

**U.S. Environmental Protection Agency**  
**Science Advisory Board**  
**Radiation Advisory Committee (RAC)**  
Summary Minutes of Public Conference Call Meeting<sup>1</sup>  
September 6, 2006

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**Committee:** Radiation Advisory Committee (RAC ) of the U.S. Environmental Protection Agency's (EPA's) Science Advisory Board (SAB). (See Roster - Attachment A.)

**Date and Time:** Wednesday, September 6, 2006 from 2:00 p.m. to 3:41 p.m. eastern standard time (See Federal Register Notice - Attachment B).

**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 for the RAC to discuss the charge, review and background materials provided by EPA's Office of Radiation and Indoor Air (ORIA) in response to the Environmental Protection Agency's draft White Paper entitled "*Modifying EPA Radiation Risk Models Based on BEIR VII*," dated August 1, 2006. During the public conference call, the RAC plans to discuss and organize to deal with specific charge assignments, and to inform the ORIA of any specific points that may need clarification or emphasis in preparation for the September 26-28, 2006 face-to-face public advisory meeting in response to this advisory activity.<sup>2</sup> The RAC will organize to begin the process of creating a draft advisory in direct response to the Environmental Protection Agency's draft White Paper. (See Meeting Agenda - Attachment C.)

**SAB/RAC Attendees:** RAC Members Dr. Jill Lipoti, RAC Chair, Dr. Bruce Boecker, Dr. Antone L. Brooks, Dr Brian Dodd, Dr. Shirley A. Fry, Dr. William C. Griffith (logged on around 3:00 pm from Paris, France), Dr. Helen A. Grogan, Dr. Richard W. Hornung, Dr. Jonathan M. Links, and Dr. Richard Vetter were present. (See Attachment A); Dr. K. Jack Kooyoomjian (Designated Federal Officer of RAC) - SAB Staff Office, participated.

**Agency Staff Attendees:** ORIA, Washington, DC: Dr. Mary E. Clark, Dr. Jerome Puskin and Dr. David Pawel.

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<sup>1</sup> 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.

<sup>2</sup> See the December 21, 2005 minutes where the RAC was initially briefed by the Agency's ORIA staff on the proposed draft White Paper concepts in a face-to-face meeting of the RAC at Montgomery, AL.

**Public Attendees:** Dr. Roger Cooke, Senior Fellow, Resources for the Future, Washington, DC.

**Meeting Summary:** The meeting followed the issues and general timing as presented in the meeting Agenda (see Meeting Agenda - Attachment C). Verbal comments were provided to the Committee by one member of the interested public during the course of the conference call meeting.

**Welcome and Introductions:** Dr. K. Jack Kooyoomjian, Designated Federal Officer (DFO), opened the meeting at approximately 2:02 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), explained the purpose of the call, indicating that the RAC operates under the requirements of the Federal Advisory Committee Act (FACA) and is chartered to conduct business under the SAB Charter. He explained that, consistent with FACA and with EPA policy, the deliberations of the 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 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 Committee's compliance with Federal ethics and conflict-of-interest laws. The 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 committee member has complied with all these provisions; there are no conflict-of-interest or appearance issues for any of the Panelists, nor did any individual need to be granted a waiver or be recused. Dr. Kooyoomjian further noted that the Form 3110-48 Financial Disclosure and Ethics Training was completed by all RAC members and is on file at the SAB, that there is no need for disclosure, and that there is no particular matter that may pose a potential conflict of interest. He advised that the RAC need not introduce themselves and their interests in relation to the White Paper Advisory since this was completed at the December 21, 2005 meeting of the RAC where the ORIA staff briefed them on this topic. Should interested parties from the public join us, we could introduce ourselves, but each individual member's relations and experiences to the issues pertaining to the discussions to take place today will in fact be required at the upcoming September 26-28, 2006 face-to-face meeting. He also advised that the biosketches of each Panelist are posted on the SAB website (see Attachment I).

RAC Panelists "logged-in," and Dr. Lipoti provided some brief opening remarks at 2:10 pm, welcoming members and participants (Roster, Attachment A), reviewed the meeting agenda (Attachment C), and then asked that Dr. Mary Clark and the ORIA Staff provide some opening remarks. After some brief remarks by Dr. Lipoti, she asked the members of the ORIA Staff and any public participants who may be on the line to also introduce themselves. No members of the public identified themselves at that time.

### Overview of the Meeting:

An Overview Discussion of the Process by the ORIA Staff: Dr. Mary Clark referred to the National Academy of Sciences (NAS) Report (See Attachment D-1), and how the SAB Advisory of the draft White Paper will be used to address issues in the charge questions. After the advisory, the Agency's ORIA staff plans to revise the "Blue Book." They will then come back to the SAB for a formal review of the Blue Book, which actually is a risk assessment of all the radionuclides. At that time, it is expected that the SAB would most likely solicit for nominations to form a panel to address that review. This current advisory was characterized by Dr. Clark as mid-course feedback on the proposed manner in which ORIA plans to use the BEIR VII advice. The ORIA Staff will either adopt, modify the BEIR VII advice, or use something entirely different that may not have been addressed by BEIR VII. Dr. Puskin also weighed in on this procedure, making some clarifying remarks. A question and answer session then followed.

The RAC members asked about the time line for the advisory, thinking that they may wish to have time to confer with consultants on the risk assessment, or to seek additional input from others to more fully answer the charge questions. Dr. Clark clarified that the risk assessment would occur after (emphasis provided) the advisory, since this is mid-stream advice that is being requested. Dr. Lipoti further clarified that under the current practices of the SAB, it is not a simple matter to add somebody else to the RAC at this time.

The RAC members asked if they could have presentations and papers from others. It was suggested that such presentations and papers can be requested from the ORIA staff, and they can decide how to handle the request. For instance, it would be helpful to understand the benefits of stationary population versus actual population.

The RAC members suggested a format which they thought would be helpful to characterize the current request in the charge as it relates to the draft White Paper in the following terms:

- Adopt:** The ORIA Staff have adopted the recommendations contained within BEIR VII. (There may be certain issues needing clarification on the manner and appropriateness of the adoption.)
- Adapt:** A modest modification was employed by the ORIA Staff. (This would need some supporting rationale and background to understand and/or accept the logic employed.)
- Change:** A different approach than what is suggested in BEIR VII was employed by the ORIA Staff. (This will most certainly need engaging discussion and a full display of the logic, background and rationale in making such a decision that departs from what is recommended in BEIR VII.), and finally,

**Add:** This was not considered in BEIR VII. (This addition will most certainly need a full disclosure and vigorous discussion on the logic, background and rationale for this unique application, which was not covered or considered by BEIR VII., for whatever reasons.)

A discussion followed. For instance, it is a big change to go from mortality to incidence. Why does the ORIA Staff want to do that change? A presentation by ORIA Staff of the background and details of the logic, followed with an open discussion is needed to understand the rationale, and the RAC may either agree or disagree on the approach taken, as well as recommend options to resolve any remaining issues on this change. Specifically, it would be very helpful in answering the charge questions to better understand the relations on epidemiologic variation across different cancers, as well as the regulatory perspective regarding incidence versus mortality. In the case of breast cancer, the ORIA Staff deviated from BEIR VII, and that will need additional discussion.

The RAC members thought that it would be helpful to identify the main categories of issues, such as the epidemiology, the populations, the models (and what the alternatives might be) and to have a presentation slide that addresses the components of BEIR VII which lead into the risk assessment.

It was thought by the RAC members that it would be helpful to have the word “incidence” stricken from Charge Question (CQ) #1, and the ORIA Staff agreed that would be helpful.

A discussion followed on CQ #2 which contains many subparts (a through h), and was recognized by the RAC participants as a substantial undertaking. It was agreed that the RAC members that would not critique or question the BEIR VII, just the ORIA modifications or adaptations, and would use the BEIR VII information as a “given.” The RAC members advised the ORIA Staff that as a rule, if the Agency was to do something that is different than what is recommended by BEIR VII, then that different proposed approach will need a detailed justification and discussion.

The ORIA Staff in some cases merely adopts the recommendations in BEIR VII. In a couple of other cases, however, the ORIA Staff thought they could improve or update BEIR VII (e.g., such as the use of more recent SEER Data as a modification in CQ #2b). In other cases, the ORIA Staff offered a minor adaptation (e.g., such as the A-Bomb survivors in using a single model as in CQ #2c). In other cases, a more substantial change is suggested by the ORIA Staff (e.g., CQ #2d where there is an alternative model for radiogenic lung cancer, which is a change from BEIR VII). What does the RAC think of the ORIA proposal of using a different model? In this case, a brief presentation on justifying the proposal of a different model would be very helpful. The presentation should also provide the rationale on what the change in that model is actually solving. For instance, in the case of CQ # 2e, the method of calculating breast cancer risk is a change, and the RAC was in consensus that a rationale would be needed from ORIA Staff that would address why there is the need for such a change.

In CQ#2f, the proposed changes for extending risk estimates to radiations of different

LET's is an addition and also needs a presentation on the rationale. In this case the rationale from ORIA Staff should address why they used the epidemiology and what it does or doesn't show, instead of relying on the science and theory.

In CQ#2g, in estimation of risks for site not specified in BEIR VII, specifically for bone and skin, the explanation should include current adaptations by the Agency. In CQ#2h, for estimation of risk due to prenatal exposure, where the draft White Paper uses ICRP recommendations, to project its risks of childhood cancers induced by *in utero* exposure, this is an addition (i.e., another radiation risk model).

For CQ#3, where the Agency proposes to adopt quantitative uncertainty bounds for each of its risk coefficients, a discussion followed whether the applicability of time into the future and other issues could be addressed in CQ#3, or whether this and other issues should be addressed in a category of "Issues Beyond the Charge."

It was recognized that ultimately the various questions being raised and addressed have to feed into the risk management, so that the Agency ORIA Staff should present these specific issues raised in the context of risk management. The ORIA Staff noted that the NAS advised to keep risk assessment separate from risk management.

The Committee discussed the uncertainty bounds, and overall guidance on the applicability of time, as well as a concern for the "big picture" issues. Dr. Brian Dodd volunteered to define the issues "beyond the charge" and to capture them a little better for the RAC members and the Agency staff to discuss in the face-to-face meeting. The Committee discussed the low dose extrapolation problem, among other issues, and the ORIA Staff advised that they can't prove what the risk is at very low doses, and they recommend and plan not to venture into that area during this exercise with the SAB's RAC.

For CQ#4, where the draft White Paper discusses some issues relating to radiogenic thyroid cancer, the ORIA Staff noted that the ORIA/NCRP study of thyroid cancer is still ongoing, and NCRP has not completed its work just yet. The RAC could comment on this. Alternatively, a presentation from the NCRP (e.g., Dr. Henry Royal) at some later date might be helpful.

**Public Comment:** At 3:15 p.m., Dr. Lipoti asked if there were any members of the public who wished to address the RAC. At this time, Dr. Roger Cooke, Senior Fellow at Resources for the Future in Washington, DC and a Professor of Risk Analysis in the Department of Mathematics at the Delft University of Technology in The Netherlands, identified himself. He provided verbal comments, highlighting the use of Geometric Averaging on page 13 in the draft White Paper, as well as page 20, where there is the possibility of uncertainty analysis being combined with risk per unit dose in order to get the cancer coefficients. His work with colleagues at the Argonne National Laboratory deals with structured expert judgement to quantify the uncertainty. He advised the Committee that he plans to attend the SAB RAC meeting and offered to provide written comments for consideration by the RAC at the September

26-28, 2006 face-to-face meeting in Washington, DC. He stated that he would get this written comments to the RAC DFO, Dr. Kooyoomjian. Dr. Lipoti commented that the Committee looks forward to sharing his and other's expertise with the SAB's RAC at the September face-to-face meeting. The Public Comments ended around 3:19 pm.

**Continued Panel Discussion:**

The RAC would like to hear from the Agency Staff first about the rationale on the changes which reflect a different approach than the BEIR VII recommendations and methodology as a higher priority for focused discussions. The next level would be the rationale for modest modifications and adaptations which the ORIA Staff views as improvements. Where there is a straight adoption of BEIR VII recommendations, that would need the least rationale.

The RAC made it clear that it is interested in discussion of uncertainty bounds, and Dr. Dodd volunteered to frame the questions in this area.

With regard to CQ #4 dealing with the White Paper discussion on issues relating to radiogenic thyroid cancer, some of the RAC members suggested that perhaps there could be a presentation at a future RAC public meeting or conference call by Henry Royal of NCRP so the RAC could get a sense where his committee is going on this topic.

Summary & Action Items from the September 6, 2006 Public Conference Call, 2-3:41 pm EST: A discussion followed on assignments, and the following matrix captures those discussions in summary fashion:

<u>CQ #</u>	<u>PERSON(S) ASSIGNED</u>
1	Lipoti
2a	Fry, Griffith
2b	Fry, Hornung
2c	Grogan
2d	Boecker, Hornung
2e	Fry, Griffith
2f	Boecker, Brooks, Griffith
2g	Brooks, Grogan
2h	Fry, Vetter
3	Links, Dodd, & Brooks
4	Dodd, Links
Beyond the Charge	Dodd

There being no additional business to be discussed, Dr. Lipoti adjourned the meeting at 3:41 pm on Wednesday, September 6, 2006.

Respectfully Submitted:

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K. Jack Kooyoomjian, Ph.D.  
Designated Federal Official  
Radiation Advisory Committee (RAC)

Certified as True:

\_\_\_\_\_/S/\_\_\_\_\_  
Dr. Jill Lipoti, Chair  
Radiation Advisory Committee (RAC)

## List of Attachments

<u>Attachment</u>	<u>Description</u>
A	Radiation Advisory Committee (RAC) Roster
B	<u>Federal Register</u> Notice: August 9, 2006, Vol. 71, No. 153, pages 45545-45546
C	Meeting Agenda dated September 6, 2006
D	Mailout Dated August 3, 2006 Containing Memo from K. Jack Kooyoomjian, Ph.D., DFO RAC to RAC Members entitled “Hard Copy of BEIR VII Phase 2,” containing the following:
D-1	<u>“Health Risks from Exposures to Low Levels of Ionizing Radiation, BEIR VII Phase 2,”</u> National Research Council of the National Academies, The national Academies Press, Washington, DC, 2006
E	Project Sheet 06-16 “Ionizing Radiation: Updated Methodology for Estimating Cancer Risks
F	Email Review Information and Review Package dated August 3, 2006 from K. Jack Kooyoomjian, Ph.D., DFO/RAC to RAC Members entitled “Review and Background Materials for Draft White Paper Advisory Entitled “Modifying EPA Radiation Risk Models Based on BEIR VII,” and containing the following:
F-1	Charge to the Science Advisory Board’s Radiation Advisory Committee on Draft White Paper ((racwhitpaperchargefinal.doc),
F-2	“Modifying EPA Radiation Risk Models Based on BEIR VII, Draft White paper,” Prepared by Office of Radiation and Indoor Air, U.S. Environmental Protection Agency, August 1, 2006 (White Paper8106.doc),
F-3	Draft Federal Register Notice (RAC WhitePaper_FRN RevDft072006Jack Rev4.rtf.,
F-4	RAC Roster(RAC 07IntRoster05032006.rtf)
G	Email Review Information and Review Package dated August 29, 2006 from K. Jack Kooyoomjian, Ph.D., DFO/RAC to RAC Members, entitled Fw: Agendas for Upcoming Sept. 6 Conference Call and Sept. 26-28, 2006 Face-to-Face Meeting of the SAB’s RAC “Pertaining to the Advisory of the Agency’s Draft White Paper Entitled ‘Modifying EPA Radiation Risk Models Based on BEIR VII’ “ and containing the following:
G-1	The Agenda for the September 6, 2006 Public Conference Call (File Name: RACWhite PaperPubAgenda090606.pdf),

**Attachment**

**Description**

- G-2 The Proposed Agenda for the September 26-28, 2006 Face-to-Face Public Meeting of the RAC  
(File Name: RACWhitePaperPubAgenda092606.pdf), and
- G-3 The August 3, 2006 Memo containing the Draft White Paper Charge, the Draft White Paper, the *Federal Register* Notice, and the RAC's Roster (See Attachment F, above)
- H Follow-up Correspondence from RAC on Charge Questions:  
H-1 Brian Dodd .... Beyond the Charge  
H-2 Jonathan Links ....Beyond the Charge
- I Biosketches of Radiation Advisory Committee
- J DFO's Marked-Up Agenda of 09/06/06 Conference Call (K. Jack Kooyoomjian)
- K DFO's Notes of 09/06/06 Conference Call
- L Miscellaneous Correspondence Relating to Conference Call (pre-& post Correspondence)

End of Record