



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF
AIR AND RADIATION

January 26, 2009

MEMORANDUM

SUBJECT: Advisory Review of the Draft Document: *EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population*

FROM: Elizabeth A. Cotsworth, Director /Signed/
Office of Radiation and Indoor Air

TO: Vanessa Vu, Director
Science Advisory Board

This is to request that the Science Advisory Board's Radiation Advisory Committee conduct a peer review of the attached draft document entitled *EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population*.

Background

In 1994, the Environmental Protection Agency (EPA) published a report, referred to as the "Blue Book," which lays out EPA's current methodology for quantitatively estimating radiogenic cancer risks. A follow-on report made minor adjustments to the previous estimates and presented a partial analysis of the uncertainties in the numerical estimates. Finally, the Agency published Federal Guidance Report 13 (FGR-13), which utilized the previously published cancer risk models, in conjunction with International Commission on Radiological Protection (ICRP) dosimetric models and U.S. usage patterns, to obtain cancer risk estimates for over 800 radionuclides, and for several exposure pathways. Prior to their publications, these three documents were first reviewed by the Science Advisory Board (SAB).

The National Research Council of the National Academy of Sciences released a report in 2006 on the health risks from exposure to low levels of ionizing radiation. Cosponsored by the EPA and several other Federal agencies, *Health Risks from Exposure to Low Levels of Ionizing Radiation BEIR VII Phase 2* (BEIR VII) primarily addresses cancer and genetic risks from low doses of low linear energy transfer (LET) radiation.

In a White Paper which was the subject of an SAB advisory review in 2006, we outlined proposed changes in our methodology for estimating radiogenic cancers, based on the contents of BEIR VII and some ancillary information. For the most part, we proposed adopting the models and methodology recommended in BEIR VII; however, in the White Paper we also noted that certain modifications and expansions were desirable or necessary for our purposes.

The Agency accepted the recommendations of SAB, and is now requesting that the Agency's Science Advisory Board review the attached draft document entitled *EPA Radiogenic Cancer Risk Models and Projections for the U.S. Population* developed as a result of this advisory review. The revised Blue Book will then serve as a basis for an updated version of FGR-13.

Specific Request

This draft document presents the scientific basis for new EPA estimates of cancer incidence and mortality risks due to low doses of ionizing radiation (IR) for the U.S. population. These estimates are based on available information, and for the most part, are calculated using models recommended in the National Research Council's BEIR VII Report.

1. As in BEIR VII, models are provided in the draft document for estimating risk as a function of age at exposure, age at risk, gender, and cancer site, but a number of extensions and modifications to the BEIR VII approach have been implemented. First, BEIR VII focused on the risk from low-LET radiation only, whereas risks from higher LET radiations are also addressed here. Second, this document presents a slightly modified approach for combining BEIR VII models for projecting risks from Japanese A-bomb survivors to the U.S. population. Third, this document goes beyond BEIR VII in providing estimates of risk for certain other cancers. Fourth, a modified method is employed for estimating breast cancer mortality risk, which corrects for temporal changes in breast cancer incidence and survival. Finally, quantitative estimates of risks for skin cancers and from prenatal exposures are included. Please comment on the appropriateness of the following either not specified in BEIR VII or else otherwise modified by EPA from BEIR VII:
 - a. 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 energy gamma rays (see Section 5).
 - b. EPA's adaptation of the BEIR VII weighted geometric mean approach for combining the EAR and ERR models for projecting risk from the LSS to the U.S. population (see Section 3.9).
 - c. Estimation of risks not specified in BEIR VII, including kidney, bone, and skin cancers, as well as for alpha particle irradiation of the liver (see Sections 3.3 and 5.1).
 - d. Method for calculating breast cancer mortality risk, accounting for the relatively long time from detection until death (see Section 3.10)
 - e. Approach for separating out nonfatal skin cancers and risks from prenatal exposures from the overall risk estimates (see Sections 3.3 and 6).
2. BEIR VII's approach to uncertainty is primarily based on data from the Life Span Study (LSS). The LSS provides a great deal of information on risks for many cancer

sites; however precision is limited by errors in dosimetry and sampling errors. The sampling errors are often quite large for specific cancer types, and the uncertainties are even larger if one focuses on a specific gender, age at exposure, or time after exposure. Another important uncertainty is the transfer of site-specific cancer risk estimates to the U.S. population, based on results obtained on the LSS population, for sites with substantially different baseline incidence rate. Compared to BEIR VII, this document provides a somewhat altered and expanded analysis of the uncertainties in the cancer risk estimates.

Regarding the uncertainty analysis contained in Section 4,

- a. Please comment on the adequacy of the approach to uncertainty analysis.
 - b. Are the distributions chosen for the various sources of uncertainty reasonable?
3. Please comment on the presentation of the following overall information and application of BEIR VII contained in the draft document:
- a. Scientific defensibility and appropriateness of the models and assumptions employed for estimating risk.
 - b. Presentations of the calculations and results.
 - c. Regarding the document's intended purpose, the accuracy, balance, and level of detail of the scientific background material presented.

If you have any questions about this request, please contact Mary E. Clark of my staff at (202) 343-9348.

Attachment

cc: Carl Mazza, OAR