Science in the Administrative Process:
A Study of Agency Decisionmaking Approaches

APPENDICES

Table of Contents

Appendix A: Roland M. Frye, Jr., "The United States Nuclear Regulatory Commission's Use of Scientific and Technical Advisory Committees" Dec. 2011

Appendix B: Roland M. Frye, Jr., "Use of Expert Elicitation at the Nuclear Regulatory Commission" Feb. 16, 2012 [to be inserted later]

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)

Appendix D: Nuclear Regulatory Commission Nonconcurrence Statement filed with respect to Yucca Mountain

Appendix E: Flow Charts of the IRIS Process over the Last Decade, excerpted from Center for Progressive Reform, Corrective Lenses for Iris, Sept.2010, at 6-7.

Appendix F: OMB Comments filed on EPA IRIS Risk Assessment, Dichloromethane (June 2011)

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 to the NRC staff and generally meets with the

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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.

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 1958 and provided that it report to the NRC staff rather

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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*)

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)

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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).

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 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]

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[16] 42 U.S.C. § 2039.

[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.

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.] § 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

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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).

supported by the staff.[31] Conversely, 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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[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 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).
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> 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).
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> 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).
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> 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).

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

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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).

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

the Commission while interim reports and regulatory guidance reviews often go to the Executive Director for Operations.[37]

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

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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.*

[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.

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 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 not, however, offer advice regarding the production aspect of

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[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).

[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:

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

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> 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, 48,623-25 (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).

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:

> 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 . . . .
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> 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]

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[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.

[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.

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) 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

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[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.*

[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.

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 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

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[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.

[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.

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 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

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[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 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).

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 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

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[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).

[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

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 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.

(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.

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

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 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

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

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

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 role in the review and

[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).

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] and, during its lifetime, met at least once with the

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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.

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

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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 renewal, 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

November 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

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10, 1999 Meeting with the Nuclear Power Institute to Discuss the Continued Development of Performance 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).

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 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

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[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.

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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.*

[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]

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

[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).

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 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]

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[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.).

[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).

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

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

[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.).

[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.*

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).

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

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[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.).

[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.

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
- 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

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

[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).

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 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]

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[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).

[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

[to be inserted later]

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

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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.

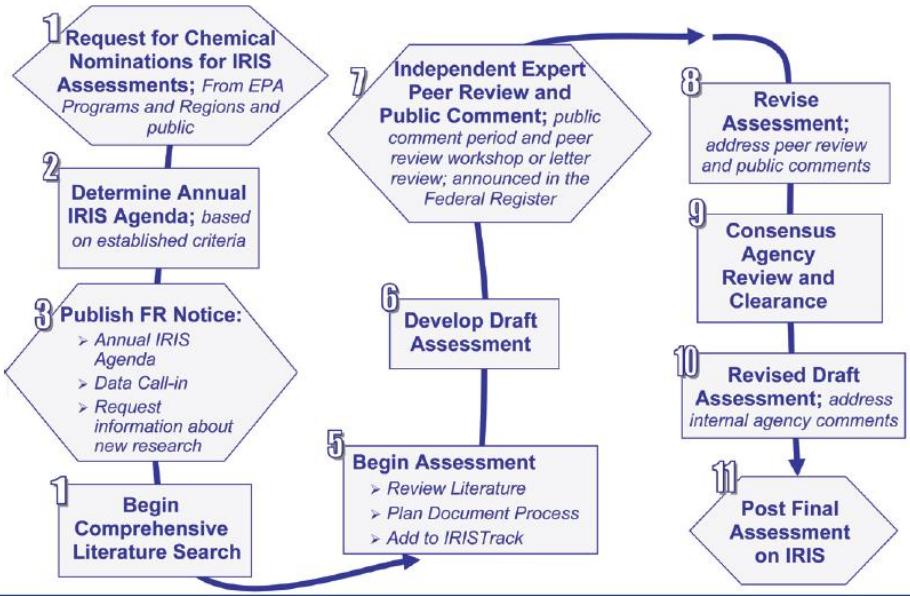

Figure 2: The process after the Bush Administration's first revisions.

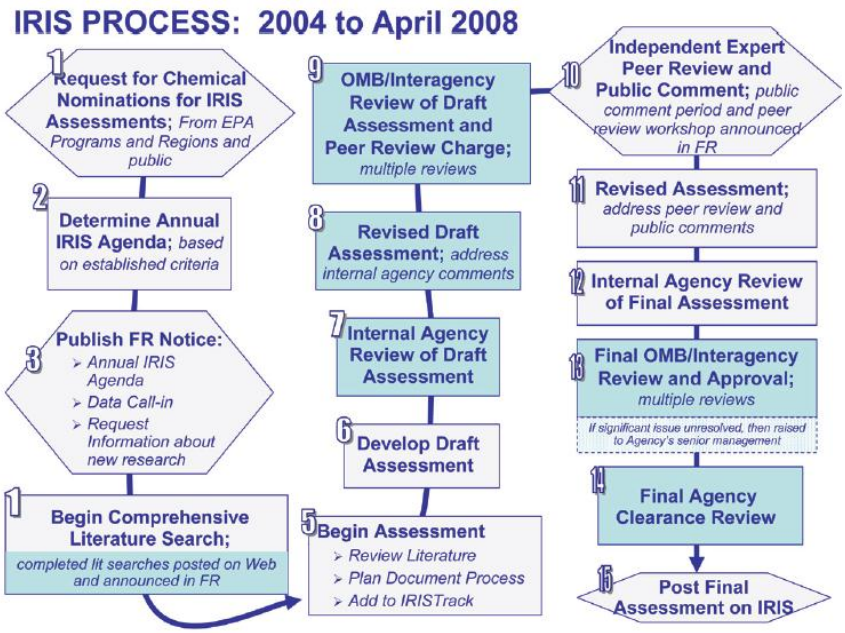

Figure 3: The process after the Bush Administration's second revisions.

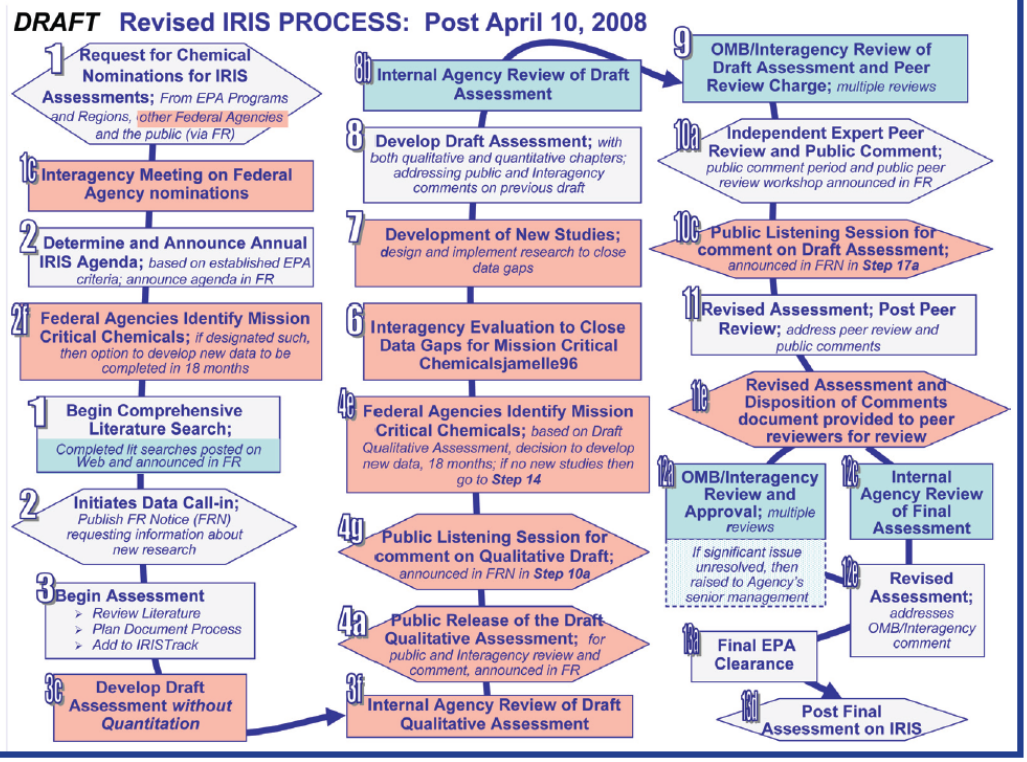

Figure 1,2, & 3: Hearing on Fixing EPA's Broken Integrated Risk Information System, Before the Subcomm. on Oversight and Investigations of the H. Comm. on Science and Technology (Jun. 11, 2009)."

Figure 4: The current process.

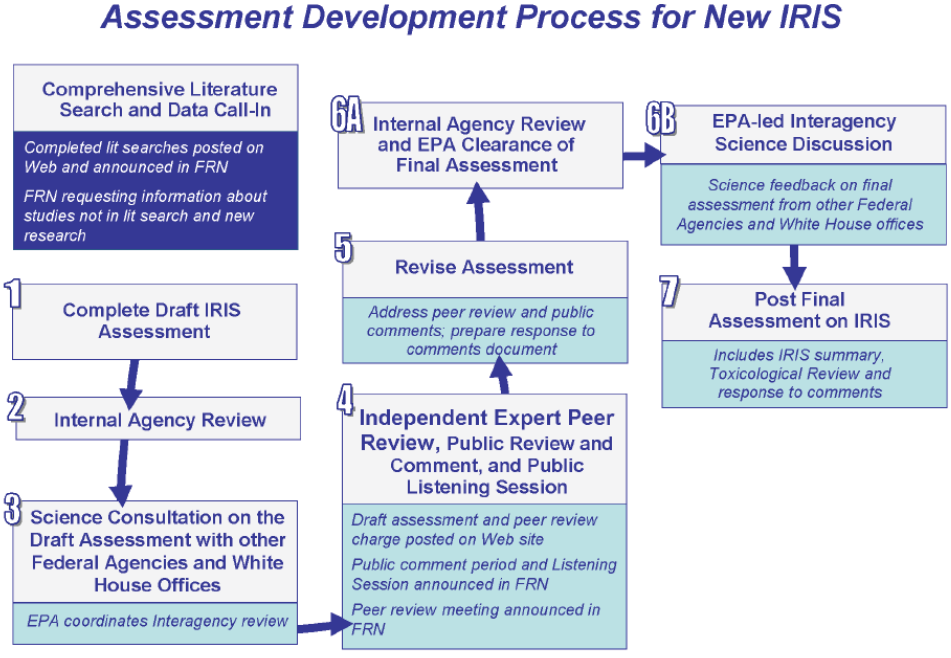

Figure 4: ENVIRONMENTAL PROTECTION AGENCY, NEW PROCESS FOR DEVELOPMENT OF INTEGRATED RISK INFORMATION SYSTEM (May 21, 2009), available at http://epa.gov/iris/process.htm.

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.