



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR  
SCIENCE ADVISORY BOARD

**MEMORANDUM**

January 29, 2009

**SUBJECT:** Formation of SAB Radiation Advisory Committee (RAC) Augmented with Additional Experts for the Peer Review of EPA Draft Document Entitled "*EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population*"

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**TO:** Vanessa T. Vu, Ph.D.  
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This memorandum documents the process and addresses the set of determinations used in forming this Science Advisory Board Panel. It provides background information on the subject SAB activity and addresses:

1. Expertise needed to address the charge;
2. How individuals were placed on the "short list" candidates for the Panel;
3. Identification of parties who are potentially interested in or may be affected by the topic to be reviewed;
4. Whether the charge involves a particular matter and how conflict of interest regulations apply to members of the Panel; and
5. How individuals were placed on the Panel.

**A. Background**

In 1994, the EPA published a report, entitled "*Estimating Radiogenic Cancer Risks*," (often referred to as the "Blue Book") which lays out the EPA's methodology for quantitatively estimating radiogenic cancer risks (<http://epa.gov/radiation/docs/assessment/402-r-93-076.pdf>). That document revised methodology for EPA's estimation of cancer risks due to low-Linear-

Energy-Transfer (LET) radiation exposures developed in light of information on the Japanese atomic bomb survivors. In 1999, a follow-on report made minor adjustments to the previous estimates and presented a partial analysis of the uncertainties in the numerical estimates (<http://epa.gov/radiation/docs/assessment/402-r-99-003.pdf>). Also in 1999 the Agency published Federal Guidance Report 13 (<http://epa.gov/radiation/docs/federal/402-r-99-001.pdf>) which utilized the previously published cancer risk models in conjunction with International Commission on Radiological Protection (ICRP) dosimetric models and the U.S.A. usage patterns, to obtain cancer risk estimates for over 800 radionuclides, and for several exposure pathways. These were later updated at ([http://www.epa.gov/radiation/federal/techdocs.html#cd\\_supplement](http://www.epa.gov/radiation/federal/techdocs.html#cd_supplement)).

In 2006, the U.S. National Academy of Sciences/National Research Council (NAS/NRC) released “*Health Risks from Exposure to Low Levels of Ionizing Radiation BEIR VII Phase 2*,” which primarily addresses cancer and genetic risks from low doses of low-LET radiation (available at <http://newton.nap.edu/catalog/11340.html#toc>).

In August, 2006 EPA prepared the draft “*White Paper: Modifying EPA Radiation Risk Models Based on BEIR VII*” (available at <http://epa.gov/radiation/docs/assessment/white-paper8106.pdf>), where the Agency proposed changes to the EPA’s methodology for estimating radiogenic cancers, based on the contents of BEIR VII. The Agency expected to adopt the models and methodology recommended in BEIR VII, but believed that certain modifications and expansions are desirable or necessary for the EPA’s purposes. EPA’s Office of Radiation and Indoor Air (ORIA) requested the SAB to review the Agency’s draft White Paper and provide advice regarding the proposed approach to dose-response assessment of radionuclides. The EPA SAB/RAC prepared an advisory entitled “*Advisory on Agency Draft White Paper entitled Modifying EPA Radiation Risk Models Based on BEIR VII*” (EPA-SAB-08-006) dated January 31, 2008 (see [http://yosemite.epa.gov/sab/sabproduct.nsf/FD9963E56C66E4FF852573E200493359/\\$File/EPA-SAB-08-006-unsigned.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/FD9963E56C66E4FF852573E200493359/$File/EPA-SAB-08-006-unsigned.pdf)).

The EPA’s Office of Radiation and Indoor Air (ORIA) has asked the SAB to review the draft document entitled “*EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population*,” dated December 2008. The document under preparation utilizes the advice contained in the NAS/NRC BEIR VII, Phase 2 report, as well as the SAB’s recently completed advisory (EPA-SAB-08-006) described above.

## **B. Determinations**

### 1) Expertise needed to address the charge:

The review will be conducted by an SAB panel consisting of members of the Radiation Advisory Committee (RAC) and invited experts to augment expertise needed for this particular review. The SAB Staff Office requested public nominations of experts in a *Federal Register* notice (73FR 21129) dated April 18, 2008 to augment expertise to the Radiation Advisory

Committee (RAC) to form an SAB panel to review the draft which at the time of the *FR* notice was under preparation. The augmented RAC will provide advice through the chartered SAB, and will comply with the provisions of the Federal Advisory Committee Act (FACA) and all appropriate SAB procedural policies, including the SAB process for panel formation described in the *Overview of the Panel Formation Process at the Environmental Protection Agency Science Advisory Board*, which can be found on the SAB's Web site at:

<http://www.epa.gov/sab/pdf/ec0210.pdf>. To augment expertise on the RAC, the SAB Staff Office was seeking nominations of nationally and internationally recognized experts with specialized expertise and experience in radiogenic cancer risk in one or more of the following areas:

- a) Radiobiology;
- b) Radiation biophysics;
- c) Cancer epidemiology related to radiation;
- d) Radiation exposure and uptake; and
- e) High-to-low dose extrapolation for LET radiation.

2) How individuals were placed on the "short list" candidates for the Panel:

On the basis of candidates' qualifications and availability to participate in the review meeting, the SAB Staff Office identified sixteen (16) candidates in addition to the RAC members. On September 8, 2008, the SAB Staff Office posted a notice on the SAB website inviting public comments on the "short list" of prospective candidates for the Panel. The notice invited comments from members of the public for relevant information, analysis or other documentation that the SAB Staff Office should consider in the selection of experts to augment the RAC's expertise for this upcoming review. No public comments were received.

3) Identification of parties who are potentially interested in or may be affected by the topic to be reviewed:

Potentially interested and affected parties include: 1) Federal, state, and local government agencies, elected officials, and non-governmental organizations (NGOs), including professional and trade organizations that focus on utilization of the risk assessments of the radionuclides for various regulatory programs for public and environmental health assessments, compliance activities, cleanup or removal activities, and for any activities related to radiation exposure and uptake to estimate short-term or chronic (i.e., lifetime) attributable risks, 2) those stakeholders involved with the interests of industries and governments that may be subject to and/or affected by policies or regulations, including cleanup, removal, remediation or compliance activities pertaining to radioactive releases to the environment, and 3) any academic/industry/government practitioners, researchers or NGOs addressing the short-term as well as the long-term acute and/or chronic exposures of radioactivity, and 4) interested members of the public concerned with the implications of consequent short or long-term exposure and uptake from environmental and other radioactive sources introduced in any manner into the environment.

4) Whether the charge involves a particular matter and how conflict of interest regulations apply to members of the Panel:

18 U.S.C. 208 provision states that:

“An employee is prohibited from participating personally and substantially in an official capacity in any particular matter in which he, to his knowledge, or any person whose interests are imputed to him under this statute has a financial interest, if the particular matter will have a direct and predictable effect on that interest [emphasis added].”

For a conflict of interest to be present, all elements in the above provision must be present. If an element is missing, the issue does not involve a formal conflict of interest. However, the general provisions in the “appearance of a lack of impartiality guidelines” may still apply and need to be considered.

Personal and Substantial Participation:

Participating personally means participating directly. Participating substantially refers to involvement that is of significance to the matter [5C.F.R. 2640.103(a)(2)]. For this review, panel members will be participating personally in the matter through attendance at meetings, teleconferences and other means.

Direct and Predictable Effect:

A direct effect on a participant’s financial interest exists if, “ ... a close causal link exists between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest .... A particular matter does not have a direct effect ... if the chain of causation is attenuated or is contingent upon the occurrence of events that are speculative or that are independent of, and unrelated to, the matter. A particular matter that has an effect on a financial interest only as a consequence of its effects on the general economy is not considered to have a direct effect.” [5C.F.R. 2640.103(a)(i)]. A predictable effect exists if, “ ... there is an actual, as opposed to a speculative, possibility that the matter will affect the financial interest.” [5 C.F.R. 2640.103(a)(ii)].

Particular Matter:

A “particular matter” refers to matters that “ ... will involve deliberation, decision, or action that is focused upon the interests of specific people, or a discrete and identifiable class of people.” It does not refer to “ ... consideration or adoption of broad policy options directed to the interests of a large and diverse group of people.” [5 C.F.R. 2640.103(a)(1)].

The Radiation Advisory Committee (RAC) activity augmented with expertise to review the draft under preparation and to be entitled “*EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population*,” **does not constitute a particular matter** because it does not include matters that involve deliberation, decision or action that is focused upon the interest of specific people, or a discrete and identifiable class of people. The augmented RAC’s activity

does not include matters which involve formal parties, nor does it extend to legislation or policy-making that is narrowly focused upon the interests of a discrete and identifiable class of persons. The SAB's augmented RAC will be reviewing risk assessment methodology for all radionuclides in all circumstances of exposure and uptake for all segments of the U.S. population, including evaluation of organ-specific cancer sites for males and females in the U.S. population. This review activity therefore qualifies as **a matter of broad general applicability**.

Appearance of a Lack of Impartiality Considerations:

The Code of Federal Regulations [5 C.F.R. 2635.502(a)] states that:

“Where an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his household, or knows that a person with whom he has a covered relationship is or represents a party to such matter, and where the person determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter, the employee should not participate in the matter unless he has informed the agency designee of the appearance problem and received authorization from the agency designee.”

Further, 5 C.F.R. 2635.502(a)(2) states that:

“An employee who is concerned that circumstances other than those specifically described in this section would raise a question regarding his impartiality should use the process described in this section to determine whether he should or should not participate in a particular matter.”

Each potential advisory panel member was evaluated against the 5 C.F.R. 2635(a)(2) general requirements for considering an appearance of a lack of impartiality. Information used in this evaluation has come from information provided by potential advisory panel members (including, but not limited to, EPA 3110-48 confidential financial disclosure forms) and public comment.

To further evaluate any potential appearance of a lack of impartiality, the following five questions were posed to all prospective advisory panel members regarding the review of EPA's radiation risk estimates:

- a) Do you know of any reason that you might be unable to provide impartial advice on the matter to come before the Panel or any reason that your impartiality in the matter might be questioned?
- b) Have you had any previous involvement with the issue(s) or document(s) under consideration, including authorship, collaboration with the authors, or previous peer review functions? If so, please identify those activities.
- c) Have you served on previous advisory panels, committees, review bodies or panels that have addressed the topic under consideration? If so, please

identify those activities.

- d) Have you made any public statements (written or oral) on the issue? If so, please identify the date, place and nature of your involvement pertaining to the public statement(s).
- e) Have you made any public statements that would indicate to an observer that you have taken a position on the issue under consideration? If so, please identify those statements.

5) How individuals were placed on the Panel:

The SAB staff conducted a review of information submitted by every prospective Panel member including the responses to the five (5) ethics questions above and the completed EPA Form 3110-48, along with information independently gathered by SAB staff. The Deputy Ethics Official of the SAB has determined that there are no conflict of interest or appearance of a lack of impartiality for the members of the Radiation Advisory Committee (RAC) augmented for the review of EPA's radiogenic cancer risk assessment.

The SAB Staff Office Director, taking all factors into account, makes the final decision about the membership of the Committee or Panel being formed. Specific criteria to be used in evaluating and individual Committee or Panel member include: (a) scientific and/or technical credentials and expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of lack of impartiality; and (e) skills working in committees, subcommittees and advisory panels; and for the Committee or Panel as a whole, (f) diversity of, and balance among, scientific expertise and viewpoints.

The augmented RAC membership includes the following:

RAC Members:

**Chair: Dr. Bernd Kahn**, Georgia Institute of Technology (GA)

**Dr. Susan M. Bailey**, Colorado State University (CO)

**Dr. Thomas B. Borak**, Colorado State University (CO)

**Dr. Faith G. Davis**, University of Illinois (IL)

**Dr. Brian Dodd**, Independent Consultant (NV)

**Dr. R. William Field**, University of Iowa (IA)

**Dr. Shirley A. Fry**, Independent Consultant, Indianapolis, (IN)

**Dr. William C. Griffith**, University of Washington (WA)

**Dr. Jonathan M. Links**, The Johns Hopkins University (MD)

**Dr. William F. Morgan**, Pacific Northwest National Laboratory (WA)

**Mr. Bruce A. Napier**, Pacific Northwest National Laboratory (WA)

**Dr. Daniel O. Stram**, University of Southern California (CA).

