United States Environmental Protection Agency
Science Advisory Board (1400) Washington, DC
EPA-SAB-RAC-ADV-99-002 December 1999 www.epa.gov/sab

AN SAB ADVISORY: REVIEW OF HEALTH RISKS FROM LOW-LEVEL ENVIRONMENTAL EXPOSURES TO RADIONUCLIDES

REVIEW OF THE OFFICE OF RADIATION AND INDOOR AIR'S FEDERAL GUIDANCE REPORT 13 - PART 1, INTERIM VERSION (FGR-13)

December 23, 1998

EPA-SAB-RAC-ADV-99-002

Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M. Street, SW
Washington, DC 20460

Re: An SAB Advisory on the Health Risks from Low-Level Exposure to Radionuclides, Federal Guidance Report No. 13 - Part 1, Interim Version (FGR 13 - Part 1)

Dear Ms. Browner:

The accompanying report was developed by the FGR 13 Review Subcommittee of the Radiation Advisory Committee (RAC) of the Science Advisory Board (SAB) in response to a request from the Office of Radiation and Indoor Air (ORIA) to review the technical aspects of the interim version of Federal Guidance Report 13 - Part 1, dated January, 1998. The Subcommittee met on May 6-7, 1998, and held two subsequent conference calls, to review the interim document with respect to the following Charge:

a) Is the methodology employed for calculating health risks from radionuclide intakes and external exposures acceptable?

b) In light of scientific information, have the major uncertainties been identified and put into proper perspective?

c) Is the proposed method for extending the list of radionuclides to include all those tabulated in Federal Guidance Reports 11 and 12 reasonable?

FGR 13 - Part 1 provides tabulations of unit risk estimates, or “risk coefficients”, for cancer morbidity and mortality attributable to exposure to any of approximately 100 radionuclides via various environmental media. Radiation doses are calculated as an intermediate step in estimating risks, but are not tabulated in the report. The risk coefficients apply to populations that approximate the age, gender, and mortality experience characterized by the current U.S. population. The report is intended by the Agency to promote consistency in assessments of the risks to health from radiation and to help ensure that radiological risk assessments are based on sound scientific information.

In our enclosed report, we address these issues and offer a few suggestions in addition to our response to the Charge. The report focuses on specific technical issues that the Subcommittee believes should be addressed prior to publication of the final version of FGR 13 - Part 1 and makes suggestions for future consideration by the Agency. The following findings and recommendations are viewed as particularly important with respect to each Charge element:

a) Methodology

1) The methodology employed for calculating health risks from radionuclide intakes and external exposures was found to be acceptable in the context of: 1) current Agency science policy choices, such as the applicability of a linear, no-threshold dose-response model for cancer risks at low doses of radiation; and 2) its intended use to support broad federal radiation protection programs such as environmental impact statements or generic rulemaking. However, the Subcommittee is concerned about reliance on unpublished reports for some of the detailed techniques employed, absence of absorbed dose rate information, and other points discussed below.

2) The lack of published reports for some of the techniques employed is a weakness of this work, for both the internal and external exposure calculations. The Subcommittee recommends that evidence of verification and quality assurance procedures be included in an Appendix to the final version of FGR 13 - Part 1.

3) The Subcommittee is concerned about the absence of radiation dose information in FGR 13 - Part 1. This makes it difficult for users to update the risk coefficients as new information on risk or dosimetry becomes available, or to employ risk models other than the linear-no threshold model used by the Agency. The Subcommittee recommends that dose information be published in electronic form.

4) Some potentially valuable information has not been addressed in FGR 13. For example, a published dosimetry model for the esophagus and trachea is not used for the internal dose calculations or discussed in the document. Risks calculated in FGR 13 - Part 1 are based on mortality (death) data, but information on cancer incidence (morbidity) is generally more accurate.

b) Uncertainty

1) Although the document does well in identifying many of the major uncertainties and describing them qualitatively, it does not provide the reader with a good sense of the overall uncertainty entailed when a specific risk coefficient is used to predict the risks of low-level exposure to radiation. The Subcommittee recommends at a minimum that: 1) the individual radionuclides of highest concern for environmental exposures be placed into categories associated with low, moderate, high, or very high uncertainty; 2) identification of these uncertainty categories be contained within the tables of risk estimates; 3) general guidance about the limits of application be provided for those radionuclides that cannot be placed into an uncertainty category, and; 4) the final version of FGR 13 - Part 1 include an appendix that describes the steps that may be taken to improve uncertainty estimates for the risk coefficients.

2) For future revisions of the Agency's reports, such as those in the FGR 13 series, the Subcommittee recommends that quantification of uncertainty be considered at the outset of the project.

3) Although the lack of scientific consensus on the estimation of lifetime cancer risks from low-level radiation is acknowledged in FGR 13 - Part 1, the Subcommittee recommends adding a concise, balanced discussion that lays out the arguments for and against the possibility of a threshold or other non-linear behavior at low dose and low dose rate.

c) Expansion

1) The Subcommittee believes that the Agency’s proposed method for extending the list of radionuclides to include those tabulated in FGRs 11 and 12 is reasonable, but recommends that risk coefficients also be presented for the inhalation of radon and its short-lived decay products. The Subcommittee would prefer that these risk coefficients be included in the final version of Part 1 if feasible.

The Subcommittee also identified and addressed several issues not raised in the Charge. These issues (and where appropriate) recommendations are listed below:

a) The Subcommittee observes that use of the FGR 13 - Part 1 risk coefficients could contribute to debate or ambiguity as to whether a regulated site meets regulatory limits, especially in cases where a regulation is stated in terms of dose limits but the supporting technical documentation might use risk calculations.

b) The Subcommittee recommends that risk coefficients for external exposure, applicable specifically to the Uranium Mill Tailings Radiation Control Act (UMTRCA) standard, be calculated and tabulated in the final version of FGR 13 - Part 1 or in a separate document.

c) The Subcommittee recommends that the title of the document be changed to "**Estimated** Health Risks from Low-Level Environmental Exposure to Radionuclides, Federal Guidance Report 13 - Part 1**: Cancer**" (emphasis added). This change conveys the important points that the tabulated risk values are estimates and that cancer is the only health effect treated in the document.

We commend the Agency on its leadership and efforts in using up-to-date scientific methods and data to develop the health risk estimates in FGR 13 - Part 1. We believe that our recommendations, except those noted in the report for future consideration, can be incorporated prior to publication of the final version and will strengthen the report and its credibility. We strongly support the Agency's stated intent to publish supporting information in an electronic form to accompany release of the final version of FGR 13 - Part 1, and we recommend that it include the data, models, and dose information used in formulating the risk coefficients.

The RAC and its Federal Guidance Report Review Subcommittee (FGRRS) appreciate the opportunity to provide this report to you and we hope that it will be helpful. We look forward to your response to this report in general and to the specific comments and recommendations in this letter in particular.

Sincerely,

/signed/
Dr. Joan M. Daisey, Chair
Science Advisory Board

/signed/
Dr. Stephen L. Brown, Chair
Radiation Advisory Committee
Science Advisory Board

/signed/
Dr. Thomas F. Gesell, Chair
Federal Guidance Report Review Subcommittee
Radiation Advisory Committee

NOTICE

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ABSTRACT

On May 6-7, 1998, the Federal Guidance Report Review Subcommittee (FGRRS) reviewed technical aspects of the draft document, "Health Risks from Low-Level Environmental Exposure to Radionuclides," Federal Guidance Report 13 - Part 1 - Interim Version (FGR 13 - Part 1). This document provides tabulations of unit risk coefficients for cancer morbidity and mortality attributable to exposure to approximately 100 radionuclides through various environmental media, in a population approximated by the age, gender, and mortality experienced in the United States.

The Subcommittee found the report to be well organized and well written and to have used up-to-date scientific methods and data to determine the health risk estimates. Although most of the important limitations of the risk estimates are noted in FGR 13 - Part 1, they are not sufficiently prominent in the current draft, given the potential for misuse or misinterpretation of the estimates. In particular, the magnitudes of the uncertainties in the computed numbers are difficult to ascertain. Other concerns included partial reliance on unpublished methodologies, lack of dose information, insufficient discussion of alternatives to the linear, no-threshold risk model, and several other technical issues. The Subcommittee found that the Agency's plan to calculate risk coefficients for an extended list of radionuclides was appropriate, except that radon and its decay products should also be included. The Subcommittee strongly supports the Agency's stated intent to publish supporting information in electronic form to accompany release of the final version of FGR 13 - Part 1, and recommends that it include the data, models, and dose values used in formulating the risk coefficients.

KEYWORDS: radionuclides; cancer; risk assessment

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Mr. Samuel Rondberg, Designated Federal Officer, Science Advisory Board (1400), U.S. EPA, 401 M Street, S.W.,Washington, DC 20460[1]

Ms. Diana L. Pozun, Management Assistant, Science Advisory Board (1400), U.S. EPA, 401 M Street, S.W.,Washington, DC 20460

TABLE OF CONTENTS

[1]Provided editorial support for this report, but did not participate in the review.

1. EXECUTIVE SUMMARY

As part of the EPA Science Advisory Board's (SAB) Radiation Advisory Committee (RAC), the FGR 13 Review Subcommittee (the Subcommittee) reviewed technical aspects of "Health Risks from Low-Level Environmental Exposure to Radionuclides," Federal Guidance Report 13 - Part 1 - Interim Version (FGR 13 - Part 1). This first report in the series provides tabulations of risk estimates, or "risk coefficients," for cancer morbidity and mortality attributable to exposure to approximately 100 radionuclides through various environmental media. Radiation doses are calculated as an intermediate step in estimating risks, but are not tabulated in the report. The risk coefficients apply to populations that approximate the age, gender, and mortality experience characterized by the 1989-91 U.S. decennial life tables. FGR 13 - Part 1 is intended by the Agency to promote consistency in assessments of the risks to health from radiation and to help ensure that radiological risk assessments are based on sound scientific information.

The Subcommittee was charged by the Agency's Office of Radiation and Indoor Air (ORIA) to focus its review on the following questions:

a) Is the methodology employed for calculating health risks from radionuclide intakes and external exposures acceptable?

b) In light of scientific information, have the major uncertainties been identified and put into proper perspective?

c) Is the proposed method for extending the list of radionuclides to include all those tabulated in Federal Guidance Reports 11 and 12 reasonable?

The Subcommittee's report addresses these questions and offers some suggestions beyond the charge. FGR 13, Part 1 is a useful addition to the complement of Federal Guidance reports relevant to the evaluation of the risks of radiation and makes important improvements in the calculation of radiation risks. The report is well organized and well written, although difficult to comprehend for all but highly technical audiences. The careful reader will note that most of the important caveats to the use of the document's results are included in the text, but not as prominently as they probably should be. In particular, the magnitudes of the uncertainties in the computed numbers are difficult to ascertain.

This review focuses on specific technical issues that the Subcommittee believes should be addressed prior to publication of the final version of FGR 13 - Part 1 and makes suggestions for future consideration by the Agency. These major findings and recommendations are summarized below (with references to the corresponding sections of the report appearing in parentheses).

Charge element a) addressed the methodology employed for calculating health risks from radionuclide intakes and external exposures. The proposed approach was found to be acceptable in the context of a) current Agency science policy choices, such as the applicability of a linear, no-threshold dose-response model for cancer risks at low doses of radiation, and b) its intended use to support broad Federal radiation protection programs such as environmental impact statements

or generic rulemaking. However, as discussed below, the Subcommittee is concerned about unpublished reports being cited for some of the detailed techniques employed, absence of dose information, and the incomplete treatment of uncertainty. (Section 3.1.1)

The lack of published reports for some of the techniques employed is a weakness of FGR 13 - Part 1, for both the internal and external exposure calculations. In particular, because dose calculation (DCAL) software is such an integral part of FGR 13 - Part 1, the Subcommittee recommends that the DCAL software and a users manual be published in electronic form prior to, or concurrently with, the final version of FGR 13 - Part 1. (Section 3.1.2)

The Subcommittee considered whether or not it would be possible to check the numerical results of the risk coefficients in some way. It concluded that a check of the risk estimates, or merely a verification of the coding of the model equations, would be a formidable task outside the scope and level of resources available to the Subcommittee. The Subcommittee recommends that evidence of verification and quality assurance procedures be included in an appendix to the final version of FGR 13 - Part 1, or be made available in a separate document. (Section 3.1.3)

The Subcommittee is concerned about the absence of radiation dose information in FGR 13 - Part 1. While the direct tabulation of risk estimates may provide a useful shortcut for the preparation of rulemaking and environmental documents, it may make the report difficult to follow by those who think of radiation safety in terms of dose and will make it difficult for users to update the risk coefficients as new information on risk or dosimetry becomes available. This approach also makes it difficult for users to employ risk models other than the linear-no threshold model used by the Agency. The Subcommittee recommends that dose information and corresponding uncertainties be published in electronic form. Alternatively the authors could identify another source of this information, such as the anticipated publication of dose information in electronic form by the International Commission for Radiation Protection (ICRP). (Section 3.1.4)

FGR 13 - Part 1 does not use or address some potentially valuable information not already incorporated into the ICRP models, such as an internal dosimetry model suggested for the esophagus and trachea. Also, recent calculations of the absorbed energy in the gastrointestinal tract could replace the very conservative assumptions used in ICRP Publication 30 and FGR 13 - Part 1. (Section 3.1.5)

Risks calculated in FGR 13 - Part I are based on mortality data. However, information on cancer incidence (morbidity) is generally much more accurate than is information on cancer mortality derived from death certificates. Although the Subcommittee understands that a change to morbidity-based estimation is a major undertaking with potentially significant policy implications, and therefore may be impossible in the short run, we recommend it be given serious consideration for future updates of FGR 13 - Part 1 and other radiation risk activities in the Agency. (Section 3.1.6)

In FGR 13 - Part 1, risk coefficients are calculated only for the default absorption types given by ICRP and for the absorption types adjacent to the default types, resulting in an incomplete list of risk coefficients. The Subcommittee recommends that: a) risk coefficients, at a minimum, be calculated for each absorption type considered by ICRP for all radionuclides, b) the default absorption types recommended by ICRP be specifically identified in the tables of FGR 13 - Part 1, and c) preference be given to using material-specific knowledge in lieu of default values when appropriate and practicable. (Section 3.1.7)

In the risk calculation for direct radiation exposure from contaminated ground and for immersion in a radioactive gas or vapor, no shielding from structures is assumed. Because most people spend the majority of their time indoors, the calculated risks in FGR 13 - Part 1 may overestimate the real risk. The document should provide some general guidance to the user as to a reasonable range of risk reduction factors and point the user to methods and references for estimating an appropriate value within that range. (Section 3.1.8)

Soil ingestion has not been considered as an exposure pathway in FGR 13 - Part 1. The Subcommittee recommends that FGR 13 - Part 1 be expanded at some time in the future to include soil intake. (Section 3.1.9)

The risk coefficients for radionuclides in food are expressed as lifetime probabilities of cancer morbidity or mortality from ingestion of 1 Bq of the radionuclide. Except for separate tables for radioiodines in milk, the radionuclides are assumed to be distributed in foods such that radionuclide activity intake per unit caloric intake would remain constant with age and gender. In real exposure scenarios, this assumption might not be correct. Although the Subcommittee is not suggesting a suite of risk factors for different food types, it recommends that the Agency include differential food scenarios in the list of risk analyses for which the FGR 13 - Part 1 tables are not appropriate. (Section 3.1.10)

The second Charge element (b) addressed the treatment of uncertainty. The major uncertainties have not entirely been identified and put into proper perspective. Although the document does well in identifying many of the major uncertainties and describing them qualitatively, it does not provide the reader with a good sense of the overall uncertainty entailed when a specific risk coefficient is used to predict the risks of low-level exposure to radiation. The Subcommittee recommends that the Agency attempt to convey better the overall impact of the multiple sources of uncertainty on the final risk numbers. In particular, it should more prominently note the debate about the applicability of the linear no-threshold model at very low doses, even though the Agency's own evaluations may discount the likelihood of alternative models. It should also be made clearer how the reliability of the calculations varies from such highly studied radionuclides as ^{239}Pu or ^{131}I to those for which most of the parameters are based on analogies with surrogates. (Section 3.2.1)

Quantitative estimates of uncertainty are clearly unnecessary for nominal values intended only for an initial screening calculation. However, the values in FGR 13 - Part 1 are not intended

for screening; rather, they are intended to provide a realistic best estimate of the average risk per unit exposure. Given the broad application expected for these risk estimates, the Subcommittee recommends at a minimum that: a) the individual radionuclides of highest concern for environmental exposures be placed into categories associated with low, moderate, high, or very high uncertainty; b) these categories be described quantitatively (e.g., a factor of less than three, three to 10, 10 to 100, and more than 100, respectively; c) these uncertainty categories be listed in the tables of risk estimates; d) general guidance about the limits of application be provided for those radionuclides for which information is insufficient to permit placement into a given uncertainty category, and e) the final version of FGR 13 - Part 1 include an appendix that describes the steps that may be taken to improve uncertainty estimates for the risk coefficients to reflect future advances in the state of knowledge of internal and external dosimetry and of the response to low doses of ionizing radiation. (Section 3.2.2)

The present state of the art in exposure, dose and risk assessment employs the use of probabilistic methods to propagate the uncertainty of all major model components through to a final estimate of dose and risk. In the case of FGR 13 - Part 1, the Subcommittee recognizes that such calculations, due to inherent complexity of the Agency's methodology, could be a major undertaking requiring extensive new resources. For future improvements of the Agency's reports, such as revisions of FGR 13, the Subcommittee recommends that quantification of uncertainty be considered at the outset of the project. (Section 3.2.3)

Although the lack of scientific consensus on the estimation of lifetime cancer risks from low-level radiation is acknowledged in FGR 13 - Part 1, the Subcommittee recommends adding a concise, balanced discussion that lays out the arguments for and against the possibility of a threshold or other non-linear behavior at low dose and low dose rates. (Section 4.4)

Model uncertainties, i.e., uncertainties in the structure of a biokinetic, dosimetric or dose-response model, are often more difficult to assess than are parameter uncertainties. Significant uncertainty can be attributed to the models themselves, apart from uncertainties in parameter values, and model uncertainty should be reflected in the text of FGR 13 - Part 1. (Section 4.5)

Although making a detailed probabilistic uncertainty evaluation for every element would be a formidable task, the Subcommittee recommends that a comprehensive uncertainty calculation be performed for one example radionuclide for each class of biokinetic model. It might be of use also to show a calculation for the inhalation of specific radon decay products

and some examples for ill-studied radionuclides to illustrate the range of uncertainties that are present in the calculations. (Section 4.6)

The third and last major element of the Charge (c) dealt with extending the list of radionuclides to include those incorporated in previous versions of FGR 13 - Part 1. The radionuclides addressed in the interim report were primarily those included in ICRP Publications

56, 66, 67, 69, and 71, which contained the models used for calculating dose rates to organs and tissues. The Subcommittee believes that the Agency's proposed method for extending the list of radionuclides to include those tabulated in FGRs 11 and 12 is reasonable, but recommends that risk coefficients also be presented for the inhalation of radon and its short-lived decay products, the largest source of collective radiation exposure (and presumably, radiation risk) to the U.S. population as a whole. If it is not feasible to include these risk coefficients in the final version of FGR 13 - Part 1, their omission should be explained and the risk coefficients included in a future revision of FGR 13 - Part 1. (Section 3.3)

During the course of the public meeting, the Subcommittee identified several additional areas where improvements or clarifications could be made to the EPA draft report, and has provided recommendations to that effect. First, the Subcommittee recommends that the title of the document be changed from "Health Risks from Low-Level Environmental Exposure to Radionuclides, Federal Guidance Report 13 - Part 1" to "**Estimated** Health Risks from Low-Level Environmental Exposure to Radionuclides, Federal Guidance Report 13 - Part 1: **Cancer**" (emphasis added). This change conveys two important points: a) The tabulated risk values are estimates and b) cancer is the only health effect treated in the document. (Section 3.4.1)

The Subcommittee also noted that use of the FGR 13 - Part 1 risk coefficients could contribute to debate or ambiguity as to whether a regulated site meets regulatory limits, especially in cases where a regulation is stated in terms of annual (or per incident) dose limits but the supporting technical documentation, such as an environmental impact statement , might use risk calculations. The Subcommittee observes that some confusion may result in any attempt to apply both the FGR 11 and 12 methodologies and the FGR 13 - Part 1 methodology on the same regulatory issue. This complication could arise even if the Agency's regulatory action itself used only one method, because an intervener from the regulated community or the public interest community could use the other method to contest the regulation. (Section 3.4.2)

The Subcommittee is concerned with the potential for misapplication of the FGR 13 - Part 1 document. As noted in the document, its approach to risk analysis is not intended to be applied to the analysis of risks to individuals associated with either past or future exposures. The Subcommittee recommends that the preface of FGR 13 - Part 1 include a more thorough discussion of the potential for misapplication and the limitations of use for FGR 13 - Part 1 risk estimates. (Section 6.3)

The Subcommittee believes that tables in any document should be understandable without reference to the text. For instance, the need for separately considering ingrowth of chain members in an environmental medium before they enter the body (e.g., by ingestion or inhalation) and the absence of uncertainty bounds in the tables are critically important to explain to users. (Section 3.4.4)

It is not clear to the Subcommittee that the listing of a single predominant cancer type in the risk tables is either useful or correct. Alternatives to the current presentation might be: a)

eliminating the columns completely or b) selecting, for example, the three tissues or organs considered to be at greatest risk, but without giving a quantitative estimate of the risk fraction associated with those tissues and organs. (Section 3.4.5)

It is stated in FGR 13 - Part 1 that "Because risk coefficients for external exposure to soil contaminated to 15 cm would differ only slightly from those for concentrations to an infinite depth, it would not be useful to provide tabulations of risk coefficients for both situations." The Uranium Mill Tailings Radiation Control Act (UMTRCA) specifies a standard for contaminated soil of 5 pCi g^{-1} in the top 15 cm and 15 pCi g^{-1} below 15 cm. The Subcommittee recommends that risk coefficients for external exposure, applicable specifically to the UMTRCA standard, be calculated and tabulated in the final version of FGR 13 - Part 1 or in a separate document. (Section 3.4.6)

In conclusion, the Subcommittee commends the Agency on its leadership and efforts in using up-to-date scientific methods and data to make the health risk estimates in FGR 13 - Part 1. We believe that our recommendations, except those noted for future consideration, can be incorporated prior to publication of the final version and will strengthen the report and its credibility. We strongly support the Agency's stated intent to publish supporting information in electronic form to accompany release of the final version of FGR 13 - Part 1, and we recommend that it include the data, models, and dose information used in formulating the risk coefficients.

2. INTRODUCTION

2.1 Background

Since the mid-1980s the United States Environmental Protection Agency has issued a series of Federal guidance documents for the purpose of providing technical information to assist Federal agencies in their implementation of radiation protection programs (EPA 1984; 1988; 1993; 1998). The newest in the series, collectively to be called Federal Guidance Report 13 (FGR 13), is intended by the Agency to promote consistency in assessments of the risks to health from radiation and to help ensure that radiological risk assessments are based on sound scientific information. The document reviewed in this Science Advisory Board (SAB) report is the interim version of Part 1 of FGR 13 (FGR 13 - Part 1), which is limited to cancer as a health outcome (EPA, 1998). The FGR 13 documents are to use state-of-the-art methods and models for estimating the risks to health from internal or external exposure to specific radionuclides, taking into account the age- and gender-specific aspects of radiation risk. FGR 13 - Part 1 provides tabulations of risk estimates, or "risk coefficients," for cancer morbidity and mortality attributable to exposure to each of approximately 100 radionuclides via various environmental media. These risk coefficients apply to populations that approximate the age, gender, and mortality experience characterized by the 1989-91 U.S. decennial life tables.

The tabulations in the final version of Part 1 are expected to extend the methodology of the interim version to the other radionuclides included in FGRs 11 and 12. Subsequent parts of FGR 13 may extend the exposure pathways and health endpoints addressed. As necessary, these publications are to be reissued to update the information provided. The Agency chose to issue Part 1 of FGR 13 as an interim report in order to provide governmental agencies and other interested parties an opportunity to become familiar with it and its supporting methodology and to provide comments for the Agency's consideration before publishing the final version.

The Agency intends that the risk estimates tabulated in FGR 13 - Part 1 be used mainly for prospective assessments of estimated cancer risks from long-term exposure to radionuclides in environmental media, such as preparation of environmental impact statements and development of assessments in support of generic rulemaking for control of radiation exposure. Although it is recognized that these risk coefficients are likely also to be used in retrospective analyses of radiation exposures of populations, the Agency emphasized that such analyses should be limited to estimation of total or average risks in large populations. The tabulations are not intended for application to specific individuals or to age or gender subgroups, for example, children, and should not be used for that purpose. Also, these risk coefficients should not be applied to accident cases involving high doses and dose rates, either in prospective or retrospective analyses. Finally, some risk assessment procedures are established as a matter of policy, and additional steps may be needed before using these risk coefficients. For example, the Agency recommends that radiation risk assessments for sites on the National Priorities List under the Comprehensive

Environmental Response, Compensation, and Liability Act (CERCLA) be performed using the Health Effects Assessment Summary Tables.

In FGR 13 - Part 1, estimated risks are tabulated directly against the radionuclide quantities without providing radiation dose information to the user. The linear, no-threshold dose-response hypothesis and the individual organ and tissue risk coefficients are integrated into the tabulated results. This approach represents a significant departure from the two previous Federal Guidance Reports (EPA 1988; 1993) in which dose quantities were tabulated as a function of radionuclide intake or soil concentration, leaving it to the user to apply the risk coefficients. For users who desire a simple way to estimate risks to populations directly from radionuclide concentrations, the approach used in FGR 13 - Part 1 represents a useful step forward. For experts in the field, however, the lack of radiation dose information and other details in the interim version of FGR 13 - Part 1 is of concern. However, the Agency has stated its intention to make available detailed supporting information in electronic form, coincident with the release of the final version of FGR 13 - Part 1.

The RAC was briefed on the subject on March 3, 1998, and subsequently formed the FGR 13 Review Subcommittee (the Subcommittee). The Subcommittee held a public meeting in Washington, DC on May 6 and 7, 1998, at which time it was briefed by, and had technical discussions with, the Office of Radiation and Indoor Air (ORIA) staff. In addition, a public teleconference was held on June 2, 1998 to discuss an internal working draft.

2.2 Charge

The SAB was asked by ORIA to focus on the following questions:

a) Is the methodology employed for calculating health risks from radionuclide intakes and external exposures acceptable?

b) In light of scientific information, have the major uncertainties been identified and put into proper perspective?

c) Is the proposed method for extending the list of radionuclides to include all those tabulated in Federal Guidance Reports 11 and 12 reasonable?

3. DETAILED FINDINGS

3.1 Assessing Methodology for Calculating Health Risks - Charge Element (a)

The first element of the charge asked the Subcommittee to assess the methodology employed for calculating health risks from radionuclide intakes and external exposures.

3.1.1 Overall Findings

The methodology is acceptable in the context of a) current Agency science policy choices, such as the applicability of a linear, no-threshold dose-response model for cancer risks at low doses of radiation and b) its intended use to support broad Federal radiation protection programs such as environmental impact statements or generic rulemaking. The preface of the draft report points out that the tabulations are not intended for application to specific individuals or age or gender subgroups, especially for retrospective analyses. The Subcommittee also cautions that they may not be appropriate for site- or situation-specific analyses for which the assumptions of the document may not be valid.

The internal dose assessment and biokinetic models used in the calculations are from the most recent publications (numbers 56, 67, 68, 69, and 71) of the ICRP (1989; 1993a; 1994b; 1995a; 1995b). In addition, the most recent model of the respiratory system (ICRP Publication 66, 1994a) is used, where appropriate. In some cases, where data are lacking and or incomplete, the parameters in the several parts of ICRP Publication 30 (1979; 1980;1981; 1988) are used in the models. The models, many of the important parameter values, and the default situations are summarized in tables presented in Chapters 4 and 5 of FGR 13 - Part 1. These calculations appear to have been made using standard techniques and represent "good science." External exposure calculations also appear to have been made using standard techniques, many of which have been used in other calculations for the Agency. However, as discussed below, unpublished reports were cited for some of the detailed techniques employed. Some specific and more detailed comments on the methodology are given in the following sections.

3.1.2 Use of Unpublished Methods

The lack of published reports for some of the techniques employed is a weakness of this work, for both the internal and external exposure calculations. This weakness did not hamper our evaluation because a Subcommittee member had been supplied with draft copies of these reports by the authors. Nevertheless, this weakness should be addressed before publication of the final version of FGR 13 - Part 1.

In particular all computations of dose and risk were performed using the dose calculation (DCAL) software developed by staff at Oak Ridge National Laboratory (ORNL), which is to be published as an ORNL/TM report. DCAL is a comprehensive computer program of biokinetic-

dose-risk models and computational systems used for radiation dosimetry and risk analyses. While DCAL has been extensively tested, and was used to support five published ICRP reports, it still needs to be published in order to become openly available and widely accepted by the scientific community. Because DCAL is such an integral part of FGR 13 - Part 1, the Subcommittee recommends that the DCAL software and a users manual be published in electronic form prior to, or concurrently with, the final version of FGR-13, Part 1.

3.1.3 Check of Numerical Results

The Subcommittee considered whether or not it would be possible to check the numerical results of the risk coefficients in some way. Checking the risk estimates in their entirety would require observing cancer rates in an exposed cohort, which is clearly impossible. Given far more time and resources than is available to the Subcommittee, it may be possible to check discrete components of the risk estimates, such as the time-dependent organ burden of a specific radionuclide as a result of a given intake, or the specific health outcomes resulting from a given dose to a specific tissue. Another approach would be an exercise through which several qualified assessment teams independently predict the lifetime risk per Bq of intake along with estimates of uncertainty, and their results and rationales compared with each other. This type of exercise has been performed internationally for environmental transfer models (BIOMOVS, 1993; BIOMOVS II, 1996; IAEA, 1995; IAEA, 1996; Thiessen et al., 1997) but such an inter-assessment comparison by independent experts has not been undertaken for the disciplines of internal dosimetry and risk. Other possibilities would be to assign one or two members of the Subcommittee the task of asking questions and working with the group at ORNL to more completely understand what was done, or to have another group run the code for a few specific test cases.

The Subcommittee concluded that a check of the risk estimates, or merely a verification of the coding of the model equations, would be a formidable task outside the scope and level of resources available to the Subcommittee. As an alternative, the Subcommittee recommends that evidence of verification and quality assurance procedures be included in an appendix to the final version of FGR 13 - Part 1, or be made available in a separate document.

3.1.4 Absence of Dose Information

Although absorbed dose rates were calculated by the authors of FGR 13 - Part 1 as an intermediate step in the estimation of risk, dose information is not provided in the document. The Subcommittee understands that the committed effective dose approach was not used in preparation of FGR 13 - Part 1, but is concerned that the lack of dose information may make the report difficult to follow by those who think of radiation safety in terms of dose and will make it difficult for users to update the risk coefficients as new information on risk or dosimetry becomes available. The lack of dose information will also make it difficult to employ risk models other than the linear-no threshold model used by the Agency.

The Subcommittee recommends that the authors publish comprehensive absorbed dose rate or other appropriate dose information in electronic form concurrently with the release of the final version of FGR 13 - Part 1. Alternatively the authors could identify another source of this information, such as the anticipated publication of dose information in electronic form by the ICRP. The Subcommittee also recommends that the dose information be accompanied with estimates of uncertainty. This would allow the reader to evaluate the importance of uncertainty in the dosimetry model as compared to the uncertainty in the dose response. The Subcommittee further recommends that the final version of FGR 13 - Part 1 include a discussion that compares and contrasts the methodologies of FGR Reports 11 and 12 (EPA, 1988; 1993) with the methodology of FGR 13 - Part 1.

3.1.5 Information Not Addressed in FGR 13 - Part 1

There are instances in which potentially valuable information, not already incorporated into the ICRP models, is not addressed or used in FGR 13 - Part 1. For example, a dosimetry model has been proposed for the esophagus and trachea for many years (Lewis and Ellis, 1979). In Chapter 5 of FGR 13 - Part 1, the authors state that no model of the esophagus has been incorporated in the mathematical phantom for internal dose calculations, whereas in Chapter 6, the discussion indicates that the esophagus has been incorporated into the mathematical model for external dose calculations (but with no literature citation). One would expect there to be some commonality between the mathematical phantom used for internal dose assessment and the phantom used in the external dose assessment portion of the work. The Subcommittee recommends that the final version of FGR 13 - Part 1 include a discussion of why an esophagus model was not considered appropriate to include in the model for internal dose rate calculations. The Subcommittee further recommends that a literature citation or a short description be given of the model of the esophagus used in the mathematical phantom for external exposure.

Recent calculations of the absorbed energy for monoenergetic electrons in the gastrointestinal tract could provide an improvement over the very conservative assumptions used in ICRP Publication 30 and FGR 13 - Part 1 (see Poston *et al*. 1996a, 1996b). These two papers have provided a better understanding of the energy dependence of the absorbed fractions in the wall of the gastrointestinal tract. For example, these data show that at 5 MeV, the absorbed fraction of energy (AF) for electrons in the gastrointestinal tract wall reaches 0.15. For lower energies, the absorbed fraction can be significantly less. For example, at 1 MeV, the AF is about 0.1 and decreases monotonically to a value of about 2×10^{-5} at 0.01 MeV. These data must be contrasted with the ICRP approach used in the calculations for FGR 13 - Part 1. It is clear that, for many beta-emitting radionuclides, the ICRP approach significantly over-estimates the absorbed energy in the wall of the tract and, therefore, over-estimates dose (and the risk). Here, the uncertainty in dose and risk is not merely a factor of two or three, but could be orders of magnitude. The Subcommittee recommends that the approach described in Poston et al. (1996a; 1996b) be considered for the final version of FGR 13 - Part 1.

3.1.6 Use of Mortality Data vs Morbidity Data

Mortality and morbidity risk coefficients are both presented in FGR 13 - Part 1. The mortality risk coefficients were determined based on data from the Japanese atomic bomb survivors and other study groups. However, the morbidity risk coefficients were calculated by taking each site-specific mortality risk and dividing it by its respective lethality fraction, that is, the fraction of radiogenic cancers at that site which are fatal. A better approach would be to develop morbidity risk coefficients directly from populations such as the Japanese bomb survivors.

Information on cancer incidence (morbidity) has long been recognized to be generally much more accurate than is information on cancer mortality derived from death certificates. Typically, incident cancers are histologically confirmed, with the information gathered by individuals trained in the collection of such data from a wide variety of sources. They are usually collected in a timely manner following diagnosis and are unaffected by variations in survival fraction geographically and over time.

Cancer mortality data, gathered from death certificates for most cancers, are often collected at a time remote from diagnosis, making epidemiologic studies of exposures problematic. Cause of death is often recorded by those to whom secondary cause of death information is not available, and it is generally not confirmed histologically or otherwise. Their accuracy varies substantially with cancer site. All of these problems are expected to hold in some measure for the principal studies of radiation-induced cancers.

The availability of cancer incidence data from studies of the atomic bomb survivors and other irradiated populations provides an opportunity to base cancer risk estimates (either for morbidity or mortality) on these more reliable statistics. Such an endeavor would also have the advantage of making the radiation cancer risk estimation process more in harmony with that used for chemicals. Although the Subcommittee understands that a change to morbidity-based estimation is a major undertaking with potentially significant policy implications, and therefore may be impossible in the short run, we recommend it be given serious consideration for future updates of FGR 13 - Part 1 and other radiation risk activities in the Agency.

Additional, more detailed discussions of the advantages of developing risk coefficients from morbidity data rather than mortality data are given in the SAB/RAC report on uncertainties in radiogenic cancer risk (SAB, 1998).

3.1.7 Absorption Types for Inhaled Radionuclides

As indicated in FGR 13 - Part 1, there are significant uncertainties in estimating absorption types for radionuclides in forms likely to be encountered in the environment. In FGR 13 - Part 1, risk coefficients are calculated only for the default absorption types given by ICRP and for the absorption types adjacent to the defaults in the ICRP publication. This approach results in an incomplete list of risk coefficients. An alternative approach, which would provide the user of FGR 13 - Part 1 the most flexibility, would be at a minimum to calculate the risks for all of the

absorption types considered by ICRP for each of the listed radionuclides, and to indicate the ICRP default type. In this way, the user would be made aware of the recommended ICRP default values, which would most likely be used in the absence of material-specific data. With more information, however, the user could also use one of the alternative risk coefficients.

Specifically the Subcommittee recommends that: a) risk coefficients be calculated for each absorption type considered by ICRP, for all radionuclides, b) the default absorption types recommended by ICRP be specifically identified in the tables of FGR 13 - Part 1, and c) preference be given to using material-specific knowledge in lieu of default values when appropriate and practicable. These additions should make the report easier to use.

3.1.8 Assumption of Full-time, Unshielded Exposure to Radionuclides in Soil

In the risk calculation for direct radiation exposure from contaminated ground and for immersion in a radioactive gas or vapor, no shielding from structures is assumed. However, most people spend the majority of their time indoors. Therefore, the calculated risks in FGR 13 - Part 1 may overestimate the real risk by factors ranging from less than two to over ten. The reduction in dose due to the inherent shielding characteristics of structures depends not only on the type, thickness and configuration of the building materials but also on the type and energy of the radiation. The external exposure calculations are made assuming that the exposed individual is outdoors for the entire period. This assumption could result in additional bias in the range of a factor of two to three. The Subcommittee realizes that it would be infeasible to incorporate structural shielding factors into the risk tables. However, the Subcommittee recommends that the document include some general guidance to the user as to a reasonable range of risk reduction factors for shielding and point the user to methods and references for estimating an appropriate value.

3.1.9 Soil Ingestion

Soil ingestion has not been considered as an exposure pathway in FGR 13 - Part 1. For most radionuclides and soils, the bioavailability from soils would be likely to be lower than for foods. Applying the ingestion risk factors for food to soil intake is likely to overestimate the dose. However, the average soil intake rate for children may be higher than for adults. The relative ratios of food intake by children to adult intake may be skewed if soil intake is included. That is, the fraction of the lifetime intake attributable to early childhood may be underestimated when soil is a significant route of exposure. The Subcommittee recommends that FGR 13 - Part 1 be expanded at some time in the future to include soil intake.

3.1.10 Appropriateness of Diet Averaging

The risk coefficients for radionuclides in food are expressed as lifetime probabilities of cancer morbidity or mortality from ingestion of 1 Bq of the radionuclide, presumed to be spread evenly over a lifetime or, if acute, spread evenly across a stationary population. The risk

coefficients take into account the variations in caloric intake per unit body weight as a function of age and gender, so that the contribution of a constant concentration of the radionuclide in food can have differing impacts on risk at different ages. Except for separate tables for radioiodines in milk, the radionuclides are assumed in FGR 13 - Part 1 to be distributed in foods such that radionuclide activity intake per unit caloric intake remains constant with age and gender.

In real exposure scenarios, this assumption of constant intake factors is incorrect, as the Agency has recognized by computing separate risk factors for milk, a food well known to be consumed differentially by children and adults. In response to Subcommittee questions, the Agency further stated orally that no other food group stood out as having a significant variability not predicted by caloric intake. The Subcommittee did not determine what level of food disaggregation was used, but pointed out that differences could well be significant for some types of food, such as fish and apple juice. During the discussion, it became clear that the types of scenarios envisioned in FGR 13 - Part 1 for application of the risk factors were not ones that would concentrate radionuclides in only a few narrow food groups. Although the Subcommittee is not suggesting a suite of risk factors for different food types, it recommends that the Agency include differential food scenarios in the list of risk analyses for which the FGR 13 - Part 1 tables are not appropriate. To the extent that all sources of exposure have not been identified, this approach may either overestimate, or underestimate, the actual exposure.

3.2 Assessing the Treatment of Uncertainty - Charge (b)

The second element of the charge asked the Subcommittee to determine if, in light of scientific information, the major uncertainties have been identified and put into proper perspective

3.2.1 Overall Findings

The major uncertainties have not entirely been identified and put into proper perspective. Although the document does well in identifying many of the major uncertainties and describing them qualitatively, it does not provide the reader with a good sense of the overall uncertainty entailed when a specific risk coefficient is used to predict the risks of low-level exposure to radiation. It is possible for a user to conclude equally that the estimates are quite reliable or almost totally uncertain. Without a better understanding of the plausible limits of uncertainty, any use of the estimates for regulatory purposes could lead to inappropriate decisions and lack of public trust. Disclosure of quantitative uncertainty is important whenever an estimate of health risk is intended to be realistic rather than a conservative screening value.

Although the Subcommittee is aware of the scientific and computational difficulties of undertaking a detailed quantitative uncertainty analysis that would examine all the potentially important sources of uncertainty, it recommends that the Agency attempt to convey better the overall impact of the multiple sources of uncertainty on the final risk numbers, as it is currently attempting to do for the uncertainties in the risk model (SAB, 1998, report in preparation). In

particular, it should more prominently note the debate about the applicability of the linear no-threshold model at very low doses, even though the Agency's own evaluations may discount the likelihood of alternative dose-response models. It should also be made clearer how the reliability of the calculations varies from such highly studied radionuclides as ^{293}Pu or ^{131}I to those for which most of the parameters are based on analogies with surrogates.

Detailed guidance for uncertainty analysis has been published in NCRP (1996). This guidance acknowledges that the quantification of the state of knowledge for exposure and risk assessment models is inherently dependent on subjective judgment. The authors of FGR 13 - Part 1 have extensive experience in the development and application of dosimetric and risk models for specific radionuclides and should be able to quantify the state of knowledge in a defensible manner, using subjective probability distributions. Alternatively, expert elicitation can be used to derive these distributions as recommended in the SAB/RAC review (SAB, 1998) of the December 1997 Draft Addendum on the uncertainty analysis in estimating radiogenic cancer risks (EPA, 1997). It is emphasized that the uncertainty should be characterized and quantified specifically for the application of the methodology in FGR 13 - Part 1 to the general U.S. population.

When providing estimates of uncertainty, the Agency should also provide guidance and incentives for the user to incorporate updates of these estimates, given improvements in the state of knowledge. Presumably, based upon its statement in the preface of the interim version of FGR 13 - Part 1, the Agency will permit updating of the risk estimates and statements of uncertainty in specific regulatory cases.

Specific and more detailed comments on aspects of uncertainty are given below.

Specification of quantitative uncertainty estimates is increasingly seen as very important for decision making. Quantitative estimates of uncertainty are clearly unnecessary for nominal values intended only for an initial screening calculation and when it is already known that the screening values are not likely to lead to a substantial underestimate of the true but unknown risk (see NCRP, 1996).

However, the values in FGR 13 - Part 1 are not intended to be used for screening calculations; rather, they are intended to provide a realistic best estimate of the average risk per unit exposure. The Subcommittee recommends that, at a minimum, the individual radionuclides of highest concern for environmental releases and exposures be categorized into those associated with low, moderate, high, or very high uncertainty. The Agency should define the numerical bounds of low, moderate, high, or very high uncertainty, but the following guidance is offered: Low uncertainty might be assigned to any coefficient likely to be in a range less than a factor of three either side of a best estimate; moderate uncertainty would be greater than a factor of three, but less than a factor of ten; high uncertainty would be greater than a factor of ten, but less than a factor of 100, and very high uncertainty would exceed a factor of 100. The Subcommittee recognizes that in some cases, the uncertainty may not be symmetrical about the best estimate. In this case, two estimates of uncertainty could be provided (e.g., the estimate of calculated risk is

unlikely to underestimate the true risk by more than a factor of 3, but under some circumstances may overestimate the true risk by a factor of 10 to 100).

The Subcommittee also recommends that identification of categories of uncertainty for radionuclides likely to be of highest concern for environmental releases and exposures be included in the tables of risk coefficients, rather than in separate tables. The Subcommittee further recommends that general guidance be given about the limits of application for those radionuclides for which information is currently insufficient to support their placement into a specific category of uncertainty and that the final version of FGR 13 - Part 1 include an appendix that indicates steps that may be taken to improve estimates of uncertainty to account for future advances in the state of knowledge for internal and external dosimetry and the dose-response for exposure to low levels of ionizing radiation.

The Subcommittee recognizes that the present state-of-the-art in exposure, dose and risk assessment employs the use of probabilistic methods to propagate the uncertainty of all major model components through to a final estimate of dose and risk. The result is usually a subjective probability distribution from which a 90% or 95% subjective confidence interval (sometimes referred to as a credibility interval) is obtained. This information is sometimes accompanied by a table or pie chart that identifies the most important variables that dominate the overall estimate of uncertainty in the risk per unit intake or per unit concentration in the environment.

In the case of FGR 13 - Part 1, the initial methodology was developed without considering the need to propagate uncertainty using probabilistic methods. In the current form of the risk models used in FGR 13 - Part 1, the Subcommittee recognizes that such uncertainty calculations, due to inherent complexity of the Agency's methodology, could be a major undertaking requiring extensive new resources. However, if the uncertainty propagation is limited to those model components already known to dominate the overall result, then the process of uncertainty analysis can be made more efficient.

For future improvements of the Agency's reports, such as revisions of FGR 13, the Subcommittee recommends that quantification of uncertainty be considered at the outset of the project and that the investigators be provided with sufficient funding and resources to characterize the state of knowledge for uncertain model components in a defensible manner. The computer algorithms should be designed at the beginning of the project to facilitate the propagation of uncertainty through to the final result.

The lack of scientific consensus on the estimation of lifetime cancer risks from low-level radiation is acknowledged in FGR 13, Part 1. Some scientists believe in an effective threshold for health effects at sufficiently low doses and low dose rates, citing numerous studies that have not demonstrated a risk at levels within the range of natural background (BEIR, 1990; Modan, 1991). Others acknowledge the possibility of a non-linear relationship not adequately treated with the dose and dose-rate effectiveness factor (DDREF) approach. Concluding a discussion on uncertainty of risk at low dose, the BEIR V report (BEIR, 1990) states “Moreover, epidemiologic

data cannot rigorously exclude the existence of a threshold in the millisievert dose range. Thus the possibility that there may be no risks from exposures comparable to external natural background cannot be ruled out. At such low doses and dose rates, it must be acknowledged that the lower limit of the range of uncertainty in the risk estimates extends to zero." The Subcommittee recommends that a concise, balanced discussion that lays out the arguments for and against the possibility of a threshold or other non-linear behavior at low dose and dose rates be included in the final version of FGR 13, Part 1. This issue has been addressed in detail by the Agency in its unpublished December 1997 Draft Addendum on the uncertainty analysis in estimating radiogenic cancer risks (EPA, 1997) and these arguments could be summarized in FGR 13 - Part 1.

The position that the Agency has taken with respect to the risk of low-LET radiation at low doses and low dose rates is somewhat comparable to the position taken by the National Council on Radiation Protection and Measurement's Report Number 126 (NCRP, 1997) in which the DDREF for whole body radiation spans an interval from one to five with values less than one and greater than five being given negligible weight. The Agency states that a more careful consideration of the uncertainty in the DDREF may be needed for cases where the dose is heavily concentrated in a few specific target tissues. The DDREF approach is defended in FGR 13 - Part 1 (p. 111) by appealing to either the dual-action theory or the saturable repair theory. The Subcommittee recommends that the authors acknowledge in FGR 13 - Part 1 the possibility of alternative models in which the reduction factor for low doses and low dose rates might not be the same, for example, the genomic instability model proposed by Scott (1997) or models that recognize a continuous dose-dose rate-response surface.

All models by definition are a simplification of reality and hence some uncertainty is unavoidable. Model uncertainties, i.e., uncertainties in the structure of a biokinetic, dosimetric or dose-response model, are often more difficult to assess than are parameter uncertainties. The current efforts by the Human Alimentary Tract Model Task Group of ICRP Committee 2 to revise the gastrointestinal tract model point out the recognized need to update the Eve model (Eve, 1966; Dolphin and Eve, 1966).

The previous respiratory tract model (TGLD 1966) was not adopted by the ICRP until 1979, 13 years after its publication (ICRP, 1979), and was not codified in the United States (10CFR20) until 1991, 25 years after its publication. By that time, deficiencies in the TGLD (1966) model were well recognized. These deficiencies, plus the large amount of new research results, were the impetus for the development of the newer ICRP Publication 66 model (ICRP, 1994a).

Uncertainties in systemic biokinetic models probably vary among elements, depending on our understanding of the metabolism of the individual elements and on the amount of data available to construct and parameterize them. Model uncertainties also depend on the specific models that are to be used. For example, none of the current generation of biokinetic models are

physiologically based toxicokinetic models, in which the biokinetics are described based on models constructed with true physiological variables and values.

The important point is that there is significant uncertainty that can be attributed to models themselves, apart from uncertainties in parameter values. Continuing scientific review will elucidate strengths and weaknesses of the models, which will need to be taken into account as they are identified. The Subcommittee recommends that model uncertainty be discussed in the text of FGR 13 - Part 1, most logically in the uncertainty section.

3.2.6 Comprehensive Uncertainty Calculation for Classes of Biokinetic Models

There is no question that making a detailed probabilistic uncertainty evaluation for every element would be a formidable task. However, the Subcommittee recommends that a comprehensive uncertainty calculation be performed for one example radionuclide for each class of biokinetic model. Possibilities include well-studied radionuclides such as ^{131}I, ^{90}Sr, ^{239}Pu, ^{137}Cs, ^{3}H, and perhaps ^{238}U and ^{226}Ra. It might be of use also to show a calculation for the inhalation of specific radon decay products. To the extent feasible, the Agency should also consider some examples for less well-studied radionuclides to illustrate the range of uncertainties that are present in the calculations. This effort is necessary for the user to appreciate the relative magnitude of the uncertainties associated with these calculations.

Also, the Subcommittee recommends that uncertainty calculations using the ICRP generic model for "calcium-like" elements (ICRP, 1993a) be presented. This model is used extensively in FGR 13 - Part 1, and an uncertainty evaluation would be extremely informative. This task would not be easy but is feasible.

Usually, a parameter value is chosen from a range of possible values found in the open literature. It would be helpful to present examples showing the range of values and indicating the specific value chosen for each parameter. In this regard, the Agency might benefit from the model of uncertainty analysis used in the NRC (1998) uncertainty analysis of internal dosimetry.

3.3 Assessing the Method for Extending List of Radionuclides - Charge (c)

The third element of the charge asked for the Subcommittee's assessment of the proposed method for extending the list of radionuclides to include all those tabulated in Federal Guidance Reports 11 and 12 (EPA, 1988; 1993).

3.3.1 Overall Findings

FGR 13 - Part 1 is not very explicit about how the extension to other radionuclides would be accomplished, but the Subcommittee did receive a briefing on the Agency’s plans for the extension at the public meeting. Although the proposed method for extending the lists of radionuclides to those in FGRs 11 and 12 is reasonable, the Subcommittee recommends that risk

coefficients also be presented for the inhalation of radon and its short-lived decay products. These radionuclides, when inhaled, are the largest source of collective radiation exposure (and presumably, radiation risk) to the U.S. population as a whole. In determining the radon risk coefficients, consideration should be given to the risk estimates found in the BEIR VI report (BEIR 1998) and in the ICRP Publication 65 on protection against radon (ICRP 1993b). The Subcommittee recommends that these risk coefficients be included in the final version of Part 1, if feasible.

The interim version of the report does not include a tabulation of risk coefficients for all of the radionuclides covered in FGRs 11 and 12. The radionuclides addressed in the interim report are primarily those included in ICRP Publications 56, 66, 67, 69, and 71 (ICRP 1989; 1994a; 1993a; 1995a; 1995b), which contained the models used for calculating dose rates to organs and tissues.

The Agency proposes to calculate risk coefficients for intakes of the remaining radionuclides in FGR 11 and for external exposures to those remaining in FGR 12. The models in ICRP Publication 72 (ICRP 1996) will be used to calculate dose rates for intakes of the remaining radionuclides in FGR 11. These dose rates will be used to calculate risk coefficients in the same manner as for the radionuclides in the interim report. The methodology for calculating the external exposure risk coefficients will also be the same as used in the interim report.

3.4 Additional Topics Identified by the Subcommittee

The following items are outside the charge to the SAB but were identified as important by the Subcommittee.

3.4.1 Recommended Change in Report Title

The Subcommittee recommends that the title of the document be changed from "Health Risks from Low-Level Environmental Exposure to Radionuclides, Federal Guidance Report 13 - Part 1" to "**Estimated** Health Risks from Low-Level Environmental Exposure to Radionuclides, Federal Guidance Report 13 - Part 1: **Cancer**" (emphasis added). This change conveys two important points: 1) The tabulated risk values are estimates and 2) cancer is the only health effect treated in the document. Note that the "Blue Book" (EPA 1994), from which the health risks used in FGR 13 - Part 1 were derived, is titled "Revised EPA Methodology for **Estimating** Radiogenic **Cancer** Risks. " (emphasis added)

3.4.2 Contribution of FGR 13 - Part 1 to Regulatory Debate and Ambiguity

Public comments on the document expressed concern that use of the FGR 13 - Part 1 risk coefficients could contribute to debate or ambiguity as to whether a regulated site meets regulatory limits, especially in cases where a regulation is stated in terms of annual (or per

incident) dose limits but the supporting technical documentation (such as an environmental impact statement) might be required to use risk calculations. The Agency responded orally that it had clearly stated that dose-based regulations would still use FGRs 11 and 12 for implementing the dose calculations and that use of the FGR 13 - Part 1 risk coefficients was not mandated for any purpose. The Subcommittee observes that some confusion may result in any attempt to apply both the FGR 11 and 12 methodologies and the FGR 13 - Part 1 methodology on the same regulatory issue, because the projection of the dose calculations to risk using standard dose-to-risk conversion factors can result in large differences from the FGR 13 - Part 1 method, as acknowledged by Agency staff. This complication could arise even if the regulatory agency action itself used only one method, because an intervener from the regulated community or the public interest community could use the other method to contest the regulation. An example is Superfund risk assessments in which dose-based limits are being used as "Applicable or Relevant and Appropriate Requirements" (ARARs) but risks are also calculated. Although the Subcommittee makes no recommendation regarding the propriety of having potentially conflicting guidance in place, it does suggest that the caveats in FGR 13 - Part 1 be strengthened to minimize any such potential for conflicts to occur.

3.4.3 Domain of Applicability

The Subcommittee is concerned with the potential for misapplication of FGR 13 - Part 1. As noted in the document, its approach to risk analyses is not intended to be applied to the analysis of risks to individuals associated with either past or future exposures. The Subcommittee recommends that the preface of FGR 13 - Part 1 include a more thorough discussion of the potential for misapplication and the limitations of use for FGR 13 - Part 1 risk estimates.

The Preface of FGR 13 - Part 1 (page iv, second full paragraph, beginning with: "The risk estimates---" through to the bottom of the page) contains an important statement describing the intended use and limitations to the applicability of FGR 13 - Part 1 methodology. Since users may fail to read the preface, the Subcommittee recommends that this important paragraph be repeated in the main body of the text at least once.

3.4.4 Clarification of the Risk Tables

The Subcommittee believes that tables in any document should be understandable without reference to the text. In FGR 13 - Part 1, however, the explanatory material required may be more than can reasonably be placed in the titles and footnotes. As an alternative, each of the risk coefficient tables could have a note, perhaps in parentheses under the title, that states "Refer to the explanation of entries in the text preceding this table for important information necessary for interpreting the table entries."

Two explanations were identified by the Subcommittee as critically important for users of the tables:

a) Ingrowth of chain members in the environmental medium is not incorporated into the risk estimates; and

b) Because scientists disagree regarding the reliability of estimates of lifetime cancer risk from low-level exposure to radiation, and because the error in such estimates may vary substantially from one radionuclide to another and from one exposure scenario to another, no attempt is made in the tables to characterize the overall uncertainty associated with any given risk coefficient. (Obviously this last statement would be modified if the authors of FGR 13 - Part 1 are able to implement some of the suggestions made in section 3.2 regarding uncertainty.)

The Subcommittee recommends that these two statements be linked clearly with the tables of risk coefficients in the final version of FGR 13 - Part 1.

3.4.5 Tabulation of Predominant Cancer Types

It is not clear to the Subcommittee that the listing of a single predominant cancer type in the risk tables is either useful or correct. The scientific basis for making such predictions is lacking in cases where the tissues at risk are limited, the type of radiation and its dose patterns (spatial and temporal) are different from those used to develop the risk coefficients (which are based predominantly on the atomic bomb survivor data), and radionuclide-specific data are sparse or absent. Alternatives to the current presentation might be: a) eliminating the columns completely, and b) selecting, for example, the three tissues or organs considered to be at greatest risk, but without giving a quantitative estimate of the risk fraction associated with those tissues and organs. This approach at least would dampen the criticism that the predominant cancer type is over-specified. The Subcommittee's recommendation is to eliminate the predominant cancer columns because of insufficient knowledge to specify the tumor locations reliably.

3.4.6 Adequacy of Soil Geometries for Use with the Mill Tailings Standards

It is stated in FGR 13 - Part 1 that "Because risk coefficients for external exposure to soil contaminated to 15 cm would differ only slightly from those for concentrations to an infinite depth, it would not be useful to provide tabulations of risk coefficients for both situations" (p. 56, last sentence). The Uranium Mill Tailings Radiation Control Act (UMTRCA) specifies a standard for contaminated soil of 5 pCi g^{-1} in the top 15 cm and 15 pCi g^{-1} below 15 cm. Because of the wide application of this standard, even beyond its original intent, it would be useful to provide tabulations of risk coefficients for dose rates from soil that is uncontaminated for the first 15 cm, but contaminated to an infinite depth below 15 cm. These risk coefficients could then be added to those for soils contaminated to an infinite depth to readily obtain overall risk coefficients for sites where the UMTRCA standards apply. This approach would need to be developed only for radionuclides and their decay products to which the UMTRCA standard is applied. The Subcommittee recommends that risk coefficients for external exposure, applicable specifically to

the UMTRCA standard, be calculated and tabulated in the final version of FGR 13 - Part 1 or in a separate document.

3.4.7 Relationship Between Exposure and Dose

In example 4 of Appendix E in FGR 13 - Part 1, a risk is derived from a measured exposure rate (in $\mu R\ h^{-1}$) using a factor of 1 rem per roentgen. Use of this factor results in an overestimate of the risk, since some self-shielding of critical organs is provided by the body itself. For example, if the sum of the dose conversion factors for an infinitely thick layer of soil for the ^{238}U decay series found in FGR 12 (EPA 1993) is compared to the exposure rate from an infinite soil source with ^{238}U in equilibrium with its decay products found in Huffert and Miller (1995), a conversion factor from $\mu R\ h^{-1}$ to $\mu rem\ h^{-1}$ of approximately 0.7 is inferred. Some realistic guidance for converting measured exposure to risk rates should be provided in FGR 13 - Part 1 if such examples are to be included.

3.5 General Conclusions

The interim version of FGR 13 - Part 1 is a useful addition to the complement of Federal Guidance reports relevant to the evaluation of the risks of radiation and makes important improvements in the calculation of radiation risks for appropriate regulatory decisions. The report is well organized and well written, although difficult to comprehend for all but highly technical audiences. The inclusion of sample calculations in the appendices should be useful for those attempting to understand the details of the extensive calculations, especially if they need to modify the computed values to fit a situation for which the standard calculations are not suited. The careful reader will also note that most of the important caveats to the use of the document's results are included somewhere in the text. However, the caveats are not as prominent as they probably should be, given the potential for misuse or misinterpretation of the document's risk estimates. In particular, the magnitudes of the uncertainties in the computed numbers are difficult to ascertain.

The Subcommittee commends the Agency on its leadership and efforts in using up-to-date scientific methods and data to develop the health risk estimates in FGR 13 - Part 1. We believe that our recommendations, except those noted for future consideration, can be incorporated prior to publication of the final version and will strengthen the report and its credibility. We strongly support the Agency's stated intent to publish supporting information in electronic form to accompany release of the final version of FGR 13 - Part 1, and we recommend that it include the data, models, and dose values used in formulating the risk coefficients.

APPENDIX A - DETAILED TECHNICAL COMMENTS

The Subcommittee offers the following specific technical comments:

a) **Suitability of Assumed Particle Diameter:** P. 53: An activity median aerodynamic diameter (AMAD) of 1 μm is assumed for the calculations. Presumably, situations will arise in which the AMAD will be different. The Subcommittee recommends that comment on this issue be made in the document and that a procedure for adjusting the coefficients (or perhaps the air concentration) appropriately be included. Another possibility is to include this information in the electronic files to be issued by the Agency.

b) **Gastrointestinal Absorption Factors**: P. 62-63: The gastrointestinal (GI) absorption factors for ingestion are usually equal to that for inhalation of absorption type F compounds. Presumably, elements are sometimes chemically bound in a relatively insoluble form, even in food or water. The document should explain how the ingestion absorption factors were selected and, if appropriate, suggest when and how an adjustment should be made if conditions indicate a lower absorption factor.

c) **Compound Speciation**: P. 71: Surrogate information for the biokinetic models is described as being based on a "chemical analogue of the element in humans." Compound speciation may be important for an element. FGR 13 - Part 1 should state to what extent the surrogate data are based on an appropriate analogue compound (as opposed to element).

d) **Effective Alpha Particle RBE**: The document states that an "effective" alpha particle RBE of 1 is used for leukemia (P. 98). It is not clear whether another such adjustment has been made for the effect of radium on bone, where the unadjusted ICRP methods do not predict radium risks correctly. More broadly, the difficulties with the whole RBE structure are not sufficiently discussed in this section.

e) **Selection of Units of Risk**: A statement about the selection of the unit in which risk is expressed should be given. The Subcommittee offers the following for consideration by the authors: "Risk coefficients are presented in units of Bq^{-1} because the Bq is the fundamental SI unit of activity."

APPENDIX B - ACRONYMS

AF	Absorbed Fraction of Energy
AMAD	Activity Median Aerodynamic Diameter
ARARS	Applicable or Relevant and Appropriate Requirements
BEIR	Biological Effects of Ionizing Radiation
BIOMOVS	Biospheric Model Validation Study
Bq	Becquerel
CERCLA	Comprehensive Environmental Response Compensation and Liability Act
Ci	Curie
cm	Centimeters
Cs-137	Cesium-137
DCAL	Dose Calculation (Software)
DDREF	Dose and Dose-Rate Effectiveness Factor
EPA	U.S. Environmental Protection Agency (U.S. EPA)
FGR	Federal Guidance Report (Includes FGR 11, 12, 13)
GI	Gastrointestinal
g	Gram
h	Hour
HRTM	Human Respiratory Tract Model
^{131}I	Iodine -131
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
LET	Linear Energy Transfer
m	Meter
MeV	Million electron Volts
NCRP	National Council on Radiation Protection and Measurements
NRC	U.S. Nuclear Regulatory Commission (U.S. NRC)
NUREG	Nuclear Regulatory (U.S. NRC Documents)
ORNL	Oak Ridge National Laboratory
ORIA	Office of Radiation and Indoor Air (U.S. EPA)
p	Pico (one trillionth, e.g., 10^{-12} Ci is a picocurie)
^{239}Pu	Plutonium-239
^{226}Ra	Radium-226
R	Roentgen
RAC	Radiation Advisory Committee (RAC/U.S. EPA/SAB/RAC)
RBE	Relative Biological Effectiveness
rem	the unit of the quantity dose equivalent
SAB	Science Advisory Board (U.S. EPA/SAB)

SI	Systeme International d' Unites (international system of units)
^{90}Sr	Strontium-90
^{238}U	Uranium
UMT	Uranium Mill Tailings
UMTRCA	Uranium Mill Tailings Radiation Control Act
U.S.	United States
μ	Micro (A millionth of given unit) [e.g., μm - Micrometer (A millionth of a m); μrem - Microrem (A millionth of a rem); μR - Micro Roentgen (A millionth of a R)]

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