United States
Environmental Protection
Agency

Office of the Administrator
Science Advisory Board
Washington, DC 20460

SAB-RAC-87-035
July 1987

EPA

Report of the Drinking Water Subcommittee of the Radiation Advisory Committee

Review of the Office of Drinking Water's Assessment of Radionuclides in Drinking Water and Four Draft Criteria Documents

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D C. 20460

July 27, 1987

SAB-RAC-87-035

OFFICE OF
THE ADMINISTRATOR

Honorable Lee M. Thomas
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Thomas:

The Radiation Advisory Committee of the Science Advisory Board has completed its review of the Office of Drinking Water's evaluation of radionuclides in drinking water and four draft criteria documents that support this evaluation, including Man-Made Radionuclide Occurrence, Radium, Radon and Uranium.

At the request of the Office of Drinking Water, the Committee addressed four issues: the weighting factors to be used in effective dose equivalent calculations, the chemical toxicity and radiotoxicity of uranium, the linearity of the dose-response curve for naturally occurring radionuclides, and the appropriate use of the relative and absolute risk models.

The Subcommittee concludes that the Office of Drinking Water has developed scientifically comprehensive assessment documents. The basis of the risk estimates developed and the text describing it, however, should be as precise, clear and consistent as possible. The documents should include a clearer exposition of the basis for the risk estimates used, the concept of effective dose equivalent and the weighting factors employed. More care and consistency in the use of quantities and units is recommended. Discussion of these issues is presented in the attached report.

The EPA has adopted the effective dose equivalent approach, which is a useful and applicable methodology in most circumstances involving radionuclides in water. A notable exception is radium, where the direct human information differs very significantly from risks derived from the effective dose equivalent concept.

The Committee appreciates the opportunity to present its scientific views and is prepared to provide additional assistance that the Agency requests. We request that the Agency officially respond to the attached report, indicating which of the recommendations the Office of Drinking Water plans to accept or reject.

Sincerely,

John Till
Acting Chairman
Radiation Advisory Committee

Norton Nelson
Chairman
Science Advisory Board

Review

of

The Office Of Drinking Water's Assessment Of

Radionuclides In Drinking Water

and

Four Draft Criteria Documents:

Man-Made Radiocuclide Occurrence

Uranium

Radium

Radon

by the

Drinking Water Subcommittee

Radiation Advisory Committee

Science Advisory Board

U. S. Environmental Protection Agency

July 1987

NOTICE

This report has been written as a part of the activities of the Science Advisory Board, a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide a balanced expert assessment of scientific issues related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of the report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute endorsement or recommendation for use.

U.S. Environmental Protection Agency
Science Advisory Board
Radiation Advisory Committee
Drinking Water Subcommittee

Roster

Chairman

Dr. Warren Sinclair, President, National Council on Radiation Protection and Measurements, 7910 Woodmont Avenue, Suite 1016 Bethesda, Maryland 20814

Members/Consultants

Dr. Seymour Abrahamson, Professor of Zoology and Genetics, Department of Zoology, University of Wisconsin Madison, Wisconsin 53706

Dr. John Harley, Box M268, Hoboken, New Jersey 07030

Dr. Andrew Stehney, Building 203, Argonne National Laborarory 9700 South Cass Avenue, Argonne, Illinois 60439

Executive Secretary

Ms. Kathleen W. Conway, Deputy Director, Science Advisory Board Radiation Advisory Committee, 401 M Street, S.W. (A-101F) Washington, D. C. 20460

Staff Secretary

Ms. Dorothy M. Clark, Staff Secretary, Science Advisory Board Radiation Advisory Committee, 401 M Street, S.W. (A-101F) Washington, D. C. 20460

Table Of Contents

I. Introduction

On January 15, 1986 EPA's Office of Drinking Water (ODW) officially requested the Science Advisory Board (SAB) to conduct a review of a number of scientific issues related to its evaluation of radionuclides in drinking water. The SAB Executive Committee considered and accepted this request and authorized its Radiation Advisory Committee to carry out the review. The latter Committee formed a Drinking Water Subcommittee to fulfill the Executive Committee's charge.

The Subcommittee subsequently received the following documents from ODW:

- Radionuclides in Drinking Water (for publication in the Federal Register)
- Criteria Document on Man-Made Radionuclides
- Criteria Document for Uranium
- Criteria Document for Radium
- Criteria Document for Radon
- Office of Drinking Water's January 15, 1986 Memorandum, "Request for Review of Scientific Basis of Proposed Recommended Maximum Contaminant Levels for Radionuclides in Drinking Water" (see Appendix I) that includes four issues for review.

The members of the Subcommittee examined these documents according to individual assignments based on their expertise. They prepared written comments on most of them prior to the open meeting in Washington on September 25-26, 1986. Dr. Abrahamson was unable to attend this meeting.

The Subcommittee developed its report in three parts. These include:

- Responses to the four issues raised by the Office of Drinking Water.
- General comments on the documents and the review as a whole
- Technical and editorial comments on each of technical documents

Individual members of the Subcommittee have also prepared detailed page-by-page editorial comments that have already been forwarded to the Office of Drinking Water.

II. Responses To The Four Issues Raised By The Office Of Drinking Water

Issue #1. "In the calculation of the effective dose equivalent, should the weighting factors developed by the ICRP or those developed by EPA based on BEIR III be used?"

The Subcommittee concludes that the ICRP weighting factors should be used in their original form because they are well established, and widely

published and used. Furthermore, they have not been invalidated in any way, and they include a component for genetic risk. Also, they form the basis of ICRP 30, Annual Limits of Intake of Radionuclides by Workers, and these are used directly by EPA.

The EPA weighting factors, although in some respects more traceable to original data than are those of the ICRP, are not as well established or widely known, and they have not been thoroughly published and justified. They do not include a component for genetic risk. Furthermore, their application would not alter the results obtained for drinking water in a significant way, except perhaps for bone. However, the Subcommittee notes that ICRP weighting factors express a result for radium more consistent with human data. It is not clear why more than one set of weighting factors is necessary.

Issue #2. "Are the radiotoxic health effects of ingested uranium sufficiently well substantiated to be used as the basis of a regulation? Should uranium be in category A (of EPA's risk assessment guidelines for cancer) and on what basis? Do you agree with the non-radiotoxicity health assessment?"

The Subcommittee considers that the radiotoxic health affects of uranium (renal effects) are not sufficiently well substantiated to form the scientific basis of regulation, but uranium should be in Category A on a presumed (but not demonstrated) likelihood of carcinogenesis. The Subcommittee agrees with the non-radiotoxicity health assessment and concludes that chemical toxicity should constitute the scientific basis used for regulation.

Issue #3. "Is the dose-response curve for naturally occurring radionuclides linear?"

The Subcommittee agrees that linearity for naturally occurring alpha emitters is appropriate in the dose range of interest.

Issue #4. "Should the relative or absolute risk model value be used?"

The Subcommittee believes there are no data enabling a clear scientific choice of relative and absolute risk models for most cancers but the recommendation made in the October 28, 1985 report by the Radiation Advisory Committee in its review of low-level radioactive waste disposal standards, namely that the risk model considered most appropriate for the specific disease be applied rather than averaging, is supported by the Subcommittee. Thus, the absolute risk model should be used for leukemia and bone cancer and the relative risk model for other sites identified as associated with radiation induction. The Subcommittee notes that averaging could be conducted in many different ways, and introduce new complexities.

III. Comments on the Office of Drinking Water's Draft Criteria Documents

A. General Comments

1. The Subcommittee believes that the choice of risk estimates in the documents is not sufficiently clear. All the numbers used should be clarified in terms of their references and scientific justification, and they should be consistently applied. Though the BEIR III (1980) and BEIR (1972) reports are referred to as the source of some estimates, considerable reliance was also placed on two documents--"Radionuclides: Background Information Document for Final Rules, Volumes I and II" (EPA 520/1-84-022-1 and 2)--that were not referenced in some criteria documents. The Subcommittee also has some concerns about the choice of the risk coefficient, which seemed to be 200 deaths/100,000 people for 0.1 rem/y for a life time exposure (BEIR I). This number agrees with a linear linear model result from BEIR III and is described in one document as a "safe" or prudent assumption for regulatory purposes. This choice corresponds to about 3×10^{-4}/rem and is high compared with the preferred linear-quadratic estimates in BEIR III (1980) or those in UNSCEAR 1977.

2. The concept of the effective dose equivalent (of ICRP) should be explained carefully as it has a central role in the documents. Also, the documents should clairfy the difference between effective dose equivalent and dose equivalent.

3. More clarity is needed in presenting equations concerned with quantities such as absorbed dose, dose equivalent and quality factor. There is also alternating use between conventional and Standard International (SI) units. EPA should consider placing conventional units first with the SI equivalent in brackets, and to use conventional units in tables with a footnote on SI equivalents.

4. The organization of some of the documents and tables could be improved. As far as possible, a logical sequence in the documents should be followed that might take the following form: metabolism and toxicology --> concentration --> dosimetry --> risk. As for the tables in Radionuclides in Drinking Water, Appendix D, the first column begins with risk numbers, whereas these should logically be located in the last column.

B. Technical and Editorial Comments

Radionuclides in Drinking Water

1. This document should present a clearer exposition for the basis of the risk estimates used, the concept of effective dose equivalent and the weighting factors employed. None of these are sufficiently clear and well developed in the draft reviewed by the Subcommittee. The Subcommittee understands the concept of effective dose equivalent and the use of weighting factors, but it recommends additional clarification because of the widespread use of the documents by scientific and non-scientific personnel.

2. The Subcommittee supports the Office of Drinking Water's adoption of the effective dose equivalent approach, a useful and applicable methodology in most circumstances involving radionuclides in water. A notable exception is radium where 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. Some modification will also be necessary for uranium since the EPA radiological risk estimates are based on radium.

3. Evidence of internal inconsistences in some of the tables (in Appendix D, for example) are noted in the detailed comments and in discussion. All tabular data should be carefully examined and revised where inconsistences occur.

4. Many available analytical procedures are equal or better than those presented in the document. EPA should consider using performance specifications for the procedures rather than prescribing a specific method.

Man-Made Radionuclides

1. The statement on Page I-2 concerning isotope concentrations that "can produce a dose equivalent of 4 mrem/yr whole-body radiation" is likely to confuse the reader because it actually refers to effective dose equivalent (EDE). The EDE concept should be introduced here and used in the document to avoid confusion with "dose equivalent."

2. The risk parameters in Table III-1 include some unclear choices: a latency period of 10 years for lung cancer but 15 years for other tumors of soft tissues; a Q of 1 for breast and thyroid, 20 for leukemia, and 10 for all others. The document should present a rationale for these choices or, possibly, they should be reconsidered.

3. The tables of radionuclide concentrations are developed on the basis of risk equal to that from a whole-body dose rate of 4 mrem/yr. No rationale is given for using this basis, only the risk estimate of 8 excess cancers (lifetime) per 100,000 people. EPA should consider alternatives, such as 5 mrem/yr and 10 excess cancers or 1 mrem/yr and 2 excess cancers. The rationale for choosing 4 mrem/yr should be stated.

4. In Table III-8, the comparison with ICRP 30 shows agreement within a factor of 2 for the beta emitters except for ^{131}I; some explanation for the large difference for ^{131}I should be given.

5. In the section on analytical procedures, it is not clear whether or not these methods are recommended or prescribed. The Subcommittee believes that the principal requirement should be performance because better procedures

may become available, and merely following a written procedure does not insure that adequate data will be obtained.

6. Unexplained inconsistencies between this document and the documents on radium and uranium are noted as follows:

a. The organ weighting factors from Table III-1 of this document differed from those given in Part VIII of the radium and uranium documents.

b. For chronic exposure, the radiation dose rates at specified times times after birth are used in this document for estimates of lifetime risks, but the radium and uranium documents use a constant radiation dose rate throughout life equal to that attained after 70 years of intake.

Uranium

1. There needs to be more emphasis on the factors, or range of factors, carried over from one section to another. This could be done by tabulation or summarization at the end of appropriate sections.

2. The weighting factors attributed to BEIR III should be credited to EPA instead. The general method of deriving these new factors should be stated briefly in each document.

3. The uranium document, in particular, is based on secondary sources. Some references to the primary literature would be helpful.

4. The lack of evidence for carcinogenesis is properly emphasized in Section VII but needs to be repeated at the top of Page VIII-3.

Radium

1. The organ risk estimates in Tables VIII-1 and VIII-2 are inconsistent with the Effective Dose Equivalent rates for the organs; it seems evident that the organ weights shown in the tables were not used to estimate the organ risks.

2. The high risk estimates for leukemia and soft-tissue cancers relative to bone cancer (Part VIII) are contradicted by epidemiological studies of radium dial painters, among whom only bone cancers and head carcinomas were found in excess over normal rates (cf. Part VI.B)

3. Contrary to statements in Part VIII, dose-response data on non-stochastic effects of radium are available for humans (Evans, R. D., 1966; Keane et. al., 1983). The possibility that non-stochastic effects may impose dose limitations should be considered (cf. Schlenker, R. A., 1984) in the Radium document.

4. The verbatim repetition in Part VII of material in Part III and Part VI.C seems unnecessary.

5. The section on "acute" health effects (VI.E) is really a general description of all radiation effects. It seems out of place as a subsection of radium effects and would be more suitable as an appendix. Also, this section omits the acute effects that actually have been ascribed to ingestion of large amounts of radium (e.g., blood dyscrasias and necrosis of the jaw bone) in early papers on radium dial painters.

Radon

1. There needs to be more emphasis on the factors, or range of factors, carried over from one section to another. This could be done by tabulation or summarization at the end of appropriate sections.

2. The radon exposure from water derives from its domestic uses, not from drinking water. This could be emphasized further, possibly by using the term "drinking and domestic water supplies."

3. The weighting factors attributed to BEIR III should be credited to EPA instead. The general method of deriving these new factors should be stated briefly in each document.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 15 1986

OFFICE OF WATER

MEMORANDUM

SUBJECT: Request for Review of Scientific Basis of Proposed Recommended Maximum Contaminant Levels for Radionuclides in Drinking Water

FROM: Joseph A. Cotruvo, Director
Criteria and Standards Division, ODW (WH-550)

TO: Terry Yosie, Director
Science Advisory Board (A-101)

I request that the SAB review the scientific basis of the proposed Recommended Maximum Contaminant Levels (RMCLs) for radionuclides in drinking water. In addition, I request that we be placed on the agenda for the SAB meeting in Las Vegas on January 21-22, 1986 to give an overview of the proposed RMCLs for radionuclides in drinking water and to discuss the specific scientific areas upon which we would like SAB to focus.

The Office of Drinking Water is currently developing the Revised National Primary Drinking Water Regulations for Drinking Water. The third phase of this rule-making process involves the development of regulations for radionuclides in drinking water. We are developing these regulations in two steps. First, we propose RMCLs, which are non-enforceable health goals that are set at levels that would result in no known or anticipated adverse health effects and which allow an adequate margin of safety. When the RMCLs have been published as a final rule, we take the second step of proposing a Maximum Contaminant Level (MCL). MCLs are enforceable standards and must be set as close to RMCLs as is feasible. Feasible means "with the use of the best technology, treatment techniques and other means, which the Administrator finds are generally available (taking costs into consideration)".

A proposal has been developed for RMCLs for radionuclides in drinking water. The proposal has cleared the red border review process and will be sent to the Office of Management and Budget this month. Publication of the proposed RMCL's in the Federal Register is anticipated in March 1985. The final RMCL and the proposed MCL are scheduled to be published in the Spring of 1987.

Support documents required in the regulatory process that summarize the occurrence and potential health effects of radionuclides in drinking water, are available for SAB review. These documents include: health effects criteria documents on radium, uranium, radon and man-made radionuclides; the proceedings of the National Workshop on Radioactivity in Drinking Water (the May 1985 issue of the Journal Health Physics); various scientific publications.

I would like the Science Advisory Board to review the scientific basis of the proposed RMCLs and to specifically focus on the four questions that are attached. A brief statement on ODW's current position is provided for each question that indicates the approach we are now taking. Much of the detailed analysis relating to these four questions and other possible questions are contained in the documentation described above. We would be happy to provide any or all the available documentation to SAB members.

In addition, I would like to encourage the SAB to consider two specific needs in our development of the rules for the RMCLs and MCLs. We have an interest in the epidemiology studies of indoor air radon levels and their relationship to lung cancers. Also, we have some concern about the current data base relating drinking water levels of radon to indoor air levels.

It is my understanding that the SAB will be reviewing the protocol for the epidemiology study in the northeast involving the Maine Medical Center, the State of Maine, and the University of Maine. We would like to add our support to this study and your review of it since the results will be most useful to us.

The largest contribution to uncertainty for the estimated population risk due to radon in drinking water is the numerical relationship between drinking water concentrations and indoor air concentrations. The existing data base for this numerical relationship is somewhat weak. The support of the SAB would be appreciated in encouraging EPA's Office of Research and Development to conduct a study broadening this data base.

If you have any questions or desire further information, please let me know or call Dr. Rick Cothern at (202)382-7584.

cc: Rich Guimond, ORP (ANR-460C)
Dave Janes, ORP (ANR-460C)

SCIENTIFIC QUESTIONS RELATING TO THE DEVELOPMENT OF THE REVISED REGULATIONS FOR RADIONUCLIDES IN DRINKING WATER

Question #1 In the calculation of the effective dose equivalent, should the weighting factors developed by the ICRP or those developed by EPA based on BEIR III be used?

Current ODW Position The ICRP weighting factors relate to occupational exposure. There are some minor adjustments needed for these factors to best describe the possible responses to general environmental exposure. The BEIR III based weighting factors describe the general environmental exposure more completely. This approach follows that used in ORP's background document for the development of the Clean Air Act regulations and is the same as that being used in the development by ORP of the low level radioactive waste standard. (See attached table from the Health Criteria Document on Man-Made Radionuclides that gives some idea of the difference due to the choice of different weighting factors)

Question #2 Are the radiotoxic health effects of ingested uranium sufficiently well substantiated to be used as the basis of a regulation? Should uranium be in category A and on what basis? Do you agree with the non-radiotoxicity health assessment?

Current ODW Position Although direct epidemiology studies have not been conducted for uranium, it is known to be a bone seeker and thus its radiotoxicity would be expected to be similar to that of radium. For this reason, we feel it should be in Category A (a known number of carcinogen under EPA guidelines) and can be used as the basis of regulation.

The primary chemically toxic effect of natural uranium is on the kidneys. The possible standard based on this non-radioactive health effect or Adjusted Acceptable Daily Intake for uranium is 60 micrograms/l as shown below assuming a 70 kg adult consuming 2 liters of water per day. The calculation is:

$$AADI = \frac{(NOAEL)(\text{animal } f_1)(\text{adult weight})}{(\text{safety factor})(\text{water consumption/day})(\text{human } f_1)}$$

$$= \frac{(1 \text{ mg/kg/day})(0.01)70 \text{ kg})}{(100(2 \text{ l day})(0.5)}$$

= 60 micrograms/l or 40 pCi/l (rounded off to one significant figure)

Included in the above determination of the AADI for uranium is a no observed adverse effect level (NOAEL) of 1 mg/kg/day, a safety factor of 100 since only animal data is used, animal

uptake of 1%, and human uptake of 5%.

Question #3 Is the dose-response curve for naturally occurring radionuclides linear?

Current ODW Position The BEIR III reports that there is some evidence that the dose-response curve for alpha emitters may be supralinear. The evidence for radium allows for the possibility of linear or a quadratic dose-reponse curve. As a scientific policy, we have assumed linearity.

Question #4 Should the relative or absolute risk model value be used?

Current ODW Position As the ORP does, we average the values predicted by the relative and absolute risk models.

Table III-8* Drinking water concentrations corresponding to a dose of 4 mrem/yr for selected nuclides comparing the results using two different organ risk coefficients; viz, the ICRP 30 set and the set used in the calculations for the present document based on BIER III.

Nuclide	Concentration in PCi/L corresponding to a dose of 4 mrem/yr using: ICRP 30	BEIR III/USEPA
^{3}H	89,000	88,000
^{58}Co	1600	2200
^{60}Co	210	240
^{89}Sr	680	880
^{90}Sr	41	46
^{129}I	20	14
^{134}Cs	74	77
^{137}Cs	110	110
^{239}Pu	13	39
^{241}Am	2.5	3.9

* From the Draft Criteria Document for man-made radionuclides in drinking water.