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30 August 2007

Granger Morgan, Chair, Science Advisory Board
Jill Lipoti, Chair, Radiation Advisory Committee
U.S. Environmental Protection Agency
Washington, D.C.
By e-mail to Miller.Tom@epamail.epa.gov
cc: Jack Kooyoomjian

Subject: Comments on the July 18, 2007 SAB review of the EPA draft White paper "Modifying EPA Radiation Risk Models Based on BEIR VII" provided for the meeting of the SAB by teleconference, 5 September 2007.

Dear Drs. Morgan and Lipoti:

The following are my comments on the July 18, 2007, SAB review of the EPA draft White paper "Modifying EPA Radiation Risk Models Based on BEIR VII" for your consideration at the September 5, 2007, teleconference call and in the process of finalization of the review.

Issue 1: "Exposed" and "non-exposed" populations

On page 4 of the letter, the review states that

> Thus, as a cautionary note, the RAC recommends that the EPA discuss potential problems associated with the use of LNT dose response model risk estimates in very low dose settings. Currently at these low doses, statistically significant differences between the cancer rates among "exposed" (defined study populations) and "non-exposed" (defined comparison populations) are not observed. These near background doses are only a fraction of those that have been found to be associated with statistically significant differences in cancer frequency between "exposed" and "non-exposed" populations.

The same or similar language also appears elsewhere (page 4 of the summary and page 23 of the review). The fact that statistically significant excess cancers due to exposures resulting from anthropogenic activities cannot be detected is not relevant to protection of

public health. The relevant fact is that over 70 years, natural background provides at least 6 rem cumulative dose, usually more. Since there is clear evidence of risk at several rem or more, the linear-no-threshold hypothesis applies and the cancers would be expected to occur. The difficulty of detecting the excess in epidemiological studies should not be allowed to confuse the central issue, which is this:

All anthropogenic doses, no matter how small, are expected to cause increased cancer risk. The best present estimate is that the increased risk is proportional to dose. One Anthropogenic exposures occur on top of cumulative natural exposures, which are large enough to create some cancer risk.

I recommend that the passage on page 4 of the letter and the companion passages (p. 4 of the summary and p. 23 of the report) be deleted and replaced by the three italicized sentences above.

2. Fetal dose and risk

Question 2h of the charge to the committee concerned fetal exposure and risk. It is reproduced below from p. 21 of the review:

> *Estimation of risk due to prenatal exposure. EPA's current lifetime risk estimates do not include risk from prenatal exposure, and BEIR VII does not provide them. The draft White Paper uses ICRP recommendations to project its risks of childhood cancers induced by in utero exposure. Please comment on the soundness of the approach described in the draft White Paper to apply ICRP as described in Section IV.*

The response of the committee is deficient in one fundamental respect because it omits important elements of risk. It also endorses an incorrect approach to estimating certain fetal doses. I consider each of these issues in turn.

Omissions of risk

The charge to the committee was not restricted to cancer risk, but to "[e]stimation of risk due to fetal exposure." Cancer risk may not be the main risk due to radiation exposure in very early stages of fetal development. Early pregnancy failures (for instance in the first two to three weeks) and malformations are also risks when exposure occurs in the first few weeks. The committee should have considered these risks. Granted that some of these risks are difficult to evaluate, notably from internal exposure (see below), but that fact itself is relevant and important enough that it should be explicit. The EPA needs to develop a research agenda to get reliable quantitative estimates of non-cancer risks of early fetal exposure. It also needs to set standards in a way that are protective and reasonably conservative.

Incorrect exposure assessment

The review has endorsed the ICRP approach for estimating fetal radiation dose (p. 2 of the letter, p. 3 of the Executive Summary, and p. 21 of the full review). For instance, p. 3 of the Executive Summary, states

> The RAC concludes that it would be reasonable for the EPA to use the referenced estimates of cancer risk from *in utero* exposure to external radiation sources, and the dose coefficients provided by the ICRP as a basis for developing its risk estimates for *in utero* radiation exposure from internally-deposited radionuclides.

This recommendation should be accompanied by a critical caveat regarding an important limitation of the ICRP risk estimates. Specifically, the ICRP 88 assumption that the dose to the embryo/fetus in the first eight weeks of pregnancy is the same as that to the uterine wall[1] is not valid for alpha emitters and for low-energy beta radiation emitters, such as tritium. The actual deposition of alpha and low-energy beta emitters in the embryo/fetus needs to be determined to estimate dose and risk.

In other words, since the ICRP's model is not valid for the cases cited, a new one is needed for the first eight weeks of development of the embryo/fetus for alpha and low-energy beta emitters. This is especially important since structural organization and a substantial component of organogenesis occur in the embryo/fetus over this period. This period is therefore especially important for the risk of malformations and early pregnancy failures. The context of this comment is provided on page 73 of IEER's report *Science for the Vulnerable* (by Arjun Makhijani, Brice Smith, and Michael C. Thorne). It is on IEER's website at:

http://www.ieer.org/campaign/report.pdf

I specifically pointed out this problem to the RAC in written comments, with specific recommendations as to how the text should be corrected. My letter of March 12, 2007, to the Designated Federal Official, written for the RAC's consideration is attached (See Attachment 1). I have been given to understand that it was transmitted to the members of the RAC. (Some of the language in this letter is drawn from my March 12, 2007 letter).

I am mystified that the July 18, 2007, draft report does not even mention this comment or deal with the issue in any way. The ICRP model is clearly inapplicable to certain radionuclides, including alpha-emitters and tritium. This is an issue of immense potential importance that should not be ignored or brushed under the rug. For instance, discharges of tritium from nuclear power plants and tritium contamination of water due to nuclear weapons activities in decades gone by, is widespread. Is the EPA going to assess the impact to developing fetuses based on an evidently incorrect model? And is the RAC willing to go on the record as having endorsed the ICRP model without due consideration of its obvious deficiencies in regard to certain radionuclides for the critical first eight weeks of pregnancy?

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[1] International Commission on Radiological Protection. *Doses to the Embryo And Fetus From Intakes Of Radionuclides By The Mother*. ICRP publication 88. Annals of the ICRP, 31(1/3) 2001. Corrected version. Oxford: Pergamon, May 2002, p. 20.

It would be understandable if the RAC had not addressed the issue due to an oversight. But given the circumstances, I would think that the RAC and the SAB would not want to find themselves in the embarrassing position of brushing a significant scientific problem under the rug, after it has clearly been pointed out to them. The embarrassment would be compounded since the problem was pointed out as part of public comment to a committee chartered under the Federal Advisory Committee Act (FACA).

In sum, the RAC has failed to properly review the ICRP model. The review must be modified to explicitly discuss the ICRP model for fetal dose, including dose from alpha-emitters and tritium during the first eight weeks of pregnancy. This modification will require substantial work. I recommend therefore that the SAB send back the review to the RAC for detailed consideration of the specifics of the ICRP model for the first eight weeks of pregnancy and of non-cancer risks extending to the first 14 weeks of pregnancy. I expect that there will be one or public meetings during which the public may provide comment on the RAC's work in progress on this point. I also recommend that the non-cancer risks discussed above be part of the same reconsideration and redrafting of the report.

Issue 3: RBE for low-energy photons and tritium beta particles

The review has concluded that an RBE for low-energy photons (<30 KeV) and low-energy beta particles, such as those from tritium, "in the range of 2 to 2.5 seems reasonable" (p. 2 of the letter, p. 2 of the Executive Summary, and p. 20 of the report).

IEER supports that shift away from an RBE of one for these radiation types and the choice of 2 to 2.5 for non-pregnant adults. However, in the case of tritium, the RAC report does not discuss the dependence of the tritium RBE on age at exposure and on the form of tritium (tritiated water versus organically bound tritium). I discussed this in some detail in my letter of March 12, 2007. I also included the table of RBEs that my colleagues and I calculated based on the research of Harrison, Khursheed and Lambert.[2] This is all reproduced in Attachment 1.

I recommend that the SAB adopt the following conclusions regarding low-energy photon and low-energy beta radiation exposure, including exposure to beta radiation from tritium.

1. An RBE in the range of 2 to 2.5 for low-energy photons and electrons, including tritiated water, should be adopted for purposes of setting radiation protection standards for non-pregnant adults.

[2] J.D. Harrison, A. Khursheed, and B.E. Lambert. "Uncertainties in dose and coefficients for intakes of tritiated water and organically bound forms of tritium by members of the public." *Radiation protection dosimetry,* v. 98, no. 3 (2002), pages 299-311.

2. An RBE of 4 to 5 for low-energy photons and electrons, including tritiated water, should be adopted in radiation standards for fetal exposure and for children.

3. The RBE for organically-bound tritium (OBT) is higher than that of tritiated water, possibly by a factor of 2 to 2.5, as indicated by Harrison, Khursheed and Lambert 2002. The EPA should initiate a review of the issue of OBT in order to develop the appropriate regulatory guidance both as regards the RBE and as regards the circumstances in which the use of a higher RBE is warranted.

4. The EPA should also initiate a review as to whether a higher RBE is warranted for prospective fathers in view of the potential exposure of germ-line cells to tritium.

I made the first three suggestions in my March 12, 2007, letter. I have added the fourth here. I note that the RAC also rejected the first three suggestions without discussion of the underlying scientific issues. The RAC and SAB are obliged to take public comment into account. My comments were based on published scientific work and a reasonable and specific critique of the draft. I do not expect that every comment be accepted, of course. But there is no evidence in the July 18, 2007, draft or any other public material that the serious underlying scientific issues were given consideration by the RAC before it forwarded the report to the SAB. On this account as well, the review should be sent back for reconsideration and redrafting.

Issue 4: Section 8 of the review: Issues beyond the charge

On page 25 the, July 18, 2007, draft of the review states

> The RAC received written and oral comments from members of the public which raised concern about the need to set radiation protection standards for the most sensitive population for specific cancer end points, instead of the use of "Reference Man." The RAC understands that in the existing Federal Guidance Report 13, EPA-ORIA has already used the current ICRP age groups (infant, 5-10, 15-20 year olds) in both the cancer risk coefficients and the underlying radiation dose coefficient. The RAC recommends that EPA continue this practice so that individuals using the Federal Guidance for assessing compliance can be explicit about ages and make appropriate assumptions.

This section is substantially different than the February 2007 draft of the review, which recommended that the EPA consider the ICRP 89 Reference Family concept as a replacement for "Reference Man."

An endorsement of FGR 13 is not a substitute for getting rid of Reference Man. First of all, the age-specific risk factors in FGR 13 are not gender-specific. The EPA averages male and female risks in its regulatory practice in a way that is entirely inappropriate, given the evolution of radiation risk assessment since FGR 11 and BEIR V. When these

latter documents were the most recent science, a sex-specific differentiation of overall cancer risk was not necessary. The risk to females as estimated in BEIR V was about 5 percent greater than the risk to males (in the case of a single exposure of 10 rem). BEIR VII is a radical departure from BEIR V. In this regard FGR 13 is a radical departure from FGR 11 as well. Yet, the review contains no discussion of sex-specific overall risk factors of exposure to radiation (other than the risk model for lung cancer in women). Neither does the report consider the implications of incorporating the age- and sex-specific risk factors for reducing overall dose limits. The implications for female children versus male children are also important, since females are at greater risk when they are young as well. The FGR 13 CD containing the numerical dose and risk conversion factors by radionuclide does not provide any sex-specific risk factors. It averages risks in a way that is prejudicial to females, including female children, since they are now known to be at higher risk overall, and at much higher risk for certain cancers.

Finally, the problem of fetal exposure also has a sex-specific aspect. Males continuously produce germ-line cells, but ova are produced when a female is in utero. Hence, in utero exposure must also consider females and males according to the risks that they face; it must also factor in inter-generational risks. I had recommended not only that the RAC specifically recommend that Reference Man be abandoned (a recommendation that was accepted in the February draft, in milder form, and then rescinded without explanation). I had also recommended that those most at risk be protected. I noted that in some situations the most at risk might be children, in other situations it might be breast feeding or pregnant women, in others, men who want to be fathers, or, in yet others, the embryo/fetus. None of these considerations found their way into the report. Even men in their potential capacity as fathers were not considered.

It should also be noted that FGR 11 is still the basis of the levels of maximum allowable exposure in many circumstances. For instance, FGR 11 and Reference Man are still the basis of ResRad, the computer model that is used to estimate the dose from residual radioactivity in soil and that is used to set clean-up levels at contaminated sites. It is unconscionable that, at a time when the ICRP itself has moved away from a concept of a young "Caucasian" male being at the center of the radiation protection universe, the RAC should maintain silence on this critical problem. It is even more mysterious that, having recognized it as an issue and made a rather mild recommendation to the EPA to wake up to a world in which there are women, children, and non-Caucasians, the RAC should have retreated, at least implicitly, into a White male domain without explanation.

I am certain that the public would be appalled should the SAB not make an explicit recommendation that the EPA reject any standards and guidance based on Reference Man. An explicit statement referring to the need to change all standards, regulations, and guidance (including models such as ResRad) is necessary. On this matter as well, the SAB should send the review back to the RAC for reconsideration, including taking public comment. I also recommend that when the RAC and SAB reject public comment that some explanation be provided as to the scientific basis for its rejection.

I will be making public comment along the lines of this letter during your September 5, 2007, teleconference call. Your DFO, Tom Miller, advised me to send you written comments in advance so that you could see if before your call and consider it. I look forward to hearing your response to the above concerns, analysis, and recommendations on September 5, 2007.

Thank very much.

Yours sincerely,

Arjun Makhijani, Ph.D.
President, Institute for Energy and Environmental Research

Attachment 1: Letter of March 12, 2007, from Arjun Makhijani to the RAC

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12 March 2007

Jack Kooyoomjian
Designated Federal Official
Radiation Advisory Committee
U.S. EPA
Washington, D.C.

Subject: Editorial suggestions for the RAC working draft dated 23 February on EPA's BEIR VII White paper.

Dear Jack

As per the discussion during the RAC conference call on 9 March 2007, I am submitting some suggestions for changes, deletions, and additions to the RAC draft of 23 February report reviewing the EPA's White Paper on BEIR VII. I have adopted your suggestion and am specifying the changes I recommend for the RAC's consideration. As you know, I deeply appreciate the RAC's exemplary openness in making room for public comment and in considering it seriously and carefully.

1. Letter p. 3, lines 45 and 46 and p. 4, lines 1 to 4, the following is stated:

> As a cautionary note, the RAC recommends that the EPA discuss potential problems associated with the use of LNT risk estimates in very low dose settings where currently statistically significant differences are not observed between the cancer rates among exposed populations relative to those among non-exposed populations and where the doses are a fraction of those associated with exposure to background radiation.

Recommendation: This sentence should be dropped.

Reason: There are no "non-exposed populations." All anthropogenic exposure occurs on top of natural background radiation. While this can be defined in different ways (such as including or not including indoor radon), over 70 years, a lower bound estimate of lifetime exposure to natural background is 6 or 7 rem. Hence any anthropogenic exposure is on top of this. Since there is clear evidence regarding the effects of low-level radiation at such levels, there is no reason to believe that increments to these levels do not add to cancer risk. Indeed, the LNT hypothesis leads one to conclude that they do. The

problem of low anthropogenic doses is that the cancers it causes are difficult to detect in the presence of those caused by natural background radiation (which could amount to a few percent of cancers) and from other non-radiogenic causes. The implication in the sentence as it stands -- that natural background radiation does not cause cancer -- is at variance with the RAC's endorsement of the LNT hypothesis.

2. p. 3 of the Executive Summary, lines 15 to 17, the RAC recommends that the EPA base its "risk estimates for *in utero* radiation exposure on those recommended by the ICRP for internally-deposited radionuclides." The same or similar sentence appears on p. 3 of the letter and on p. 21 of the report.

Recommendation: A caveat needs to be added in all these places as follows:

"An important limitation of the ICRP risk estimates should be kept in mind. Specifically, the ICRP 88 assumption[3] that the dose to the embryo/fetus in the first eight weeks of pregnancy is the same as that to the uterine wall is not valid for alpha emitters and for low energy beta radiation emitters, such as tritium. The actual deposition of alpha and low-energy beta emitters in the embryo/fetus needs to be determined to estimate dose and risk. The EPA should monitor the science in this area and initiate a scientific inquiry as to dose estimation methods that might be adopted to overcome this limitation of the ICRP model."

The rationale is self-evident. The ICRP's model is not valid and a new one is needed for the first eight weeks for alpha and low-energy beta emitters, particularly as structural organization and a substantial component of organogenesis occur in the embryo over this period. The context of this comment is provided on page 73 of IEER's report *Science for the Vulnerable* (by Arjun Makhijani, Brice Smith, and Michael C. Thorne). It is on IEER's website at:

http://www.ieer.org/campaign/report.pdf

I have also sent you a copy of the pdf electronic file, as you requested.

3. On page 21, the draft report states:

> The dose to the embryo/fetus from internally-deposited radionuclides has been reviewed (NCRP, 1998; ICRP 2000) and ICRP (2001) provides organ/tissue dose coefficients (Sv/Bq) to the embryo/fetus from chronic intake of individual radionuclides by the mother. These data can be used to develop cancer risk estimates for the embryo/fetus exposed coincidentally to radiation delivered at low dose rates from the same sources

Besides the caveat above for the first eight weeks, cancer risk is far too restrictive a view of the exposure to the embryo/fetus, notably in the early stages. The RAC should point this out.

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[3] ICRP 88 p. 20.

Recommended addition on page 21: "The embryo/fetus experiences other risks than cancer due to exposure in the early period. Indeed, cancer risk may not even be the main risk in the first 14 weeks, covering the pre-implantation period and organogenesis. Risks of malformations, induction of severe mental retardation and changes in IQ, early failed pregnancies, and immune system compromise due to irradiation of red marrow stem cells during their formation (between weeks 10 and 12) in this period need to be examined. The EPA should initiate a scientific inquiry as to what can be gleaned from existing scientific literature on these topics."

I also recommend the following sentence be added to the summary and the letter:

"The EPA should initiate a scientific inquiry into the appropriate model to be used to assess the exposure of the embryo/fetus to alpha and low-energy beta emitters during the first eight weeks of pregnancy, and to assess non-cancer risks to the embryo/fetus during the first 14 weeks of pregnancy. One useful discussion of the kinds of risks that might be studied can be found in Makhijani, Smith, and Thorne 2006."

4. On page 2 of the letter, page 2 of the summary and page 19 of the report, the RAC concludes that the RBE for low energy photons (<30 KeV) and tritium beta particles "in the range of 2 to 2.5 seems reasonable."

IEER supports that shift away from an RBE of one for these radiation types. However, in the case of tritium, the RAC report does not discuss the dependence of the tritium RBE on age at exposure and on the form of tritium (tritiated water versus organically bound tritium). As discussed in Makhijani, Smith, and Thorne, the research of Harrison, Khursheed and Lambert[4] shows that taking both these factors into account is important – the table below is derived from that paper. Note that the table below, reproduced from *Science for the Vulnerable*, was calculated using FGR 11; the values would be about ten percent lower if the dose conversion factor in FGR 13 is used. There is no reason to assume that low energy photons would be different than low energy beta particles in the matter of age dependence.

1. Suggested changes at the three locations: Edit the sentence in question in all three places to read: "The RAC concurs that an effectiveness factor in the range of 2 to 2.5 seems reasonable for low-energy photons and electrons for purposes of setting radiation protection standards for (non-pregnant) adults. However, research indicates that the RBE for tritium exposure is age-dependent (Harrison, Khursheed, and Lambert 2002). An RBE of 4 to 5 should be adopted in radiation standards for fetal exposure and for children for low energy photons and electrons."

[4] J.D. Harrison, A. Khursheed, and B.E. Lambert. "Uncertainties in dose and coefficients for intakes of tritiated water and organically bound forms of tritium by members of the public." *Radiation protection dosimetry,* v. 98, no. 3 (2002), pages 299-311.

2. Suggested addition for page 19 of the report for organically bound tritium. "The RBE for organically-bound tritium (OBT) is higher than that of tritiated water, possibly by a factor of 2 to 2.5, as indicated by Harrison, Khursheed and Lambert 2002. The EPA should initiate a review of the issue of OBT and in order to develop the appropriate regulatory guidance both as regards the RBE and as regards the circumstances in which the use of a higher RBE is warranted."

Integrated Relative Biological Effectiveness of Tritiated Water and Organically Bound Tritium

Age	Form of tritium	5% Confidence limit	Median	95% Confidence limit
Adult	HTO	1.2	2.3	3.8
Adult	OBT	2.3	5.0	11.6
Fetus (maternal ingestion during pregnancy)	HTO	2.1	4.4	8.1
Fetus (maternal ingestion during pregnancy)	OBT	4.0	9.8	23.1

Source: Makhijani, Smith, and Thorne, p. 61. Based on Harrison, Khursheed, and Lambert 2002.
Note: Values calculated using the ingestion dose conversion factor for tritium in FGR 11.

5. Section 8 of the report (p. 26) covers "Issues Beyond the Charge" of the RAC. This recommendation is greatly needed, and therefore much appreciated. While the reference to ICRP 89 and the Reference Family concept is useful in getting the agency to move away from the highly restrictive and outdated (to say the least) concept of Reference Man in ICRP 23, this recommendation does not provide adequate guidance on the breadth and complexity of issues involved. The IEER report, *Science for the Vulnerable*, provides a detailed discussion of this issue. In view of the above, the following addition is recommended in Section 8:

"While the reference to ICRP 89 and the Reference Family concept is useful in getting the agency to move away from the highly restrictive and outdated (to say the least) concept of Reference Man in ICRP 23, this recommendation does not provide adequate guidance on the breadth and complexity of issues involved. For instance, is the concept of a "Reference" anything suitable for radiation protection, or should those most at risk be protected? In some situations the most at risk might be children, in other situations it might be breast feeding or pregnant women, in others, men who want to be fathers, or, in yet others, the embryo/fetus (the last, for instance, in the case of a declared pregnancy in the workplace). An IEER report, *Science for the Vulnerable*, provides a detailed discussion of this issue. The RAC is not endorsing this report, but is referring to it as one possible starting point, along with ICRP 89, in the EPA's move away from the ICRP 23 concept of Reference Man."

Again, I really appreciate the consideration you have given my comments so far and your willingness to consider the above as you complete editing your report.

Yours sincerely,

Arjun Makhijani, Ph.D.
President, Institute for Energy and Environmental Research