

U.S. Environmental Protection Agency
Science Advisory Board
Radiation Advisory Committee (RAC)
Augmented for Review of the Agency's Radiogenic Cancer Risk Assessment
Summary Minutes of Public Conference Call Meeting¹
July 22, 2009

Committee: U.S. Environmental Protection Agency's (EPA's) Science Advisory Board (SAB) Radiation Advisory Committee (RAC) augmented for review of EPA's radiogenic cancer risk assessment. (See Roster - Attachment A)

Date and Time: Wednesday, July 22, 2009 from 1:00 p.m. to 4:00 p.m. eastern daylight time (See Federal Register Notice¹).

Location: This is a conference call with no location announced. All participants were connected via the conference lines.

Purpose: The purpose of this public conference call meeting is to conduct edits^b to the latest (July 15, 2009 working draft) of the augmented RAC. During the public conference call, the augmented RAC will also receive public comments in review of "*EPA's Radiogenic Cancer Risk Models and Projections for the U.S. Population,*" draft December 2008 (also referred to as the "Blue Book").

SAB/Augmented RAC Attendees: Dr. Bernd Kahn, RAC Chair, Dr. Susan Bailey, Dr. Thomas Borak, Dr. Faith Davis, Dr. Brian Dodd, Dr. Shirley A. Fry, Dr. Ethel Gilbert, Dr. William C. Griffith, Dr. Peter Groer, Dr. David Hoel, Dr. Genevieve Matanoski, Dr. William F. Morgan, Dr. Dale Preston, Dr. Genevieve Roessler, and Dr. Daniel Stram being present. (Drs. R. William Field, Richard Hornung, Jonathan Links, and Mr. Bruce Napier were not present.) (See Roster, Attachment A)

Designated Federal Officer: Dr. K. Jack Kooyoomjian, SAB Staff Office

¹ NOTE: Please note that these minutes represent comments that are individual statements and opinions and are not necessarily consensus comments at this stage of the process in the review of any given topic. In all cases, the final SAB report to the EPA Administrator represents the consensus on the topic.

² See the February 27, 2009 conference call minutes pertaining to the beginning of the formal review of this activity, the March 23-25, 2009 face-to-face meeting minutes where the presentations and review took place, the June 18, 2009 teleconference call to review the June 10, 2009 public working draft report, as well as this July 22, 2009 teleconference call to review the July 15, public working draft report.

Agency Staff Attendees: Members of the EPA Office of Radiation and Indoor Air (ORIA) Washington, DC Staff Office included Dr. Mary E. Clark, Dr. David Pawel, and Dr. Jerome Puskin.

Public Attendees: The members of the public included Mr. Douglas P. Guarino, Associate Editor of Inside EPA (Inside Washington Publishers).

Meeting Summary: The meeting followed the issues and general timing as presented in the meeting Agenda². Written public comments were provided to the augmented RAC by Mr. Mark Cole, Deputy Executive Director of the NBTS, and after the conference call from Ms. Elizabeth Wilson, Executive Director of the ATBA. The augmented RAC members were focused on a variety of fine-tuning edits to the latest (July 15, 2009) working draft of their report, and after some discussion, completed assignments to its members and reached consensus on those edits.

Welcome and Introductions: Dr. K. Jack Kooyoomjian, Designated Federal Officer (DFO), opened the meeting at approximately 1:04 pm with identification of the participants logging into the call and with opening remarks. He introduced himself as the DFO for the Radiation Advisory Committee (RAC) augmented for the review of the EPA's radiogenic cancer risk assessment, explained the purpose of the call, indicating that the augmented RAC operates under the requirements of the Federal Advisory Committee Act (FACA) and conducts business under the auspices of the chartered SAB. He explained that, consistent with FACA and with EPA policy, the deliberations of the augmented RAC are conducted in public meetings, for which advance notice is given. He explained that he is present to ensure that the requirements of FACA are met, including the requirements for open meetings, for maintaining records of deliberations of the augmented RAC, and making available the public summaries of meetings, as well as providing opportunities for public comment.

Dr. Kooyoomjian also commented on the status of this Panel's compliance with Federal ethics and conflict-of-interest laws. The augmented RAC follows the Committee and Panel Formation Process, as well as determinations made by the SAB staff and others pertaining to confidential financial information protected under the Privacy Act. Each person on the augmented RAC has complied with all these provisions; hence, there are no conflict-of-interest or appearance issues, nor did any individual need to be granted a waiver or be recused. Dr. Kooyoomjian further noted that the Form 3110-48 Financial Disclosure (or the SGE-450 Form for government employees) and Ethics Training was completed by all augmented RAC participants and is on file at the SAB. He advised that there is no particular matter that may pose a potential conflict of interest. He also noted that the biosketches of each participant are posted on the SAB website. Dr. Kooyoomjian noted that there is no need for disclosure from individual members at this time, since the individual participants had introduced themselves and their relation to the topic at the earlier meetings, unless any public participant had not heard of their introductions earlier; otherwise we would re-introduce the participants. Hearing no request for this, he proceeded directly with the meeting.

Dr. Bernd Kahn, Chair of the augmented RAC, provided some brief introductory remarks and overview at 1:14 p.m., and then asked if anyone wished to make any overview comments regarding the clean working draft dated July 15, 2009. Dr. Kahn then asked for everyone to focus on the Letter to the Administrator and the Executive Summary.

The following represents brief summary highlights representative of the comments and polishing edits that took place. For instance, Dr. Fry remarked that the current edits are in good shape for today's dialogue and she liked the current edits in the Letter to the Administrator. She offered some edits to the first paragraph of the Executive Summary, noting that the Letter to the Administrator has language that she thought needs to be incorporated into the Executive Summary.

Dr. Roessler recommended that in page 1 of the letter to the Administrator, we change "survey" to "evaluation." Dr. Borak recommended in the Executive Summary, pg. 1 lines 20-23 that the bold italics recommendation should also be placed in the Letter to the Administrator.

Dr. Preston remarked that everyone seems to agree with the recommendations and logic for the use of the arithmetic mean over the geometric mean in the Letter to the Administrator, and that some of this language should also be incorporated as clearly stated in the Executive Summary.

Dr. Fry suggested that on page 9, line 8, "equivocal" should be in quotation marks, because that is how Boice & Miller (1999) wrote it.

Dr. Gilbert recommended for the Executive Summary that the first full paragraph on RBE value for low LET radiation be also clarified for alpha values. She noted that there is some confusion on alpha emitters and while some might have inferred from the language that perhaps they differed from BEIR VII, they did not. She also recommended adding a statement that "...the RAC also agrees to the approach for estimating lung and cancer risk with alpha emitters."

Dr. Kahn went page-by-page through the text and the augmented RAC members offered a variety of suggestions and clarifying edits. For instance, Dr. Roessler noted that on page 3, line #2 in the Letter to the Administrator, FRG should be FGR (for Federal Guidance Report) for consistency. The RAC members concurred on some pages with no recommended edits. Where appropriate, references were recommended to support the text statements.

Agency Comments on Draft Report: At 1:35 p.m. Dr. Kahn asked Dr. Mary E. Clark, ORIA's Assistant Director for Science if the ORIA Staff had any remarks to offer pertaining to the current (July 15, 2009) working draft report. Dr. Clark did not have any specific comments at this time and expressed an interest in hearing the comments from the augmented RAC members. Dr. Jerome Puskin of the ORIA staff offered a reference (Health Protection Agency (HPA) 2007).

The committee continued in its edits to the text. Dr. Hoel offered a comment pertaining to the current working draft text, page 11, line 18 regarding the National Institute for Occupational Safety and Health (NIOSH) Interactive Radio-Epidemiology Program (IREP) Relative Biological Effectiveness (RBE) value. Drs. Fry & Hoel discussed briefly the use of RBEs greater than 1, noting that the NIOSH IREP uses it.

Dr. Preston noted that on page 12, lines 40-42, the observations of tumor sites could leave out the animals (Preston 2007 was cited in that portion of the working draft text). Dr. Gilbert cited the paper by Dr. Michael Fry and at least one other paper. Dr. Hoel cited animal experiments and the Life Span Study (LSS) data and the variation in excess rate. Dr. Gilbert noted the importance of variation across population, as contrasted to variation by cancer site.

The augmented RAC suspended their discussions at approximately 1:45 p.m. to entertain public comments as called for in the agenda.

Public Comments: At 1:45 p.m., Dr. Kahn asked if there were any members of the public who wished to address the augmented RAC. No member of the public wished to address the augmented RAC at this time. Dr. Kooyoomjian read a letter from Mr. Mark Cole, Deputy Executive Director of the National Brain Tumor Society (NBTS).³ The NBTS applauded the RAC's recommendation in the draft report, p. 23 to include radiogenic cancer risk to the brain in the Blue Book in the context of the other discussed cancer sites. The comment period ended at 1:51 p.m. [**POSTSCRIPT:** E-mail correspondence³ from Ms. Sheryl Cash, Communications Manager of the American Brain Tumor Association (ABTA) on behalf of Ms. Elizabeth Wilson, Executive Director of the ABTA arrived during the conference call, and was not acknowledged as received until after the conclusion of the conference call. This commentary was a statement in support of inclusion of Section 5.2.4 on Radiogenic Brain Cancer into the current working draft.]

Continued Discussion of Edits: Dr. Hoel recommended additional comments on cancer and cancer categories, including brain and tumor to be added to Section 5 in response to charge question number 3. Dr. Fry recommended that EPA review the anticipated report. Dr. Hoel volunteered to draft the edits to Section 5.

For page 14, Section 3.4.3 (Skin) and Section 3.4.4 (Liver), there were no comments.

For page 15, line 19, Dr. Griffith thought that the Muggenburg et al. 1996 reference was okay, but that the Muggenburg 1998 reference in the bibliography could be dropped. For page 15, lines 12 & 13, Dr. Gilbert suggested ending the sentence at RBE of 20, and dropping the sex-specific RBEs, and Dr. Fry agreed that this should be done. Dr. Gilbert further recommended to drop the Kreisheimer et al. 2000 reference on page 15, line 13.

For page 15, line 33, Dr. Griffith volunteered to look for a reference for animal studies and leukemia, noting that it is difficult because it has a negative result. Dr. Fry suggested that there might be an UNSCEAR reference, and Dr. Griffith seemed to recall a BEIR V reference.

For page 16, line 25 and lines 27 & 28, pertaining to prenatal cancer risk, Dr. Preston noted that Boice & Miller interpreted the studies differently. He will send his edits to Dr. Kahn in the next day or two. For page 16, line 27, Dr. Fry questioned Wakeford 1997, thinking that it might be Stahl & Wakeford 1997.

For page 17 dealing with Section 4 and the uncertainty analysis, Dr. Matanoski sought clarification on the acronym list pertaining to Type I and Type II errors. Drs. Borak (Scribe) and Stram (Lead) for Sub-Group C pertaining to the Uncertainty Analysis (Includes Topics 2a & 2b, & pertinent aspects of Topics 3a, 3b, and 3c) will clarify the acronyms on page 41 in the acronym list. Specifically, Dr. Borak will have acronyms consistent with the text. A discussion followed on Type I and Type II decision errors. Dr. Matanoski suggested that the parentheses on Type I, Type II, and Type III errors on pages 17 and 18 in Section 4.2.1 and elsewhere could be dropped.

For page 18, there were no additional comments.

For page 19, line 30, Dr. Preston commented on the Monte Carlo Markov Chain calculations with different values, and offered to write something to clarify this. Dr. Stram also offered to work on the re-write for page 19, line 30 on this topic.

For page 20, lines 7 & 13 and elsewhere, Dr. Dodd observed the question style in the text and suggested that it should be changed. Also, for page 20, line 15, Dr. Borak suggested to rephrase the statements so they will not be left “hanging” as a question. Dr. Borak volunteered to take care of these edits, and will also check Tables 4.1 & 4.2 for consistency.

For page 22, Section 5, there was a brief discussion on the references, which appeared to be correct.

For page 23, Dr. Gilbert observed that the RAC recommendation in Section 5.2.4 referring to Radiogenic Brain Cancer is not a trivial analysis, and, in fact, is a very nontrivial task. Dr. Davis noted that she had intended for the language to be softened somewhat in the RAC recommendation. Dr. Gilbert noted that she would be a little happier with that approach. Dr. Davis will re-word this accordingly. Dr. Matanoski mentioned that children and adenoids should be mentioned to be complete. A discussion followed regarding precise doses, added complications that are non-malignant, the observation that the pituitary gland can show tumors, and the need to be sure that it is comprehensive. Dr. Davis recalled the Blue Book mandate of cancer models, and that she was not intending to delve into the non-malignant and malignant issue. She would be happy to see the Agency discuss this, however.

For page 23, line 23 on radiogenic thyroid cancer, Dr. Fry thought that it would be helpful to add a couple of the more recent Chernobyl references.

For page 24, there were no comments.

For page 25, lines 27-29 pertaining to a balanced consideration of sources of error, Dr. Kahn thought that this could use some clarification. This was concurred by Drs. Borak, Dodd and Stram. Dr. Kooyoomjian will approach Dr. Links to clarify and improve the text on page 25, lines 27-29. For page 25, line 37, Dr. Fry suggested to add “et al.” to Schubauer-Berigan 2007.

For page 26, Section 5.4.4, Dr. Preston suggested that the term “holistic” should be dropped in the title. He thought that a discussion of a step-wise path would be better.

For page 29 references, line 28, Dr. Kahn recommended deleting Kreisheimer et al. 2000. Dr. Gilbert volunteered to check page 29 references that need to be deleted. Dr. Preston indicated that he also needs to correct and delete some references.

For page 31 references, line 36 pertaining to Ron et al., Dr. Kahn thought that we should keep the Ron et al., reference and cite it appropriately in the text on page 14, Section 3.4.3 pertaining to skin carcinomas. Dr. Preston added that Ron et al. should go in the basal & non-fatal area in front of Shore 2001.

For page 32, line 15, Dr. Kahn noted that Shore et. al. 2002 and Shore 2001 should go in the same place as Shore 2001. Dr. Gilbert noted that she didn't use Shore et al. 2002, because it wasn't low dose. She further recommended that we could drop Shilnikova et al. 2003, page 32, lines 11-13.

For page 34, line 15 references, Dr. Gilbert recommended that we could leave Vrijhead et al. 2008. Dr. Fry thought we could cite this reference in Section 5 (specifically Section 5.4.3 on Cancer Subtypes). Drs. Fry and Matanoski suggested that we could cite Vrijhead et al. 2008 in page 25, Section 5.4.2. Dr. Fry also thought that Vrijhead et. al. 2008 needs to be cited. In addition, she thought that some possible radiogenic cancer risk verbiage would be in order. Dr.

Preston suggested that if we drop whether it is radiogenic, then the reference can be used. He also suggested that we could also use the Richardson reference, which is not currently cited. He recommended that we need the Richardson reference. Dr. Fry volunteered to send the Richardson reference to Dr. Kahn.

For the Appendix acronyms, it was suggested to add CT for Computed Tomography. Dr. Kooyoomjian volunteered to do the search on the remaining acronyms.

Dr. Griffith thought that the Ramsey 2006 basal cell carcinoma eMedicine website reference could be dropped. He also thought that the Shore 2001, Preston et al. 2007, Karagas et al. 1999 and the Ramsey 2006 references deal with the issue in detail.

ADJOURN: There being no additional business to conduct, Dr. Kahn thanked all the participants, and adjourned the meeting at 2:42 p.m.

Summary & Action Items from the July 22, 2009 Public Conference Call, 1:00 p.m. – 2:42 p.m. EDT: This brief summary captures highlights of items of interest to the augmented RAC in preparation for closure edits and for creating the Quality Review Draft for review by the SAB Charter Board. The action items are briefly summarized as follows:

- 1) Numerous edits were provided to polish and clarify the language in the Letter to the Administrator, the Executive Summary and throughout the text of the July 15, 2009 working draft, as well as the references and acronyms sections for clean-up of the text and are represented in the context of summary discussions in these minutes (see above text);
- 2) The augmented RAC was comfortable with the collective edits, and volunteered to provide the various “clean-up” and polishing edits within the next week to 10 days;
- 3) Written public comments supportive of inclusion of Section 5.2.4 pertaining to radiogenic brain cancer were provided by representatives of the National Brain Tumor Society (NBTS) and the American Brain Tumor Association (ABTA);
- 4) The augmented RAC will prepare the Quality Review Draft to provide the SAB Charter Board on schedule and as planned for their September public meeting.

Respectfully Submitted:

Certified as True:

_____/S/_____
K. Jack Kooyoomjian, Ph.D.
Designated Federal Official
SAB Radiation Advisory Committee (RAC)
Augmented for Review of EPA’s
Radiogenic Cancer Risk Assessment

_____/S/_____
Dr. Bernd Kahn, Chair
SAB Radiation Advisory Committee (RAC)
Augmented for Review of EPA’s
Radiogenic Cancer Risk Assessment

Attachment A. Roster

**U.S. Environmental Protection Agency
Science Advisory Board (SAB) Radiation Advisory Committee (RAC)
Augmented for the Review of EPA's Radiogenic
Cancer Risk Assessment**

CHAIR

Dr. Bernd Kahn, Professor Emeritus, Nuclear and Radiological Engineering Program, and Director, Environmental Radiation Center, Georgia Tech. Research Institute, Georgia Institute of Technology, Atlanta, GA

MEMBERS

Dr. Susan M. Bailey, Associate Professor, Department of Environmental and Radiological Health Sciences, Colorado State University, Fort Collins, CO

Dr. Thomas B. Borak, Professor, Department of Environmental and Radiological Health Sciences, Colorado State University, Fort Collins, CO

Dr. Faith G. Davis, Senior Associate Dean and Director of Graduate Studies, Professor of Epidemiology, Division of Epidemiology and Biostatistics, School of Public Health, University of Illinois at Chicago, Chicago, IL

Dr. Brian Dodd, Independent Consultant, Las Vegas, NV

Dr. R. William Field, Professor, Department of Occupational and Environmental Health, College of Public Health, University of Iowa, Iowa City, IA

Dr. Shirley A. Fry, Independent Consultant, Indianapolis, IN

Dr. William C. Griffith, Associate Director, Institute for Risk Analysis and Risk Communication, Department of Environmental and Occupational Health Sciences, University of Washington, Seattle, WA

Dr. Jonathan M. Links, Professor and Deputy Chair, Department of Environmental Health Sciences, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, MD

Dr. William F. Morgan, Director of Radiation Biology and Biophysics, Biological Sciences Division, Fundamental & Computational Sciences Directorate, Pacific Northwest National Laboratory, Richland, WA

Mr. Bruce A. Napier, Staff Scientist, Radiological Science & Engineering Group, Pacific Northwest National Laboratory, Richland, WA

Dr. Daniel O. Stram, Professor, Department of Preventive Medicine, Division of Biostatistics and Genetic Epidemiology, Keck School of Medicine, University of Southern California, Los Angeles, CA

CONSULTANTS

Dr. Ethel S. Gilbert, Staff Scientist, U.S. National Institutes of Health, National Cancer Institute, Rockville, MD

Dr. Peter G. Groer, Professor Emeritus, University of Tennessee, Dept. of Nuclear Engineering, Tampa, FL

Dr. David G. Hoel, Distinguished University Professor, Medical University of So. Carolina, Department of Biometry & Epidemiology, Charleston, SC

Dr. Richard W. Hornung, Director of Biostatistics and Data Management, Division of General & Community Pediatrics, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

Dr. Genevieve Matanoski, Professor, Department of Epidemiology, Johns Hopkins University, Baltimore, MD

Dr. Dale L. Preston, Principal Scientist, Hirosoft International, Eureka, CA

Dr. Genevieve S. Roessler, Professor Emerita and Radiation Consultant, Department of Nuclear and Radiological Engineering, University of Florida, Elysian, MN

SCIENCE ADVISORY BOARD STAFF

Dr. K. Jack Kooyoomjian, Designated Federal Officer, US EPA, Science Advisory Board (1400F), 1200 Pennsylvania Avenue, NW, Washington, DC, 20460

Materials Cited

The following meeting materials are available on the SAB website, <http://www.epa.gov/sab> , at the [July 22, 2009 Augmented RAC Meeting](#) page.

¹ *Federal Register* Notice: Thursday, May 28, 2009, Vol. 74, No. 101, pages 25529-25530

² Meeting Agenda for July 22, 2009, Radiation Advisory Committee Augmented for Review of the Agency's Radiogenic Cancer Risk Assessment

³ Consolidated Public Comments Submitted to the Augmented RAC for July 22, 2009