

**U.S. Environmental Protection Agency**  
**Science Advisory Board**  
**Radiation Advisory Committee (RAC)**  
Summary Minutes of Public Face-to-Face Meeting<sup>a</sup>  
March 23, 24 & 25, 2009

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**Committee:** Radiation Advisory Committee (RAC) of the U.S. Environmental Protection Agency's (EPA's) Science Advisory Board (SAB) augmented to Review the Agency's Radiogenic Cancer Risk Assessment. (See Roster - Attachment A.)

**Date and Time:** 9:00 A.M. to 5:30 P.M., Monday, March 23, 2009; 8:30 A.M. to 5:30 P.M., Tuesday, March 24, 2009; and 8:30 A.M. to 1:55 P.M., Wednesday, March 25, 2009. (See Federal Register Notice<sup>1</sup>)

**Location:** Marriott Key Bridge Hotel, 1401 Lee Highway, Arlington, VA 22209

**Purpose:** The purpose of this meeting was to conduct a review<sup>b</sup> on the Agency's draft Blue Book, entitled "*EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population, Draft December 2008*". The RAC will organize to begin the process of creating a draft report within the meeting in direct response to the Charge Questions relating to the Environmental Protection Agency (EPA)/Office of Radiation and Indoor Air (ORIA) draft Blue Book.

**SAB/RAC Attendees:** RAC Members for all 3 days: Dr. Bernd Kahn, Dr. Susan Bailey, Dr. Thomas Borak, Dr. Brian Dodd, Dr. R. William Field, Dr. Shirley A. Fry, Dr. Ethel S. Gilbert, Dr. William C. Griffith, Dr. Peter G. Groer, Dr. David G. Hoel, Dr. Richard W. Hornung, Dr. Jonathan M. Links, Dr. Genevieve Matanoski, Dr. William F. Morgan, Mr. Bruce A. Napier, Dr. Dale L. Preston, Dr. Genevieve S. Roessler, and Dr. Daniel O. Stram were present. (See Attachment A); Dr. K. Jack Kooyoomjian (Designated Federal Officer of RAC - in all three days), Dr. Anthony Maciorowski and Dr. Vanessa Vu (in portions of each day) - SAB Staff Office, participated.

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<sup>a</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>b</sup> See the February 27, 2009 conference call minutes where the Augmented RAC discussed the planning for the March 23-25, 2009 meeting, discussed the charge questions, determined if the review and background materials provided by the Agency were adequate to respond to the charge questions, requested specific items to be presented or clarified during their presentation of March 23, 2009, heard from the public regarding this review topic, and formally began this review activity.

**SAB/RAC Members Not Present:** Dr. Faith G. Davis was not present, due to illness.

**Agency Staff Attendees:** ORIA, Staff for all 3 days: Dr. Mary E. Clark, Dr. Jerome Puskin and Dr. David Pawel; Dr. Jon Edwards.

**Public Attendees:** Ms. Diane D'Arrigo, Nuclear Information and Resource Service (NIRS); Ms. Megan Groll, NIRS; Mr. Douglas Guarino, Inside EPA

**Meeting Summary:** The discussion generally followed the issues and general timing as presented in the meeting Agenda<sup>2</sup> except where otherwise noted.

March 23, 2009:

**Convene the Meeting:**

Dr. K. Jack Kooyoomjian, Designated Federal Officer (DFO), opened the meeting at approximately 9:01 a.m. with opening remarks. He introduced himself as the DFO for the Radiation Advisory Committee (RAC), augmented for review of the Agency's Radiogenic Cancer Risk Assessment (RA), explaining the purpose of the meeting, 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 member of the RAC, augmented for this review, has complied with all these provisions; there are no conflict-of-interest or appearance issues for any of the reviewers, nor did any individual need to be granted a waiver or be recused. Dr. Kooyoomjian further noted that the Form 3110-48 Financial Disclosure, SF 450 Form for Federal participants, and Ethics Training was completed by all members of the augmented RAC 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 members introduce themselves and their interests in relation to the Blue Book review. He also advised that the biosketches of each RAC member are posted on the SAB website. He advised that we have one public speaker who had formally requested to comment today, Ms. Diane D'Arrigo of the NIRS.

### **Welcoming Remarks:**

Dr. Vanessa Vu, provided some brief welcoming remarks and discussed a possible time line for this review. She thought that perhaps a June to September time frame might work, if everything goes smoothly, as perhaps having the Quality Review Draft ready for review by the SAB's Charter Board. She indicated that Drs. Kooyoomjian and Kahn will discuss the logistics in more detail and that Dr. Mary E. Clark, Assistant Director for Science on the ORIA Staff will introduce the topic. She then handed the meeting over to Dr. Kahn.

### **Introductory Remarks, Review of the Agenda, and Introduction of Committee and Guests:**

At 9:18 am Dr. Kahn, Chair of the RAC welcomed everyone, gave a brief introduction to the logistics of the review, and then asked each of the members of the augmented RAC to introduce themselves. He asked that they highlight their experience as it relates to the topic at hand, and any special research interests they might have in the topic, including that of their colleagues and institutions where they work, or activities in professional societies and other affiliations related to the topic. He began the introductions with himself and then asked Dr. Roessler to start the introductions. Drs. Jon Edwards, Jerome Puskin, Mary Clark, and David Pawel of the ORIA Staff also introduced themselves.

### **Agency/ORIA Presentations:**

#### **Overview of Agency Draft Blue Book and Charge Questions:**

Dr. Mary Clark, Assistant Director for Science introduced herself and the ORIA Staff and gave a very brief introduction to the topic, acknowledging previous draft Blue Book reviews and the recent draft White Paper advisory activity by the RAC, leading up to this review. Dr. Jon Edwards, Director of the Radiation Protection Division (RPD) of ORIA provided an overview briefing<sup>3</sup> at 9:37 am. Dr. Edwards elaborated on how the draft Blue Book review and revisions will ultimately lead to revising Federal Guidance Report (FGR) 13. He elaborated on the age-averaged risk coefficients, and that the revised FGR 13 will have gender, age, and organ-specific information. He discussed the limitations on age averaged risk coefficients for children and age-specific populations.

Dr. Edwards touched on the need to revise the Blue Book now to incorporate the current science with approximately 15 years of follow-up studies of the Japanese Atomic Bomb survivors, the improved dosimetry for Life-Span Studies (LSS), the newer information from other epidemiological studies, and the process to reflect and interpolate these with recent U.S. mortality and incidence data. He touched on the many data sources that National Academy of Sciences (NAS) drew upon to create the BEIR VII report, and recognized the significant value of the independent advice previously provided by the SAB/RAC reviews of the Agency's draft Blue Book. He discussed the scientific integrity of EPA's risk assessment process, the sound science

foundation built upon the previous and current draft Blue Book<sup>4</sup>, and the value of retaining transparency of understanding how decisions are reached by the Agency, the value of the open public process and all that this entails. He also touched upon the credibility of the peer review process to reach scientific consensus from the augmented RAC to critique EPA's interpretation of BEIR VII, and EPA's approach to handling the uncertainties, as well as the comments we have received and will receive from the public.

At 9:51 am Dr. Mary Clark stressed the following: (1) She was confident that the points raised by ORIA staff to the SAB's augmented RAC in the charge questions will be directly addressed; (2) She expressed confidence that the forthcoming presentation by Drs. Puskin and Pawel will highlight key areas of the Agency's draft Blue Book that ORIA is requesting specific review and comment; (3) She observed that there are some natural breaks in the slide presentations such as pages 44, 61 and 90 to allow for discussion and Q&A; and (4) She noted that the earlier draft Blue Book, as well as FGR-13 was previously peer-reviewed by the SAB/RAC.

At 9:54 am, Dr. Kahn observed that with all the background materials that have been provided to the augmented RAC, it is clear that there is a long chain of open public dialogue and revisions by ORIA directly tied to advice from the SAB/RAC and its previous review bodies. The question now that all this information has been provided is what does the ORIA staff really want to do with all this? ...and ... How will it all come together? He gave illustrative examples of what and how this might come together, touching on the relevance of beta-particle doses in FGR 13, for instance.

At 9:58 a.m. Dr. Puskin and Dr. David Pawel began their presentation.<sup>5</sup> Dr. Puskin touched on the background and history of the previous reviews bringing us up to current specific topics pertaining to risk projections. He highlighted the approach to obtain nominal estimates, the risks at low dose and dose-rates, the BEIR VII models and possible modifications and extensions, such as bone and cancer models, prenatal exposures, the uncertainty analysis and relative biological effectiveness (RBE) for higher linear energy transfer (LET) radiation. Dr. Puskin noted that the risk characterization, which estimates the magnitude of risks, provides the scientific basis of the risk estimates, and characterizes the uncertainties (both sources and magnitudes), providing EPA managers with critical information upon which to base decisions. He touched on the process that is envisioned for revising EPA cancer risk coefficients, leading to revision of FGR-13, which follows mostly the BEIR VII recommendations, but will incorporate such additional items as the new International Commission of Radiation Protection (ICRP) dosimetry and the EPA risk coefficients.

Dr. Puskin reminded the RAC members of the four (4) conditions for modifying BEIR VII, namely (1) that it is not treated in BEIR VII (e.g., skin, bone, high-LET radiation), (2) more recent and relevant data are available (e.g., vital statistics), (3) compelling evidence of more appropriate methods (e.g., breast cancer), and (4) implementation requirements which necessitate adoption of alternative strategies (e.g., stationary population). A discussion followed on the various reasons a mean value might be higher, and the different assumptions that might have lead

to a higher risk estimate. Other points raised included the possibility of using uncertainty distributions to derive central estimates, the Linear No Threshold (LNT) hypothesis (such as ICRP Publication 99 which states that there is no compelling evidence for a threshold, but the question remains open), the generation of clustered damage, and the implications of epidemiology studies of less than 100 mGy per day. A discussion followed on a variety of topics, such as the fact that BEIR VII did not explicitly adopt the linear-quadratic model for solid cancers, the variety of medical exposures (such as prenatal x rays, exposures to fluoroscopy patients and scoliosis patients), as well as a wide variety of chronic exposure scenarios, such as nuclear power and defense workers, medical workers, the Taiwanese building residents, the Chernobyl cleanup workers and related scenarios.

Discussions continued on a variety of topics, such as leukemia risks in recent studies, and patterns of dose-response for cancer incidence, where BEIR VII relies on the idea that the slope is low at low dose-rates, the property of risks at low doses and dose-rates, and the uncertainties at low doses. Discussions touched on the EPA risk models and projections for low-LET radiation, the site-specific models, having followed advice from the White Paper Advisory, the variety of scenarios to calculate Lifetime Attributable Risk (LAR), the methods for combining risk projection models, and the logic for choice of values somewhere between the two extremes. A discussion took place on whether LAR projections should continue to be based on a weighted geometric mean (GM), or an arithmetic mean (AM). A discussion followed on combined risk projections for specific sites, including stomach, liver, prostate, and lung.

BREAK - The participants took a break at 10:45 am and re-convened at 11:08 am.

Dr. David Pawel began his presentation. He touched on Chapter #3 in the draft Blue Book (beginning at page 21) on the risk models used and the estimates derived for low level radiation exposures. He believes that the Agency/ORIA has followed BEIR VII “religiously,” but there were exceptions, such as with the breast cancer data. He touched on the form of the site-specific models, and the BEIR VII solid cancer models, as well as the age and time patterns in the excess relative risk (ERR) and the excess absolute risk (EAR) model for breast cancer. A detailed discussion followed on projections for selected cancer sites, such as breast cancer mortality, the central nervous system and brain, the thyroid cancer risk estimates, prenatal exposures, skin cancer and Basal Cell Carcinoma (BCC) incidence models and projections. The risk models and projections were compared with ICRP and United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) in projections of LAR to the U.S. population. Dr. Pawel discussed the Agency’s rationale to follow BEIR VII in some cases, and when it might be prudent to depart from BEIR VII. Discussions took place on sampling variability (the traditional approach) which is based on maximum likelihood estimates, as well as those instances where there is insufficient data for specific sites, or where there is sampling variability. Discussions followed on the Bayesian approach for all solid cancer risk and site-specific cancer risks in the life span study (LSS) and what prior distributions should be used for baseline rates and the ERR model parameters for cancer sites. The linear dose-response, age-at-exposure, and attained age parameters and the 95% uncertainty limits were discussed for specific cancer sites, such as the stomach, colon, liver, bladder and prostate.

Discussion took place on Dose and Dose-Rate Effectiveness Factor (DDREF) uncertainty, risk transport uncertainty, where it is impossible to characterize uncertainty for the “true” risk, which spans somewhere between the EAR and ERR projections, as well as the model uncertainty associated with the dosimetry. Other sources of uncertainty discussed included errors in disease detection diagnosis, and misclassification among different cancer types.

Questions were raised by the RAC on the thyroid cancer risk estimates and the degree of accuracy the Agency might be striving to achieve, as well as the philosophy behind the choice of values. Dr. Puskin observed that the NCRP chose to average the ERR per Gy, but that BEIR VII chose not to do this. Also discussed were pre-natal exposures and the risks between childhood and adult exposures. Dr. Puskin observed that within the atomic bomb survivors, for instance, you do not see any distinction between the adult and childhood exposures. One of the RAC members observed that leukemia is the main outcome in the A-bomb studies. Another RAC member observed that with the A-bomb survivors, the stress of the exposure incidents might have aborted the fetuses. It was also observed by the ORIA staff, in a big picture sense, that the prenatal exposures are not considered a big contributor to risk, because the fetus is in utero only 1% of its life.

Discussions followed on skin cancer, the Basal Cell Carcinoma (BCC) incidence model, and some complications in extrapolation from the Japanese to the US population being problematic, because of the interaction of infrared radiation (IR) and ultraviolet radiation (UV). The Agency staff discussed their refined approach to the BCC incidence model. The RAC discussed the common practice to count multiple skin cancers and the implications for skin cancer incidence data. Dr. Puskin observed that simply a change in lifestyle have affected the Japanese rates.

LUNCH BREAK: 12:00 noon to 1:15 pm.

### **Agency/ORIA Presentations Continued:**

Dr. Pawel continued with p. 56 of the briefing dealing with the risk model projections and a comparison with the ICRP and UNSCEAR model projections. Both are primarily based on the 1958-1998 LSS incidence data. Similar solid cancer risk models will affect modifiers, such as gender, age-at-exposure, attained age, etc. The RAC members enquired about, commented on, and clarified some of the lifetime risk projection methodologies. For instance, it was observed that UNSCEAR examined excess absolute risk (EAR) and chose to prefer the excess relative risk (ERR) model. Another RAC member observed that UNSCEAR chose both risks, because Europe is very much like the US. However, in projecting mortality to incidence, it is observed that mortality is higher in Europe as compared to the U.S. The BEIR VII approach was discussed, and the discussion addressed such topics as sampling variation, risk transport, and DDREF, the distributional assumptions, the width of the uncertainty intervals (e.g., are they too wide? The short answer is for some sites, probably “yes,” but for solid cancer, probably “no”). Discussions occurred on sensitivity analysis and uncertainty analysis, the derivation of central risk projections

and the uncertainty intervals. It was observed that the traditional (Bayesian) approach cannot be used in some cases, because there are insufficient data on some specific sites.

The Agency staff (Dr. Pawel) outlined a Bayesian approach to be used for all solid cancer risk in the life span study (LSS), as well as for all site-specific cancer risks in the LSS. Discussion points raised by the augmented RAC included the observation that the uncertainty analysis, as such, is primarily sensitivity analysis, and not everybody appreciates understanding the intrinsic uncertainties in the estimates that are done. At the end of this discussion by Dr. Pawel, a RAC member complimented him for “spelling it out” so explicitly regarding the steps in the risk assessment process. Another RAC member enquired regarding the bounds of uncertainty and where the “true risk” might be. It was observed by another RAC member that the likelihood models are relatively the same, when other items (such as transport) drive the uncertainty. In this case, the LSS data stay where they are. Dr. Pawel remarked that they only used ERR, but then corrected for transport. A discussion followed on risk transport uncertainty (p. 86 of briefing), where it was acknowledged by the ORIA staff that it is impossible to characterize uncertainty for “true” risk outside the interval spanned by EAR & ERR projections. In the case where the “true” risk is well within the interval spanned by the two extremes, then they assumed the distribution is either uniform or log-uniform, and then assigned a probability of 0.25 to each of these two distributions.

The Agency quantified uncertainties, such as those associated with dosimetry, errors in disease detection diagnosis, selection bias, and temporal patterns, as was recommended by the SAB/RAC. However, this does not account for misclassification among different cancer types. There was a discussion of other types of radiation, including moderate LET (includes x-rays and lower energy y-rays, as well as some betas), and high LET alphas. There was some discussion on the comparison of high and low-LET tracks traversing the cell nucleus, and examples of complex clustered damage in deoxyribonucleic acid (DNA). Other topics included a discussion of risks from medical x-rays, the relative effectiveness of x-rays and y-rays, and alternatives for assessing risks from medical x-rays. A presentation and discussion also took place on radiobiology theory and RBE experiments contained in the report of the Committee Examining Radiation Risks of Internal Emitters (CERRIE, briefing pages 98-100). Also a discussion took place on the biophysical approach to estimating the RBE for lower energy photons and electrons (Briefing pages 101 – 107), as well as sites for which there are human data on alpha particle risk, including targets for alpha emitters (briefing, pages 109-113) colon, liver, bone, bone marrow, lung, and stomach (ingested radon). A discussion followed on the various data sets, such as for U<sup>224</sup>, and Ra<sup>226</sup>, as well as the uncertainties in the high-LET risk estimates.

**Public Comments:** At 3:39 pm Dr Kahn stopped the discussion to allow for public comments, which were scheduled to take place at 3:15 pm. Ms. Diane D’Ariggo, Radioactive Waste Project Director of the Nuclear Information & Resource Service (NIRS) provided comments on the Agency’s draft Blue Book. She advised that there is interest in EPA’s public health standard setting for radionuclides, as is expressed in such documents as the “Blue Book” and Federal Guidance Report (FGR) -13. She advised the participants that she had attended all the White Paper advisory meetings. She noted that EPA was part of a group of public agencies that hired

the NAS for the development of BEIR VII. She also noted concerns of the NAS/BEIR VII Chair and the LNT model in the NAS BEIR VII activity, and observed that they did adjust their committee composition, as a result of some discussions. She observed that she and others did not have the opportunity to comment on the current augmented RAC, which is now assembled. She observed that the results of this review may want to implement better science, but there is a lot of uncertainty. She expressed a need to protect the public, and does not wish to accept any unnecessary weakening of the public health protection standards.

She expressed that, whether the individuals on the augmented RAC have goals that are for or against nuclear projects, you do not need to politicize science. She viewed this activity as a weakening of science, an unnecessary weakening of public protections of radiation standards, and a justification for releasing of radioactive materials. Further, she hasn't heard of any non-cancer health effects in the guise of improved science. The recommendations of this committee (the augmented RAC of the SAB) will be very significant. She noted that other organizations will be providing comments and raising the same concerns that were expressed in the White Paper advisory.

In looking at the tables, when compared to BEIR VII or EPA's proposed numbers, in almost every instance, it appears the numbers are less protective. (One of the RAC members asked which tables she might be referring to, and in response, Ms. D'Arrigo cited Chapter 4 Uncertainty Tables in the draft Blue Book). Specifically, Ms. D'Arrigo pointed to 4 tables in a row in Chapter 4 (Table 4-3A, p. 73 dealing with EPA projection and uncertainty distribution for LAR for male cancer incidence; Table 4-3b, p. 74 EPA projection and uncertainty distribution for the LAR for female cancer incidence; Table 4-3c, p. 75 EPA projection and uncertainty distribution for the sex-averaged LAR for cancer incidence, and Table 4-4b, p. 77 comparing EPA projection and uncertainty distributions for female cancer incidence. (NOTE: DFO observes that Ms. D'Arrigo may have also intended to cite Table 4-4a, p. 76 dealing with male cancer incidence).

[NOTE: The RAC members pointed out to Ms. D'Arrigo to please observe Table 3-11 on p. 54 which provides LAR projections for incidence; Table 3-12, p. 56 which provides LAR projections for mortality, and Table 3-14, p.58, which provides Comparison of EPA and BEIR VII LAR incidence and mortality calculations.]

Ms. D'Arrigo remarked that we have had a description of why the numbers are all different, but that she has a concern of selective intent by ORIA to allow less protection, resulting in a situation that the public has less protection. She asked the Committee members as individuals to not go along with this. It is her opinion that a lot of synergistic effects could have been factored in, but were not.

Ms. D'Arrigo noted that people in Europe were concerned with the Committee Examining Radiation Risks of Internal Emitters (CERRIE). The NIRS was formed to respond directly to this activity and espouse greater awareness. She ended her comments at 3:57 pm.

Dr. Kooyoomjian offered attention of the RAC to Mr. Peter Cranes' potassium letter. Mr. Crane was not present, but asked that his comments pertaining to potassium iodide be forwarded to the RAC members.

The ORIA Staff were provided an opportunity also to comment, but they (Dr. Jon Edwards and other ORIA staff) had no comment at this time.

### **Open Discussion by the RAC:**

One RAC member observed that the existing risk assessment (RA) paradigm stands, but should be looked at in the broader expectation of RA. Examples offered were Lowest Observed Adverse Effect Level (LOAEL) and No Observed Adverse Effect level (NOAEL), and what you do with the science as you go forward to the regulation. Safety factors should be applied following the RA, and attention should be given to qualitative aspects of RA.

At 4:01 pm, another RAC member observed that if the RA is looking at the items that make the most difference, then what are we doing the uncertainty estimate for? It was suggested that the RAC should clarify what it means to be looking at confidence intervals, what they (the confidence intervals) are used for, where the missing pieces (for the RA) are, and whether the assumptions are wrong or off-base. In reply, Dr. Puskin of the ORIA staff advised that just having the condition of a wide uncertainty interval itself is enough to advise people to be aware of the issues.

Dr. Kahn noted that beyond FGR-13 in the regulations, ultimately there is going to be a number created and it would be useful for the Agency/ORIA to announce their plans, and whether it is going to be the 95% confidence interval, and perhaps someday become the regulatory limit. Dr. Puskin, in response, remarked that we do not use the upper confidence limit in the regulation; instead, we look at exposure limits, along with the uncertainty bounds, to help the Agency staff determine what confidence we have in the data. One RAC member remarked that this description of the uncertainty intervals is really a statement of the "state of knowledge" on that particular item. At 4:08 pm, following some brief open discussion, the committee proceeded to a discussion in sub-groups to address the specific charge questions.

One RAC member observed that in translating the data from Japanese to the U.S. population, the data are very different in a number of respects. In summary, some highlights discussed were as follows: ...For example breast cancer is mostly pre-menopausal, and cancer of the lower end esophagus and upper end stomach is also very different. Skin cancer isn't that much different for the U.S. population. Bone cancer in black persons isn't present for 15-20% of the population, and the U.S. population risk profile is much different compared to the Japanese. For instance, overall, the U.S. population has very different patterns of survival, which differ by race. Some items cannot be quantified within the current confines and state of the science. The EPA has its own RA forum to discuss the current state of the science, as well as other related matters that might go beyond the present-day Blue Book.

One RAC member suggested that a RA regulatory guide for radiation is probably what is needed. Another RAC member encouraged EPA decision-makers to use those probability distributions that are currently available to aid in their decision-making.

Dr. Kahn asked the Agency staff if they will have the FGR-13 reviewed by the RAC at some point in the future. He advised that the RA numbers derived from the Blue Book review are going to certainly find their way into the FGR-13 format, and it was his thought that these numbers need to be judged in an open peer review venue as to whether they are “correct,” what might be their limits (ranges), and other issues. He advised that the whole world is waiting to see whether the Agency will have vastly higher or vastly lower levels. He thought that providing a table as in the old Blue Book with the dosimetry would be helpful, but it was not mentioned by the ORIA staff in their presentations.

One RAC member thought that the overall increase in the LAR is not due to changes in the Biological Effects of Ionizing Radiation (BEIR) models; rather, it was attributable in the Surveillance, Epidemiology, and End Results (SEER) model and the better state-of- knowledge for specific cancers, such as prostate cancer. It was observed by one RAC member that EPA’s low dose can be viewed as a regulatory over-exposure, and EPA’s low dose is in actuality a high dose. It was noted that accuracy errors and uncertainty estimates ought to be within each-other’s uncertainty range, and that significant figures should be of concern.

Other issues raised by the RAC members include synergistic effects other than smoking, and the LAR projections of incidence. (See Blue Book, p. 54, for LAR projections of incidence with the new EPA projections and the companion FGR 13 (1999) estimates for males and females.) The new totals are higher, and there is concern for the basis of the incidence data and the propagation of very large random errors. It was observed that cancer incidence data and big discrepancies deserve a comment. It was thought that using stationary population is a good idea. Further discussions by the RAC suggested that there is a need to identify colon, lung, breast, and residual cancer risk, and that bone cancer, and the radium dial painters risk estimates need closer examination. It was thought that overall, the differences associated with transport may not be all that different, and the main rationale should be to make the overall uncertainty analysis easier.

Dr. Puskin noted that high and low LET of liver cancer is different in the Japanese population. He also observed that the incidence of leukemia is very rare in the Japanese population. A discussion took place on mortality versus incidence, the Chechen/Mayak workers, the non-Hodgkins Lymphoma of shipyard workers, the uncertainties with the biokinetics of radionuclides and how they can be combined in the high, low and medium ranges, as well as a discussion on the uncertainties of internal dosimetry.

There being no further business to discuss for today, Dr. Kahn adjourned day 1 of the meeting at 5:34 pm.

March 24, 2009:

**Convene the Meeting**<sup>c</sup>

Dr. K. Jack Kooyoomjian, Designated Federal Officer (DFO), opened the meeting at 8:38 a.m. As with yesterday's meeting, he introduced himself as the DFO for the Radiation Advisory Committee (RAC) augmented for review of the Agency's radiogenic cancer risk assessment (RA), explained the purpose of the meeting, 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.

Members of the public present at this day includes the following: Ms. Diane D'Arrigo, Nuclear Information and Resource Service (NIRS); Ms. Megan Groll, NIRS; and Mr. Douglas Guarino, Inside EPA.

At 8:45 am, Dr. Kahn, Chair of the augmented RAC, discussed planning the day's activities. He opened the discussion on Charge Question 1 (See Charge Questions<sup>6</sup>). The discussion opened with Sub-Group B, Chaired by Dr. Wm. Morgan to discuss Charge Question 1a, namely approaches described for extending risk estimates to radiations of different LETs, - in particular, deriving site-specific risk estimates for alpha or low energy electron and photon radiations based on models derived from the A-bomb survivors, who were primarily exposed to higher gamma rays. The open discussion covered a number of issues relating to this topic. Such issues included recognition of the large amount of data on low energy protons which allows one to calculate for a low-energy photon, the cut-off for low energy beta, that the National Council on Radiation Protection and Measurements (NCRP) would look at the micro-dosimetry. A discussion also followed on some of the data, such as the Comfort & Goodhead theoretical and empirical data and other sources, such as the CERRIE report, the National Institute for Occupational Safety and Health (NIOSH) Interactive RadioEpidemiological Program's (IREP's) different RBEs, where it assigns higher RBEs to low LETs. Other discussions included recognition that there is a lot of evidence that tritium has an RBE of 2. A discussion followed that the risk estimates should be based on the "generally accepted use," and that EPA shouldn't be breaking ground here. The RAC also recognized that the International Commission on Radiological protection (ICRP) is considered to be a fairly conservative organization. It was suggested that a peer reviewed article from the Agency would be helpful in this area. It was

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<sup>c</sup> The RAC members organized into three Sub-Groups. Sub-Group A was to deal with information based on the BEIR VII Report, which includes Charge Question (CQ) topics 1b&d, & pertinent aspects of CQ topics 3a, b & c. Sub-Group B was to deal with information not based on the BEIR VII report, and includes CQ topics 1a, c & e and pertinent aspects of CQ topics 3a, b & c. Sub-Group C was to deal with the uncertainty analysis, which includes CQ topics 2a, &b and pertinent aspects of CQ topics 3a, b & c.

recognized that in the White Paper advisory, the RAC recommended a higher RBE.

A discussion followed on using an arithmetic mean (AM), and the implications for stomach cancers. It was suggested that the AM would allow additivity to combine hazards before-hand.

Some of the RAC members recognized the CQ as coming in two parts, and for examining aspects of both CQs. It was thought that the hazards should be combined before-hand, and that there are mathematical reasons to have more discussion on ERR and EAR hazards and when to do it. A discussion followed on how to get the best central estimates and on radiogenic cancer risk for ages 50-60 and 50-70. It was not all that difficult to show that there is no guarantee that the risks were additive. In fact, it was recognized that one cannot take the BEIR VII approach for the Geometric Mean (GM), because the combined values do not necessarily add up. For coherence, aesthetics, and additivity, among other features, some of the RAC members thought particularly that additivity was a good feature to have, and that is possible with the AM, whereas the GM is a non-linear operator.

A discussion took place where the RAC became more comfortable to recognize that it should not be problematic to differ from BEIR VII. While it was thought the RAC should not be subjective when obtaining a risk coefficient, it was acknowledged that when subjective assumptions are used, people tend to think on a linear scale, and some arguments tend to think on an additive scale. It was thought that there are circumstances where BEIR VII had to make a judgment call and in their interpretation, they saw a 70% relative risk and a 30% absolute risk, and it was thought that by moving toward an AM, it would be more intuitive. In consideration of public comments, the RAC members recognized that the GM weighs toward the lower risk estimate, but that the AM might be more transparent and comfortable for the public, especially for its additivity properties.

CQ 1c - - Estimation of risks not specified in BEIR VII, including kidney, bone, and skin cancers, as well as for alpha particle irradiation of the liver:

The RAC members engaged in a philosophical discussion on the merits of the BEIR VII methodology, the conservative estimates, and the property of additivity brought about by the AM. The RAC members were leaning toward the EPA to use the more conservative approach, except where there is compelling evidence. In their discussion, they referred to the term, "Scientific Equi-Poise," and it was recognized that the EAR and ERR are not examples of scientific equi-poise. More discussion followed on this point. Additional discussion followed on stomach versus breast cancer, and that the RAC had endorsed the RBE for bone cancer, and that at this juncture, it is unclear how the Agency is going to deal with skin cancer. It was recognized that there are problems with dosimetry for pre-natal exposures, and that the model needed to be fixed to reflect age-dependence for skin cancers and pre-natal exposures. It was recognized by the RAC members that the ICRP has developed a weighting scheme on skin cancer, and that the Agency/ORIA had adopted the old ICRP weighting for skin cancer. It was also recognized that there are peer-reviewed papers on the public health and financial costs. It was also recognized

that the draft Blue Book has some information on “residual cancer,” but it is not a lot of information. A discussion followed on separating out prostate cancer, because it could overwhelm the data, and to separate out kidney cancer. It was noted by the ORIA staff that this adjustment was in fact done for the Excess Absolute Risk (EAR) model.

When the next step is taken, there is a question of the isotopic effects (that is, one, two or more atoms having the same atomic number, but different mass numbers). Specifically, it was thought that the Blue Book revisions should address the isotopic effects topic, rather than hoping that nobody notices it. A discussion also took place on the topic of diagnostic misclassification, and to what extent did BEIR VII account for this. It appears that BEIR VII just accepted the diagnostic classification, and did not take it any further.

It was noted that Chronic Lymphocytic Leukemia (CLL) rates in Europe are about twice the rate of the U.S. population. The RAC members observed that the CLLs are treated by an oncologist on the outside, and that this is a problem, that they (ORIA staff) left out. Because CLL rates are so low in Japan, the conclusion is that this group is not the best to use. A discussion followed on whether it is worth it to recommend separating ovarian and Carcinoma In-Situ (CIS) tumors. For whatever it is worth, the Agency ORIA staff observed that it doesn't seem to make much of a difference. A discussion followed on the Israeli and New York Jewish children data. A conclusion followed that the ORIA staff should include skin cancer data, noting that it is very high. It was also recommended that Ra<sup>226</sup> should be considered for bone risk estimates. Several papers were cited, including that of David Hoel & Bruce Karnes 2004/5, and the Munich conference on Radium. It was also noted that there are big differences between Ra<sup>224</sup> and Ra<sup>226</sup>. For instance, Ra<sup>224</sup> tends to go to bone surfaces, and different target cells are involved. It was recognized that this is a classic data set. The radium dial painter study was recognized as an outlier. In the Ra<sup>226</sup> study, while we don't know the intakes, the body burden is very high. The ORIA staff observed that the only real (usable) number for risk estimates is from Ra<sup>224</sup>, and there is some evidence of a threshold. A RAC member thought the Argonne National Laboratory did the study and took measurements numerous times and has many (approx. 10,000) pages of data entries. He also noted that while this data is complicated to analyze, in his opinion, it is worth it to study, and that they are all high doses. It was noted that the International Agency for Research on Cancer (IARC) is looking at this and they are meeting the first week in June, 2009. A RAC member also observed that the Radium Workers Study is different than the Radium Dial Painters Study.

In further discussion with respect to Radium, a RAC member thought that it appears that the ORIA staff does not like the past analysis of thresholds and the epidemiology study, but that radionuclide exposure and form of dose delivery exists for Ra<sup>224</sup> and it mimics Plutonium. Another RAC member supported this statement, and noted that the RAC did support this in the White Paper Advisory, that it is an ubiquitous exposure to the public, and that some note should be made for Ra<sup>226</sup>, as well as pre-natal exposures.

BREAK 10:24 am Reconvene 10:45 am

Sub-Group B (information not based on the BEIR VII Report), Chaired by Dr. Wm. Morgan & Dr. Dr. Genevieve Roessler is Scribe:Resumed CQ #3a, b & c:

Dr. Kahn noted that this is an important area. For instance, if we were to recommend a new direction, or slightly new direction, are we talking just tritium, weak x rays, or all radiation?

One RAC member posed a philosophical view of whether we should look for a “best” decision or take a most conservative perspective where there is “equi-poise.” Another RAC member noted that the Committee may not reach consensus on “equi-poise.” Dr. Vanessa Vu advised the augmented RAC that the Agency has developed revised cancer guidelines in 2002 where EPA is encouraged to use the best science, should use curve-fitting, and especially where you don’t have a lot of data, then use default settings. She characterized this as the Agency’s “limited tier” approach.

Another RAC member cited the recommendations of the International Commission on Radiation Units (ICRU) and noted that when the RAC reviewed the Agency’s draft White Paper, the RAC was following generally accepted practice and assigned a higher RBE to tritium.

The Agency’s ORIA staff noted that for RA, their practice is to use the “best number.” For these numbers, the risk is not the same as the RBE. For instance on tritium, it may be clear that a higher RBE exists, and there may be a question if there is enough information, both from theoretical and experimental grounds, to use a higher RBE. Part of the Agency’s problem is the methodology of what they are working, and they are not afraid of writing the text and having the RAC commenting on this later.

A discussion followed on the method for calculating breast cancer. The consensus is that this method is good enough. A discussion followed by the RAC on the gap of incidence to mortality, the relative survival function, and recognition by the ORIA staff that the relative survival function from the draft White Paper to the draft Blue Book estimates survival obtained from the literature.

An approach on LSS data, once data is collected on detailed sites, is to try to do an empirical base calculation, but allow for variability for risk estimates that are not as well understood as others. This, of course, would lead to separate risk models with wider uncertainties. The empirical base approach allows pulling back toward the mean, if it is needed. This is helpful in the case for small numbers. However, if there is a point of discussion, it might be preferable to side with the Relative Risk Model (RRM).

A discussion took place on whether it is really necessary to estimate “priors.” The overall number of parameters are larger than originally thought (there were approx. 13 parameters). Some of the RAC members made the case for seeking a better understanding and logic, and thought that this would parallel results that we would get from an empirical base. A discussion followed on Table 4-1, page 63 in the draft Blue Book pertaining to prior distribution for the ERR model parameters. One RAC member observed that all this differs from BEIR VII. For

instance, the age effects might actually be helpful to people. A spirited discussion took place on approaches to the central estimate. One RAC member thought that it would be helpful to construct a table for each uncertainty for each site, and to see if a sensitivity analysis on the risk coefficients could give better confidence in the central estimate.

The spirited discussion continued on the topic of how one might conduct a sensitivity analysis. One RAC member envisioned the sensitivity analysis by purposely and systematically varying the point estimate by a number of increments, and the assumed ERRs versus the EARs on the other items and look at the percentage difference in the risk estimates. Implicitly the uncertainty analysis does, to some extent get “washed out.” There is some question whether such an analysis is feasible. The ORIA staff thought that for transport uncertainty, it would be workable. It was observed by another RAC member that basically the uncertainty analysis takes the most sensitive parameters with the actual model of the risk estimates. There was a discussion on how to conduct a “reality check” on such an analysis. One RAC member was bothered by the confidence limits for the LAR projection in the draft Blue Book, p. 54, Table 3-11. It was thought that if the sensitivity analysis picked up the three things that make a factor of 2 or 3 and not the ones that make a 10% or 15% difference, then that might be a useful exercise.

The ORIA staff responded that they basically understand the thrust of the discussion by the Committee, and can look at this to generally characterize the distribution(s), the uncertainty analysis and which are more or less significant contributors to uncertainty.

1:50 p.m. CQ 2b Discussion: Are the Distributions Chosen Reasonable?

It was observed that the current Life-Span Study (LSS) data are very close to empirical and some understanding of the outcomes and the variances would be helpful. There were follow-up questions regarding the factor of 3-5, and working with the uncertainty distribution(s). One RAC member pointed to Table 4-3c, p. 75 and the last column on the ratios of the upper limit to the lower limit in the EPA projection and uncertainty distribution for the sex-averaged LAR for cancer incidence. A question arose regarding how much of this is due to the transfer of one population to another? That is, how much uncertainty would be there for transferability from the Japanese/Hiroshima population to the U.S. population? ...and ... What is the uncertainty for the LAR sites all combined? Another RAC member remarked that BEIR VII did that for all uncertainty, and observed that the transfer is minor.

Another RAC member observed that the SEER data is not complete until 5 years after it is estimated, and that they are always lower than what they actually are, so you either take the current estimates, or basically wait for 5 years. A discussion took place on the data range in 1998-2002, the data on 2000, 1990, etc for the census data.

BREAK FOR LUNCH at 12:07 p.m. Reconvene at 1:30 p.m.

1:30 p.m. CQ 2b Discussion: Are the Distributions Chosen Reasonable?: Continued:

The RAC members wanted to clarify some of the issues in the Bayesian analysis. For instance, on p. 16 of the draft Blue Book, the DDREF is log-normal with a mean of one. According to the ORIA staff, the DDREF is centered around 1.5. A discussion followed on whether this is a random DDREF. The ORIA staff responded that errors in dosimetry would affect the curvature of dose/response and that the DDREF was based on the curvature of the A-Bomb survivor data and other studies. This might be described as a random quadratic effect. It was observed by a RAC member that the neutron RBE has a log-normal distribution with regard to the A-Bomb survivors. Another RAC member asked what is the probability that the neutron RBE is greater? The ORIA staff responded that this is a random multiplier, and that this uncertainty distribution on average, would lower the risk estimates.

A discussion took place on Table 4-2, p. 65 of the draft Blue Book on the non-sampling sources of uncertainty. It was suggested that the DDREF shows up twice and needs clarification. One member observed that with the dosimetry, he is always being “beaten up” by others, because the (dosimetric) uncertainty is large. Another RAC member observed that this is being given a lot more thought by others, so she is going to pass on commenting on this for now.

A discussion followed on the effect of curvature on the RBE. The ORIA staff remarked that some of the information came from the open literature, and that there are random errors in dosimetry. One RAC member observed that the bias in dose/response may not be systematic errors, that there may be multiple effects from random linear dose/response, and that this may need a sensitivity analysis. Another RAC member offered that having the ORIA staff saying that they cannot do much better than what is in the current draft Blue Book would be valuable, since the 90 to 95% confidence intervals are close to what is expected. It was thought that it might be helpful to take some excerpts from the White Paper advisory and share it with the reader of the Blue Book.

At 2:10 p.m., Dr. Kahn asked if there were any items pertaining to CQ #3. [Discussion on CQ #3 – encompasses the presentation of the following overall information and application of BEIR VII contained in the draft document pertaining to a) Scientific defensibility and appropriateness of the models and assumptions employed for estimating risk; b) Presentations of the calculations and results; and c) regarding the document’s intended purpose, the accuracy, balance, and level of detail of the scientific background material presented.]

One RAC member suggested that it would be helpful to have a clear statement on the document’s purpose. Another RAC member had comments on the RBE for medical x rays, and that the low dose to a physician is about 0.5 Grey.

At 2:15 pm. to 2:19 p.m., an open discussion on procedures took place. It was agreed that the RAC would convene for the rest of the afternoon into the three Sub-Groups (A, B & C) and meet in the same room for concurrent writing sessions until about 4:30 pm, when everyone would re-convene at that time to discuss their materials as a whole committee, with each Sub-

Group leading their discussion item. In this way, all discussions take place in one room, and the results will be discussed by the whole committee.

The Committee took a break from about 2:20 p.m. to 2:35pm.

WRITING SESSION: (2:15 pm to 4:26 p.m.) – The following represents very brief summaries and overviews of the general discussions that took place. (For more detail, refer to the draft written materials prepared by members during the meeting<sup>7</sup>).

Sub-Group A: (Dr Dale Preston is Lead & Dr. Brian Dodd is Scribe):  
(Includes Topic 1b &d, & pertinent aspects of Topics 3a, b & c.)

The Sub-Group had an overview discussion of the Geometric Mean (GM) approach and the ERR & EAR approach. After some discussion and reflection on this topic, they ultimately reached the conclusion to recommend calculation of the Arithmetic Mean (AM) as the more transparent approach as compared to the GM. For instance, they recognized that the problem of coherence disappears, that there is additivity, and other benefits accrue to the RA if the AM is used.

They discussed breast cancer modeling and basically endorsed the method outlined by the ORIA staff. They noted further that it probably should be used for other outcomes. They stressed that emphasis on incidence is important regarding radiogenic cancer. They further recommended that the ORIA staff should utilize more comparisons with BEIR VII, UNSCEAR and IARC estimates.

Sub-Group B: (Dr. Wm. Morgan is Lead and Dr. Genevieve Roessler is Scribe):  
(Includes Topic 1a, c, & e, & pertinent aspects of Topics 3a, b, & c.)

The Sub-Group discussed isotopes and different LETs, and strongly encouraged the ORIA staff to look at the radium dial painters study for Ra<sup>226</sup> & Ra<sup>228</sup>. The RBE for Tritium seems very good. They were concerned for the RBE if 1.4 is from medical exposures, and suggested that this needs to be carefully thought out by the ORIA staff. They discussed specific cancer sites, including the bone, liver, skin & kidney. For the Thorotrasts, they are happy with the literature clarification as basal cell sarcomas. They want the numbers put in a more clear fashion in the presentation. They remarked that the pre-natal exposures were relatively clear, and that the IARC will be doing a big review. It was thought that the RAC should discuss whether there should be more information pertaining to these items in the revised Blue Book.

Sub-Group C: (Dr. Daniel Stram is Lead and Dr. Thomas Borak is Scribe):  
(Includes Topics 2a & b, & pertinent aspects of Topics 3a, b & c.)

Dr. Stram advised that it took a while to understand the uncertainty distribution and shared parameters, including the Bayesian iterations to coordinate parameters for everything in the model. This discussion will provide better insight into the DDREF, transportability and the

main points. The only thing not currently covered by this Sub-Group is CQ 3c and Dr. Kahn will ask them and the Committee for comments. One RAC member observed that uncertainty discussions on the RBE values would be helpful. The ORIA staff noted that the range on RBE is 3 to 30. That RAC member pointed out that in an earlier Blue Book, it was proposed to keep the same range (RBE of 3-30), but there was a need to specify the distribution.

There being no additional business to discuss, Dr. Kahn thanked the participants and adjourned the meeting at 4:50 pm.

March 25, 2009:

Dr. Kooyoomjian, the SAB/RAC DFO re-convened the meeting at 8:34 am with brief opening remarks pertaining to this as a continuation of the public meeting of March 23 and 24, 2009. At 8:38 am he turned the meeting over to Dr. Bernd Kahn, Chair of the augmented RAC to conduct the review of the Agency’s radiogenic cancer risk assessment, who briefly touched on expectations of what the RAC should accomplish today. Dr. Kahn thanked the RAC participants for taking quality time to focus upon and conduct this review. He then turned to Dr. Jack Kooyoomjian, the RAC DFO to discuss the schedule. The schedule was discussed briefly as follows:

<b>DATE</b>	<b>DESCRIPTION OF ACTIVITY</b>
April 10, 2009	The 3 Sub-Groups confer and submit in approximately 2 weeks their first draft composite to be delivered to Dr, Kahn by April 10, 2009
May 3, 2009	Dr. Kahn, as senior editor, prepares rough composite draft to deliver to the entire augmented RAC for their review and comment
June, 2009 (approx.)	Public Teleconference to Discuss Draft Report [Preferably some time in first 2 weeks of June. Dr. Kooyoomjian will poll the augmented RAC for the best date(s). POSTSCRIPT: This ultimately became the June 18 <sup>th</sup> scheduled teleconference.]
July, 2009 (approx.)	Possible second public teleconference, if needed, to complete discussion of draft and prepare the quality review draft for submission to the SAB Charter Board in August/September time frame. [POSTSCRIPT: This became the July 22, 2009 scheduled public conference call.]
Sept 23-24, 2009 (approx.)	SAB Charter Board September review of August Quality Review Draft.

Dr. Vanessa Vu, SAB Staff Office Director, briefly touched on the expectations for the SAB Charter Board review to be held on September 23 & 24, 2009 in Washington, DC. It was thought that this schedule might be reasonable to achieve, barring any complications.

**Public Comments:** At 8:47 am, Dr. Kooyoomjian invited any member of the public to offer comments. At this time, Ms. Diane D'Arrigo of NIRS spoke and offered verbal comments, since she did not have any written materials to hand out to the RAC and other participants. She appreciated spending the last two days going through the documents and listening to the engaging dialogue. She did complain that she was disappointed in the meeting logistics and that she would have liked to have a telephone line to conference call for others to be connected into the meeting room. She did not like those limitations, where no provisions were made for conference call hookups for the interested public. Her main points are briefly summarized as follows:

- It is clear to her what EPA & ORIA are up to. 27 of 28 risk numbers are smaller (that is, pose larger risk to the public);
- She sees this as a case of ORIA manipulating the data to shift risk;
- In her view, if the majority of the Committee (the augmented RAC) were critical, she would think that the RAC's advice would at least utilize the arithmetic mean instead of the geometric mean;
- It is her contention that many in the RAC have interests in the nuclear industry. (NOTE: The Committee members disagreed very strongly with her statements, and especially on this point. There was courteous, but strong objection and some very crisp and direct dialogue and "push back" on this topic from a number of people from the Committee, as well as from the Program Office staff in direct response to her comments. In summary, the ORIA staff as well as the Committee found these statements to be quite insulting. It was pointed out to Ms. D'Arrigo that people on the Committee have worked their entire professional careers on this highly focused subject matter, that some of the Committee have worked on grants for people who have been injured on the nuclear power issue, that this is defamation of character; also, many people around the table asserted that they have spent a lifetime devoted to do good quality and reputable science.
- Ms. D'Arrigo responded that she was not trying to personally insult individuals;
- She believed that it is true that the reputations of people in the process are at stake, and she is glad that the Chernobyl report has been considered and that the concerns of some RAC members were incorporated in the process;
- She does not believe, however, that this process is protecting the most vulnerable members of the population;
- She indicated that there is a growing discussion on ischemic (?) heart disease, but fears that it will be ignored in the process;
- She also felt that the synergistic effects appeared to be dropped in the discussion;
- She believes that the precautionary principle should be adopted;
- She cited a quote from Joel Tickner of May 1997 regarding the potential harm from hazardous substances (endocrine disruptors and synthetic chemicals) in the environment and use of the precautionary principle;
- She also cited the problem in previous studies and the limits of the present state of scientific knowledge regarding the effects on ecosystems, other exposures, and the time lag of effects;
- She completed her public comment at 9:00 am, again urging application of the precautionary principle.

Dr. Kooyoomjian asked if anyone else wished to comment. There were no further requests for public comment, and the public comments portion of the meeting was closed at 9:00 am.

### **Continued Discussion:**

At 9:01 am, Dr. Vanessa Vu, following the public comment, touched on the vital importance of establishing the scientific basis of judgments, the critical nature and importance of obtaining independent scientific and consensus judgments on behalf of the Agency's science endeavors in an open and transparent manner. Dr. Jonathan Edwards of ORIA seconded Dr. Vu's comments pertaining to scientific integrity, the critical value and nature of obtaining sound science, maintaining transparency of the process, as well as openness and credibility throughout the process. He took strong exception to the charges that were leveled toward both the RAC and the Agency/ORIA participants in the public comments portion of the meeting.

Others spoke regarding their confidence in the scientific credibility of this process that is being undertaken, the openness of the process, and the numerous opportunities to comment on the multiple revisions of the draft report that will be prepared.

At 9:08 am, the Sub-Groups continued their discussion with the whole RAC and then were to re-convene to complete the writing sessions in the same meeting room at the Marriott Key Bridge Hotel. Sub-Groups A, B, and C read their March 25, 2009 drafts. The following represents brief summaries of the highlights that took place in each Sub-Group:

#### **Sub-Group A: Information Based on the BEIR VII Report (Dr. Dale Preston is Lead and Dr. Brian Dodd is Scribe):**

Sub-Group A recommended use of the arithmetic mean (AM), which allows for additivity of age groups and provides a better venue for presenting ERR & EAR estimates. The Sub-Group A participants recognized and recommended that additional logic is needed to support this conclusion, and that some summaries give a sense as to why it would lead to the difference as compared to use of the Geometric mean (GM), which has been recommended in the past. The RAC Chair (Dr. Kahn) asked if there were any comments on the excess absolute risk (EAR) recommendation, but none were offered at this time.

The Sub-Group A participants thought they could take a similar approach with other cancers, such as prostate and uterus. One Sub-Group A member recommended edits to the non-cancer discussion, but recommended to still refer to the stochastic data. Another Sub-Group A member responded that at this point, it is difficult to quantify such (non-cancer) risk, but that it would be helpful to make more comparisons to UNSCEAR and IARC.

It was noted that changes due to incident rates need editing, and that the change from the GM to the AM will partially correct this. It was thought that Sub-Group A should recommend via the RAC that the ORIA staff should clearly indicate when a dose and dose-rate (DDR)

adjustment was used. Again, the RAC Chair (Dr. Kahn), encouraged the Sub-Group A participants to be helpful by pointing out these specific items in their write-up.

Sub-Group B: Information not based on the BEIR VII Report (Dr. Wm. Morgan is Lead and Dr. Genevieve Roessler is Scribe):

Sub-Group B discussed the example of Benzo (a) Pyrene synergism with other “insults” (i.e., pollutants). It was observed that the Sub-Group B participants probably do not have that much of a problem with the life span study (LSS), but exposures with other pollutants that would create a really sick group would demonstrate the problems created by synergism.

A discussion followed pertaining to low-energy electron and photon radiation. The approach offers a way to do this, but the risk coefficients for population x rays may be an apparent contradiction. The Sub-Group B participants thought that it is important to distinguish between the RBE diagnostic and therapeutic photon energies. The Sub-Group B participants observed that the cohorts that are medically irradiated need to be better described and defined by the ORIA staff. The ORIA staff clarified that spondelitic leukemia has come out lower than the A-Bomb survivor data, and in BEIR VII, there are older studies of medical technicians. The ORIA staff observed and remarked that sometimes there are medical inconsistencies that cannot easily be resolved.

One Sub-Group B member thought it would be helpful to understand what kind of x ray studies would be contributing to understanding the LSS data. One member cited the Hunter & Murad meta-analysis of the epidemiological data. A discussion followed on lung, liver, kidney and bone data. It was briefly summarized as follows:

Bone- This is a contentious area. Need to look at Ra<sup>226</sup> and Ra<sup>228</sup>.

Skin - Good, & need to clarify that BCC is the area to consider.

Liver – The RAC recommended further study and the ORIA staff did pick up on the thorooplast patients. The Sub-Group B participants asked the Agency staff if they could break out the types of liver cancers. One RAC member raised the RBE issue, and noted that if we wanted to be conservative, we would generate a lower RBE. Another RAC member objected to the term “conservative.” A Sub-Group B member observed that in cases where they might object to use of the RBE, or a range, perhaps one could recommend use of the lower number; however, he understands that it is intellectually appealing to be consistent. Another RAC member made the suggestion to drop the word, “conservative” in the text.

The Sub-Group B participants discussed the colloidal suspension of thorium in liver as needing to be addressed. One RAC member has written on cancer in the Mayak workers, and observed that there is huge uncertainty and the results are dramatically different between males and females. It was remarked that one can show the confidence intervals for the original estimates, but not for the RBEs.

Kidney – It was observed by one RAC member that the statement on kidney is fine, but there is not a recommendation. He noted that the conclusion in the draft Blue Book is OK on this.

One RAC member made a clarification to the Sub-Group B draft text that there is a 6% excess relative risk within the radium dial painters population. Another RAC member pointed out that while there is a nice statement here, it currently does not have a recommendation. Another RAC member further observed that one could leave the statement to be general or specific to all risk (radiation as well as chemical risk).

Lung – One RAC member believes that he needs to incorporate lung and leukemia risks into his write-up for alpha emitters. He also observed the separate model with an RBE of 20 for lung risk, and noted that the information is fairly preliminary at this time. He further observed that the RBEs in the annual study would be consistent with an RBE of 20, and some would not.

Pre-Natal – One of the RAC Sub-Group B members asked if there are any additional studies addressing the risk of utero and age of fetus at the time of actual exposure to radiation. Another RAC member observed that the risk by trimester of exposure does not see much variation (approx. 1,000 people exposed above 5 milliREM).

One Sub-Group B member observed that it is generally assumed that all three trimesters have the same risk. Another observed that there are “windows of susceptibility” and that we may not see this for all adults. It was also observed that the stem cells are there.

Sub-Group C: Uncertainty Analysis (Dr. Daniel Stram is Lead and Dr. Thomas B. Borak is Scribe):

The Sub-Group C members noted the uncertainty with the lifetime attributable risk (LAR) Type 2 parameters, where there is little or no information in LSS data. This ends up with a distribution where picking these parameters is highly important. It was also cited that there is a need to identify the fraction. Another issue is why is the Bayesian uncertainty analysis giving intervals that are not necessarily symmetric? It appears in the write-up that there is a joint analysis of separate cancers. The Sub-Group C participants were asking the Agency ORIA staff for clarification in the joint analysis. It appears that there is a joint analysis of separate cancers. Also, the assumption of commonality may be reasonable, but it may need a bit more clarity in the use of the likelihood function. The Sub-Group C participants are not objecting to the approach. In response, the Sub-Group C participants will add this discussion to the write-up regarding the likelihood functions.

There are other issues, such as depiction of priors. It is not an issue for data in the LSS, which would dominate the priors. The Sub-Group C participants thought that there needs to be more clarity on information about the choices (e.g., log-normal with a distribution of 1).

The Sub-Group C participants think that the Monte Carlo approach with random estimates of parameters (especially for Type 2 errors) and the coordinate correlation for each step, such as with the transfer weight factors, the DDREF which is used, etc. explains approx. 50% of the variation, and this is very useful.

The Sub-Group C participants concluded as to where the text probably needs to be revised, and noted that the basic risk question centers on risk transfer. The Sub-Group C participants appreciate why some populations are susceptible to different kinds of cancers (e.g., African Americans to non-African Americans), noting that individual susceptibility to risk factors change in different populations. It is therefore reasonable to assume that if the baseline is similar in the Japanese and the US populations are similar - - - but there is no guarantee that you can transfer risk.

The Sub-Group C participants see a need to discuss population risk differences and similarities, as well as weighting in the models for transfer of risk. The relative risk parameters seem similar for different populations. For instance, Mayak workers, Chechen study -- - arguing that consideration for putting more weight on the relative risk model, rather than the absolute risk model. The gut feeling of the Lead for Sub-Group C (Dr. Stram) is that there is too much emphasis on the absolute risk model.

A RAC member observed that the excess risk rates seem to be similar to the U.S. population, that ICRP and BEIR put all the weight on the excess absolute risk model, and also observed that he thinks we will see large differences by sites.

Another RAC member observed that BEIR VII gives more weight, and does provide a fairly thorough discussion of all the rates. The ORIA staff promised to pay a little more attention to “where the ball ends up,” and remarked that ultimately in the best estimate, ORIA leans toward BEIR VII.

One RAC member concluded that we want to deal with significant uncertainty analysis, and another RAC member urged to use BEIR VII when in doubt or if there is any question. The ORIA staff observed that in the Bayesian analysis, they did look at the likelihood estimates. In response, one RAC member remarked that she doesn’t fully understand the implications - - - but that if it gives results similar to the central estimates, that gives her some comfort. The ORIA staff observed that the functional form of the likelihood estimate is the same (or close to) BEIR VII.

One RAC member observed that, in a sense, the sensitivity analysis is an instrument to enlighten us. Another RAC member observed that genetics, life-style and epi-genetic information all play a role, but he would be cautious to blame genetics for everything.

One RAC member asked if we have a recommendation to wait to see more coherence between estimates and the uncertainty estimate? The RAC is not objecting to the different uncertainties, based on the different assumptions. The Committee simply believes that that the

explanation needs to be abundantly clear, and that the reasoning needs to be more detailed, with elicitation of the priors. The Committee is asking that in the main body of the text, or in the appendix, the rationale be clearly spelled out.

LUNCH: The Committee took a break for lunch at 12:01 pm. They reconvened at 1:11pm.

Reconvened:

The RAC re-convened. Dr. Kahn asked for the revisions of text from the three Sub-Groups by April 10<sup>th</sup>, with a cc to Jack Kooyoomjian, DFO for the augmented RAC.

CQ #3 Discussion: (To be added later as appropriate to the respective Sub-Group draft materials):

The following is a very brief summary of highlights of the discussions that took place:

CQ3a – Scientific Defensibility and Appropriateness of Models:

EPA depends on UNSCEAR, ICRP and others. Some approaches are different, so that where different groups use differences in the RBE, there is a need for ORIA to explain differences between one or the other.

CQ 3b – Presentations and Calculations and Results:

In brief, ORIA did a good job. More is to follow in the written materials.

CQ 3c – Document’s Intended Purpose:

- This draft Blue Book logically leads to FGR-13. A discussion took place on Becquerels in air, water, and so forth. More to follow in written materials,
- What is this going to be used for? This was asked by various users, and needs to be answered,
- Some items in FGR-13 and others are “need to know,” but maybe not used in FGR-13 -- - but shows how “clever you are,”
- What is needed are clear illustrative examples of how the revised and improved knowledge will be applied for different isotopes,
- ORIA staff discussed in a qualitative way whether there are (or are not) changes,
- Presentation is remarkable in many ways. Especially with the application of uncertainty, everyone agrees that ORIA should present a number associated with uncertainty,
- One application could be that ORIA does not have to do much with the minor uncertainties (e.g., close to 1.0 or 1.2),
- Also, uncertainties could be a guide to certain measurements, and they certainly need to be put into context.

At this point, Dr. Kahn went around the table and asked each member to raise one (1) issue, if they felt a message needed to be given beyond what we have already conveyed to the ORIA staff. We started with Mr. Bruce Napier, as follows:

- Mr. Bruce Napier – he passed for the present.

- Dr. Richard Hornung – ORIA has done an enormous amount of high priority work. You have done a very thorough job, and congratulations.
- Dr. Jon Links – To the extent we do something novel and that it contradicts something done a year ago, (e.g., Geometric Mean versus Arithmetic Mean), we need to justify it, showing the complete logic.
- Dr. Wm. Morgan – He appreciates the complexities involved in this exercise, and welcomed the opportunity to engage.
- Dr. Daniel Stram – He hopes that the comments deal with simple clarity, but not in the matter of uncertainty.
- Dr. Genevieve Matanoski – The Agency (ORIA) has done a good job. There are a lot of things to think about, such as non-cancer end-points. Brain tumors are a problem (both malignant and non-malignant). Simple growth may be a factor.
- Dr. Dale Preston – In the LSS we did include unspecified tumors (to agree) with Dr. Matanoski. He is quite impressed with this exercise. He believes that it is the most thorough effort and amount of work to express uncertainties.
- Dr. Genevieve Roessler – Comments on mostly low energy photons. What is really needed on this draft is a thorough explanation of the logic. Method for RBEs – are they discrete values off of the curve?
- Dr. William (Bill) Field – He recognized this exercise as a tremendous effort, with attention to detail. He noted some of the perception issues regarding the biases of the process. He encouraged the ORIA staff as they go forward with edits, to look at leukemia and to see if it is possible to split this out.
- Dr. Brian Dodd – Passed, and remarked that they did a good job.
- Dr. Shirley Fry – Thanked ORIA and re-iterated comments of the group. Asked how the Blue Book is reflected in FGR-13.

Dr. Jerome Puskin spoke and offered that he heard a lot of good, thoughtful comments. One thing he wanted to highlight is how energy emerges from a photon is a complicated issue, and he recognized that they need to greatly expand their discussion on this. The peer review paper could be authored by some party such as Keith Ackerman, for instance.

- Dr. Wm Morgan - He mentioned the HBA report on RBE. Could make an Appendix to the Blue Book report regarding biophysical approach to show how to calculate the numbers.

- Dr. Bernd Kahn – He thought that the Appendix could be separately published.
- Dr. Jerome Puskin – The advice on RBE is pretty clear. ORIA will review the evidence on radium dial painters. They will fix the skin cancer portion of the text. The advice of pre-natal is reasonably straight-forward.
- Dr. Mary Clark – She thanked Dr. Kahn and the augmented RAC and Dr. Vu for a productive three days with very helpful comments. This was much-appreciated by the ORIA staff.
- Dr. David Pawel - He thanked everyone. He found this to be a very pleasant and satisfying experience, and was very grateful for the opportunity to have this constructive and thoughtful exchange. The review provided thoughtful understanding of many points. In particular, the detailed and candid follow-up to the charge questions is appreciated.
- Dr. Jon Edwards – The ICRP models on biokinetics and dosimetry will be used in FGR-13, but the Blue Book is also used.
- Dr. Shirley Fry – She believes that a written summary on how decisions are made based on the scientific information would be helpful. Do you put the logic there in the Blue Book revisions, or someplace else? May need this logic displayed in FGR-13.
- Dr. Wm. Griffith – He congratulated ORIA staff. He noted that it takes courage for anyone who works on RBEs. It will be interesting to see what the next iteration will look like.
- Dr. Ethel Gilbert – She is also impressed with the ORIA work in the Blue Book. Congratulations on a good job!
- Dr. David Hoel – He thanked the ORIA staff for the excellent work.
- Dr. David Pawel – He offered the following insights that have registered strongly with him:
  - o He commented on the pre-recommendation of weighted Arithmetic Mean from transfer to the US population,
  - o He sees that they (the augmented RAC) have accepted the methods for breast cancer methodology,
  - o He acknowledged that there were a lot of comments related to the need for clarity of the presentation,

- He sees the need for providing more details about the updated SEER data,
  - Everything conveyed during these 3 days is clear and makes sense to him,
  - The uncertainty analysis – He sees the need to make an effort to describe in detail the logic and the subjective priors and to identify which areas deal with public factors,
  - The sensitivity analysis – He understands that they need to put things in context, and,
  - Methods Analysis & Uncertainty Analysis – It is clear what is needed regarding comments on radiation, the need to provide clarity in the presentation and in the dealing with the uncertainty analysis, and to provide consistency regarding the places where it will help to clarify issues.
- Dr. Jon Edwards – In his closing remarks, he noted that it was a pleasure to work with Drs. Puskin, Pawel and Clark in ORIA. He particularly appreciates that the SAB/RAC is dedicated to helping EPA use the best possible science in their decision-making, and he looks forward to their report.

**Concluding Remarks and Adjournment:**

At 1:50 pm, Dr. Kahn offered brief concluding remarks. He thanked the EPA/ORIA staff for their collegial exchange, and the RAC members for their contributions. He also thanked Dr. Vu and Dr. Kooyoomjian for their hospitality and providing a forum for productive dialogue. There being no further business to discuss, the meeting was adjourned at 1:55 pm.

Respectfully Submitted:

Certified as True:

\_\_\_\_\_/S/\_\_\_\_\_  
 K. Jack Kooyoomjian, Ph.D.  
 Designated Federal Official  
 Radiation Advisory Committee (RAC)  
 Augmented for Review of the Agency’s  
 Radiogenic cancer Risk Assessment

\_\_\_\_\_/S/\_\_\_\_\_  
 Dr. Bernd Kahn, Chair  
 Radiation Advisory Committee (RAC)  
 Augmented for Review of the Agency’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**

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**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

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**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

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

#### **SCIENCE ADVISORY BOARD STAFF**

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## Materials Cited

The following meeting materials are available on the SAB website, <http://www.epa.gov/sab> , at the [March 23-25, 2009 SAB RAC Meeting](#) page.

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<sup>1</sup> *Federal Register* Notice: Tuesday, February 3, 2009, Vol. 74, No. 21, pages 5934-5935

<sup>2</sup> Meeting Agenda, RAC Augmented for the review of EPA's Radiogenic Cancer Risk Assessment, March 23-25, 2009

<sup>3</sup> The Scientific Basis and Need for Updating U.S. Radiogenic Cancer Risk Estimates: Presentation by Jon Edwards, EPA ORIA.

<sup>4</sup> EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population, Draft December 2008

<sup>5</sup> SAB Review of "Blue Book": EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population. Presentation by Puskin and Pawel, EPA ORIA

<sup>6</sup> Charge for Cancer Risk Estimation from Exposure to Ionizing Radiation - Revised Blue Book. Memorandum dated January 26, 2009 from Elizabeth A. Cotsworth, Director, Office of Radiation and Indoor Air, to Vanessa Vu, Director, Science Advisory Board

<sup>7</sup> Written Materials Prepared by the Augmented RAC During the March 23-25, 2009 Meeting