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CIRRPC

Science Panel Report No. 9

USE OF BEIR V AND UNSCEAR 1988 IN RADIATION RISK ASSESSMENT

Lifetime Total Cancer Mortality Risk Estimates at Low Doses and Low Dose Rates for Low-LET Radiation

December 1992

COMMITTEE ON INTERAGENCY RADIATION RESEARCH AND POLICY COORDINATION

Office of Science and Technology Policy
Executive Office of the President
Washington, DC 20506

The Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) is chartered under the Committee on Life Sciences and Health through the Federal Coordinating Council for Science, Engineering and Technology, Office of Science and Technology Policy, Executive Office of the President, Washington, DC 20506.*

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COMMITTEE ON INTERAGENCY RADIATION RESEARCH
AND POLICY COORDINATION
1019 Nineteenth Street, NW, Suite 700
Washington, D.C. 20036

MEMORANDUM

To: Dr. D. Allan Bromley, Chair
Federal Coordinating Council for Science, Engineering and Technology

Thru: Dr. James O. Mason, Chair James O. Mason JAN - 8 1993
Committee on Life Sciences and Health

From: Dr. Alvin L. Young, Chair A L Young
Committee on Interagency Radiation Research and Policy Coordination

Date: December 30, 1992

Subject: CIRRPC Science Panel Report #9

I am pleased to transmit to you the enclosed report entitled "Use of BEIR V and UNSCEAR 1988 in Radiation Risk Assessment: Lifetime Total Cancer Mortality Risk Estimates at Low Doses and Low Dose Rates for Low-LET Radiation" for publication as CIRRPC Science Panel Report #9. This is the second task undertaken by CIRRPC in response to a Department of Defense request that CIRRPC develop a coordinated Federal position on risk assessment for low levels of ionizing radiation.

This report has been reviewed and approved by the CIRRPC Science Panel, CIRRPC, and the Committee on Life Sciences and Health. A satisfactory compromise has been achieved on all issues raised during the review process, and it is the consensus of all of the member agencies of the above committees that the report be forwarded for publication.

If you concur with our recommendation that this report be published by CIRRPC, please indicate your concurrence by your signature below and return a signed copy to Dr. Young.

D. Allan Bromley
Dr. D. Allan Bromley

January 12, 1993
Date

Enclosure

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Lifetime Total Cancer* Mortality Risk Estimates at Low Doses and Low Dose Rates for Low-LET Radiation

I. INTRODUCTION

In November 1986, the Department of Defense (DoD) asked the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) to develop a coordinated Federal position on risk assessment for low levels of ionizing radiation (1). Since Federal risk assessment activities are based primarily on the scientific data and analyses in authoritative review documents prepared by groups like the National Academy of Sciences' Committee on the Biological Effects of Ionizing Radiation (BEIR), the National Council on Radiation Protection and Measurements (NCRP) and the United Nations' Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), DoD proposed that the CIRRPC Science Panel undertake the task of providing coordinated interagency positions on the use of information in the reports of such groups. The practice has been for individual Federal agencies to interpret and decide independently how to use the information provided in such reports.

The first effort under this request was initiated in July 1987 with the establishment of a CIRRPC Science Subpanel to review the BEIR IV report *Health Risks of Radon and Other Internally Deposited Alpha-Emitters* (2) and to provide a report on the potential for consistent use of BEIR IV in Federal risk assessment. That Subpanel's report on the use of BEIR IV in Federal risk assessment was published as Science Panel Report No. 8 entitled *Ionizing Radiation Risk Assessment - BEIR IV* (3).

* In this report, "total cancer" is a descriptive term meaning leukemia plus solid cancer. The descriptive term does not mean either the number of excess cancers as computed in BEIR V or the number of premature cancers as computed in UNSCEAR 1988. (See footnote 7 on page 7.)

The second effort under the DoD request was initiated in March 1989, stimulated by the publication of the 1988 UNSCEAR report *Sources, Effects and Risks of Ionizing Radiation* (4) and knowledge that the BEIR V report *Health Effects of Exposure to Low Levels of Ionizing Radiation* (5) was in preparation. A second CIRRPC Science Subpanel (see Appendix A) was tasked to address the use of BEIR V and UNSCEAR 1988 in a coordinated manner in Federal risk assessment for health effects associated with low levels of low-LET (linear energy transfer) ionizing radiation such as is produced by x rays and gamma rays. The Subpanel was charged with extracting the quantitative risk estimates from the reports, with discussing uncertainties surrounding the risk estimates, and with developing advice for Federal agencies on the application of the risk estimates to their risk assessment activities (6).

The Subpanel sought to establish, if possible, a Federal consensus on the quantitative risk estimates[1] that could be applied to the risk assessment[2] tasks that are the responsibility of Federal agencies. The Subpanel's main objective was to identify areas of fundamental scientific agreement, after reviewing the diversity of analytical approaches and models in the BEIR V and UNSCEAR 1988 reports. The Subpanel did not generate independent scientific analyses of the original epidemiological data.

The Subpanel's scope of work did not include the application of the risk estimates to such risk assessment tasks as: evaluating revisions in the radiation protection system such as the dose limits for occupational or public exposure; performing risk assessments concerning the impact of specific ionizing radiation sources; or evaluating real or potential radiation accident scenarios.

Although the BEIR V and UNSCEAR 1988 reports were the focus of the Subpanel's effort, they were not the only source reports consulted. The Subpanel also consulted the 1977 recommendations of the International Commission on Radiological Protection (ICRP) (7), the 1980 BEIR III report of the National Academy of Sciences (8), the 1988 report from the United Kingdom's National Radiological Protection Board (NRPB) (9), the 1990 report from the Radiation Effects Research Foundation

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[1] In this report, a risk estimate is a statement that expresses the probable number of occurrences of specified health effects attributable to ionizing radiation, for a reference group of individuals of specified demographic composition over a specified time period after exposure to a reference quantity of ionizing radiation. An example is a risk estimate of 4.5×10^{-3} for lifetime total cancer mortality in the general population of the United States for a whole-body absorbed dose of 0.1 Gy (10 rad). A risk estimate is obtained from analysis of relevant scientific information.

[2] In this report, a risk assessment is a quantitative statement of the potential health consequences of a real or postulated ionizing radiation exposure to an appropriate group of individuals. A risk assessment applies the appropriate risk estimates and requires that credible estimates be obtained of the quantity of ionizing radiation that was or would be experienced by the group of individuals.

(RERF) (10) which provides the basic observations on the Life Span Study of the Japanese atomic-bomb survivors, and the recommendations and supporting technical annexes of the ICRP that were adopted in 1990 (11).

As a result of its deliberations, the Subpanel recommends two nominal risk estimates for lifetime total cancer mortality following whole-body exposure to low levels of low-LET ionizing radiation, one for the general population and one for the working-age population (see Section II). The recommended risk estimates reflect the general agreement of information in BEIR V and UNSCEAR 1988 for total cancer mortality. The Subpanel's risk estimates and associated statements are intended to meet the needs of the Federal agencies for: (a) values that are current; (b) values that are relevant to the low-dose and low dose-rate ionizing radiation exposures principally encountered in carrying out Federal responsibilities; (c) a statement of the change in the estimates of lifetime total cancer mortality relative to estimates in previous authoritative review documents; and (d) a practical statement on the scientific uncertainty associated with applying the lifetime total cancer mortality values at very low doses.

The recommended risk estimates for lifetime total cancer mortality are applicable for a whole-body irradiation. For a partial-body irradiation, where either one or a specific number of tissues are irradiated and others are not, one needs the appropriate risk estimates for lifetime cancer mortality and the absorbed doses for the tissues of interest to perform a risk assessment for the relevant cancers.

BEIR V and UNSCEAR 1988 provided lifetime cancer mortality risk estimates for certain individual tissues or groups of tissues. However, differing judgments were used in the two reports to develop these risk estimates. These differing judgments would need to be reconciled before nominal risk estimates for specific cancers can be recommended for consensus use by Federal agencies.

II. RECOMMENDATIONS: LIFETIME TOTAL CANCER MORTALITY RISK ESTIMATES AT LOW DOSES AND LOW DOSE RATES FOR LOW-LET RADIATION

A. SUMMARY STATEMENT

The aggregate risk estimates for lifetime total cancer mortality in BEIR V and UNSCEAR 1988, as projected principally from the observations at higher doses and the high dose rate for whole-body exposure of the Japanese atomic-bomb survivors, are very similar. The Subpanel accepted each aggregate risk estimate without attempting to reconcile the differences in the details of the risk estimates for individual cancer sites or the methods of analysis and of lifetime projection presented in the two reports.

The Subpanel modified each aggregate risk estimate, as appropriate, by an interim dose-rate effectiveness factor (DREF) of 2 for low doses and low dose rates. Selection of this interim DREF value of 2 is consistent with the general discussions in BEIR V and UNSCEAR 1988 and with the value adopted by the ICRP in its current recommendations (11). The Subpanel's use of a DREF value of 2 does not preclude revision of that value and of the Subpanel's nominal risk estimates when more complete scientific information is available. Application of this DREF value results in the Subpanel's recommended nominal risk estimate for the general population of 4.5×10^{-3} for lifetime total cancer mortality at the reference whole-body absorbed dose of 0.1 Gy (10 rad). The recommended nominal risk estimate for the working-age population, that is, individuals between the ages 18 to 65, is 3.5×10^{-3}.[3]

NOTE

The Subpanel's nominal value for the general population for lifetime total cancer mortality for low-LET ionizing radiation, delivered at low doses and low dose rates, is 2.0 times the corresponding value in the 1980 BEIR III report and 3.6 times the value used by ICRP in 1977. The Subpanel's nominal value for the working-age population is 2.8 times the value used by ICRP in 1977. The differences between the Subpanel's nominal risk estimates and the values that have been used by Federal agencies vary, depending on each Federal agency's previous policy or practice

[3] Individual agencies may have preferences for specific methods of analysis or of lifetime projection that were utilized in BEIR V or UNSCEAR 1988, or that have been developed since those reports. These preferences may result in risk estimates for lifetime total cancer mortality at the reference whole-body absorbed dose of 0.1 Gy (10 rad) that are slightly different than the Subpanel's recommended nominal values. Individual agencies are not precluded from expressing and using their preferred risk estimates, which are expected to be in the ranges shown below:

General population: 4.0×10^{-3} to 5.0×10^{-3}
Working-age population: 3.0×10^{-3} to 4.0×10^{-3}.

concerning selection of risk estimates. Therefore, each agency would need to evaluate the magnitude of the change that would result from adoption of the Subpanel's recommended values.

The Subpanel also developed a statement on the scientific uncertainty associated with applying the nominal risk estimates for the reference dose of 0.1 Gy (10 rad) to the absorbed doses well below 0.1 Gy (10 rad) that are often encountered in practice. The Subpanel recommends that a statement accompany the numerical estimates of cancer deaths resulting from such risk assessments whenever the numerical estimates are provided for use in a decision-making process or for release as public information. An example of such a statement is:

> The numerical estimate of cancer deaths presented was obtained by the practice of linear extrapolation from the nominal risk estimate for lifetime total cancer mortality at 0.1 Gy (10 rad).* Other methods of extrapolation to the low-dose region could yield higher or lower numerical estimates of cancer deaths. Studies of human populations exposed at low doses are inadequate to demonstrate the actual level of risk. There is scientific uncertainty about cancer risk in the low-dose region below the range of epidemiologic observation, and the possibility of no risk cannot be excluded.[4]
>
> * 4.5×10^{-3} for the general population; 3.5×10^{-3} for the working-age population.

In addition, the Subpanel recommends, for comparative purposes, that an estimate of the number of cancer deaths that would normally occur over the lifetime of the population (i.e., the baseline risk) also accompany the numerical estimate of cancer deaths attributed to the additional ionizing radiation exposure experienced by the population. The Subpanel suggests for this purpose, in the absence of a more appropriate local demographic value, the value of 19% from BEIR V that was computed for the normal expectation of cancer deaths in the 1980 United States life table population. The corresponding value from BEIR V computed for the working-age population was also about 19%.

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[4] As another example, individual agencies may wish to quote the full commentary given on page 181 of BEIR V on the limitations in using risk models and epidemiologic data to estimate the risk of cancer at very low doses, either in addition to the Subpanel's recommended statement or in place of the statement. The BEIR V commentary is reproduced on pages 12-13 of this report.

B. RATIONALE

Risk Estimates in BEIR V and UNSCEAR 1988 at 0.1 Gy (10 rad)

The aggregate risk estimates for lifetime total cancer mortality given in BEIR V and UNSCEAR 1988 for a single whole-body exposure and for the general population, when projected at 0.1 Gy (10 rad)[5] absorbed dose, are:

BEIR V

For the United States population, using United States vital statistics for 1980;

0.95×10^{-3} (leukemia) + 6.95×10^{-3} (solid cancers)
(Table 4-2, page 172, average for equal numbers of males and females).

Similar values would be obtained if the results given in Table 4-2, page 172, for continuous lifetime exposure to 1 mGy/y (0.1 rad/y) were normalized to an accumulated absorbed dose of 0.1 Gy (10 rad).[6]

The values given in BEIR V are for excess cancer deaths (i.e., the difference in the number of cancer deaths estimated for the exposed and unexposed populations).

= 790×10^{-6} fatal cancer / rad

[5] Risk estimates are provided in BEIR V at 0.1 Gy (10 rad). Risk estimates are provided in UNSCEAR 1988 at 1.0 Gy (100 rad). The basic analysis of the Life Span Study of the Japanese atomic-bomb survivors by the Radiation Effects Research Foundation observed excess cancer mortality of statistical significance at absorbed doses as low as 0.2 to 0.5 Gy (20 to 50 rad) (10). The Subpanel selected 0.1 Gy (10 rad) as the reference absorbed dose for presentation of lifetime total cancer risk estimates to be consistent with the reference absorbed dose given in BEIR V.

[6] The values computed from the results for a continuous lifetime exposure of 1 mGy/y (0.1 rad/y) in Table 4-2 for an equal number of males and females are 0.89×10^{-3} (leukemia) and 6.69×10^{-3} (solid cancers) for 0.1 Gy (10 rad). The values are approximately 6% (leukemia) and 4% (solid cancers) lower than the values for a single exposure to 0.1 Gy (10 rad). The average years of life for the United States population statistics used in BEIR V are 77.6 years for females and 70.1 years for males (12).

UNSCEAR 1988

For the Japanese population, using Japanese vital statistics for 1982;

0.97×10^{-3} (leukemia) + 6.1×10^{-3} (solid cancers)
(age-averaged risk coefficients; multiplicative risk projection; Table 63, page 528); one way

1.0×10^{-3} (leukemia) + 9.7×10^{-3} (solid cancers)
(age-specific risk coefficients; multiplicative risk projection; Table 62, page 527). another way

No preference for either of these two sets of risk estimates is expressed in UNSCEAR 1988.

The values given in UNSCEAR 1988 are for premature cancer deaths (i.e., the number of excess cancer deaths plus the number of cancer deaths that would occur earlier than expected).[7]

Selection of the Dose-Rate Effectiveness Factor (DREF)

The aggregate risk estimates for lifetime total cancer mortality given in BEIR V and UNSCEAR 1988 were projected principally from the observations at higher doses and the high dose rate in the Life Span Study of the Japanese atomic-bomb survivors exposed primarily to low-LET radiation, that is, gamma rays. Extensive evidence from scientific observations in plant, animal and cellular systems suggests that it is necessary to modify risk estimates derived from exposure at high doses and high dose rates by a dose-rate effectiveness factor (DREF) when they are applied to low doses and low dose rates of low-LET radiation (13). The BEIR V and UNSCEAR 1988 reports provided general discussion and advice on the application of the DREF, but, except for leukemia in BEIR V,[8] both reports left the selection of a DREF value to the user.

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[7] Premature cancer deaths attributable to radiation are not excess deaths unless they occur in persons who would not otherwise die of cancer. The ratio of estimates of excess cancer deaths to estimates of premature cancer deaths is about 0.8. The Subpanel has elected not to modify either the BEIR V or UNSCEAR 1988 values for this difference.

[8] BEIR V states that the value of 0.95×10^{-3} for leukemia contains an implicit DREF of 2, as a consequence of the linear-quadratic dose response model preferred by BEIR V, and should not be further reduced. The other values from BEIR V and UNSCEAR 1988 have not yet had a DREF applied, and both reports advise that a DREF is appropriate.

DREF values in the range of 2 to 2.5 can be derived from the previous 1980 BEIR III report by comparing the results in Tables V-16, V-17, V-18 and V-20 obtained from linear and linear-quadratic dose-response models (8). UNSCEAR 1988 reiterates the advice provided by NCRP in its 1980 report (13), namely that the DREF lies between 2 and 10. The ICRP indicates that it used a DREF value of 2.5 in its 1977 recommendations (11), and has adopted a value of 2 in its 1990 recommendations, based primarily on its observation that the limited human epidemiological data suggest a value in the lower region of the range 2 to 10. The ICRP acknowledged that its choice was somewhat arbitrary and perhaps conservative in the lower direction, and that the recommendation could change if new, more definitive information became available. BEIR V emphasizes that no additional DREF should be applied to its risk estimate for leukemia and that a DREF value of 2 or more would be appropriate for solid cancers. BEIR V also provides a summary of DREF values based on laboratory animal studies for various categories of biological endpoints (Table 1-4, page 23, reference 5). BEIR V gives "narrow"[9] DREF ranges of 3 to 5 for life shortening and of 2 to 5 for tumorigenesis, with a best estimate of 4 for both endpoints in animal studies.

The scientific evidence for selection of a particular value of DREF is equivocal. The means are not yet available to reconcile the values associated with the limited human data with those from the more extensive experimental data. It is beyond the Subpanel's purview to resolve this scientific uncertainty, but adopting a consensus DREF value or convention is imperative if Federal risk assessments at low doses and low dose rates are to be made. The Subpanel, therefore, recommends an interim DREF value of 2. This value is consistent with the general discussions in BEIR V and UNSCEAR 1988, and with the current recommendation of the ICRP.

The Subpanel stresses the interim nature of this DREF value of 2, pending the availability of more definitive scientific information. It notes that UNSCEAR intends to study this matter further (4) and that the NCRP has the matter under consideration as part of its scientific review of the current NCRP recommendations. The Subpanel encourages these and similar efforts by authoritative groups.

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[9] These ranges are denoted as the "narrow range of values" in Table 1-4. BEIR V also gave the "observed full range of values" in Table 1-4. The "observed full range of values" is 3 to 10 for life shortening and 2 to 10 for tumorigenesis.

Nominal Risk Estimate for Low Doses and Low Dose Rates—General Population

Applying the interim DREF value of 2 to the lifetime solid cancer mortality value from BEIR V and to each of the 2 sets of leukemia and solid cancer values from UNSCEAR 1988 (and presenting each value to the nearest 0.1×10^{-3}) results in the following risk estimates at 0.1 Gy (10 rad) applicable to low doses and low dose rates:

BEIR V

1.0×10^{-3} (leukemia) + 3.5×10^{-3} (solid cancers) =
4.5×10^{-3} (excess total cancers)

UNSCEAR 1988

0.5×10^{-3} (leukemia) + 3.1×10^{-3} (solid cancers) =
3.6×10^{-3} (premature total cancers)
(age-averaged risk coefficients)

0.5×10^{-3} (leukemia) + 4.9×10^{-3} (solid cancers) =
5.4×10^{-3} (premature total cancers)
(age-specific risk coefficients).

The Subpanel did not have a compelling scientific basis for selecting any one of the three risk estimates for total cancers shown above in preference to any other one. The Subpanel gave the three risk estimates equal weight and consideration. Therefore, the Subpanel recommends a nominal risk estimate of 4.5×10^{-3} for the lifetime total cancer mortality for the general population at the reference whole-body absorbed dose of 0.1 Gy (10 rad), when exposure is in the low-dose and low dose-rate region.[10] The Subpanel's nominal risk estimate is applicable to cumulative whole-body absorbed doses for the exposure conditions normally encountered by the general population from environmental, consumer and diagnostic medical sources. For doses and dose-rate exposure conditions not meeting the definition of low dose and low dose rates, use of the Subpanel's nominal risk estimate would not be appropriate.

The normal expectation of death from cancer from all causes for all persons in the 1980 United States life table population is 19.0% based on United States vital statistics for that year (Table 4-2, page 172, lifetime analysis, reference 5).

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[10] The ICRP applies a DREF of 2 for absorbed doses below 0.2 Gy (20 rad) regardless of dose rate, and for cumulative doses equal to or greater than 0.2 Gy (20 rad) when the dose rate is less than 0.1 Gy/h (10 rad/h). The Subpanel presents this definition of the low-dose, low dose-rate region as a practical guide in the use of its nominal risk estimates.

Nominal Risk Estimate for Low Doses and Low Dose Rates—Working-Age Population

In a working-age population, that is, individuals between the ages 18 to 65, the corresponding nominal risk estimate for lifetime total cancer mortality is somewhat lower, due to removal of the higher relative contribution projected for the younger age groups. Using the results for a working-age population in Table 4-2, page 172, of BEIR V and the DREF value of 2 for solid cancers, one can compute a risk estimate of 3.55×10^{-3} for excess total cancers at the reference whole-body absorbed dose of 0.1 Gy (10 rad), when delivered during the working-age period of 18 to 65 years.[11,12] The Subpanel recommends a nominal risk estimate of 3.5×10^{-3} at 0.1 Gy (10 rad) for the working-age population.[13] This nominal risk estimate for low doses and low dose rates (see footnote 10) is applicable to cumulative whole-body absorbed doses for the exposure conditions normally encountered by the working-age population. For doses and dose-rate exposure conditions not meeting the definition of low dose and low dose rate (see footnote 10), use of the Subpanel's nominal risk estimate would not be appropriate.

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[11] The values from Table 4-2 for an equal number of males and females are 26.2×10^{-3} (solid cancers) and 3.55×10^{-3} (leukemia) for 0.47 Gy (47 rad), i.e., 47 years of exposure at 0.01 Gy/y (1 rad/y). Dividing each of these values by 4.7 gives values for a 0.1 Gy (10 rad) accumulated whole-body absorbed dose of 5.57×10^{-3} (solid cancers) and 0.76×10^{-3} (leukemia). A DREF of 2 is then applied to the solid cancer value; the leukemia value has an implicit DREF of 2 and is not changed. The resulting value for 0.1 Gy (10 rad) delivered at low doses and low dose rates is the sum of 2.79×10^{-3} (solid cancers) and 0.76×10^{-3} (leukemia), which yields 3.55×10^{-3} (excess total cancers).

[12] Similar values can be computed using information given in UNSCEAR 1988. Using the results for the working-age population given in UNSCEAR 1988 (Table 71, page 532, multiplicative risk projection, age-averaged and age-specific risk coefficients), and a DREF of 2 for total cancers, the values are 3.5×10^{-3} (premature total cancers, age-specific) and 4.0×10^{-3} (premature total cancers, age-averaged). The UNSCEAR 1988 information is for individuals in the Japanese population between the ages 25 to 64 years.

[13] The following examples are given to illustrate the use of the nominal risk estimate. If each member of a group of workers received a whole-body absorbed dose of low-LET radiation equal to the annual occupational dose limit of 0.05 Gy (5 rad) each year from age 18 to 65, the cumulative whole-body absorbed dose for each member would be 2.35 Gy (235 rad). The associated risk estimate of lifetime total cancer mortality for the group would be:

$$[(2.35 \text{ Gy}) (3.5 \times 10^{-3} \text{ per } 0.1 \text{ Gy})] = 8.2 \times 10^{-2}.$$

In the more typical case of a group of workers, each of whom received an average whole-body absorbed dose of 0.002 Gy (0.2 rad) per year from age 18 to 65, the cumulative whole-body absorbed dose for each member would be 0.094 Gy (9.4 rad), and the corresponding risk estimate for the group would be:

$$[(0.094 \text{ Gy}) (3.5 \times 10^{-3} \text{ per } 0.1 \text{ Gy})] = 3.3 \times 10^{-3}.$$

The normal expectation of death from cancer from all causes for persons of age 18 and above in the 1980 United States life table is 19.3% based on United States vital statistics for that year (Table 4-2, page 173, working-age analysis, reference 5).

Comparison of Nominal Risk Estimates to Corresponding Values in BEIR III and in the 1977 Recommendations of the ICRP

In the 1980 BEIR III report, the corresponding value for lifetime total cancer mortality for the general population at 0.1 Gy (10 rad) for low doses and low dose rates is 2.26 x 10^{-3} (i.e., the sum of the average values for males and females for leukemia and solid cancers for the linear-quadratic dose-response model: refer to Table V-16, page 203, for leukemia; refer to Table V-19, page 206, the relative risk entries, for solid cancers).

In the 1977 recommendations of the ICRP (7), as stated in ICRP Publication 45 (14), the value for lifetime total cancer mortality at 0.1 Gy (10 rad) for low dose and low dose rates is 1.26 x 10^{-3}. The ICRP value was applicable to both the general population and the working-age population.

Therefore, the recommended Subpanel value for the general population is 2.0 times the noted BEIR III value. The recommended Subpanel value for the general population is 3.6 times the noted ICRP Publication 45 value; the recommended Subpanel value for the working-age population is 2.8 times the noted ICRP value.

C. SCIENTIFIC UNCERTAINTY

Confidence Limits for BEIR V and UNSCEAR 1988 Risk Estimates for Lifetime Cancer Mortality at Reference Absorbed Dose of 0.1 Gy (10 rad)

UNSCEAR 1988 presents 90% confidence limits for the general Japanese population lifetime premature cancer mortality risk estimates for leukemia and solid cancers for the estimate using age-averaged risk coefficients (Table 63, page 528). The upper and lower 90% confidence limits range between 0.7 and 1.3 times the point estimate for leukemia, and between 0.8 and 1.2 times the point estimate for solid cancers.

BEIR V provides 90% confidence limits for the uncertainty in its risk estimates due to the sampling variation associated with its preferred lifetime risk projection models for the United States population. The 90% confidence limits are given in Table 4-2 for the male and female lifetime excess cancer mortality risk estimates for total cancers, for solid cancers and for leukemia, for each of the three exposure scenarios. The upper and lower 90% confidence limits range between 0.6 and 1.8 times the point estimates for solid cancers, and between 0.7 and 1.9 times the point estimates for total cancers. The upper and lower 90% confidence limits for the smaller numerical leukemia component are larger and range between 0.3 and 3.7 times the point estimates for leukemia.

BEIR V also investigated other sources of uncertainty not accounted for in the BEIR V preferred models for the lifetime risk estimates (page 224). These sources of uncertainty included misspecification of the models, differences between populations, errors in the Japanese dosimetry system, and for leukemia and other cancers, differences due to sex. BEIR V indicates these additional sources of uncertainty increase the width of the confidence intervals given in Table 4-2 by a factor of 1.4 (page 180). This is interpreted by the Subpanel as an increase in the confidence interval for excess total cancers from an interval of 0.7 to 1.9 times the point estimates to an interval of 0.5 to 2.1 times the point estimates. With this interpretation, the uncertainty in the BEIR V lifetime excess total cancer mortality risk estimates, from the sources of uncertainty considered, is approximately a factor of 2 in either direction.

Uncertainty in Cancer Risk at Absorbed Doses of Low-LET Ionizing Radiation Well Below 0.1 Gy (10 rad)

Data on exposed human populations contribute little to scientific understanding of lifetime total cancer mortality at absorbed doses below about 0.2 to 0.5 Gy (20 to 50 rad) (10). It has been the practice of those conducting risk assessments and those responsible for radiation protection advice to use a linear extrapolation from risk estimates, such as the Subpanel's recommended nominal values at 0.1 Gy (10 rad), to project risks at much lower doses. While this is a practical approach for estimating the potential number of cancer deaths for risk assessment scenarios at much lower doses, it does not reflect the basic scientific uncertainty concerning cancer risk at absorbed doses well below 0.1 Gy (10 rad).

BEIR V addressed the limitations in using risk models and epidemiologic data to estimate the risk of cancer at very low doses; its full commentary from page 181 is reproduced below:

> Finally, it must be recognized that derivation of risk estimates for low doses and dose rates through the use of any type of risk model involves assumptions that remain to be validated. At low doses, a model dependent interpolation is involved between the spontaneous incidence and the incidence at the lowest doses for which data are available. Since the committee's preferred risk models are a linear

function of dose, little uncertainty should be introduced on this account, but departure from linearity cannot be excluded at low doses below the range of observation. Such departures could be in the direction of either an increased or decreased risk. 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 radiation 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 Subpanel developed the statement included on page 5 (as part of its overall Summary Statement) to provide needed perspective on the scientific uncertainty in cancer risk at absorbed doses well below 0.1 Gy (10 rad). The Subpanel recommends the Federal agencies include such a statement prominently with their risk assessments.

REFERENCES

(1) Letter from the Assistant to the Secretary of Defense for Atomic Energy, Department of Defense, to the Chairman, Committee on Interagency Radiation Research and Policy Coordination (November 10, 1986).

(2) Health Risks of Radon and Other Internally Deposited Alpha-Emitters. BEIR IV Report. Washington, DC: National Academy of Sciences, 1987.

(3) Ionizing Radiation Risk Assessment-BEIR IV. Science Panel Report No. 8. Washington, DC: Committee on Interagency Radiation Research and Policy Coordination, 1991.

(4) Sources, Effects and Risks of Ionizing Radiation. United Nations Scientific Committee on the Effects of Atomic Radiation. New York: United Nations, 1988.

(5) Health Effects of Exposure to Low Levels of Ionizing Radiation. BEIR V Report. Washington, DC: National Academy of Sciences, 1990.

(6) Work Statement for CIRRPC Science Subpanel on the Use of BEIR V and UNSCEAR 1988 in Risk Assessment (February 17, 1989).

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APPENDIX A

Membership of CIRRPC Science Subpanel on Use of BEIR V and UNSCEAR 1988 in Risk Assessment

Chairman

Dr. Marvin Rosenstein
Department of Health and Human Services
Food and Drug Administration

Members

Dr. Gilbert W. Beebe
Department of Health and Human Services
National Institutes of Health

Dr. Frank J. Congel
Mr. Charles A. Willis (Alt.)
Nuclear Regulatory Commission

CAPT William J. Flor, MSC, USN
Department of Defense

Dr. Daniel Hoffman
Department of Health and Human Services
Centers for Disease Control

Mr. Christopher Nelson
Environmental Protection Agency

Mr. Anthony A. Weadock
Department of Energy

ORAU/CIRRPC Technical Liaisons

Dr. William A. Mills
Ms. Diane S. Flack

APPENDIX B

Current Membership of CIRRPC Science Panel

<u>Chairman</u>

Dr. Randall S. Caswell
Department of Commerce

<u>Vice-Chairman</u>

Dr. Marvin Rosenstein
Department of Health and Human Services

<u>Executive Secretary</u>

Dr. Jerome Puskin
Environmental Protection Agency

<u>Members</u>

Department of Agriculture
Mr. John T. Jensen
Dr. Ronald E. Engel (Alt.)

Department of Commerce
Mr. Charles M. Eisenhauer
Dr. Bert M. Coursey (Alt.)

Department of Defense
CAPT William J. Flor, Ph.D.
CAPT Robert L. Bumgarner, MC, USN (Alt.)

Department of Energy
Dr. Robert W. Wood
Dr. Matesh Varma (Alt.)

Department of Health and Human Services
Dr. Gilbert W. Beebe
Dr. Bruce W. Wachholz (Alt.)

Department of Housing and Urban Development
Mr. Richard J. Alexander
Mr. Joel Segal (Alt.)

Department of the Interior
Dr. Edward Landa

Department of Labor
Dr. Sheldon R. Weiner
Ms. Margie E. Zalesak (Alt.)

Department of Transportation
Mr. George A. Brown
Ms. Kristen Smith Curling (Alt.)

Department of Veterans Affairs
(vacant)

Environmental Protection Agency
Mr. J. William Gunter
Dr. Jerome Puskin (Alt.)

Federal Emergency Management Agency
Mr. Marlow J. Stangler
Mr. George C. Meyer (Alt.)
Mr. Michael S. Pawlowski (Alt.)

National Aeronautics and Space Administration
Dr. Frank M. Sulzman
Dr. Walter Schimmerling (Alt.)
Dr. Donald Robbins (Alt.)

National Science Foundation
Dr. Arthur Kowalsky

Nuclear Regulatory Commission
Dr. Donald A. Cool