific analysis that FDEP presented as part of its July 2009 draft numeric nutrient criteria,[49] as well as FDEP's numerous comments on different aspects of EPA's proposed January 2010 final rule.

Comment [MS28]: See comment MS4

In addition, the Agency also received and carefully considered substantial stakeholder input from 13 public hearings in six Florida cities during the 2010 comment period. EPA reviewed and evaluated further analysis and information included in the more than 22,000 comments on the January 2010 proposal and an additional 71 comments on the August 2010 supplemental notice and request for comment. Finally, in reviewing its 2010 application of the reference condition approach for purposes of this proposal, EPA also considered FDEP's current rule, along with the technical approaches and scientific analysis supporting that rule, submitted to EPA on June 13, 2012.[50]

1. Selection of Reference Sites

[49] FDEP. 2009. *Draft Technical Support Document: Development of Numeric Nutrient Criteria for Florida's Lakes and Streams.* Florida Department of Environmental Protection, Standards and Assessment Section. Available electronically at: http://www.dep.state.fl.us/water/wqssp/nutrients/docs/tsd_nutrient_crit.docx. Accessed October 2010.

[50] *State of Florida Numeric Nutrient Criteria Development Plan*, Prepared by: Bureau of Assessment and Restoration Support, Division of Environmental Assessment and Restoration, Florida Department of Environmental Protection Tallahassee, FL, March 2009; *Technical Support Document: Development of Numeric Nutrient Criteria for Florida Lakes, Spring Vents and Streams*. Florida Department of Environmental Protection, Standards and Assessment Section, 2012.

This section summarizes how EPA applied the reference condition approach in developing the December 2010 rule, including how EPA selected the set of reference sites and how it aggregated data associated with those stream segments. EPA classified Florida streams into five stream regions based on similar geographical and watershed characteristics. The proposed numeric streams criteria would apply to five separate stream Nutrient Watershed Regions (NWRs): Panhandle West, Panhandle East, North Central, West Central and Peninsula (north of Lake Okeechobee, including the Caloosahatchee River Watershed to the west and the St. Lucie Watershed to the east).

To derive numeric nutrient criteria for streams, EPA first identified biologically healthy sites that exhibited the least amount of human disturbance and that were known to support designated uses, i.e., support natural populations of aquatic flora and fauna. EPA applied several screening factors to ensure these sites reflected least-disturbed, biologically healthy conditions. The screening factors included landscape development intensity index (LDI) scores less than 2.0 (an indicator of lower impact surrounding land use), average nitrate concentrations less than 0.35 mg/L (an indicator of lower anthropogenic nitrogen concentrations), exclusion of waters that are identified as water quality-limited for nutrients and/or dissolved oxygen on Florida's EPA-approved CWA section 303(d) list, and an FDEP-derived index of the stream macroinvertebrate community (stream condition index, or SCI) where average scores are greater than 40 (an indicator of a healthy macroinvertebrate community). The result of this rigorous analysis was a set of reference sites that, although not pristine, reflected healthy conditions that were supporting designated uses, and thus free from harmful, adverse effects on natural populations of aquatic flora and fauna due to nutrient pollution. EPA has confidence that

these reference sites are supporting designated uses and natural populations of flora and fauna, and, as set out more fully in Section III.C.2, has confidence that if the TN and TP concentrations are attained or maintained at the concentrations that are among the highest observed at these sites, then designated uses and natural populations of aquatic flora and fauna will be protected in other streams. Additionally, as discussed further in Section III.C.3, additional lines of evidence from the available scientific data and information support EPA's conclusion in that they indicate that harmful, adverse effects are likely to occur to natural populations of aquatic flora and fauna at levels higher than these concentrations.

In remanding EPA's streams criteria, the Court preliminarily concluded that EPA's technical and scientific approaches in deriving streams criteria based on the reference condition approach were defensible. Specifically, the Court reasoned: "Each side criticizes the Administrator's implementation of this approach. Thus, for example, each side criticizes the Administrator's selection of sample streams. The environmental parties criticize the duration and frequency components. These are matters of scientific judgment on which the rule would survive arbitrary-or-capricious review". Order at 63.

2. Selection of Stream Criterion-Magnitude

After selecting the reference set of streams, EPA then examined the statistical distributions of the data associated with stream sites that passed all of the screening factors in order to identify an appropriate criterion-magnitude to protect designated uses and natural populations of aquatic flora and fauna. EPA organized the data (TN and TP values) and calculated the geometric mean of the annual geometric mean of TN and TP

concentrations for each stream segment that contained reference sites. EPA used all samples from reference sites within a given stream segment in a given year to calculate the annual geometric mean for that stream segment. EPA used the geometric mean of these annual geometric means for each stream segment so that each stream segment represents one average concentration in the distribution of concentrations for each NWR. EPA used geometric means for all averages because concentrations were log-normally distributed. EPA then identified specific statistics, or percentiles, associated with each stream NWR reference condition data distribution as the stream criterion-magnitude for that region.[51] Based on the effectiveness of the data quality screens in four of five NWRs, EPA has concluded that the 90th percentile of annual average concentrations would be protective. EPA could not use all of the screening factors outlined in Section III.C.1. in the previous section in order to identify reference sites in the remaining region, the West Central Region, because the use of those screens resulted in the identification of only one stream segment as a reference site. For this reason, EPA utilized only the SCI and 303(d) listed screens to identify reference conditions in the West Central NWR, and this approach does not rely on a quantitative assessment of potential human disturbance through the use of surrounding land cover analysis of stream corridor and watershed land development indices. Because of the use of fewer data screens to identify reference conditions in that NWR and EPA's attendant lower confidence that these sites are least-disturbed conditions that support designated uses and natural populations of aquatic flora

[51] For the West Central region, where reference sites were identified using only the SCI approach, there is less confidence that these sites are least-disturbed and represent minimally-impacted conditions. Unlike in the other NWRs, this approach does not rely on a quantitative assessment of potential human disturbance through the use of surrounding land cover analysis of stream corridor and watershed land development indices, among other things. Therefore, because of the lower confidence level, EPA is proposing the streams criteria in the West Central region using a more conservative percentile of 75% rather than the upper end percentile of 90% of the distribution from the SCI sites.

and fauna, EPA has determined the 75th percentile of annual average concentrations, rather than the 90th percentile, is the protective criterion-magnitude for that region. For the remaining stream regions, EPA considers the 90th percentile of the annual average concentrations observed in the reference condition distribution as an appropriate concentration to specify the criterion-magnitude because the Agency is confident that theses least-disturbed sites more closely represent minimally-impacted, biologically healthy reference conditions, which support the State's Class I and III designated uses.

However, the Court found that EPA did not provide sufficient rationale explaining why it chose the 90th percentile (75th percentile in the West Central) of the reference site data distribution as the stream criterion-magnitude. That is, EPA did not explain why increasing nutrient levels above the upper percentile of annual average concentrations measured in reference condition streams would result in harmful, adverse effects on natural populations of aquatic flora and fauna in Florida's streams. The Court reasoned: "The Administrator apparently concluded only that an increase above this level ordinarily causes a change in flora and fauna—not that it causes a harmful change. If there is a basis in sound science for disapproving a nutrient increase that causes any increase in flora and fauna, not just a harmful increase, the Administrator did not cite it. And even if the Administrator's conclusion was that an increase in nutrients to a level above the 90th percentile ordinarily causes a harmful change in flora and fauna, the Administrator again did not cite a sound science basis for the conclusion." Order at 7.

For all stream regions, EPA could have selected a criterion-magnitude at the 75th percentile of the frequency distribution of concentrations at reference sites, or any lower percentile of the frequency distribution of the general population of a stream class (i.e.,

"all-streams" population from impaired to least-impacted), to derive the numeric criteria as recommended by EPA's published streams criteria guidance.[52] EPA selected the 90th percentile. EPA found support in an EPA nutrient criteria guidance manual that recommends percentiles from the 75th to the 95th percentile of the frequency distribution of the reference population, where the higher percentile values are "best used to define the criteria when there is great confidence that the group of reference waters truly reflects reference conditions as opposed, for example, to best available condition."[53]

The selection of the 90th percentile reflects EPA's level of confidence that these least-disturbed sites more closely represent minimally-impacted conditions, while not set at the extreme upper end of the distribution (95th or 100th percentile). This is because these highest observed annual average concentrations (i.e., 95th or 100th percentile) have rarely been observed at any reference site and are most likely to be heavily influenced by extreme event factors (e.g., hurricanes, droughts). Thus these highest observed concentrations could be outliers that are not representative of conditions that would typically support designated uses and natural populations of aquatic flora and fauna. Therefore, EPA has less confidence that such highest observed concentrations would continue to be supportive of designated uses and natural populations of aquatic flora and fauna if maintained in all streams at all times.

Alternatively, the selection of a much lower percentile, such as a representation of the central tendency of the distribution (i.e., 50th percentile), would not be appropriate because it would imply that half of the conditions observed at reference sites would not

[52] US EPA. 2000b. Nutrient Criteria Technical Guidance Manual: Rivers and Streams. EPA-822-B-00-002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.
[53] US EPA. 2007. Nutrient Criteria Technical Guidance Manual: Wetlands. EPA-822-R-07-004. U.S. Environmental Protection Agency, Office of Water, Washington, DC.

support designated uses and natural populations of aquatic flora and fauna, when EPA's analysis indicates that they do. For the West Central Region, EPA relied on the75th percentile due to the Agency's lower level of confidence as discussed in more detail in the previous section. By setting the criteria at these concentrations, EPA believes the designated uses, i.e., natural populations of aquatic flora and fauna, will be protected when these concentrations are attained in the majority of the streams in the regions. For those streams that are shown to accommodate or require higher or lower concentrations, the SSAC provision is provided in EPA's rule as discussed in Section III.C.5.

EPA has concluded, after its reevaluation of the reference condition data set and the resulting reference site data distributions of annual average TN and TP concentrations that EPA continues to have confidence that the upper percentile of annual average nutrient concentrations observed in the reference sites will support designated uses and natural populations of aquatic flora and fauna. As explained in the prior section, based on its evaluation of available scientific data and information, EPA used its best professional judgment and published guidance to conclude that TN and TP concentrations in excess of these values are not likely to protect designated uses and natural populations of aquatic flora and fauna. Additionally, as discussed in a subsequent section, EPA's review of additional lines of evidence from the available scientific data and information, including past scientific analyses, new analyses, and the peer-reviewed scientific literature, all support the conclusion that harmful, adverse effects on natural populations of aquatic flora and fauna from excess nitrogen and phosphorus are more likely to occur if concentrations increase above the proposed streams criteria set at these upper percentiles of reference conditions.

3. Harmful, Adverse Effects Due to Exceedence of EPA's Proposed Streams Criteria

Additional lines of evidence from empirical stressor-response analyses and the peer-reviewed scientific literature, which indicate that harmful, adverse effects are likely to occur to natural populations of aquatic flora and fauna due to exceedances of the proposed streams criteria,[54] support EPA's conclusion that the upper percentile of the reference condition data distribution is the appropriate nutrient criterion-magnitude for Florida's streams.

In developing this proposal, EPA reviewed the empirical, stressor-response analyses between nutrients and different biological response indicators (e.g., algal biomass, SCI) conducted prior to promulgation of the December 2010 final rule, and also reviewed any new analyses. The results of these analyses support the Agency's conclusion that harmful, adverse effects to natural populations of aquatic flora and fauna are likely to occur if TN and TP concentrations increase above the proposed streams criteria.[55]

Three technical support documents[56] in the Agency's original rulemaking record and the technical support document associated with this proposed rule include scientific

[54] USEPA. 2000. Nutrient Criteria Technical Guidance Manual: Rivers and Streams. EPA–822–B–00–002. U.S. Environmental Protection Agency, Office of Water, Washington, DC.
[55] *Technical Support Document for EPA's Proposed Rule for Numeric Nutrient Criteria to Protect Florida's Streams and Downstream Lakes*. USEPA, 2012.
[56] *Technical Support Document: Development of Numeric Nutrient Criteria for Florida Lakes and Streams*. Florida Department of Environmental Protection, Standards and Assessment Section, June 2009; *Proposed Methods and Approaches for Developing Numeric Nutrient Criteria for Florida's Inland Waters*. U.S. EPA 2009; *Technical Support Document for U.S. EPA's Proposed Rule for Numeric Nutrient Criteria for Florida's Inland Surface Fresh Waters*. U.S. EPA 2010.

analyses demonstrating that harmful changes or adverse effects are more likely to happen as TN and TP concentrations increase above EPA's proposed streams criteria.

The effects of TN and TP on an aquatic ecosystem are well understood and documented. There is a substantial and compelling scientific basis for the conclusion that excess TN and TP will have adverse effects on streams.[57,58,59,60,61,62,63,64,65,66,67,68,69,70,71] As discussed in Section II in the earlier section, excess nitrogen and phosphorus in streams, like other aquatic ecosystems, increase vegetative growth (plants and algae), and change the assemblage of plant and algal species present in the system. Notwithstanding the difficulty associated with identifying the TN and TP concentrations that are known to

[57] Biggs, B.J.F. 2000. Eutrophication of streams and rivers: dissolved nutrient–chlorophyll relationships for benthic algae. *Journal of the North American Benthological Society* 19:17–31
[58] Bothwell, M.L. 1985. Phosphorus limitation of lotic periphyton growth rates: an intersite comparison using continuous-flow troughs (Thompson River system, British Columbia). *Limnology and Oceanography* 30:527–542
[59]Bourassa, N., and A. Cattaneo. 1998. Control of periphyton biomass in Laurentian streams (Quebec). *Journal of the North American Benthological Society* 17:420–429
[60] Bowling, L.C., and P.D. Baker. 1996. Major cyanobacterial bloom in the Barwon-Darling River, Australia, in 1991, and underlying limnological conditions. *Marine and Freshwater Research* 47: 643–657
[61] Cross, W. F., J. B. Wallace, A. D. Rosemond, and S. L. Eggert. 2006. Whole-system nutrient enrichment increases secondary production in a detritus-based ecosystem. *Ecology* 87: 1556–1565
[62] Dodds, W.K., and D.A. Gudder. 1992. The ecology of Cladophora. *Journal of Phycology* 28:415–427
[63] Elwood, J.W., J.D. Newbold, A.F. Trimble, and R.W. Stark. 1981. The limiting role of phosphorus in a woodland stream ecosystem: effects of P enrichment on leaf decomposition and primary producers. *Ecology* 62:146–158
[64] Francoeur, S.N. 2001. Meta-analysis of lotic nutrient amendment experiments: detecting and quantifying subtle responses. *Journal of the North American Benthological Society* 20: 358–368
[65] Moss, B., I. Hooker, H. Balls, and K. Manson. 1989. Phytoplankton distribution in a temperate floodplain lake and river system. I. Hydrology, nutrient sources and phytoplankton biomass. *Journal of Plankton Research* 11: 813–835
[66] Mulholland, P.J. and J.R. Webster. 2010. Nutrient dynamics in streams and the role of J-NABS. *Journal of the North American Benthological Society* 29: 100-117
[67] Peterson, B.J., J.E. Hobbie, A.E. Hershey, M.A. Lock, T.E. Ford, J.R. Vestal, V.L. McKinley, M.A.J. Hullar, M.C. Miller, R.M. Ventullo, and G. S. Volk. 1985. Transformation of a tundra river from heterotrophy to autotrophy by addition of phosphorus. *Science* 229:1383–1386
[68] Rosemond, A. D., P. J. Mulholland, and J. W. Elwood. 1993. Top-down and bottom-up control of stream periphyton: Effects of nutrients and herbivores. *Ecology* 74: 1264–1280
[69] Rosemond, A. D., C. M. Pringle, A. Ramirez, and M.J. Paul. 2001. A test of top-down and bottom-up control in a detritus-based food web. *Ecology* 82: 2279–2293
[70] Rosemond, A. D., C. M. Pringle, A. Ramirez, M.J. Paul, and J. L. Meyer. 2002. Landscape variation in phosphorus concentration and effects on detritus-based tropical streams. *Limnology and Oceanography* 47: 278–289
[71] Slavik, K., B. J. Peterson, L. A. Deegan, W. B. Bowden, A. E. Hershey, J. E. Hobbie. 2004. Long-term responses of the Kuparuk River ecosystem to phosphorus fertilization. *Ecology* 85: 939 – 954

protect against harmful effects by protecting and maintaining a given biological response at a protective level measured in Florida's streams, the available science clearly indicates that adverse responses to nutrient pollution occur.

For example, excess nitrogen and phosphorus promote the increased growth of opportunistic and short-lived plant species that die quickly, leaving more dead vegetative material available for consumption by lower tropic levels. Excess nitrogen and phosphorus can promote the increased growth of less palatable nuisance algae species that result in less food available for filter feeders. These negative changes can alter the habitat structure by covering the stream or river bed with periphyton (attached algae), and/or clogging the water column with phytoplankton (floating algae), both of which can adversely affect natural or desirable aquatic life. Excess nitrogen and phosphorus can also lead to the increased growth of algae that produce toxins that can be toxic to fish, invertebrates, and humans. Chemical characteristics of the water, such as pH and concentrations of dissolved oxygen (DO), can be affected by excess nitrogen and phosphorus, leading to low DO conditions and hypoxia that cannot support aquatic life. All of these adverse effects change the balance of the natural populations of aquatic flora and fauna expected to occur. In turn, each of these negative changes can lead to other negative changes in the stream community and ecology and, ultimately, to harmful, adverse effects to the overall function of the linked aquatic ecosystem and subsequent failure to support designated uses.

In light of this well-established paradigm, EPA reviewed the latest peer-reviewed scientific literature and found many nutrient thresholds where harmful, adverse effects in streams are coincident with or occur above EPA's proposed streams criteria. In these

examples, there are regional and site-specific factors (e.g., precipitation, temperature, flow) that may account for the differences in the nutrient threshold concentrations, but, in general, EPA's proposed streams criteria are consistent with the range of thresholds of harmful, adverse effects documented in the peer-reviewed scientific literature. For example, TN and TP concentrations ranging between 0.659-0.714 mg/L and 0.048-0.071 mg/L, respectively, have been associated with moderate levels of productivity, or mesotrophy, in rivers and streams.[72] Higher concentrations of nutrients lead to eutrophy, which is what numeric nutrient criteria, in general, are intended to prevent. As another example, increases in suspended chlorophyll-*a*, decreases in water clarity, and decreases in macroinvertebrate and fish abundance in Wisconsin rivers and streams were observed over a TN and TP range of 0.5-2.0 mg/L and 0.035-0.150 mg/L, respectively.[73] Adverse increases in productivity (i.e., organic matter supply), also known as eutrophication, can negatively alter the metabolism of aquatic systems and lead to adverse environmental conditions such as depressed dissolved oxygen concentrations that cannot support aquatic life. These conditions, in turn, can harm macroinvertebrate and fish communities, creating changes to the balance of the natural populations of these aquatic fauna. The TN and TP concentrations above which these adverse effects are more likely to occur are coincident with EPA's proposed streams criteria TN and TP concentrations.

Many of the thresholds reported in the latest peer-reviewed scientific literature vary in comparison to the proposed criteria for Florida's streams due to site- and

[72] Dodds, W.K. 2006. Eutrophication and trophic state in rivers and streams. *Limnol. Oceanogr.* 51(1):671-680.
[73] Robertson, D.M., B.M. Weigel, and D.J. Graczyk. 2008. Nutrient concentrations and their relations to the biotic integrity of nonwadeable rivers in Wisconsin. US Geological Survey and US Department of the Interior professional paper 1754; Robertson, D.M., D.J. Graczyk, P.J. Garrison, L. Wang, G. LaLiberte, and R. Bannerman. 2006. Nutrient concentrations ant their relations to the biotic integrity of wadeable streams in Wisconsin. US Geological Survey and US Department of the Interior professional paper 1722.

regional-specific factors such as climate and stream flow. However, the nutrient concentrations reported in the literature demonstrate and confirm that harmful, adverse effects occur as TN and TP concentrations increase in streams and are likely to occur as concentrations increase above the criteria concentrations that EPA has selected for Florida streams. EPA considers the association of the TN and TP concentrations with documented harmful, adverse effects to be compelling and supportive of this proposed rule. For a complete list of comparable nutrient thresholds reported in the scientific literature, see "*EPA Proposed Rule TSD for Florida's Streams and DPVs for Unimpaired Lakes*" (Chapter 1, Scientific Literature).

4. Additional evidence of harmful effects in Florida streams above EPA's proposed criteria

In addition to reviewing the peer-reviewed scientific literature mentioned in the prior section, EPA reviewed analyses conducted by FDEP that demonstrated that excess nitrogen and phosphorus adversely affect streams. In its technical support document for deriving numeric nutrient criteria, FDEP stated: "The results of the analyses generally indicate that many of the biological measures evaluated exhibit a statistically significant adverse response to nutrient pollution; however, the relationships between the biological response variables and nutrient levels were confounded by numerous other factors such as color, pH, conductivity, and canopy cover. While DEP believes the effect of nutrients on the biological communities is not clear enough to be used as the sole basis for establishing numeric nutrient criteria, the observed relationships between nutrients and the various biological measures demonstrate the need for nutrient criteria to prevent

adverse biological effects in Florida streams. While the analysis in this chapter did not produce numeric thresholds that could be used as water quality criteria, the relationships that were determined, while relatively weak, do support the values derived using the Nutrient Benchmark Approach. Both the analysis of the Rapid Periphyton Survey (regarding probability of increased algal thickness) and the analysis of the second change point in the stream periphyton response to nutrients indicate that the biological response to nutrient enrichment will generally occur at levels higher than the values generated using the Benchmark Distribution Approach".[74]

EPA has reviewed the available periphyton data in Florida streams and has verified that a harmful, adverse increase in the amount of algal coverage (> 6 mm thick over more than 25% of the stream bottom) will be substantially more likely as concentrations of TN and TP increase above EPA's proposed numeric streams criteria. This adverse biological response represents harmful, adverse changes to the natural populations of aquatic flora that occur as concentrations increase above the protective values in EPA's proposed numeric streams criteria. For more information on the likelihood of increases in the amount of algal coverage at varying concentrations of TN and TP, see "*EPA Proposed Rule TSD for Florida's Streams and DPVs for Unimpaired Lakes*" (Chapter 1, Stressor-Response Relationships).

EPA also reviewed the available stream fauna data, specifically FDEP's multi-metric index of stream macroinvertebrates (e.g., insect larvae, worms), which FDEP developed as an indicator of stream health.[75] The index, called the stream condition index

[74] *Technical Support Document: Development of Numeric Nutrient Criteria for Florida Lakes, Spring Vents and Streams*. Florida Department of Environmental Protection, Standards and Assessment Section, 2012, p. 110-111.
[75] *Technical Support Document for EPA's Proposed Rule for Numeric Nutrient Criteria to Protect*

(SCI), is a generic index, indicating the aggregate impact of human disturbance on stream macroinvertebrates. It measures the number and diversity of various invertebrate taxa (i.e., individuals sharing the same general identity) and was not designed to be uniquely responsive to nutrients, but nutrients may contribute to adverse impacts. The SCI score for a given sample can range between 0 and 100, where 0 represents a highly degraded community and 100 represents the highest quality community. EPA re-analyzed Florida-specific stream data and found that stream macroinvertebrate community index scores predictably decrease below a level EPA and FDEP consider biologically healthy as a function of increasing TN and TP concentrations.

Furthermore, when ambient TN or TP concentrations were greater than EPA's proposed criteria, SCI scores indicated that, on average, faunal populations were imbalanced. For example, SCI scores ranged from 30 to 50 when ambient TP concentrations were equivalent to EPA's proposed TP criteria for each of the five stream NWRs. A SCI score of 50 has been identified by scientific experts to be associated with the loss of rare native taxa and with the replacement of some sensitive or ubiquitous taxa by more pollutant tolerant taxa – this is a level where there is some negative change in the natural populations of aquatic fauna, but is still considered a score that represents a biologically healthy condition; whereas a SCI score of 30 has been associated with unbalanced distribution of major groups from what is expected – this is a level where there is a profound harmful change in the natural populations of aquatic fauna.[76]

EPA applied the average SCI of 40 as one of many screening factors in selecting reference sites that were considered to be biologically healthy. EPA believes an average

Florida's Streams and Downstream Lakes. USEPA, 2012.
[76] *Technical Support Document for U.S. EPA's Final Rule for Numeric Criteria for Nitrogen/Phosphorus Pollution in Florida's Inland Surface Fresh Waters*. U.S. EPA 2010, pp. 49-51.

SCI of 40 is a level where there is some negative change in the natural populations of aquatic fauna, but before profound harmful change has occurred.[77] Following the court's remand of the streams criteria, EPA evaluated data in Florida streams and found that when the nutrient concentrations exceed EPA's proposed numeric streams criteria, the SCI score is 45-70% more likely to be less than 50, meaning that it is more likely that there will be some negative change as TN and TP concentrations increase above EPA's proposed streams criteria. In addition, when the nutrient concentrations exceed EPA's proposed numeric streams criteria, the SCI score is 17-34% more likely to be less than 30, meaning that it is more likely that there will be profound harmful change. Thus, the concentrations of EPA's proposed numeric streams criteria represent levels above which harmful change begins to be more likely. This adverse biological response represents harmful, adverse changes to the natural populations of aquatic fauna that occur at concentrations above the protective values in EPA's proposed numeric streams criteria. For more information on the likelihood of SCI scores at varying concentrations of TN and TP, see "*EPA Proposed Rule TSD for Florida's Streams and DPVs for Unimpaired Lakes*" (Chapter 1, Stressor-Response Relationships).

When considered together and in light of the conclusions drawn by FDEP[78], the previous and new analyses all indicate that a predictable harmful, adverse change (i.e., increase in TN and TP concentrations causing imbalance in natural populations of aquatic flora or fauna) would likely occur if levels of TN and TP exceed the proposed streams criteria.

[77] *Technical Support Document for U.S. EPA's Final Rule for Numeric Criteria for Nitrogen/Phosphorus Pollution in Florida's Inland Surface Fresh Waters*. U.S. EPA 2010.
[78] *Technical Support Document: Development of Numeric Nutrient Criteria for Florida Lakes and Streams*. Florida Department of Environmental Protection, Standards and Assessment Section, June 2009, p. 96.

5. EPA's rule includes the SSAC provision and process to address any uncertainties associated with the reference condition approach

EPA recognizes the uncertainties associated with setting numeric nutrient criteria based on the reference condition approach. The case law is clear, however, that in protecting human health and the environment, EPA can act in light of scientific uncertainty and choose to act proactively. *American Iron & Steel Institute*, 115 F.3d 979, (D.C. Cir. 1997)("[I]t is within EPA's discretion to decide that in the wake of uncertainty, it would be better to give the values a conservative bent rather than err on the other side."). While it was appropriate for EPA to act to adopt numeric nutrient criteria for streams based on the reference condition approach even in the face of some scientific uncertainty, EPA also recognized that site-specific water quality conditions may make it appropriate to adopt either more or less stringent numeric nutrient criteria for a specific water body or set of water bodies. To address those situations, and as discussed previously in this proposal, EPA's December 2010 final rule authorized and established a specific administrative process for adopting, site-specific alternative criteria ("SSAC").

D. Proposed Numeric Criteria for the State of Florida's Streams

EPA is proposing numeric nutrient criteria for TN and TP in five geographically distinct watershed regions of Florida's streams not covered by the State of Florida's Rule classified as Class I or III waters under Florida law (Section 62-302.400, F.A.C.). The proposed TN and TP criteria are listed in Table B-1. The proposed criteria are the same criteria published in EPA's final rule signed on November 14, 2010 and published at 75

FR 75762 (December 6, 2010). For purposes of this proposed rule and in response to the Court's February 18, 2012 order, EPA is proposing these criteria values and explaining how the proposed criteria will ensure the protection of the Florida's Class I and III designated uses by avoiding harmful changes in TN and TP concentrations that would result in an imbalance of natural populations of aquatic flora or fauna. EPA requests comment on its proposed numeric nutrient criteria for Florida's streams and supporting rationale.

Table B-1. EPA's Proposed Numeric Criteria for Florida Streams not covered by the State of Florida's Rule.

Comment [MS29]: See comment MS4

Nutrient Watershed Region	Instream Protection Value Criteria	
	TN (mg/L) *	TP (mg/L) *
Panhandle West [a]	0.67	0.06
Panhandle East [b]	1.03	0.18
North Central [c]	1.87	0.30
West Central [d]	1.65	0.49
Peninsula [e]	1.54	0.12

Watersheds pertaining to each Nutrient Watershed Region (NWR) were based principally on the NOAA coastal, estuarine, and fluvial drainage areas with modifications to the NOAA drainage areas in the West Central and Peninsula Regions that account for unique watershed geologies. For more detailed information on regionalization and which WBIDs pertain to each NWR, see the Technical Support Document.

[a] Panhandle West region includes: Perdido Bay Watershed, Pensacola Bay Watershed, Choctawhatchee Bay Watershed, St. Andrew Bay Watershed, Apalachicola Bay Watershed.

[b] Panhandle East region includes: Apalachee Bay Watershed, and Econfina/Steinhatchee Coastal Drainage Area.

[c] North Central region includes the Suwannee River Watershed.

[d] West Central region includes: Peace, Myakka, Hillsborough, Alafia, Manatee , Little Manatee River Watersheds, and small, direct Tampa Bay tributary watersheds south of the Hillsborough River Watershed.

[e] Peninsula region includes: Waccasassa Coastal Drainage Area, Withlacoochee Coastal Drainage Area, Crystal/Pithlachascotee Coastal Drainage Area, small, direct Tampa Bay tributary watersheds west of the Hillsborough River Watershed, Sarasota Bay Watershed, small, direct Charlotte Harbor tributary watersheds south of the Peace River Watershed, Caloosahatchee River Watershed, Estero Bay Watershed, Kissimmee River/Lake Okeechobee Drainage Area, Loxahatchee/St. Lucie Watershed, Indian River

Watershed, Daytona/St. Augustine Coastal Drainage Area, St. John's River Watershed, Nassau Coastal Drainage Area, and St. Mary's River Watershed.

* For a given waterbody, the annual geometric mean of TN or TP concentrations shall not exceed the applicable criterion concentration more than once in a three-year period.

E. Proposed Numeric Criteria to Ensure the Downstream Protection of the State of Florida's Unimpaired Lakes

Similar to the Court's opinion regarding EPA's streams criteria, the Court found that EPA had not explained in sufficient detail how exceedances of the default DPV for unimpaired lakes would lead to "harmful effects" in the downstream lake. Order at 70. Thus, the Court invalidated the option for establishing default DPVs to protect unimpaired lakes in EPA's final rule and remanded it to the Agency for further action. Order at 85. This proposed rule provides three options for establishing a default DPV for unimpaired lakes and clarifies that the proposed options would ensure the attainment and maintenance of the numeric lake criteria so as to prevent harmful effects from occurring in a downstream lake.

EPA is proposing default DPV approaches for TN and TP that would provide for the attainment and maintenance of downstream water quality standards for Florida's unimpaired lakes pursuant to 40 CFR §131.10(b) when modeling approaches are unavailable. For this proposed rule, EPA is providing for public comment three default approaches available for use when modeling cannot be performed to derive DPVs that ensure the attainment and maintenance of the numeric lake criteria that, in turn, protect the designated uses in Florida's lakes. The default approaches would be applicable to streams that flow into unimpaired lakes, but could also be used for streams that flow into impaired lakes. The default approaches would supplement EPA's promulgated DPVs for

the protection of downstream lakes, which are codified at 40 CFR §131.43(c)(2)(ii), consistent with the February 18, 2012 Court order. Order at 85.

Briefly, EPA's final rule provided that DPVs apply to tributary streams at the point of entry to the lake, also referred to as the pour point. The final rule specified that where sufficient data and information are available, DPVs may be established through application of the BATHTUB model. See 40 CFR §131.43(c)(2)(ii)(B). EPA's final rule also specifically authorizes FDEP or EPA to use a model other than BATHTUB when either FDEP or EPA determines that it would be appropriate to use another scientifically defensible modeling approach that results in the protection of downstream lakes. 40 CFR §131.43(c)(2)(ii)(B). A lake-specific DPV derived through such modeling provides the most refined DPV for a stream at the pour point. Where sufficient information is not available to derive TN and/or TP DPVs using water quality modeling and the lake does not attain the applicable TN, TP, and/or chlorophyll-*a* criteria or is un-assessed, criteria values for TN and/or TP that apply to that lake are to be used as the default DPVs. 40 CFR §131.43(c)(2)(ii)(D). See id. EPA believes that this approach, which the Court upheld, is protective because the TN and TP concentrations entering the lake are unlikely to need to be lower than the criterion concentration necessary to be protective of the lake itself.

In the final rule, water quality modeling was EPA's preferred approach for the derivation of DPVs. Water quality modeling is the most rigorous and most data-demanding method and results in the most refined DPVs. The default methods were intended only for use where there is insufficient data to use a model. While using a default option to develop DPVs requires less data, it also generally leads to more

stringent criteria to account for the uncertainties associated with these less refined approaches.

The rule proposed today provides three options for a default DPV that would apply in cases when there are insufficient data to use a water quality model for any unimpaired lake for which EPA has promulgated numeric nutrient criteria. The three default options EPA is proposing are not intended to supersede or limit the two approaches EPA provided in the final rule, codified at 40 CFR §131.43(c)(2)(ii), which were upheld by the Court. Order at pp. 69-70, 85. Rather, the default options are intended to provide flexibility in deriving a DPV in the situation where there is not sufficient information to develop a DPV using a water quality model. Thus, EPA views the proposed DPV options as supplemental to EPA's other established approaches for deriving DPVs. All three options for default DPVs are designed to ensure that the unimpaired lake criteria would be attained and maintained when the inflowing stream's TN and TP concentrations meet the DPV at the pour point.

The first proposed default option simply utilizes the downstream lake criteria as the DPV applicable at the pour point to the lake. EPA refers readers to 40 CFR §131.43(c)(1) for the applicable TN and TP lake criteria, which would serve as the DPV. EPA believes that this proposed option is protective because it is unlikely that the TN and TP concentrations entering the lake need to be lower than the criterion concentration necessary to be protective of the lake itself.

The second proposed default option uses Florida-specific stream and lake data to empirically link the DPV to the attainment and maintenance of Florida's lake criteria in each of the three lake classes. This option utilizes Florida's extensive stream and lake

data to compute a linear regression model, which relates the inflowing stream TN and TP concentrations to the TN and TP concentrations in the downstream lake. EPA developed a linear regression model for each of the three lake classes based on EPA's lake dataset provided in the final rule and Florida's stream data from its statewide water quality database[79].

The linear regression equation is used to predict what the inflowing stream's TN and TP concentrations need to be in order for the lake concentrations to meet the lake criteria EPA established in the December 6, 2010 final rule. EPA's calculated TN and TP DPVs for each lake class using this approach are provided in Table C-1. The approach is described in further detail in the *EPA Proposed Rule TSD for Florida's Streams and DPVs for Unimpaired Lakes*.

For this proposed option, in circumstances where additional lake and stream data are available, the linear regression equation could be updated using this new data and used to calculate default DPVs that are reflective of newer, more site-specific information.

Table C-1. EPA's proposed DPVs for each lake class using the second default approach.

	Default Option 2	
Lake Class	TN DPV (mg/L)	TP DPV (mg/L)
Colored Lakes	1.59	0.11
Clear, High Alkaline Lakes	1.40	0.09
Clear, Low Alkaline Lakes	0.87	0.06

[79] IWR Run 40.

The third proposed default option utilizes stream data that is spatially linked to and temporally coincident with the downstream lake when it is attaining the applicable lake criteria. This proposed option is a reference condition-based DPV approach that is conditioned upon the downstream lake attaining all applicable numeric nutrient criteria, TN, TP, and chlorophyll-*a*, including the duration and frequency components of the applicable lake criteria. To compute a reference condition-based DPV, the period of record during which the downstream lake was attaining all applicable criteria must be determined. At a minimum, and pursuant to 40 CFR §131.43(c)(1), the lake must not exceed any applicable numeric nutrient criteria, which are expressed as annual geometric means, more than once in a three-year period. If this condition is met, then a DPV for that lake can be computed using TN and TP data from the stream discharging into the lake coincident in time with the period of record when the lake was attaining all applicable numeric nutrient criteria. Because of the hydrologic link between streams and lakes, it follows that nitrogen and phosphorus concentrations in the stream would be sufficient to meet the lake criteria provided that the lake was meeting all applicable numeric nutrient criteria. In general, this approach is less refined compared to the modeling approach EPA promulgated at 40 CFR §131.43(c)(1)(ii)(B) because it does not incorporate the water quality parameters and data that would be necessary to derive a site-specific DPV, for either TN or TP, using a water quality model such as BATHTUB. Nonetheless, EPA believes that the data and information that would support this third approach, in the absence of additional data that would support modeling, is still sufficient to ensure the protection of the downstream lake because of the hydrologic linkage between the stream and downstream lake. A DPV calculated under this option may be more stringent than a

DPV calculated using a water quality model. This default approach is intended to ensure that water quality standards are not only restored when found to be impaired, but are maintained when found to be attained, consistent with the Clean Water Act. Higher levels of TN and/or TP may be allowed in watersheds where it is demonstrated that such higher levels will fully protect the lake's water quality standard. To the extent that it is determined that the default DPV for a given lake tributary is over protective, applying a water quality model as set out in EPA's preferred approach will result in a more refined definition of the DPV for that tributary.

As discussed earlier, the calculation of the DPV using the three default options requires that the lake criteria be explicitly considered. The applicable numeric lake criteria can be found at 40 CFR §131.43(c)(1). EPA recognizes that lake criteria may be modified pursuant to the modified lake criteria provision at 40 CFR §131.43(c)(1)(ii). Where lake criteria are modified in accordance with this provision, the modified criteria would be the applicable criteria in any of the three default DPV approaches. The duration and frequency components of DPV magnitudes computed using the proposed default approaches would be an annual geometric mean not to be exceeded more than once over a three-year period. These components of the proposed approaches align with the duration and frequency of both the numeric lake criteria, codified at 40 CFR §131.43(c)(1), and the streams criteria which are proposed to be codified at 40 CFR §131.43(c)(2).

As in the final rule, protection of downstream lakes using the options described in this proposed rule is accomplished through establishment of a DPV. The applicable criteria for streams that flow into downstream lakes include both the instream criteria for

TN and TP and the DPV, which is a concentration or loading value at the point of entry of a stream into a downstream lake that ensures the attainment and maintenance of the numeric lake criteria. EPA selected the point of entry into the lake as the location to measure water quality because the lake responds to the input from the pour point and all contributions from the stream network above this point in a watershed affect the water quality at the pour point. When a DPV is exceeded at the pour point, the waters that collectively comprise the network of streams in the watershed above that pour point are considered to not attain the DPV for purposes of CWA section 303(d). The State may identify these impaired waters as a group rather than individually.

Contributions of TN and/or TP from sources in stream tributaries upstream of the pour point are accountable to the DPV because the water quality in the stream tributaries must result in attainment of the DPV at the pour point into the lake. The spatial allocation of load within the watershed is an important accounting step to ensure that the DPV is achieved at the point of entry into the lake. How the watershed load is allocated may differ based on watershed characteristics and existing sources (e.g., areas that are more susceptible to physical loss of nitrogen; location of towns, farms, and dischargers), so long as the DPV is met at the point of entry into the downstream lake. Where additional information is available, watershed modeling could be used to develop allocations that reflect hydrologic variability and other water quality considerations. For protection of the downstream lake, what is important is an accounting for nutrient pollution loadings on a watershed scale that results in meeting the DPV at the point of entry into the downstream lake.

As in the December 6, 2010 final rule, this proposal provides that additional DPVs may be established in upstream locations to represent sub-allocations of the total allowable loading or concentration. Such sub-allocations may be useful where there are differences in hydrological conditions and/or sources of TN and/or TP in different parts of the watershed. In addition to the explanations provided earlier, EPA refers the reader to its technical support document associated with the December 6, 2010 final rule for specific information supporting how harmful, adverse effects are more likely to occur in lakes at TN and TP concentrations above the established numeric lake criteria (Chapter 2, Derivation of EPA's Numeric Nutrient Criteria for Lakes).

EPA requests comment on the three proposed default approaches, including whether implementation of DPVs calculated using the default approaches would ensure the attainment and maintenance of the downstream numeric lake criteria in Florida's unimpaired lakes. The proposed default DPV approaches and DPVs are aimed at the protection of unimpaired lakes. However, EPA recognizes that the second and third options may also be appropriate for the protection of impaired lakes and offer additional flexibility to the default DPV approach for impaired lakes, which is codified at 40 CFR §131.43(c)(2)(ii)(D). EPA requests comment on applying the second and third default DPV options to impaired lakes as well as unimpaired lakes. In addition, EPA requests comments on whether the Agency should promulgate default DPV values in addition to default DPV approaches to be used in situations when modeling is unavailable.

F. Applicability of Criteria When Final

EPA proposes that the numeric nutrient criteria for Florida's streams not covered by Florida's Rule and the DPVs for unimpaired lakes described in this rule be effective for CWA purposes 60 days after EPA publishes final criteria, and apply in addition to any other criteria for Class I or Class III waters already adopted by the State and submitted to EPA (and for those adopted after May 30, 2000, approved by EPA). EPA requests comment on this proposed effective date.

In addition to this proposal, EPA has proposed to stay the December 6, 2010 Final Rule[80] (75 FR 75762) to November 15, 2013 (See http://water.epa.gov/lawsregs/rulesregs/florida_inland.cfm) [~~**add link for the stay proposal here**~~]. This date should closely coincide with the effective date of this proposed rule, which is approximately 60 days following the publication of the final rule (i.e., shortly after August 31, 2013).

For water bodies that Florida has designated as Class I and III, any final EPA numeric nutrient criteria will be applicable CWA water quality criteria for purposes of implementing CWA programs including permitting under the NPDES program, as well as monitoring and assessment, and establishment of TMDLs. The proposed criteria in this rule, when finalized, would be subject to Florida's general rules of applicability to the same extent as are other State-adopted and/or federally-promulgated criteria for Florida waters. Furthermore, states have discretion to adopt general policies that affect the application and implementation of WQS (40 CFR 131.13). There are many applications of criteria in Florida's water quality programs. Therefore, EPA believes that it is not

[80] Federal Register, Vol. 75, No. 233, 75762, December 6, 2010. Water Quality Standards for the State of Florida's Lakes and Flowing Waters.

necessary for purposes of this proposed rule to enumerate each of them, nor is it necessary to restate any otherwise generally applicable requirements.

It is important to note that no existing TMDL for waters in Florida will be rescinded or invalidated as a result of finalizing this proposed rule, nor will this proposed rule when finalized have the effect of withdrawing any prior EPA approval of a TMDL in Florida. Neither the CWA nor EPA regulations require TMDLs to be completed or revised within any specific time period after a change in water quality standards occurs. TMDLs are typically reviewed as part of states' ongoing water quality assessment programs. Florida may review TMDLs at its discretion based on the State's priorities, resources, and most recent assessments. NPDES permits are subject to five-year permit cycles, and in certain circumstances are administratively continued beyond five years. In practice, States often prioritize their administrative workload in permits. This prioritization could be coordinated with TMDL review. Because current nutrient TMDLs were established to protect Florida's waters from the effects of nitrogen and phosphorus pollution, the same goal as EPA's numeric nutrient criteria, the Agency believes that, absent specific new information to the contrary, it is reasonable to presume that basing NPDES permit limits on those TMDLs will result in effluent limitations as stringent as necessary to meet the federal numeric nutrient criteria.

IV. Under What Conditions Will Federal Standards Be Either Not Finalized or Withdrawn?

Under the CWA, Congress gave states primary responsibility for developing and adopting WQS for their navigable waters. (*See* CWA section 303(a)-(c)). EPA is

proposing numeric nutrient criteria for flowing waters outside the South Florida Region not covered by the State of Florida's Rule and DPVs for unimpaired lakes to meet the Agency's obligations under the Consent Decree. EPA notes if Florida's Rule will not take effect due to subsection 62-302.531(9), F.A.C., EPA would expect to finalize the criteria in this proposed rulemaking for all flowing waters (i.e., streams) located outside of the South Florida Region that are designated as either Class I or Class III. EPA solicits comment on this potential outcome. EPA recognizes that Florida has exercised the option to adopt and submit to EPA numeric nutrient criteria for some of the State's Class I and many of the State's Class III waters and EPA has approved those criteria as consistent with CWA section 303(c) and implementing regulations at 40 CFR part 131. Consistent with CWA section 303(c)(4), EPA does not intend to proceed with the final rulemaking for those waters for which EPA has approved Florida's criteria, provided that the newly approved State water quality standards will be allowed to go into effect, FDEP will be allowed to implement them consistent with their Implementation Document, and, with respect to numeric DPVs, that the district court modifies the Consent Decree consistent with EPA's amended Determination that numeric DPVs are not necessary to meet CWA requirements in Florida.

EPA is not obligated under the Consent Decree to promulgate regulations setting forth numeric nutrient criteria in all Class I and III lakes and flowing waters if the State of Florida submits and EPA approves new or revised WQS for these waterbodies. EPA approved ~~such~~ revisions on November 30, 2012 and is in discussions with Florida regarding waters not covered by the State's numeric nutrient criteria.

Comment [MS30]: Accepted addition with removal of the word "such".

Pursuant to 40 CFR §131.21(c), if EPA does finalize this proposed rule, the EPA-promulgated WQS would be applicable WQS for purposes of the CWA until EPA withdraws the federally-promulgated standard. Withdrawing the Federal standards for the State of Florida would require rulemaking by EPA pursuant to the requirements of the Administrative Procedure Act (5 U.S.C.551 *et seq*.). EPA would undertake such a rulemaking to withdraw the Federal criteria when EPA is assured that numeric nutrient criteria that fully meet the requirements of section 303(c) of the CWA and EPA's implementing regulations at 40 CFR part 131 are in effect.

Among the newly-approved state water quality standards are numeric criteria for nutrients that apply to a set of streams, as that term is specifically defined in the newly-approved state water quality standards. Under the Consent Decree, EPA is relieved of its obligation to propose numeric criteria for nutrients ~~for any waters for which~~ once after FDEP submits and EPA approves new or revised water quality standards ~~before EPA proposes~~for lakes and flowing waters. Thus, under normal circumstances, EPA would be clearly relieved of its obligation to propose numeric criteria for nutrients ~~in streams~~ Florida covered in its newly-approved state water quality standards. ~~However, another~~ EPA notes that a provision included in Florida's Rule, specifically subsection 62-302.531(9), F.A.C., casts some doubt as to whether the newly approved state water quality standards will go into effect if EPA proposes and promulgates numeric nutrient criteria for streams not covered by the newly approved State water quality standards. Therefore, it is unclear whether an EPA's proposal to "gap fill", or establish numeric criteria for nutrients for Florida streams that FDEP does not cover in its Rule, would trigger 62-302.531(9), F.A.C. and result in Florida's streams criteria not taking effect.

Comment [MS31]: Suggest using "after".

Comment [MS32]: Rejected addition of "lakes and flowing waters". EPA disagrees w/ OIRA's addition. EPA's Consent Decree extends beyond just lakes and streams. Accepting this change would result in a statement that implies the CD only applies to streams.

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Comment [MS33]: Accepted strikeout

Comment [MS34]: Accepted edit.

Comment [MS35]: We do not have the specifics to make adjustments in this section at this time.

In addition, due to a recent administrative challenge~~d~~ filed in the State of Florida Department of Administrative Hearings, there is uncertainty as to whether FDEP will be able to implement its newly approved state water quality standards consistent with FDEP's "Implementation of Florida's Numeric Nutrient Standards" (Implementation Document). ~~EPA approved portions of Florida's new or revised water quality standards based on the Agency's understanding that FDEP will implement the streams criteria as provided in its Implementation Document. .~~ Thus, EPA approved portions of Florida's new or revised water quality standards subject to the State being able to implement them as provided in its Implementation Document. If, as a result of legal challenge, FDEP is unable to implement its Rule as provided in its Implementation Document, EPA would intend to revisit ~~portions of~~ its November 30, 2012 approval of Florida's new or revised water quality standards. EPA has therefore reserved its authority to withdraw or modify ~~portions of~~ that approval.

In light of the above, EPA seeks comment on finalizing a rule that applies EPA's streams criteria to streams meeting EPA's definition of "stream" that are not covered under Florida's numeric interpretation of narrative nutrient criteria at 62-302.531(2)(c), F.A.C. This would serve to fill gaps in coverage if Florida's streams criteria are in effect, or apply to all streams if Florida's streams criteria are not in effect for any reason, including those mentioned above. EPA's ~~current~~ understanding is that it is obligated to propose numeric criteria in streams not covered by 62-302.531(2)(c) F.A.C. under the consent decree. EPA acknowledges that it is possible that there may be approaches that are similarly protective of designated uses in a subset of the uncovered Class III waters and seeks comment on alternatives.

Comment [MS36]: Accepted strikeout.
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Comment [MS37]: Accepted strikeout.

Comment [MS38]: Accepted strikeout
Comment [MS39]: EPA recognizes this is repetitive, but feels it is necessary in order to be very clear and minimize confusion.

~~EPA also seeks comment on alternative "gap filling" measures for waters not covered by numeric nutrient criteria in the State of Florida's rule. Florida recently submitted and EPA approved new or revised WQS for Class I and III lakes and flowing waters. Under the Florida rule, a narrative nutrient standard would continue to provide in-stream protection to some Class III waters (e.g., non-perennial water segments, tidally influenced segments; and ditches, canals and other conveyances that are man-made or predominantly channelized or physically altered, are used primarily for water management purposes, and have marginal or poor stream habitat components), and these waters would benefit from improved protection of downstream waters in Florida's revised WQS.~~

Comment [MS40]: Addition rejected. The would violate the determination and consent decree. EPA's determination addressed the need for numeric nutrient criteria, and EPA remains focused on this approach. It would not be helpful to ask for comment on something contrary to what we're required to do.

Finally, as described in EPA's November 30, 2012 approval of Florida's new or revised water quality standards, while EPA believes that the provisions addressing downstream protection will provide for quantitative approaches to ensure the attainment and maintenance of downstream waters consistent with 40 CFR 131.10(b), the provisions themselves, however, do not consist of numeric values. Because EPA is currently subject to a Consent Decree deadline to sign a rule proposing numeric downstream protection values (DPVs) for Florida by November 30, 2012, EPA is proposing numeric DPVs to comply with the Consent Decree. However, EPA has amended its January 2009 determination to specify that numeric criteria for downstream protection are not necessary and that quantitative approaches designed to ensure the attainment and maintenance of downstream water quality standards, such as those established by Florida, are sufficient to meet CWA requirements. As such, EPA will ask the court to modify the

Consent Decree consistent with the Agency's amended determination, i.e., to not require EPA to promulgate numeric DPVs for Florida. Accordingly, EPA approved the State's downstream protection provisions subject to the district court modifying the Consent Decree to not require EPA to promulgate numeric DPVs for Florida. If the district court agrees to so modify the Consent Decree, EPA will not promulgate numeric DPVs for Florida. However, if the district court declines to so modify the Consent Decree, EPA would intend to promulgate numeric DPVs for Florida and would also expect to revisit its November 30, 2012 approval of the State Rule's downstream protection provisions to modify or withdraw its approval. Therefore, EPA has also reserved its authority to do so in its approval document.

V. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is a "significant regulatory action." Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. Burden is defined at 5 CFR §1320.3(b). It does not include any information collection, reporting, or record-keeping requirements.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this action on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR §121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise that is independently owned and operated and is not dominant in its field.

Under the CWA WQS program, states must adopt WQS for their waters and must submit those WQS to EPA for approval; if the Agency disapproves a state standard and the state does not adopt appropriate revisions to address EPA's disapproval, EPA must promulgate standards consistent with the statutory requirements. EPA also has the authority to promulgate WQS in any case where the Administrator determines that a new

or revised standard is necessary to meet the requirements of the Act. These state standards (or EPA-promulgated standards) are implemented through various water quality control programs including the NPDES program, which limits discharges to navigable waters except in compliance with an NPDES permit. The CWA requires that all NPDES permits include any limits on discharges that are necessary to meet applicable WQS.

Thus, under the CWA, EPA's promulgation of WQS establishes standards that the State implements through the NPDES permit process. The State has discretion in developing discharge limits, as needed to meet the standards. This proposed rule does not itself establish any requirements that are applicable to small entities. As a result of this action, the State of Florida will need to ensure that permits it issues include any limitations on discharges necessary to comply with the standards established in the proposed rule. In doing so, the State will have a number of choices associated with permit writing. While Florida's implementation of the rule may ultimately result in new or revised permit conditions for some dischargers, including small entities, EPA's action, by itself, does not impose any of these requirements on small entities; that is, these requirements are not self-implementing. Thus, I certify that this rule will not have a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act

This proposed rule contains no Federal mandates under the regulatory provisions of Title II of the Unfunded Mandates Reform Act for state, local, or tribal governments or the private sector. The State may use these resulting water quality criteria

in implementing its water quality control programs. This proposed rule does not regulate or affect any entity and, therefore, is not subject to the requirements of sections 202 and 205 of UMRA.

EPA determined that this proposed rule contains no regulatory requirements that might significantly or uniquely affect small governments. Moreover, WQS, including those promulgated here, apply broadly to dischargers and are not uniquely applicable to small governments. Thus, this proposed rule is not subject to the requirements of section 203 of UMRA.

E. Executive Order 13132 (Federalism)

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. EPA's authority and responsibility to promulgate Federal WQS when state standards do not meet the requirements of the CWA is well established and has been used on various occasions in the past. The proposed rule will not substantially affect the relationship between EPA and the states and territories, or the distribution of power or responsibilities between EPA and the various levels of government. The proposed rule will not alter Florida's considerable discretion in implementing these WQS. Further, this proposed rule will not preclude Florida from adopting WQS that EPA concludes meet the requirements of the CWA, after promulgation of the final rule, which would eliminate the need for these Federal

standards and lead EPA to withdraw them. Thus, Executive Order 13132 does not apply to this proposed rule.

Although section 6 of Executive Order 13132 does not apply to this action, EPA had extensive communication with the State of Florida to discuss EPA's concerns with the State's water quality criteria and the Federal rulemaking process. In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and state and local governments, EPA specifically solicits comment on this proposed rule from State and local officials.

F. Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments)

Subject to the Executive Order 13175 (65 FR 67249, November 9, 2000) EPA may not issue a regulation that has tribal implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by tribal governments, or EPA consults with tribal officials early in the process of developing the proposed regulation and develops a tribal summary impact statement.

During its previous rulemaking and development of water quality standards for Florida's lakes and flowing waters, EPA concluded that the rule[81] may have tribal implications. Ultimately, however, EPA felt that the rule would neither impose substantial direct compliance costs on tribal governments, nor preempt Tribal law. Therefore, EPA met with the Seminole Tribe on January 19, 2010 and requested an

[81] 75 FR 75762, December 6, 2010. Water Quality Standards for the State of Florida's Lakes and Flowing Waters.

opportunity to meet with the Miccosukee Tribe to discuss EPA's rule, although a meeting was never requested by the Tribe.

Because this current proposal re-proposes the same numeric nutrient criteria with further explanation on how the criteria will ensure the protection of the Florida's designated uses by avoiding harmful changes in nutrient levels, and provides for the same approaches for determining DPVs as in the final rule with some additional flexibility, EPA determined that tribal consultation will not be needed. However, EPA will specifically solicit additional comment on this proposed rule from tribal officials during the public comment period.

G. Executive Order 13045 (Protection of Children From Environmental Health and Safety Risks)

This action is not subject to EO 13045 (62 FR 19885, April 23, 1997) because it is not economically significant as defined in EO 12866, and because the Agency's promulgation of this rule will result in the reduction of environmental health and safety risks that could present a disproportionate risk to children.

H. Executive Order 13211 (Actions That Significantly Affect Energy Supply, Distribution, or Use)

This rule is not a "significant energy action" as defined in Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 (May 22, 2001)), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer Advancement Act of 1995

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104–113, section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rulemaking does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations)

Executive Order (EO) 12898 (59 FR 7629, Feb. 16, 1994) establishes Federal executive policy on environmental justice. Its main provision directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule does not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it will afford a greater level of protection to both human health and

the environment if these numeric nutrient criteria are promulgated for Class I and Class III waters in the State of Florida.

List of Subjects in 40 CFR Part 131

Environmental protection, Florida, Nitrogen and phosphorus pollution, Nutrients, Water quality standards.

Dated: November 30, 2012

Lisa P. Jackson,

Administrator.

For the reasons set out in the preamble, 40 CFR part 131 is proposed to be amended as follows:

PART 131 – WATER QUALITY STANDARDS

1. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq*.

Subpart D-[Amended]

2. Section 131.43 is amended by:

a. Revising (c)(2)(i).

b. Revising paragraph (c)(2)(ii)(C).

c. Revising paragraph (f).

The revisions read as follows:

§ 131.43 Florida.

*** * * * ***

(c) * * *

(2) *Criteria for streams*.

(i) The applicable instream protection value (IPV) criteria for total nitrogen (TN) and total phosphorus (TP) for streams within each respective nutrient watershed region are shown on Table 2.

Table 2:

Nutrient Watershed Region	Instream Protection Value Criteria	
	TN (mg/L) *	TP (mg/L) *
Panhandle West [a]	0.67	0.06
Panhandle East [b]	1.03	0.18
North Central [c]	1.87	0.30
West Central [d]	1.65	0.49
Peninsula [e]	1.54	0.12

Watersheds pertaining to each Nutrient Watershed Region (NWR) were based principally on the NOAA coastal, estuarine, and fluvial drainage areas with modifications to the NOAA drainage areas in the West Central and Peninsula Regions that account for unique watershed geologies. For more detailed information on regionalization and which WBIDs pertain to each NWR, see the Technical Support Document.

[a] Panhandle West region includes: Perdido Bay Watershed, Pensacola Bay Watershed, Choctawhatchee Bay Watershed, St. Andrew Bay Watershed, Apalachicola Bay Watershed.

[b] Panhandle East region includes: Apalachee Bay Watershed, and Econfina/Steinhatchee Coastal Drainage Area.

[c] North Central region includes the Suwannee River Watershed.

[d] West Central region includes: Peace, Myakka, Hillsborough, Alafia, Manatee, Little Manatee River Watersheds, and small, direct Tampa Bay tributary watersheds south of the Hillsborough River Watershed.

[e] Peninsula region includes: Waccasassa Coastal Drainage Area, Withlacoochee Coastal Drainage Area, Crystal/Pithlachascotee Coastal Drainage Area, small, direct Tampa Bay tributary watersheds west of the Hillsborough River Watershed, Sarasota Bay Watershed, small, direct Charlotte Harbor tributary watersheds south of the Peace River Watershed, Caloosahatchee River Watershed, Estero Bay Watershed, Kissimmee River/Lake Okeechobee Drainage Area, Loxahatchee/St. Lucie Watershed, Indian River Watershed, Daytona/St. Augustine Coastal Drainage Area, St. John's River Watershed, Nassau Coastal Drainage Area, and St. Mary's River Watershed.

* For a given water body, the annual geometric mean of TN or TP concentrations shall not exceed the applicable criterion concentration more than once in a three-year period.

(ii) *Criteria for protection of downstream lakes*.

(A) * * *

(B) * * *

(C) When the State or EPA has not derived a DPV for a stream pursuant to paragraph (c)(2)(ii)(B) of this section, and where the downstream lake attains the applicable chlorophyll-*a* criterion and the applicable TP and/or TN criteria, then the DPV for TN and/or TP will be determined using any of the following options: For the first option, the DPV for TN and/or TP applicable at the pour point to the lake is the applicable TN and/or TP criteria for the downstream lake codified in 40 CFR §131.43(c)(1), similar to paragraph (c)(2)(ii)(D) of this section. For the second option, the

DPV for TN and/or TP applicable at the pour point of the receiving lake is found in Table 3.

Table 3:

	Default Option 2	
Lake Class	TN DPV (mg/L)	TP DPV (mg/L)
Colored Lakes	1.59	0.11
Clear, High Alkaline Lakes	1.40	0.09
Clear, Low Alkaline Lakes	0.87	0.06

For the third option, the DPV for TN and/or TP applicable at the pour point to the lake is computed using TN and TP data from the stream discharging into the lake coincident in time with the period of record when the lake was attaining all applicable nutrient criteria pursuant to 40 CFR §131.43(c)(1). These default approaches supplement EPA's promulgated DPVs for the protection of downstream lakes in paragraphs (c)(2)(ii)(B) and (D) of this section.

~~(f) *Effective date*. This section is effective January 6, 2013 except for §131.43(c)(2)(i) and 131.43(c)(2)(ii)(C), which are effective [INSERT DATE 60 DAYS FROM PUBLICATION OF FINAL RULE IN THE **FEDERAL REGISTER**] and §131.43(e), which is effective February 4, 2011.~~

Comment [MS41]: EPA added a sentence in the preamble. See page 25. The reader can go to the link for more info including how it relates to this proposal.

Comment [MS42]: EPA checked on this to be certain of the proper format and style.