UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

APR 11 1990

MEMORANDUM FOR: Chairman Carr
Commissioner Roberts
Commissioner Rogers
Commissioner Curtiss
Commissioner Remick

FROM: James M. Taylor, Executive Director for Operations

SUBJECT: EVALUATION OF RECENT REPORTS ON HEALTH EFFECTS OF LOW-LEVEL IONIZING RADIATION

Recently, two major reports dealing with the health effects of ionizing radiation have been published. At the end of 1988, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) published a report entitled "Sources, Effects and Risks of Ionizing Radiation" and in December 1989, the National Research Council's Committee on the Biological Effects of Ionizing Radiation (BEIR) published a report entitled "Health Effects of Exposure to Low-Levels of Ionizing Radiation - BEIR V." Enclosed is the staff's preliminary evaluation of the BEIR V and UNSCEAR 1988 reports.

The staff is involved in several efforts to evaluate these reports, including a Science Subpanel of the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC). The results of these reviews are not yet available. Thus, the NRC staff cannot at this time completely assess the impact of BEIR V and UNSCEAR 1988 on all aspects of existing and proposed NRC radiation protection regulations and policies. Once the CIRRPC Science Panel report has been completed and reviewed, the staff anticipates being in a position to provide a more complete evaluation. The scheduled completion date for the CIRRPC Science Panel report has not been established, but is likely to be late this year. In the interim, it is recommended that the estimated risk of fatal cancer from exposure to protracted low-level (environmental and occupational exposures), low Linear Energy Transfer (LET) radiation be taken as 500 per million person-rem (5×10^{-4} per rem). This number is consistent with values given in BEIR V and UNSCEAR 1988.

If this recommendation is adopted, then the risk coefficients for fatal cancer currently used by NRC staff in risk assessments would be approximately doubled. However, no impact is foreseen on the Commission's evolving Policy Statement on Exemptions from Regulatory Control. The Policy Statement (SECY-89-360) used a value of 5×10^{-4} per rem to translate dose to risk. The staff also believes that the promulgation of the revision of 10 CFR Part 20 should proceed in a timely manner. Any changes that might be necessitated as a result of full

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evaluation of BEIR V and UNSCEAR 1988 can be accommodated at a later date, after a scientific consensus emerges regarding any necessary reduction in the dose limits.

James M. Taylor
Executive Director
for Operations

Enclosure:
Evaluation Report

cc: SECY
OGC
GPA

Enclosure

Evaluation of Recent Reports on Health Effects of Low-Level Ionizing Radiation

Introduction

In the last year, two major reports dealing with the health effects of ionizing radiation have been published. At the end of 1988, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) published a report entitled "Sources, Effects and Risks of Ionizing Radiation" and in December 1989, the National Academy of Sciences, National Research Council, Committee on the Biological Effects of Ionizing Radiation (BEIR) published its latest report entitled "Health Effects of Exposure to Low-Levels of Ionizing Radiation - BEIR V." The objective of these reports was to update previous reports (UNSCEAR 1977 and 1982 and BEIR III, 1980) to reflect additional information on the epidemiology and dosimetry of radiation exposure and effects. This update was necessary because of: (1) the recently completed reassessment of doses received by the atomic-bomb survivors in Hiroshima and Nagasaki, (2) accumulation of several more years of follow-up data, (3) additional information obtained from studies of other populations exposed to radiation, (4) increased understanding of cellular mechanism of radiation carcinogenesis, and (5) the development of new computational techniques and statistical tools to analyse the epidemiologic data.

The BEIR V report was done upon the request of and with funding from the Office of Science and Technology Policy's Committee on Interagency Radiation Research and Policy Coordination (CIRRPC). The Nuclear Regulatory Commission (NRC) is a member of CIRRPC, and as such provided part of the funding for BEIR V. Although the BEIR V Committee's risk estimates might impact radiation protection standards in the future, the BEIR Committee was not asked to, and did not, recommend levels for such standards.

Summary of Findings

The BEIR V and UNSCEAR 1988 reports address similar areas of radiation health-effects. The following summary of findings is based upon the BEIR V report which addresses primarily the late health risks of low Linear Energy Transfer (LET) radiation, especially from brief acute exposures to x or gamma radiations (low-LET radiation). The main effects discussed in BEIR V are induction of cancers, genetic disorders and developmental abnormalities such as mental retardation following irradiation in utero. Additional findings related to high-LET radiation from internally deposited radionuclides, and in particular radon, were published as BEIR IV in 1988.

Cancer Induction

Excess cancers have been observed mostly following relatively large doses of radiation delivered at high dose rates. The observation time of the exposed populations, such as the Japanese atomic bomb survivors at Hiroshima and Nagasaki, does not yet extend through the lifetimes of all the irradiated individuals. Therefore, assumptions must be made about how the observations at high doses and dose rates should be applied at low doses and low dose rates for radiation of a given type and how risks from radiation might vary long after the time of exposure.

Previously, the BEIR III report had examined three dose response functions: (1) linear, in which effects are directly proportional to dose at all doses; (2) linear-quadratic, in which effects are very nearly proportional to dose at very low doses and proportional to the square of the dose at high doses; and (3) quadratic, in which the risk varies as the square of the dose at all dose levels. All mathematical functions in the BEIR III report assumed that there is no dose below which there is no excess health risk. For low-LET radiation, BEIR III recommended the use of a linear quadratic dose response function.

To extend the estimate of risk from radiation exposure beyond the years of observation, some type of projection model must be used. In the BEIR III report, both a relative risk and an absolute risk projection model were used. The relative risk projection model assumes that the increased risk due to radiation exposure is a percentage of natural incidence of cancer in the population. The model then projects the currently observed percentage increase in cancer risk per unit dose into future years. An absolute risk model assumes that the increased risk of cancer is a fixed absolute increase in probability, independent of the natural incidence rate. The absolute model then projects the average observed number of excess cancers per unit dose into the future. Because the baseline rate of cancer incidence rises dramatically with age, the relative risk projection model predicts a larger number of radiation induced cancers in the aging population for years beyond the period of observation; consequently, the average lifetime risk calculated according to the relative risk model is higher. The BEIR III Committee did not specify which projection model is the appropriate choice for most radiogenic cancers.

The BEIR V Committee in its estimates of radiation induced fatal tumor risk uses the linear dose response and relative risk projection model. UNSCEAR 1988 also uses the linear dose response model and, although it presents results based on both the absolute and relative temporal risk projection models, it states that the epidemiologic data support the use of the relative risk projection model. Both reports agree that the use of the absolute risk projection model is no longer tenable for most cancer sites in view of the data now available.

There are, however, additional variables and assumptions used in derivation of risk estimates. These include the minimum latency period (time between irradiation and appearance of radiogenic cancer), variation of risk with gender, translation of effects observed in one population to another (e.g., from Japanese to U.S. population), variation of risk with age at exposure, and variation of risk with time after exposure. The treatment of the last two variables, age at exposure and time since exposure, is significantly different in UNSCEAR 1988 and BEIR V. Also the method of lifetime risk estimation is different in the two reports. BEIR V calculates the incremental lifetime risk

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of cancer mortality (i.e., excess cancer deaths in a population), whereas UNSCEAR 1988 (and BEIR III) calculates lifetime risk of fatal radiogenic cancer (i.e., number of premature cancer deaths in a population). The later estimate is larger by about 20 percent, because a premature cancer death might not be "excess" if the cause of death would have been cancer at a later time in life.

The UNSCEAR 1988 and BEIR V reports base their estimates of fatal cancer risk primarily on effects that have been observed only at relatively high doses and high dose rates. Both reports indicate that accumulation of the same dose of low-LET radiation over long periods of time (weeks, months), as is the case with environmental and occupational exposures, is expected to reduce the life-time risk appreciably. Unfortunately, neither report gives adequate numerical guidance to specify such risk reduction. However, both reports indicate that it is reduced at least by a factor of 2.

The estimates of excess life-time cancer mortality in an exposed population are essentially the same in UNSCEAR 1988 and BEIR V. Assuming a risk reduction factor of 2 for protracted exposures (low dose rate), these estimates are on the order of 5×10^{-4} per rem and are about twice as large as the estimates based on the most frequently used model in BEIR III (linear quadratic dose-response, relative risk temporal projection).

Genetic Effects

Irradiation of the reproductive organs can cause increased incidence of disorders of genetic origin among the offspring of the irradiated individuals. Such disorders can manifest themselves in the first generation following parental irradiation and/or in future generations. The risk estimates adopted by the BEIR V Committee are based on a doubling dose (dose required to double the mutation rate in man) of 100 rem and are essentially the same as used in previous UNSCEAR reports (1972, 1977, 1982, and 1986) and within the range of doubling dose estimates in BEIR III. These risk estimates are based on experimental animal data since no suitable human data are available. The very limited human data suggests that risk estimates based on animal data are conservative. BEIR V states, . . . "attempts to estimate doubling doses from data on Japanese atomic-bomb survivors have consistently led to values larger than those derived from the animal data, and consequently they imply lower risks. Although risks calculated from animal data have large confidence intervals, estimates from those exposed to radiation in Hiroshima and Nagasaki are known with even less precision. In spite of these uncertainties, the data suggest a real difference, with the estimated lower 95 percent confidence limit of the human data approximating the median of a large number of values obtained in mice. If it is assumed that the apparent difference is real, humans would be less sensitive to radiation induction of mutations in germs cells than mice."

Developmental Abnormalities

The effects of prenatal irradiation on the development of the embryo and fetus include embryonic death, gross congenital malformations, growth retardation, and central nervous system abnormalities. Recent observations on Japanese atomic-bomb survivors suggest that irradiation at 8 to 15 weeks of embryonic development carries the greatest risk for severe mental retardation.

These effects have been described in an UNSCEAR 1986 report, in NUREG/CR-4214, Rev. 1, 1989, and are also addressed in Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure." The risk coefficients for mental retardation given in BEIR V do not differ from those currently used by NRC staff.

Ongoing Efforts

The models of cancer induction in individual organs of the human body following exposure to low-level of ionizing radiation given in BEIR V are extremely complex and differ in calculational methodology from those described in UNSCEAR 1988 and previous BEIR reports. These differences are especially significant in the BEIR V treatment of the effect of age at exposure and time post exposure on risk of induction of specific cancers. The validity and applicability of models and risk coefficients in BEIR V is currently being reviewed and assessed by CIRRPC, the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), an NRC contractor, and by other federal agencies. CIRRPC's Science Panel has already established a subpanel concerning implications of the BEIR V and UNSCEAR 1988 reports. This subpanel will concentrate on the use of the information in BEIR V and UNSCEAR 1988 in a consistent way by Federal agencies in their risk assessment activities. The NRC staff has a representative on this subpanel and also has representatives on the CIRRPC Science Panel and the CIRRPC Policy Panel.

NUREG/CR-4214, Revision 1, 1989, "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis," contains health effects models and risk coefficients intended for use in severe accidents analyses, probabilistic risk assessments, emergency response planning, safety goal analyses, and cost/benefit analyses. In anticipation that the BEIR V and other recent reports could have implications for the health effects and risk coefficients models used in NUREG/CR-4214, the NRC staff has initiated a research project to develop any modifications that might be necessary in the risk models currently used.

The International Commission on Radiological Protection (ICRP) is preparing a revision of its basic recommendations - ICRP Publication 26, 1977, on the basis of information presented in UNSCEAR 1988 and BEIR V. A draft of the ICRP report was received by the staff for comment in March 1990, and final recommendations by the ICRP are expected in the first quarter of 1991. Also, the National Council on Radiation Protection and Measurements (NCRP) is critically reviewing the information presented in UNSCEAR 1988 and BEIR V and preparing recommendations on health effects risk coefficients for radiation protection purposes. A draft of the NCRP report is anticipated in the summer of 1990.

Impact of BEIR V Report on Commission Activities

The following sections provide a brief summary of some of the potential impacts of the BEIR V and UNSCEAR 1988 reports on certain areas of risk assessment and rulemaking. Prior to completion of the ongoing analyses described above, the NRC staff can not fully assess the impact of BEIR V on NRC regulatory policy. The staff will continue to monitor the progress of these analyses. In the interim, it is recommended that the estimated risk of fatal cancer from

exposure to protracted low-level (environmental and occupational exposures), low-LET radiation be taken as 500 per million person-rem (5×10^{-4} per rem). This number is in accordance with values given in BEIR V and UNSCEAR 1988.

Risk Assessment Analyses

Based on a recommendation that the fatal cancer risk is on the order of 5×10^{-4} per rem, the risk coefficients for fatal cancer given in NUREG/CR-4214, Rev. 1, 1989, "Health Effects Models for Nuclear Power Plant Accident Consequence Analysis," will have to be approximately doubled. The estimates of risk for genetic abnormalities and effects in the developing embryo/fetus are not changed as a result of the BEIR V report, and thus there is no impact on the estimates contained in NUREG/CR-4214 for these areas. Although the fatal cancer risk estimate is increased, the factor of 2 is within the range of uncertainties for evaluations of nuclear power plant accidents.

Policy Statement on Exemption from Regulatory Concern

In SECY-89-360, the staff formulated a policy statement on exemptions from regulatory control that reflected guidance provided by the Commission in a Staff Requirements Memorandum of October 13, 1989. A discussion of the information available to the staff on the health effects of radiation was included in Appendix A of the Policy Statement - "Dose and Health Effects Estimation." In that discussion, the staff calculated hypothesized incremental annual risk and hypothesized lifetime risk from continuing annual dose using a risk coefficient of 5×10^{-4} per rem for low-LET radiation. Selection of this value was made with general knowledge of the then pending conclusions of the BEIR V report. As a result, the risk basis of the policy's individual and collective dose criteria are consistent with BEIR V as indicated in the memorandum to the Commission from the Executive Director for Operations dated January 10, 1990. No change to the policy statement is required at this time. /Agree

Revision of 10 CFR Part 20

The revisions to the Commission's basic radiation protection standards in 10 CFR Part 20 reflect decreases in the allowable doses both for occupational exposure and for control of doses to members of the public. The direction of these changes is consistent with the new risk estimates which indicate higher potential risks associated with radiation exposure.

The staff has ongoing studies to evaluate the impact upon the nuclear industry of major additional reductions in the dose limits. However, until the recommendations of the ICRP and the NCRP (and possibly revised Federal guidance) are available, the staff believes that further reductions in the dose limits are not urgently required. Due to the practice of ALARA and the existence of other regulations (such as Appendix I to 10 CFR Part 50), radiation doses to the majority of workers and the public are well below the current (or revised) Part 20 dose limits. Therefore, only a few individuals are exposed at or near the limits, and most of these will not be exposed at such levels for many years. /Agree

Modification of the current revised Part 20 would require rulemaking and at least an additional round of public comments. Based upon past experience, this could introduce a delay of three years in the issuance of the revised Part 20. The staff believes that the Part 20 revision should be issued expeditiously and, if the situation warrants, amended at a later date after a scientific consensus emerges on revised dose limits. At that time, the staff should also have available information to estimate the impacts of a dose limit reduction rulemaking.