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AN SAB REPORT: RADIONUCLIDES IN DRINKING WATER

REVIEW OF THE OFFICE OF DRINKING WATER'S CRITERIA DOCUMENTS AND RELATED REPORTS FOR URANIUM, RADON, AND MAN-MADE BETA-GAMMA EMITTERS BY THE RADIATION ADVISORY COMMITTEE

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ABSTRACT

EPA's Office of Drinking Water developed draft criteria documents and related reports that were the basis for new drinking water standards for uranium, radium, radon and man-made beta-gamma emitting radionuclides during the period November 1989-July 1990. The Radionuclides in Drinking Water Subcommittee of the Science Advisory Board's Radiation Advisory Committee reviewed these documents during the summer of 1990.

The overall quality of the four draft criteria documents submitted to the Subcommittee for its review was not good. Taken as a set, the documents are inconsistent in approach and with Agency practice in the derivation of drinking water criteria for other contaminants. The Subcommittee found that comments from a 1987 review had not been incorporated. Previous SAB recommendations that are directly relevant to these documents were not addressed in the drafts submitted for review. Technical decisions contrary to those recommended by the SAB were presented without justification and without acknowledgement of the existence of the SAB-recommended alternatives. Relevant recommendations of the National Research Council's Committee on the Biological Effects of Ionizing Radiation 1988 and 1990 reports were ignored or selectively adopted without explanation or rationale. Uncertainties associated with (a) selection of particular models, (b) specific parameters used in the models, and (c) the final risk estimates are not adequately addressed in any of the documents.

Revised background documents have subsequently been prepared by the Office of Drinking Water to support their proposal published in the Federal Register July 18, 1991.

KEYWORDS: Uranium, Radon, Beta-Gamma Emitters, Radionuclides, Drinking Water

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1. INTRODUCTION

At the May 1990 meeting of the Science Advisory Board's Radiation Advisory Committee (RAC) in Washington, D. C., the Office of Drinking Water (ODW) presented its plans to propose regulations for radionuclides in drinking water, as directed by the Safe Drinking Water Act. Although the ODW was the lead office in this effort, it was assisted by the Office of Radiation Programs (ORP). At that time, criteria documents were being prepared for the ODW by contractors for uranium, radium, radon, and manmade radionuclides. The RAC was requested to review the criteria documents and related material, as they became available, to assess their scientific credibility and correctness. The RAC considered and accepted this request and formed a Radionuclides in Drinking Water Subcommittee to conduct the reviews.

During the course of the review, the following criteria documents that had been developed for the ODW were received:

a. *Drinking Water Criteria Document for Uranium*, draft dated November 1989

b. *External Review Draft for the Quantification of Toxicological Effects Document on Radium* (TR-1242-67), draft dated 10 July 1990

c. *Quantitative Risk Assessment for Radon in Drinking Water*, draft dated May 1990

d. *Quantitative Risk Assessment for Beta Particle and Gamma Emitters in Drinking Water*, draft dated May 1990

The Subcommittee also received the following related materials:

a. *Human Radon-222 Lifetime Risk Estimates from Ingestion*, an EPA Memorandum by J. S. Puskin

b. *A Calculation of Organ Burdens, Doses, and Health Risks from Rn-222 Ingested in Water*, a draft report by D. J. Crawford-Brown

c. *Radon Transferred from Drinking Water into House Air*, a draft report by C. T. Hess *et al.*

d. *Radon Bio-Transfer After the ingestion of Radon Rich Drinking Water*, a draft report by W. L. Brown (a student of Dr. Hess).

The first three of these documents bear directly on the risk estimates made for radon in drinking water in the Quantitative Risk Assessment for Radon in Drinking Water.

The draft documents were distributed to the Subcommittee as they were completed and deemed ready for public review by the ODW. The members of the Subcommittee all reviewed the documents and prepared comments for discussion. Because of funding limitations, it was determined that the Subcommittee would not be able to meet to discuss its comments and prepare its report on each document. Instead, it was decided to conduct the reviews using telephone conference calls. These calls were announced in the *Federal Register* and were open to the public Conference call "meetings" of the Subcommittee were held on 4 June, 11 June, 18 June, 9 July, 16 July, 23 July, 6 August, and 20 August.

Following the conference call on a particular topic, a draft summary letter was circulated to the Subcommittee members, staff members of the ODW and ORP, and to members of the public who had participated in the discussion. These draft letters were prepared as reviews proceeded to provide timely input to the ODW which had a tight time schedule to prepare revised criteria documents prior to issuing the proposed regulations in the *Federal Register*. The draft summary letters were then discussed during a subsequent public conference call.

Following receipt of the formal charge for the review from the ODW, which identified five specific issues in addition to the general concern that the documents be scientifically sound, the Subcommittee decided that it would be more appropriate to consolidate all its conclusions in a single report. At that point, the goal of providing the ODW and ORP with comments and discussion promptly to facilitate revisions of the documents had already been achieved. The charge also requests that the Subcommittee review the draft notice to be published in the *Federal Register*. A letter report will be prepared by the Subcommittee as part of that review. The review comments will be made available to the ODW promptly, prior to formal transmittal.

The technical part of the Subcommittee report is divided into three parts. Section 2 contains general comments about the group of documents reviewed and some generic issues that the ODW should address when revising them. In Section 3 the Subcommittee presents its responses to the five specific questions in the formal charge for the review. Section 4 contains the most important scientific comments on each of the documents or group of documents that deal with a particular radionuclide category. At the beginning of each of these sections, a summary of the Subcommittee's findings is presented in boldface type. Detailed comments and discussion follow the summary paragraph. Comments related to technical and editorial details were transmitted separately to the ODW during the course of the review. A list of these transmissions is given in Appendix A. The formal charge for the review is included in Appendix B.

2. GENERAL COMMENTS AND GENERIC ISSUES

The overall quality of the four draft criteria documents submitted to the Subcommittee for its review was not good. Taken as a set, the documents are inconsistent in approach and with Agency practice in the derivation of drinking water criteria for other contaminants. The Subcommittee found that comments from a 1987 review had not been incorporated. Previous SAB recommendations that are directly relevant to these documents were not addressed in the drafts submitted for review. Technical decisions contrary to those recommended by the SAB were presented without justification and without acknowledgement of the existence of the SAB-recommended alternatives. Relevant recommendations of the National Research Council's Committee on the Biological Effects of Ionizing Radiation were ignored or selectively adopted without explanation or rationale. Uncertainties associated with (a) selection of particular models, (b) specific parameters used in the models, and (c) the final risk estimates are not adequately addressed in any of the documents.

Many comments, recommendations, and clarifications made during the 1987 review of ODW documents by a previous Drinking Water Subcommittee had not been incorporated into the current draft criteria documents. While some more recent references have been added, these additions were apparently not the result of a thorough review and did not reflect new evaluations of critical issues related to the risk assessments. The draft reports contain irrelevant information and incorrect definitions of fundamental technical terms. In general, the criteria documents do not include definitive descriptions of the models being used, the basis for selection of the models, or the basis for the choices of individual parameters.

The draft documents were inconsistent in their approach to risk assessment, variously employing highly conservative and non-conservative assumptions. The radiation risk factors employed differed among the documents, indicating an *ad hoc* approach rather than a thorough review and reevaluation of the risk factors for ionizing radiation. In the document for manmade beta-gamma emitters, the risks were expressed for only a single value of public exposure (4 mrem/y). For that guide value, current estimates of the overall radiation risk factor suggest that the lifetime risk of 10^{-4}, normally considered an upper bound for drinking water criteria development, would be exceeded.

The documents do not reflect the recommendations of the National Research Council's Committee on the Biological Effects of Ionizing Radiation (BEIR) as presented in two recent (1988, 1990) reports. These reports are *Health Risks of Radon and Other Internally Deposited Alpha-Emitters* (called *BEIR IV)* and *Health Effects of Exposure to Low Levels of Ionizing Radiation* (called *BEIR V).* These reports were prepared by expert committees at the request of the Agency (and others), yet the Agency ignores or selectively adopts their recommendations without providing any basis for doing so. Similar treatment of expert advice is

given recommendations of the committees assembled by the Agency for the National Workshop on Radioactivity in Drinking Water, published in Volume 48, Number 5 of *Health Physics* (1985).

The recommendations of a previous SAB review of documents on radionuclides in drinking water have also been ignored without any discussion or even mention. The SAB previously recommended (SAB-RAC-87-035) that the Agency should normally employ the effective dose equivalent concept of the International Commission on Radiological Protection (ICRP) when estimating doses and risks. However, the same recommendation identified radium and uranium as exceptions to this practice. For radium, the SAB recommended instead that the human epidemiologic data be used as the basis for the risk assessment and noted that changes would also be necessary for uranium as the Agency had based the uranium risk estimate on that for radium. Contrary to the cited recommendation, in the current set of draft criteria documents the Agency has employed dose and risk calculational models which are not the effective dose equivalent approach defined by the ICRP. The Agency has then applied these models to estimate the risks for both radium and uranium without mentioning the previous SAB recommendation. Use of a tissue dose to risk calculational approach is also contrary to the analyses presented in the *BEIR IV* report.

The failure to employ the effective dose equivalent concept is also contrary to other Agency policy. In fulfilling its Federal Radiation Council responsibilities, the Agency has recommended, and in 1987 the President approved, the application of the effective dose equivalent concept for occupational exposure. While the Agency once argued that the ICRP concept was intended only for occupational exposure, that argument was never valid. To cite two specific cases, application of the concept to exposure of members of the public was discussed by the ICRP as early as 1980 *(ICRP Publication 30, Part 2)* and a recent report *(ICRP Publication 56)* addresses the development of calculations of the effective dose equivalent for a range of population age groups, including infants.

None of the draft criteria documents adequately addresses the question of the overall uncertainties in the risk estimates and there is no discussion of the uncertainties associated with the selected values of individual parameters employed in the calculational models. No analyses of the sensitivity of the estimated risks to the choice of models or of specific parameter values have been performed. In revising the criteria documents, the ODW would be wise to implement the recommendations of the SAB that are expressed in the *Resolution on the Use of Mathematical Models by EPA for Regulatory Assessment and Decision-Making*. The Subcommittee believes these comments to be in concert with the Administrator's views expressed (in the letter of 14 June 1990 to Dr. Loehr of the Science Advisory Board) regarding the *Resolution on the Use of Mathematical Models by EPA for Regulatory Assessment and Decision-Making*.

3. RESPONSES TO THE FIVE SPECIFIC QUESTIONS LISTED IN THE CHARGE TO THE SUBCOMMITTEE

The formal charge from the ODW (see Appendix B) identified five specific issues which the ODW believed to be significant. The ODW requested that particular attention be paid to these topics by the reviewers. Each of the issues, which were phrased as questions, is addressed in one of the following subsections. A brief answer is given in boldface type for each question and some additional discussion of the question follows. More details are presented in Section IV in the discussions related to the individual documents.

3.1 Uranium Metabolism

Q: **"Are the estimates of the absorption, distribution, and excretion of uranium when ingested appropriate and supported by the data?"**

A: **No. The basis for the metabolic model chosen and the value of the gut-to-blood absorption factor (f_1) have not been adequately discussed. The chosen value of f_1 appears to have been arbitrarily selected from among the highest of all reported values. The uncertainties associated with parameter and model selections are not discussed.**

The draft criteria document for uranium does not provide justification for the choices of (1) a metabolic model and (2) the parameter values needed to implement that model. In particular, one metabolic parameter which directly affects the calculated tissue burden and radiation dose is f_1, the fraction of ingested uranium absorbed into blood from the gastrointestinal (GI) tract. The choice of $f_1 = 0.2$ in the draft criteria document appears to be arbitrary and contrary to recent data in the scientific literature. It was noted, in a review prepared by an expert committee for the Agency, published in *Health Phys.*48,601 (1985), that none of the uranium metabolism models examined by the committee was completely consistent with all the experimental data. That committee recommended a value of f_1 of 0.014 for use in establishing public drinking water standards.

A fundamental decision that is required, and must be discussed in the final document, is whether such models and parameter choices should be those appropriate for typical members of the exposed U. S. population or for a subgroup which, for example, is iron deficient and doesn't eat breakfast. During a conference call, the existence of persons in these subpopulations, both of which would exhibit higher than average uranium absorption from the GI tract, was offered as a possible basis for the selection of $f_1 = 0.2$.

3.2 Radon Risk–Ingestion

Q: "Do the estimates in the documents form an appropriate basis for assessing the risks of directly ingesting water containing radon?"

A: There is a conflict with other Agency practice in the assumption of a tap water consumption rate of 0.66 liters per day (L/d) and the assumption of a 20% volatilization loss between the tap and container. The basis for and uncertainty associated with the assumed values are not adequately addressed.

The assessment of the risks of ingestion of drinking water containing radon conflicts with Agency practice for other drinking water contaminants. It employs a consumption rate of 0.66 L/d of tap water that has not been treated in a manner that would volatilize the radon contained in it. Neither the basis for this number nor its variability was described in the report. The Subcommittee found that it was apparently based on an Agency analysis of the 1977-78 USDA Nationwide Food Consumption Survey, published in *Health Phys.* **50**,145 (1986). Similarly undocumented was the assumption that 20% of the radon volatilizes at the tap prior to consumption of the water. Although this exposure reduction may be reasonable, the data upon which it is based are not appropriately cited. The Subcommittee notes that these two assumptions differ from those used by the Agency in comparable evaluations of volatile chemicals. In those cases a consumption rate of 2 L/d, without consideration of volatilization, is employed.

The final criteria document for radon in drinking water must address this issue and reflect a consistent position for the Agency's evaluations. For that document to be an appropriate basis for the radon ingestion risk, it must also provide a comprehensive discussion of the uncertainties associated with the various parameters selected and the overall uncertainty of the risk calculations for the ingestion pathway.

3.3 Risks From Radon in Water

Q: "What is an appropriate basis for estimating the risks from radon in water?"

A: Both the direct (ingestion) and indirect (inhalation) exposure routes require careful assessment. The draft document treats both pathways; however, possible inhalation exposures to high concentrations at the point of use have not been addressed. The ingestion pathway was discussed in Section 3.2. Assessment of uncertainties is an essential component of the evaluation of both pathways.

There are two pathways for exposure to radon in drinking water and both require careful assessment. The first of these is the direct consumption of tap water (discussed above). The second is exposure to airborne radon that is volatil-

ized as a result of a variety of household uses. The presence of radon in tap water will not normally significantly increase exposure for most people compared to background airborne radon and daughter products or to elevated levels in houses resulting from radium in soil. However, the typical lifetime risks from radon in tap water are estimated to be in the range of concern to the Agency in its formulation of drinking water standards.

The need for an evaluation of the uncertainty in model parameters and in the overall results of the calculations, cited above for the ingestion pathway, also applies to the inhalation pathway. Application of an average air to tap water concentration ratio overlooks the potential exposure to high concentrations at the point of radon release, such as from showering. The revised analysis must address the contribution of such exposures to the total. The risk assessment for airborne radon in the draft criteria document differs from that in *Estimation of Risks from Indoor Radon Exposure,* draft dated February 1990, which was previously submitted by the ORP to the RAC for review. The final criteria document must be consistent with the ORP position as updated to reflect the recent literature and the RAC comments.

3.4 Best Basis for Radium Risk Estimates

Q: **"What relative emphasis should be placed on the epidemiology data and modeled risk estimates for evaluating radium risks?"**

A: **The report of the previous Drinking Water Subcommittee (SAB-RAC-87-035) recommended against basing the risk assessment for radium on a calculational model in view of the available human epidemiologic data, and the present Subcommittee concurs with that recommendation. Furthermore, the BEIR IV report based the estimated risk from radium on the epidemiologic data.**

As noted in Section 2, this is the second time that the RAC has formed a Drinking Water Subcommittee to review criteria documents for radionuclides in drinking water. The report to the Agency (SAB-RAC-87-035) of the first Subcommittee recommended against the use of the effective dose equivalent approach for radium because " . . . direct human observation differs significantly from risks derived from the effective dose equivalent concept. It is essential that the human data be fully discussed and made clear." Since the time of the previous review, the National Research Council has published the *BEIR IV* report which thoroughly discusses the human data on radium and analyses of the risks of radium intake. The *BEIR IV* risk estimates are based upon the human epidemiologic data, not on the risks that would be estimated using dose calculational models.

The failure of the Agency to heed the advice of the previous SAB review and now the guidance of the BEIR Committee--without presenting any substantive rationale for disregarding the advice--detracts from the credibility of the radium risk assessment and that of the Agency. It also raises questions about the

interaction between the Agency and the SAB. It appears that in this case the SAB review has been used to add legitimacy to an inappropriate procedure. This is not an acceptable mode of operation for the SAB.

The Agency's model for dosimetry of the radium nuclides is not well described in the draft criteria document. There is no diagram of the model, no tabular summary of the assumed distribution of radium among compartments, and no retention functions for the various compartments. The results of calculations using the Agency's dosimetry and risk models are also not presented. It may be that the reason for the omission of the calculated doses and risks is the very one given in the previous SAB report; namely, the risk calculations made using these models predict consequences that are quite different from the human experience following radium ingestion.

The Subcommittee reiterates the recommendation of the previous review regarding the primacy of the human exposure data for estimating risks from radium ingestion. A detailed discussion of the differences between the human data and the predictions of the dosimetry and risk modeling approach is presented in Section 4.2 of this report.

3.5 Methodology for Risks from Man-made Radionuclides

Q: **"Is the methodology for assessing risks from man-made radionuclides (both individually and collectively) appropriate?"**

A: **No. There is no criteria document for man-made alpha-emitters. The draft document employed a set of *ad hoc* risk factors that have not been reviewed. The document also assumed a regulatory level instead of the normal practice of determining a risk factor per unit exposure and deriving the guide value. The document does not employ the effective dose equivalent concept and does not adequately address uncertainties in the input parameters and risk estimates.**

The answer to this question must be "no" for the following reasons. First, it must be noted that the criteria document presented to the Subcommittee for review did not address the risks associated with the presence of manmade alpha-emitting radionuclides (such as ^{238}Pu and ^{239}Pu, ^{241}Am, ^{242}Cm) in drinking water. Second, the draft document employed a set of ad hoc risk factors which are inconsistent with the "official" Agency radiation risk estimates. Third, the methodology does not address uncertainties in the input parameters or in the overall results of the risk calculation. Fourth, the document assumes a regulatory level of 4 mrem/year when, as a criterion document, it should define the potential risks from a unit quantity of radiation exposure. The presumed guide value may correspond to a calculated risk level that is outside the range of risks normally accepted for contaminants in drinking water. Fifth, the Agency has failed to adopt the SAB recommendation to employ the ICRP effective dose equivalent concept for beta and gamma emitters. Although the concentration guides in the appendix of

the criteria document are based on that concept, the footnote states that the values are only "for comparison" because the ICRP system is not used in the document.

4. COMMENTS ON IMPORTANT ISSUES IN THE CRITERIA DOCUMENTS AND RELATED REPORTS SUBMITTED TO THE SUBCOMMITTEE

The four subsections that follow contain the most important specific comments and recommendations made by the Subcommittee as the result of its review of the criteria documents and associated reports that were submitted for review. The general comments and generic issues have been listed in Section 2 of this report. Brief responses to specific Agency questions were given in Section 3. More detailed discussions of these issues are contained in this section. Other detailed technical comments, editorial comments, and technical documents were transmitted to the ODW during the course of the review and discussions (see Section 5). In each of the subsections, a summary of the findings is presented first and is followed by detailed discussion and commentary.

4.1 Uranium Criteria Document

Key scientific decisions are not justified. The basis for the Agency's choices of risk estimation methods, metabolic models, and specific metabolic factors are not adequately presented. The uncertainties associated with parameters, models, and risk estimates are not addressed. Previous SAB comments and recommendations were not addressed or incorporated in the current draft document.

The Subcommittee was asked to assess the scientific credibility and correctness of the *Drinking Water Criteria Document for Uranium,* draft dated November 1989. Within this framework, the Subcommittee offers the following recommendations and observations.

a. The document requires substantial revision to provide a credible basis for key scientific decisions made by the Agency. There are two areas in which the document lacks credibility. The first is the selective adoption of recommendations of the National Research Council whose advice on matters particularly related to this document was specifically sought by the Agency. The second is the selection of particular models or model parameter values without justification of the choices, some of which appear quite arbitrary and contrary to information available in the scientific literature.

The ***BEIR IV*** report was jointly requested by the Agency and the Nuclear Regulatory Commission to study the biological effects of internally deposited alpha-emitting radionuclides and their decay products. However, the report of the BEIR Committee is selectively utilized without justification or explanation in the criteria document.

1. The criteria document takes the position, as presented in the *BEIR IV* report, that the radiogenic cancer risks of uranium can be presumed and estimated on the basis of its similarity to the long-lived radium isotopes. Then the Agency fails to employ the radium/uranium analogy to estimate risk. Instead: "The U. S. EPA estimates the cancer risk associated with ingestion of natural uranium through an explicit calculation of organ doses, followed by application of risk factors" (page VIII-14). This is in direct contradiction of the *BEIR IV* conclusion that, if there is a risk, it is for bone sarcoma. The EPA calculation presented on page VIII-17 attributes a greater risk of cancer to organs other than bone.

2. The text on page VIII-12 implies that the risk factors for radium presented on that page and the one for uranium completed on the following page are from the *BEIR IV* report. In fact these are taken directly from the paper of Mays *et al.* (*Health Phys.* 48,635 (1985)). The *BEIR IV* report states (page 298):

> *"The most probable effect, if any, of exposure to uranium would be expected to be an increase in bone sarcomas. It is certainly reasonable to believe that this can result from high-specific-activity uranium. The likelihood of sarcomas resulting from population exposure to natural exposure (sic) is exceedingly low and is only demonstrable if a linear dose-response relationship is assumed.*[32] *If the dose-response relationship is quadratic, then virtually no effect would be expected as a result of exposure to natural uranium. Assuming a linear relationship and a constant nonoccupational intake of 1 pCi/day. Mays et al.*[32] *estimate that the risk of bone-sarcoma induction over a lifetime is 1.5 bone sarcomas/million persons. In the United States this may be contrasted with the naturally occurring incidence of bone sarcomas of about 750. This evidence suggests that exposure to natural uranium is unlikely to be a significant health risk in the population and may well have no measurable effect."*

The basis for the statement at the bottom of page VIII- 13 of the draft criteria document, that the *BEIR IV* Committee " . . . recommended that a linear extrapolation be adopted to provide a conservative estimate, consistent with protection of the public health" may be elsewhere in the *BEIR IV* report, but was not found by the Subcommittee.

3. The uncertainty in the risk estimate for uranium must be discussed in the revision of the criteria document. Because th

carcinogenic potential of uranium is based on that of radium, several important aspects of the radium results presented in the *BEIR IV* report are quite relevant to the uranium risk estimate. In the radium investigations, no tumors were observed for skeletal doses of less than several hundred rads. Cumulative endosteal surface doses from ingestion of uranium at environmental levels are estimated to be on the order of 1 rad, so the extrapolation is not a trivial one. The paper by Mays *et al. (Health Phys.* 48,635 (1985)), from which the risk estimate on page VIII-13 was taken, explicitly recognized that the lower bound risk estimate for radium was zero and used a risk coefficient that was half of their maximum linear, no threshold estimate. The *BEIR IV* report contains a detailed discussion of the uncertainties and bounding estimates of the bone sarcoma risk. The current version of the criteria document ignores this important aspect of the report prepared by the National Research Council for the Agency's use.

4. The value and uncertainty of another parameter are crucial to the estimation of risks from uranium ingestion using the radium analogy. This is the ratio of the skeletal content to the daily ingestion. Estimates of 25 and 11 were used by Mays *et al.* for radium and uranium, respectively. The distributions of these ratios should be reexamined in view of additional data from new literature reports. The basis for the selections of parameter values used in the risk estimate must be presented and the overall uncertainty of that estimate discussed quantitatively.

5. If a dosimetric approach is chosen and justified for uranium (contrary to the *BEIR IV* radium analogy) another set of parameter selection and uncertainty issues must be addressed. In the draft document, the choice of a specific uranium metabolism model from several competing models is not discussed. A sensitivity analysis to show the effect of the choice of the models, and model parameter values, on the dosimetric results used in the risk estimate would be most useful.

One parameter known to directly affect the dose calculations is f_1, the fraction absorbed into blood from the gastrointestinal tract. In the draft criteria document, the choice of $f_1 = 0.2$ appears to be quite arbitrary and contrary to recent data in the scientific literature. If the report and decisions based upon it are to survive critical review, the basis for this choice must be defended scientifically. A first step in this process would be the presentation in the draft report of a frequency distribution of the data on f_1

from which the value is selected. The basis for any exclusion of results in the literature from those considered by the Agency must be clearly presented.

Based on discussions on the conference call meetings there appear to be four issues affecting the estimate of f_1 in the draft report. The first is the allegation that the data presented by Wrenn are biased. In the published paper (Wrenn *et al., Radiation Protection Dosimetry*, **26**,119 (1989)) data for only 10 of the 12 subjects are reported. All of the reported estimates are an order of magnitude or more below 0.2. This work was performed for the Agency so the Agency's reasons for ignoring it must be clearly identified. Objections to the analysis and recommendations of a committee (Wrenn, Durbin, Howard, Lipsztein, Rundo, Still, and Willis) convened by the Agency have also not been presented in the draft criteria document. Their report--"*Metabolism of Ingested U and Ra*"--containing detailed appendices and discussion of models and experimental data, was published as part of a special issue on Radioactivity and Drinking Water (*Health Phys.* **48**,601 (1985)). The work of Spencer et al. (*Radiation Research*, in press, preprint provided to Agency) must also be considered in the revision of the uranium criteria document.

Secondly, there are reports of higher uptake fractions in the Soviet Union and perhaps other countries. Two issues need to be addressed: the quality of the data and its relevance to the U. S. population.

The third issue was the possible effect of diet and habits--iron deficiency and the no-breakfast syndrome--on the uptake of uranium. Both iron deficiency and fasting have been shown to lead to increased uptake in animals. Issues to be resolved in this area are the fraction of the U. S. population that is considered to be "iron deficient" and whether the estimated deficiency is comparable to that of the rats in the experimental work. With regard to the skipped breakfast, by choice or economic necessity, the paper of Bhattacharyya *et al. (Radiation Protection Dosimetry,* **26**,·159 (1989)) shows results for plutonium that indicate that no-breakfast was equivalent to a 24-h fasting period in raising f_1. For uranium, two fed baboons absorbed 0.45 and 0.57% while four different fasted baboons absorbed 1.3, 5.1, 5.9, and 5.2% of the ingested amounts of uranium, respectively. The fraction of the U. S.population not eating breakfast and the average amount of water drunk before consumption of lunch need to be quantified before the effect of this behavior can be known. However, the uptake fractions for the fasted animals were a factor of four lower than the average value currently assumed by the Agency.

Lastly, there was a question about the self-consistency of the ICRP uranium metabolism model. It seems clear that consistency should be a criterion in selection of a model and parameters for it; however, it was noted in the paper "Metabolism of Ingested U and Ra" (cited above) that

none of the uranium models examined by the committee was completely consistent with all of the experimental data. In any event, inconsistency in or incompleteness of a model of uranium metabolism is not a basis for ignoring experimental measurements of specific parameters.

b. Many comments, recommendations, and clarifications made by the 1987 RAC Drinking Water Subcommittee have not been incorporated into the current draft document. While some additional references have been added, other relevant material has not been included. The addition of references to the list does not appear to have been accompanied by any reevaluation of the critical issues. The document also suffers from inclusion of irrelevant data, particularly that on the *inhalation* toxicology of uranium, incorrect definitions of fundamental quantities and units (committed dose equivalent, rad, roentgen), and other organizational and editorial problems. These are addressed in detailed comments that have been provided to the ODW. Appropriate revisions will increase the credibility of the Agency's document by making it more accurate and intelligible.

4.2 Radium Criteria Document

The Agency has ignored the earlier recommendation of the SAB regarding the best risk estimation method for radium as well as the subsequent guidance in *BEIR IV* without any defensible rationale. The uncertainties associated with parameters, models, and risk estimates are not addressed. Assumptions about the values of important parameters require justification. The metabolic and dosimetric model employed by the Agency is not presented, nor are any detailed results of dose and risk calculations that could be compared with alternative models.

The Subcommittee was asked to assess the scientific credibility and correctness of the *External Review Draft for the Quantification of Toxicological Effects Document on Radium* TR-1242-67), draft dated 10 July 1990. Within this framework, and mindful of the previous review, the Subcommittee offers the following recommendations and observations.

a. The previous Drinking Water Subcommittee of the RAC recommended (SAB-RAC-87-035) against use of the effective dose equivalent approach for radium because " . . . direct human observation differs significantly from risks derived from the effective dose equivalent concept. It is essential that the human data be fully discussed and made clear." Since the time of the previous review, the National Research Council has published the *BEIR IV* report which thoroughly discusses the human data on radium and analyses of the risks of radium intake. The *BEIR IV* risk estimates are based upon the human epidemiologic data, not on the risks that would be estimated via calculations of the effective dose equivalent or the Agency's dose and risk models.

Radium is in a different category from other radionuclides because there is direct human experience upon which the best estimates of risk are based. The epidemiologic data show that bone sarcomas and head carcinomas represent the

dominant risks of ingestion of radium. In the highly exposed groups, induction of bone sarcomas exceeded leukemia induction by a factor of 10 to 100. There have been no bone sarcomas and no leukemias in the low dose groups. Below systemic radium intakes (to blood) of 100 μCi and 25 μCi, respectively, no bone sarcomas or head carcinomas have been found, even though substantial numbers of individuals were exposed at the lower levels.

A detailed discussion of risk estimates based on the human exposure information is presented in the *BEIR IV* report. For bone carcinomas, Schlenker has made estimates of the central and bounding risk estimates in the range of effective radium intakes of 0.5 to 100 μCi (the range where no cancers were observed). For systemic intakes less than about 20 μCi, the lower bound estimate or risk from radium intake is zero. For intakes of about 2 μCi or less, the central estimate of the total risk is equal to the natural risk. That is, the central estimate of the risk of radium intake at that level is also zero. The difference between the upper and lower bounding estimates of total risk (natural plus radium intake) for the 95% confidence interval is about a factor of two at 0.5 μCi.

Only the upper bound value for the 95% confidence interval suggests that there is any risk for intakes lower than 0.5 μCi. Extrapolation of that approximately linear function would be consistent with the Agency's approach for other carcinogens as a means of providing a bounding estimate of the risk at low doses. An alternative approach, also based on the human exposure data, is that of Mays *et al. (Health Phys. 48, 635* (1985)), which was prepared at the Agency's request for the National Workshop on Radioactivity in Drinking Water. Calculations made using this approach are presented in the draft criteria document for comparison with the Agency's chosen path.

The dosimetry/risk modeling approach adopted by the Agency predicts risks that are lower by factors of approximately 2 and 3 for ^{226}Ra and ^{228}Ra, respectively, than those predicted by the analysis by Mays *et al.* of the human epidemiologic data. On its face, this may seem to be satisfactory agreement; however, the dosimetry/risk modeling approach does not predict the bone sarcomas and head carcinomas that have been seen in the human populations exposed to high systemic intakes of radium. Instead, dosimetry/risk modeling calculations of the total risk are dominated by the risk of leukemia (^{226}Ra) and breast cancer, leukemia, and lung cancer (^{228}Ra). Nonetheless, the Agency accepts " . . . the outputs of this model as provisional best estimates of risk . . ." (page 46). Use of a model that gets about the right answer (for total risk) but for the wrong reasons is neither a correct nor an acceptable approach.

The failure of the Agency to heed the advice of the previous SAB review and now the guidance of the National Research Council--without presenting any substantive rationale for disregarding the advice--detracts from the document's credibility and that of the Agency. It also raises questions about the interaction between the Agency and the SAB. The SAB recommendation, supported by the NAS report, is apparently being dismissed because of a desire "to increase consis-

tency among risk assessments for other radionuclides and in other media" (page 52). If that is the case, the SAB review is being used only to add legitimacy to an inappropriate procedure. This is not an acceptable mode of operation for the SAB.

It should perhaps also be noted here that the *BEIR IV* report's guidance for uranium risk assessment was also not followed by the Agency. It was suggested in one of the conference calls that the *BEIR IV* analyses for radium and uranium "contained errors" that were being documented by the Agency. If they are alleged to be significant, the nature of those errors must be specified and the rationale presented for any conclusion that the BEIR Committee guidance is substantially flawed.

b. Uncertainties are not adequately addressed in the document. There is little discussion of the uncertainties associated with selected values of parameters used in estimating risk. As an example, the gut-to-blood uptake fraction (f_1) of 0.2 obtained in one experiment is adopted with no discussion of any other experimental measurements of this parameter. The range of individual results for the ingestion of mock radium paint was given, but that information was not used. The variability of this and other important parameters must be addressed in a discussion that relates specifically to the risk assessment for radium in drinking water. Exaggeration of uncertainties is also inappropriate. The statement on page 6 that risk estimates from the different models can differ by several orders of magnitude does not reflect the state of knowledge of the risk of cancer from ingestion of ^{226}Ra and ^{228}Ra (the radium isotopes of interest to the ODW). That risk is based upon data from human exposures and is relatively well defined.

c. The experiments conducted by Maletskos *et al.*, relied upon by the Agency for the value of f_1, had a specific purpose, namely to determine the relative uptakes to blood of radium and thorium ingested in mock dial paint (C. J. Maletskos *et al.*, "*The metabolism of intravenously administered radium and thorium in human beings and the relative absorption from the human gastrointestinal tract of radium and thorium in simulated radium dial paints*," in Radium and Mesothorium Poisoning and Dosimetry and Instrumentation Techniques in Applied Radioactivity, Massachusetts Institute of Technology Report MIT-952-3 (1966)). As was pointed out in the published record of the discussion of a related paper (C. J. Maletskos *et al.*, "*Retention and Absorption of ^{224}Ra and ^{234}Th and Some Dosimetric Considerations of ^{224}Ra in Human Beings*," in Delayed Effects of Bone-Seeking Radionuclides, University of Utah Press (1969)), the subjects were all in an age group (63-83) which frequently exhibits elevated calcium uptakes. That radium uptake may be inhibited by antacids was shown by one of the subjects whose uptake was at most 0.06. The data on the variability among individuals and for different means of determining the initial uptake to blood are useful for the needed uncertainty analysis.

Even more important however is a comparison of the results for ingestion of mock radium paint to those for uptake of radium from drinking water. The Maletskos *et al.* paper refers to a finding of $f_1 \approx 0.15$ for food and drinking water

The original reference cited by Maletskos *et al.* is an Argonne National Laboratory (ANL) report that should be consulted. Other comparable work should be sought. *NCRP Report No. 94* states that uptake from water is about twice that from foods, also citing an ANL publication. The series of published symposia on *The Natural Radiation Environment* may provide useful information as well.

d. The assumption (page 31) that the dose to children will be three times higher than that to adults requires justification. As the paper by Muth and Globel (*Health Phys.* 44, Suppl. 1, 113 (1983)) states, the referenced measurements may be influenced by calcium deficiency. Also, the plotted data in their paper indicate concentrations in the range 80-105 fCi/g ash for the three youngest groups; however, their Table 1 shows a mean for 90 cortical bone samples for neonatal deaths (ages 7 to 365 d) of 6.4 fCi/g (fresh weight). According to *NCRP Report No. 94,* the factor for conversion to ash weight for fresh cortical bone is 0.6, so the tabulated data do not agree with the plot. Other measurements also disagree with the plotted peaks of radium concentration in infants and 10-year-olds. The data on ^{226}Ra concentrations in bones from New York and San Francisco do not show the presumed age dependence (Halden, Fisenne, and Harley: "*Radium-226 in Human Diet and Bone*" published in *Science* 140, 1 (1963). The mean concentrations reported there were in the range 9-12 fCi/g ash, in agreement with Table 1 of Muth and Globel. Data for ^{226}Ra in the bone of infants who died before the age of one year (published in the Proceedings of the 11th Bioassay Conference, 1965) also do not show a peak compared to other age groups.

e. If it is to be included in the report, the Agency's model for dosimetry of the radium nuclides must be presented in more detail than is currently provided in the text and Section 1 of Table 5. There is no diagram of the model nor any information on the compartmental distribution assumptions or retention half-times for the various compartments. On the basis of alternative calculations, it does not appear to be the same as the radium retention model originally presented in *ICRP Publication 20* and used in *ICRP Publication 30.* A reference is needed for the radium daughter retention fraction of 0.3, Item 1.3 in Table 5, (presumably, *ICRP Publication 30, Part 1).*

The predicted doses to specific tissues or a breakdown of the predicted cancer risks for the various tissues are also missing from the report. An alternative calculation, using the dosimetry model for radium in *ICRP Publication 30* and the Agency's risk factors (the aggregated estimates from Table 6-7 of the 1989 NESHAP'S document, EPA/520/1-89-005), provides insight into the predicted distribution of risk. For ^{226}Ra, the total risk is estimated to be about 8×10^{-5} per μCi ingested. More than half of the predicted risk is due to leukemia; only about one-third is due to bone cancer and none is due to head carcinomas. For ^{228}Ra, the total risk is estimated to be about 2×10^{-4}. The approximate breakdown by type is bone cancer: 10%; leukemia: 20%; lung cancer 21%; breast cancer: 39%; and gonadal tumors: 9%. As the SAB stated in 1987, the predicted cancers do not agree with the observed consequences of human ingestion of radium.

The Agency's radium model apparently estimates tissue dose distributions for ^{226}Ra and ^{228}Ra that are different from those predicted by the ICRP radium model. The Agency's model predicts a greater risk from ingestion of ^{226}Ra than from ^{228}Ra (see Table 6 of the draft criteria document), while the ICRP model predicts the reverse (values given above). This is an issue that requires clarification, particularly if the Agency fails to follow the advice it has received in this and previous reports.

4.3 Documents Related to Radon

The radon risk assessment document does not treat uncertainties associated with parameters, models, or the results of risk calculations. The risk estimate for exposure to airborne radon presented in the document disagrees with an Agency position paper previously submitted to the SAB for review and the general approach of document is itself inconsistent in with that taken in the other drinking water criteria documents. The selected values of two important parameters differ from those used in the Agency's assessments of risk from other volatile contaminants in drinking water. The basis for selection of the specific values is not adequately described and uncertainties associated with the parameters are not discussed.

The Subcommittee was asked to assess the scientific credibility and correctness of the *Quantitative Risk Assessment for Radon in Drinking Water,* draft dated May 1990. Also received were the following related materials: *Human Radon-222 Lifetime Risk Estimates from Ingestion,* an EPA Memorandum by J. S. Puskin; *A Calculation of Organ Burdens, Doses and Health Risks from Rn-222 Ingested in Water,* a draft report by D. J. Crawford-Brown; *Radon Transferred from Drinking Water into House Air,* a draft report by C. T. Hess *et al.; Radon BioTransfer After the Ingestion of Radon Rich Drinking Water,* a draft report by W. L. Brown (a student of Dr. Hess). The first three of these documents bear directly on the risk estimates made for radon in drinking water in the *Quantitative Risk Assessment for Radon in Drinking Water.* The Subcommittee offers the following recommendations and observations which are primarily directed toward the draft criteria document but include some guidance for the draft reports as well. Additional comments were provided to the ODW during the review process.

a. The Subcommittee notes that this document is one of a series of criteria documents related to drinking water criteria and that there are inconsistencies among the documents that detract from their credibility. The document on uranium, for example, appears to make an overly conservative estimate of the risk in the face of substantial contrary information; however, the analysis for radon tends to minimize the risk by neglecting potential short-term intense exposures, such as from showering, and by using a lower value for the consumption of drinking water than is used in comparable evaluations for volatile chemicals. Both uranium and radon have been classified Group A carcinogens by the Agency.

Criteria documents normally discuss the exposure of the population to the pollutant under consideration. In the Introduction, it must be clearly stated that the document covers both ingestion of Rn in water and inhalation exposure to Rn daughters which results from the domestic use of water. While the latter is the larger of the two exposures considered, for most individuals it will be only a fraction (perhaps 10% to 25%) of everyday exposure to the outdoor background radon concentration. The presence of radon in tap water will not normally significantly increase exposure to airborne radon daughter products. However, typical individual lifetime risks are estimated to be in the range 10^{-6} to 10^{-4}. This is the range of risk of concern to the Agency in the formulation of drinking water standards.

b. A failing shared with the other drinking water criteria documents for radionuclides is the absence of a satisfactory discussion of the uncertainties associated with selected values of parameters used in estimating risk and the overall uncertainty associated with the result of the risk calculations. Notable parameters values presented without substantive discussion of variability were the chosen equilibrium factor of 0.5 for radon daughter products, the selected value of 10^4 for the dimensionless ratio of the concentration of ^{222}Rn in indoor air to that in tap water, and the consumption rate of 0.66 liters of tap water per day. The variability of these and other important parameters must be addressed in a discussion that relates specifically to the risk assessment for radon in drinking water. The Subcommittee believes these comments to be in concert with the Administrator's views expressed (in the letter of 14 June 1990 to Dr. Loehr of the Science Advisory Board) regarding the Resolution on the *Use of Mathematical Models by EPA for Regulatory Assessment and Decision-Making*.

c. The risk assessment for airborne radon and its daughter products in this document differs from that in *Estimation of Risks from Indoor Radon Exposure* (a draft document dated February 1990) which was previously submitted to the Radiation Advisory Committee for review. The Radiation Advisory Committee discussed that document with the Office of Radiation Programs. The Committee's written comments on radon risk will be transmitted seperately. Relevant references from the recent literature that should be considered are included in these comments.

The section of the document that discusses the epidemiologic studies of miners is badly outdated and does not reflect current thinking. A recent open literature publication that should be consulted is *Review of Radon and Lung Cancer Risk* by Samet and Homung *(Risk Analysis,10, 65* (1990)). The significance of risk reduction with time since exposure is not discussed and the paper by Lubin *et al.* (J. H. Lubin, Q. You-Lin, P. R. Taylor, Y. Shu-Xiang, A. Schatzkin, M. Bao-Lin, R. Jian-Yu, and X. Xiang-Zhen, Quantitative evaluation of the radon and lung cancer association in a case control study of Chinese tin miners, Cancer Res. 50,174 (1990)) indicating that there is no enhanced risk for children is not even mentioned. While the Agency may choose to assign a higher risk coefficient for young people with only limited supportive evidence, or to cautiously ignore a

reduction of risk with increasing time since exposure, the currently available scientific information on these topics must be presented.

On page 19 of the criteria document, it is stated that it is inappropriate to derive a Reference Dose for radon. Because the concentrations required to produce noncarcinogenic effects are so high (and are unachievable in the context of radon in drinking water), the two appendices are not relevant to the risk assessment for radon.

e. The basis for and variability of the assumed intake of 0.66 liters of tap water per day is not well documented. A. G. Ershaw and K. P. Cantor (*Total Water and Tapwater Intake in the United States: Population-Based Estimates of Quantities and Sources,* May 1989, prepared under National Cancer Institute Order Number 263-MD-810264, Epidemiology and Biostatistics Program, National Cancer Institute, Bethesda, MD 20892) found that the average tap water consumption for 26,000 people (excluding pregnant women, lactating women, and breast-fed children) was 1193 ± 702 mL/day. The consumption rate varied with age; for adults (ages 20-64) it was about 1250 mL/day. Their definition of tap water consumption included water consumed directly as a beverage or used to prepare food and beverages so the amount drunk directly would be smaller, but it isn't clear that it would be as small as 660 mL/day. These estimates should be compared with those from the previously referenced Agency publication. The bases for choosing a particular direct consumption rate and for the assumed 20% loss of radon between the faucet and the glass must be presented and defended.

f. A similar comment applies to the presentation of the dimensionless ratio of the indoor air concentration to the tap water concentration. The draft report by Hess *et al.*, cited above, indicates ratios lower than the assumed value of 10^{-4}. The criteria document must reflect the distribution of all the available measurement results, the basis for selecting the nominal value, and the uncertainty associated with that value.

In this connection, the Subcommittee believes that additional analysis and review of the data in the draft report by Hess *et al.* is needed. The methodology requires some clarifications as well and there are inconsistencies between the text and data tabulations and figures. Their measurements are useful for the radon risk analysis; clear presentation of these results will be beneficial to a complete review of the water-to-air transport process.

f. Application of a generic air to tap water concentration factor in the calculation of exposure to airborne radon and daughter products overlooks the potential exposure to high concentrations at the point of release of the radon, primarily in the bathroom during and after a shower. Measurements of other volatilized contaminants indicate that such exposures are comparable to or greater than the whole house exposure. Relevant papers discussing such exposures have been provided to the Office of Drinking Water. The revised criteria document

must address both the daily acute and the general exposure pathways. The degree of radon daughter equilibrium is an important variable in this assessment.

g. Although the current set of risk calculations suggests that the risk of actual ingestion of radon in tap water is substantially lower than the risk from airborne activity released by tap water usage, that aspect of the risk assessment also deserves close attention by the Agency. It would be useful, for example, to include in the final report by Crawford-Brown a comparison of the compartmental half-lives with those observed in human studies that employed other rare gases (Kr, Xe). The analysis of uncertainty of the risk estimate, begun in the draft report by Crawford-Brown, must be continued. The importance of this aspect of the risk assessment process has been stressed repeatedly by the Radiation Advisory Committee and its working groups.

h. The quality of the document affects its credibility. Even as a draft, it should not contain incorrect definitions of fundamental technical terms or basic fallacies. The ability of the Agency to guide and review the risk assessment is called into question as is the capability of the contractor performing it. Specific written technical comments have been provided to the ODW and additional details have been made discussed during the conference calls.

4.4 Man-made Radionuclides Document

The document employs ad hoc risk factors that have not been reviewed. The document does not rely upon the effective dose equivalent concept, contrary to previous recommendations of the SAB. Instead of providing the basis for selection of a guide value, the level of 4 mrem/y was assumed. Uncertainties in parameters, models, and calculated risks are not addressed. In particular, the previously recognized uncertainty due to variations in chemical form of the radionuclide has been removed from the current draft.

The Subcommittee was asked to assess the scientific credibility and correctness of the *Quantitative Risk Assessment for Beta Particle and Gamma Emitters in Drinking Water*, draft dated May 1990. Within this framework, the Subcommittee offers the following recommendations and observations.

a. Probably the most significant issue raised by the review of this document is the lack of consistency in the use of radiation risk factors and previous Agency commitments to the Science Advisory Board. The criteria document employs a multiplicative factor of two to revise the Agency's Low-LET Risk Estimates for Regulatory Purposes in response to the recently published *BEIR V* report. However, in previous correspondence from Administrator Thomas and the ORP, the RAC was advised that revisions of the risk estimates, based on the *BEIR V* and United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) reports, would be made in consultation with the Radiation Advisory Committee. Application of revised risk factors is currently being conducted on an *ad hoc* basis. Inasmuch as the latest reports indicate increased risk per unit dose

it would seem that review of those reports and recommendations for revisions of the low-LET risk factors would be a high priority item for the Agency. The drinking water criteria documents may be published using current estimates and produce a mistaken impression of the radionuclide concentration guides and the expenditures that will be required to achieve them. For example, that the calculated risk (in the criteria documents) for the 4 mrem/y criterion exceeds 10^{-4} and is therefore outside the normally acceptable range for risks associated with drinking water.

b. Another inconsistent policy issue identified by the review deals with the application of the effective dose equivalent concept of the ICRP. Results which employ the concept are presented, for illustration only, as that system of risk estimation is not used in the document (according to the footnote to the table). However, in fulfilling its Federal Radiation Council responsibilities, the Agency has recommended and in 1987 the President approved the application of the effective dose equivalent concept for occupational exposure. As noted previously, the 1987 Drinking Water Subcommittee recommended the use of the ICRP's effective dose equivalent concept with certain exceptions. In 1988, the RAC approved a resolution (SAB-RAC-88-026) stating that the effective dose equivalent, rather than the dose equivalent to specific organs, should be applied as a basis for regulations dealing with radiation exposure.

c. As a criteria document, the report should define the potential risks from exposure to the manmade beta- and gamma-emitters, rather than define the regulatory value, so the concentration guide values would be more appropriately presented on a per mrem (exposure standard) basis. The document should provide the scientific basis for the regulations. No basis for the selection of 4 mrem/year is given in the document. As noted above, it may correspond to a risk level that is outside the Agency's normally acceptable range for contaminants of drinking water.

d. Table A-1, titled "Effective Dose Equivalent," contains the useful derived information for individual radionuclides. However, the results presented are simultaneously repudiated in a footnote to the table. The table is mistitled, extremely difficult to understand, and inconsistent with previously presented concentration guide values (in the 1986 announcement of proposed rulemaking). The former presentation recognized that the parameter f_1 depends upon chemical form; the current draft document does not.

e. This document also fails to present a satisfactory discussion of the uncertainties associated with selected values of parameters used in estimating concentration guides and the overall uncertainty associated with the result of those calculations. As noted above, and in connection with the uranium drinking water criteria document, the value of the concentration guide is directly proportional to the parameter f_1 which is quite variable. Neither this variability nor the uncertainties associated with the dose calculations is discussed. The uncertainties associated with the risk coefficients, which are presented with as many as five

significant figures in Table V-2, are apparently not understood by the authors. A detailed presentation of uncertainties is needed in this document. The authors should summarize relevant information on the important parameters where necessary and should not refer the reader to another document. The decision-maker should be presented with the recommended criteria and measures of the uncertainties associated with the recommendations.

f. Table V-1, as presented in the document, is misleading. It should also include the numbers of radiogenic cancers estimated to have occurred in the various exposed populations. In the case of the Life Span Study of the Japanese survivors about 400 of the nearly 6000 cancers are attributable to the radiation doses received in 1945.

APPENDIX A

LISTING OF SEPARATE TRANSMITTALS TO THE ODW

A list of materials provided to the Office of Drinking Water by the Drinking Water Subcommittee during the course of the review of the draft criteria documents follows. The materials consisted of technical and editorial comments and technical information relevant to the subjects under consideration.

a. 19 April 1990 letter from John Harley to Kathleen Conway with undated comments on the uranium (U) criteria document and a preprint of a paper by Spencer *et al.* titled *Measured Intake and Excretion Patterns of Naturally Occurring ^{234}U, ^{238}U, and Calcium in Humans*

b. 19 April 1990 letter from John Harley to Kathleen Conway on the U criteria document

c. 4 June 1990 letter from Julian Andelman to Paul Voillequé following the conference call on the U criteria document

d. 5 June 1990 letter from John Harley containing comments on the EPA radon criteria document

e. 8 June 1990 memorandum from Kathleen Conway to Greg Helms transmitting the draft letter report on the U criteria document, individual comments, two technical papers from the EPA's National Workshop on Radioactivity in Drinking Water *(Health Phys.* **48** (1985)): *Metabolism of Ingested U and Ra* and *Cancer Risk from the Lifetime Intake of Ra and U Isotopes*, and two related papers: *Gastrointestinal Absorption of Plutonium and Uranium in Fed and Fasted Adult Baboons and Mice: Application to Humans* and *Gastrointestinal Absorption of Soluble Uranium from Drinking Water by Man*, both published in *Radiation Protection Dosimetry*, 26 (1989)

f. 11 June 1990 letter from John Harley containing comments on the Crawford-Brown paper

g. 11 June 1990 letter from John Harley containing comments on the Hess paper

h. 18 June 1990 letter from Julian Andelman containing comments on the draft radon drinking water criteria document

i. 18 June 1990 letter from John Harley containing comments on thesis distributed by Dr. Hess

j. 19 June 1990 letter from John Harley to Paul Voillequé

k. 19 June 1990 letter from John Harley to Kathleen Conway

l. 19 June 1990 memorandum from Julian Andelman to Subcommittee transmitting papers on exposures in showers and homes to volatile organic ir water; papers titled: *Significance and Treatment of Volatile Organic Compounds in Water Supplies; Real-Time Air Measurements of Trichloroethylene in Domestic Bathrooms Using Contaminated Water; Inhalation Exposure from Contaminated Water Uses: A Behavioral Model for People and Pollut-*

ants; and *Air Quality Model for Volatile Constituents from Indoor Uses of Water*

m. 19 July 1990 FAX from Julian Andelman to Kathleen Conway containing comments on the Manmade Beta-Gamma Emitters document

n. 16 July 1990 letter from John Harley to Kathleen Conway with comments on the radium criteria document

o. 1 August 1990 draft letter report of the Subcommittee's comments and recommendations regarding the radon criteria document

p. 1 August 1990 draft letter report of the Subcommittee's comments and recommendations regarding the manmade beta-gamma emitters criteria document

q. 10 August 1990 draft letter report of the Subcommittee's comments and recommendations regarding the radium criteria document

r. 17 August 1990 letter from Paul Voillequé transmitting the Yang and Nelson paper: *An Estimation of Daily Food Usage Factors for Assessing Radionuclide Intakes In the U. S. Population (Health Phys. 50,* 245 (1986))

s. 20 August 1990 letter from Julian Andelman to Kathleen Conway with comments on the radium criteria document

t. 7 September 1990 memorandum from F. Henry Habicht to LaJuana S. Wilcher on *Radionuclides in Drinking Water: Proposed Maximum Contaminant Level Regulation*

u. 14 September 1990 Draft of Final Report of the Subcommittee

v. 21 September 1990 letter from Isabel Fisenne to John Harley with comments on the uranium criteria document

w. 23 September 1990 letter from John Harley to Paul Voillequé

x. 13 October 1990 Draft Report titled *Review of the Office of Drinking Water's Criteria Documents and Related Reports for Uranium, Radium, Radon, and Manmade Beta-Gamma Emitters*

y. 25 October 1990 briefing materials used by Paul Voillequé to present Subcommittee report to the Radiation Advisory Committee

z. 4 December 1990 letter from Leonard Hamilton, Brookhaven National Laboratory transmitting tow informal reports BNL-4477 1, *Evaluation of Health Risks Associated with Proposed Ground Water Standards at Selected Inactive Uranium Mill-Tailings Sites*, and BNL-44772, *Health Analysis for Ingestion of Contaminants from Existing Groundwater Contamination at Selected UMTRA Project Sites*

aa. 6 December 1990 letter from John Harley to Paul Voillequé