Presented at the Symposium on Known Effects of Low Level Radiation Exposures, Division of Cancer Control and Rehabilitation of the National Cancer Institute, Mideast Center for Radiological Physics, Pittsburgh, PA, April 25, 1979

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THE 1979 REPORT OF THE ADVISORY COMMITTEE ON THE BIOLOGICAL EFFECTS OF IONIZING RADIATION (THE BEIR REPORT)

THE EFFECTS ON POPULATIONS OF EXPOSURE TO LOW LEVELS OF IONIZING RADIATION

IMPLICATIONS FOR NUCLEAR ENERGY AND MEDICAL RADIATION

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The 1979 Report of the Advisory Committee on the Biological Effects of Ionizing Radiation (The BEIR Report)

The Effects on Populations of Exposure To Low Levels of Ionizing Radiation

Implications for Nuclear Energy and Medical Radiation[1,2]

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THE BEIR III REPORT

1979 Report of the Committee on the

Biological Effects of Ionizing Radiation

National Academy of Sciences-National Research Council

INTRODUCTION

My assignment this morning is to try to give some sort of general background of the implications the 1979 Report of the Committee[1] on the Biological Effects of Ionizing Radiation, National Academy of Sciences-National Research Council, (The BEIR Report) may have on societal decision-making in the regulation of activities concerned with the health effects of low-level man-made radiation (Table 1). I shall try to discuss how certain of the areas addressed by the 1979 BEIR Committee Report attempt to deal with the scientific basis for establishing appropriate radiation protection guides, and how such a Report may not necessarily serve as a review and evaluation of existing scientific knowledge concerning radiation exposure to human populations. Whatever I may consider important in these discussions, I speak only as an individual, and in no way do I speak for the BEIR Committee whose present deliberations are soon to become available. It would be difficult for me not to be somewhat biased and directed in favor of the substance of the BEIR Reports (1-3), since as an individual, I have been sufficiently close to the ongoing scientific deliberations of agreement and disagreement as they developed over the past 9 years.

I think the best thing for me to do is to describe very briefly some of the characteristics of certain aspects of the past and present BEIR Reports (1-3) which may apply to <u>societal decision-making</u> as regards present and future <u>nuclear energy needs and medical care services</u> wherever possible, and to speculate with some educated guessing what we might expect in future deliberations of such expert committees. We need consider only those problems about which most information is now available, only one-third of a century since the

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[1] Committee on the Biological Effects of Ionizing Radiations, National Academy of Sciences - National Research Council, Washington, D.C.

Table 1

The 1979 BEIR Report

1. Societal Decision-Making
2. Nuclear Energy Needs and Medical Care Services
3. Epidemiological and Experimental Studies
4. Public Acceptance
5. Concept of Risks to Health
6. Risk Estimates, Risk/Cost-Benefit
7. Comparison of Risks

birth of the atomic age following the bombings of Hiroshima and Nagasaki, to provide some understanding of those epidemiological and experimental studies likely to be of significance to critical societal factors which must ultimately be considered by all of us, and what relation these studies might have to the affairs of mice and man. Since decisions are to be made involving them, public acceptance must be gained on the basis of providing society with the services that it requires, or that it considers it requires, in the areas of nuclear energy needs and medical care, but with minimum, and wherever possible, negligible risks to its health and its environment.

At the same time, I want to raise a number of questions relating to the need and the wisdom of inclusion of numerical risk estimates in unofficial and official documents, since such documents and such numbers are available to all, to be used and quoted in and out of context. Further, I shall address the appropriate use of such risk estimates for assessment of risk-benefit relationships in the areas of medical radiation exposure and nuclear energy production. And lastly, I would like briefly to conjecture with you on the importance of keeping in proper perspective those pragmatic responsibilities of an informed society in the comparison and assessment of all its activities in which there are both acceptable and unacceptable risks, to try to get you to stand up and argue with me and with members of this symposium, or preferably argue with others in this room.

Why Do We Have Advisory Committees on Radiation?

Responsible public awareness of the possible health effects of ionizing radiations from nuclear weapons and weapons testing, from medical and industrial radiation exposure, and from the production of nuclear energy has called for expert advice

and guidance (Table 2). And, advisory committees on radiation of national and international composition have for many years met and served faithfully and effectively to report on three important matters of societal concern: (1) to place into perspective the extent of harm to the health of man and his descendants to be expected in the present and in the future from those societal activities involving ionizing radiation; (2) to develop quantitative indices of harm based on dose-effect relationships; such indices could then be used with prudent caution to introduce concepts of the regulation of population doses on the basis of somatic and genetic risks; and (3) to identify the magnitude and extent of radiation activities which could cause harm, to assess their relative significance, and to provide a framework for recommendations on how to reduce unnecessary radiation exposure to human populations. To a greater or lesser extent, each advisory committee on radiation--such as the UNSCEAR[2], the ICRP[3], the NCRP[4], and the BEIR--deal with these matters, but the reports of these various bodies are expected to differ because of the charge, the scope, and the composition of the Committee, and public attitudes existing at the time of the deliberations of that committee, and at the time of the writing of that particular report. The main difference of the BEIR is not so much from new data or new interpretations of existing data, but rather from a philosophical approach and appraisal of existing and future radiation protection resulting from an atmosphere of constantly changing societal conditions and public attitudes.

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[2]United Nations Scientific Committee on the Effects of Atomic Radiation, New York

[3]International Commission Radiological Protection, Sutton, Surrey, England

[4]National Council of Radiation Protection and Measurements, Washington, D.C.

Table 2

Why Do We Have Advisory Committees on Radiation?

1. To place into perspective the extent of harm to the health of man and his descendants to be expected in the present and in the future from those societal activities involving ionizing radiation;

2. To develop quantitative indices of harm based on dose-effect relationships; such indices could then be used with prudent caution to introduce concepts of the regulation of population doses on the basis of somatic or genetic risks;

3. To identify the magnitude and extent of radiation activities which could cause harm, to assess their relative significance, and to provide a framework for recommendations on how to reduce unnecessary radiation exposure to human populations.

What is the BEIR Report?

The BEIR Report of the National Academy of Sciences - National Research Council Committee on the Biological Effects of Ionizing Radiation is the record of deliberations of an expert scientific advisory committee (the BEIR Committee) and deals with the scientific basis of the health effects in human populations exposed to low levels of ionizing radiation. The Report broadly encompasses two areas: (1) it reviews the current scientific knowledge---laboratory experiments and epidemiological surveys---concerning radiation exposure of human populations and the long-term health effects of low-level ionizing radiation; (2) it evaluates and analyzes these long-term health effects---both somatic and genetic effects---in relation to the risks from exposure to low level ionizing radiation. The BEIR Committee is an advisory committee of the National Academy of Sciences - National Research Council. It presently consists of 22 scientific members, selected for their special scientific expertise in areas of biology, biophysics, biostatistics, epidemiology, genetics, medicine, physics, public health, and the radiological sciences. The Report of this advisory committee has, in the past, become an important reference text as a scientific basis for the development of appropriate and suitable radiation protection standards.

How Will The 1979 BEIR Report Be Of Value?

The BEIR Reports of 1972 (2) and 1977 (3), the Report of the 1955 BEAR Committee[5] (4,5), the parent Committee, and the forthcoming 1979 BEIR-III Report (1)

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[5]Committee on the Biological Effects of Atomic Radiation, National Academy of Sciences - National Research Council, Washington, D.C.

all differ from one or more of the other Committee Reports of the UNSCEAR (6-9), the ICRP (10-13), the NCRP (14,15) and of other national councils and committees (16,17), in five important ways (Table 3). First, the BEIR Report is not intended to be an encyclopedic reference text, but rather a usable document. A usable document is soon frayed, dog-eared, underlined, and marginated. Thus, the conclusions, recommendations, and appendices are purposefully presented in a straightforward way so that the Report will be useful to those responsible for decision-making concerning regulatory programs involving radiation in the United States. There is no intent, that I can perceive in the BEIR Reports, to make the task any easier or to set the direction for those decision-makers who must take into account the considerations of science and technology and the relevant sociological and economic matters in the development of such regulatory programs. The BEIR Committee has seriously deliberated these issues, and has responsibly addressed them to a greater or lesser extent.

Second, the experimental data and epidemiological surveys are carefully reviewed and assessed for their value in estimating numerical risk coefficients for the health hazards to human populations exposed to low levels of ionizing radiation. Such devices require scientific judgment and assumptions based on the available data only, and has led to disagreement not only outside the committee room, but among committee members, as well. But such disagreement centers not on the scientific facts or the epidemiological data, but rather on the assumptions and interpretations of the available facts and data. Therefore, the BEIR Report uses a particularly valuable format for decision-making, viz., the numerical risk estimates derived are presented logically after the evaluation of the scientific facts and the epidemiological data, and the scientific assumptions on which they are based.

Table 3

How Will the 1979 BEIR Report Be of Value?

1. Useful document for decision-makers
2. Estimation of numerical risk estimates, e.g., cancer
3. Does not set radiation protection standards
4. Consideration of medical-dental radiation exposure
5. Risk-assessment, benefit-risk assessment

Third, the BEIR Report does not set radiation protection standards. However, it suggests that those that do should always consider societal needs at that time, so that standards are established on levels of radiation exposure which are not necessarily absolutely safe, but rather those which are considered as appropriately safe for the existing circumstances at the time to fill society's needs.

Fourth, medical and dental radiation exposure is considered of appropriate concern to the health of the public. In view of the enormous growth of medical and dental radiological health care delivery in the United States, the BEIR Committee recommends that medical and dental radiation exposure can and should be reduced to a large extent without impairing the medical or dental benefits to be derived by the individual and to society (1-3).

Fifth, no other advisory committee on radiation has so consistently recommended the need to assess the benefits from radiation to be derived in relation to the risks from radiation to be incurred (1-3). However difficult, tedious and pedestrian this task may be, the BEIR Committee recognized that in any society with limited resources, risk assessment alone could prove to be an academic exercise without some form of benefit assessment to which it can relate. Such benefit-risk, and subsequently cost-effectiveness assessments are essential for societal decision-making for establishing appropriate radiation protection standards. Decisions can and must be made on the value and cost of any technological or other societal effort to reduce the risk by reducing the level of radiation exposure. This would include societal choices centered on alternative methods involving nonradiation activities available through a comparison of the costs to human health and to the environment (2).

What Are The Health Effects of Low Levels of Ionizing Radiations?

My remarks will be restricted primarily to those long-term health effects in humans following exposure to x-rays and to gamma rays from radioactive sources, since these are the ionizing radiations most often encountered in medicine and in nuclear industries. Briefly, low-level ionizing radiations can affect the cells and tissues of the body in three important ways (Table 4). First, if the damage occurs in one or a few cells, such as those of the blood-forming tissues, the irradiated cell can occasionally transform into a cancer cell, and after a period of time there is an increased risk of cancer developing in the exposed individual. This health effect is called carcinogenesis. Second, if the fetus is exposed during pregnancy, injury can occur to the developing cells and tissues, leading to developmental abnormalities in the newborn. This health effect is called teratogenesis. Third, if the injury is in the reproductive cell of the testis or ovary, the hereditary structure of the cell can be altered, and the injury can be expressed in the descendants of the exposed individual. The health effect is called mutagenesis or a genetic effect.

There are a number of other possible biological effects of ionizing radiations, such as cataracts of the lens of the eye, or impairment of fertility, but these three important health effects - carcinogenic, teratogenic and genetic - stand out because: (a) a considerable amount of scientific information is known from epidemiological studies of exposed human populations and from laboratory animal experiments; and (b) we believe that any exposure to radiation at low levels of dose carries some risk of such deleterious effects. Furthermore, as the dose of radiation increases above very low levels, the risk of these deleterious effects increases in the exposed human populations.

Table 4

Health Effects of Low Levels

Of Ionizing Radiations (1)

1. a) Carcinogenesis - one or a few cells

   b) Teratogenesis - cells of embryo or fetus

   c) Mutagenesis - germ cells

2. Any exposure carries some health risk

3. As radiation doses increase, deleterious health effects increase

It is these latter observations that have been central to public concern about the possible health effects of low-level ionizing radiation, and the task of determining standards for protection for the health of exposed populations. Reports of expert advisory committees are in close agreement on the broad and substantive issues of such health effects.

Based on careful statistical analyses of epidemiological surveys of exposed human populations, in conjunction with extensive research in laboratory animals on (a) dose-response relationships of carcinogenic, teratogenic and genetic effects, and on (b) mechanisms of cell and tissue injury, a number of important conclusions on the health effects of ionizing radiation has emerged (Table 5).

1. In regard to radiation-induced cancer, the solid cancers arising in the various organs and tissues, such as the female breast and the thyroid gland, rather than leukemia, are the principal late effects in individuals exposed to radiation. The different organs and tissues vary greatly in their relative susceptibility to radiation-induced cancer. The most frequently occurring radiation-induced cancers in man include primarily in decreasing order of susceptibility, the female breast, the thyroid gland, especially in young children and females, the blood-forming organs (causing leukemia), the lung, certain organs of the gastrointestinal tract, and the bones. There are influences, however, of age at the time of irradiation, of sex, and of the radiation factors and types affecting the cancer risk.

2. The effects on growth and development of the embryo and fetus are related to the stage at which exposure occurs. It would appear that a threshold level of radiation dose may exist below which gross effects will not be observed. However, these levels would vary greatly depending on theparticular abnormality.

Table 5

Health Effects of Low Levels

Of Ionizing Radiations

1. Solid cancers are principal late effects.

2. Tissues vary greatly in relative susceptibility to radiation-induced cancer.

3. Susceptibility in decreasing order: female breast, thyroid gland, blood-forming organs, lung, gastrointestinal tract, bones.

4. Teratogenic effects in embryo and fetus related to stage.

5. Threshold level for gross teratogenic effects.

6. Mutagenic effects based on laboratory mouse experiments. Risks increase linearly with dose.

3. The paucity of human data from exposed populations has made it necessary to estimate genetic risks based mainly on laboratory mouse experiments. Our knowledge of fundamental mechanisms of radiation injury at the genetic level permits greater assurance for extrapolation from laboratory experiments to man. Mutagenic effects are related linearly to radiation dose. With new information of the broad spectrum and incidence of serious genetically-related disease in man, such as mental retardation and diabetes, the risk of radiation-induced mutations affecting future generations takes on a new and special meaning.

However, there is still very much we do not know about the potential health hazards of low-level ionizing radiation (Table 6).

1. We do not know what the health effects are at dose rates as low as a few hundred millirem per year. It is probable that if health effects do occur, they will be masked by environmental or other factors that produce similar effects.

2. The epidemiological data on exposed human populations is highly uncertain as regards the forms of the dose-response relationships for radiation-induced cancer, and this is especially the case for low dose levels. Therefore, it has been necessary to estimate human cancer risk at low doses primarily from observations at relatively high doses. To do this, the linear no-threshold hypothesis has been frequently used, recognizing the lack of our scientific understanding of fundamental mechanisms of radiation-induced cancer in man. In considering the many forms of the dose-response relationships applied to epidemiological data, the linear model has emerged as the simplest and the most conservative, but not necessarily the universally correct form. However, it is not known whether the cancer incidence observed at high dose levels applies also at low levels.

Table 6

What We Do Not Know About Health Effects

Of Low-Level Ionizing Radiations

1. Effects at very low levels (a few hundred mrem).

2. Dose-response relationships for radiation induced cancer.

3. Cannot estimate repair of injured cells and tissues at low doses and dose rates.

4. Precise radiation doses absorbed.

5. Complete cancer incidence in irradiated populations.

6. Role of competing host factors---biological, chemical, or physical.

3. As yet, we have no reliable method of estimating the repair of injured cells and tissues of the body exposed to very low doses and dose rates. And, further, we cannot identify those persons who may be particularly susceptible to radiation injury.

4. From the epidemiological surveys of irradiated populations exposed in the past, we have only limited information on the precise radiation doses absorbed by the tissues and organs, and we do not know the complete cancer incidence in each population, since new cases of cancer continue to appear with the passing of time. Thus, any estimation of risks to health based on such limited dose-response information must be incomplete.

5. Finally, we do not know the role of competing environmental and other host factors - biological, chemical or physical factors - existing at the time of exposure, or following exposure, which may affect and influence the carcinogenic, teratogenic, or genetic effects of low-level ionizing radiation.

Should We Determine Radiation Risk Estimates?

Radiation is firmly-established as a technological activity of modern man; there is no easy way of assessing its worth in medicine, in industry, and especially in energy, and in war and in peace (Table 7). But its potential or real benefits do not necessarily outweigh the potential or real risks to human health and to the environment in every instance. What is needed is a method for comparison of these risks and benefits for societal approbation and guidance (1-3). It is logical that to a large extent such guidance and regulation of population doses should be based on the quantitative estimation of risk (1). And here we have a quantitative approach. This concept was introduced by the original 1955 BEAR Committee (5,6), and at that time, the

Table 7

Should We Determine Radiation

Risk Estimates?

1. Risks versus benefits
2. Quantitative estimation of risks to health
3. Dose-response relationships
   a. Carcinogenesis
   b. Teratogenesis
   c. Mutagenesis
4. Radiation-induced cancer in man
5. Linear, no-threshold, dose-response relationship

basis of genetic risks was used. But, with the emergence of a large body of scientifically convincing epidemiological data on radiation-induced cancer in exposed human populations, the use of numerical risk estimates, particularly in official documents, begs the question of how safe is appropriately safe for those societal activities in which radiation exposure however small, is nevertheless unavoidable? Thus, it is not surprising that including numerical estimates of serious risks to health in official documents will always prove to be a controversial issue. This arises out of the most perplexing problem of all, and about which we know so little, that of the dose-response relationships for radiation-induced human cancer at low levels of dose (18-20). Here, there is a very large literature, but very little quantitative information on human exposure to radiation with which to work in order to make broad and fundamental societal decisions.

A general hypothesis for estimating the excess cancer risk in irradiated human populations, based on theoretical considerations, extensive experimental animal studies and epidemiological surveys, suggests that a complex dose-response relationship exists between radiation dose and cancer incidence (18-21). The most widely accepted model (Figure 1), based on the available information and consistent with both knowledge and theory, takes the complex linear-quadratic form $I(D) = (\alpha_0 + \alpha_1 D + \alpha_2 D^2) \exp(-\beta_1 D - \beta_2 D^2)$, where I is the cancer incidence in the irradiated population at dose D in rad, and α_0, α_1, α_2, β_1 and β_2 are non-negative constants. The multicomponent curve contains an initial upward-curving linear and quadratic functions of dose which represent the process of cancer induction, i.e., carcinogenesis. This is modified by an exponential function of dose which represents the competing effect of cell killing at high doses. The dose-response function illustrated

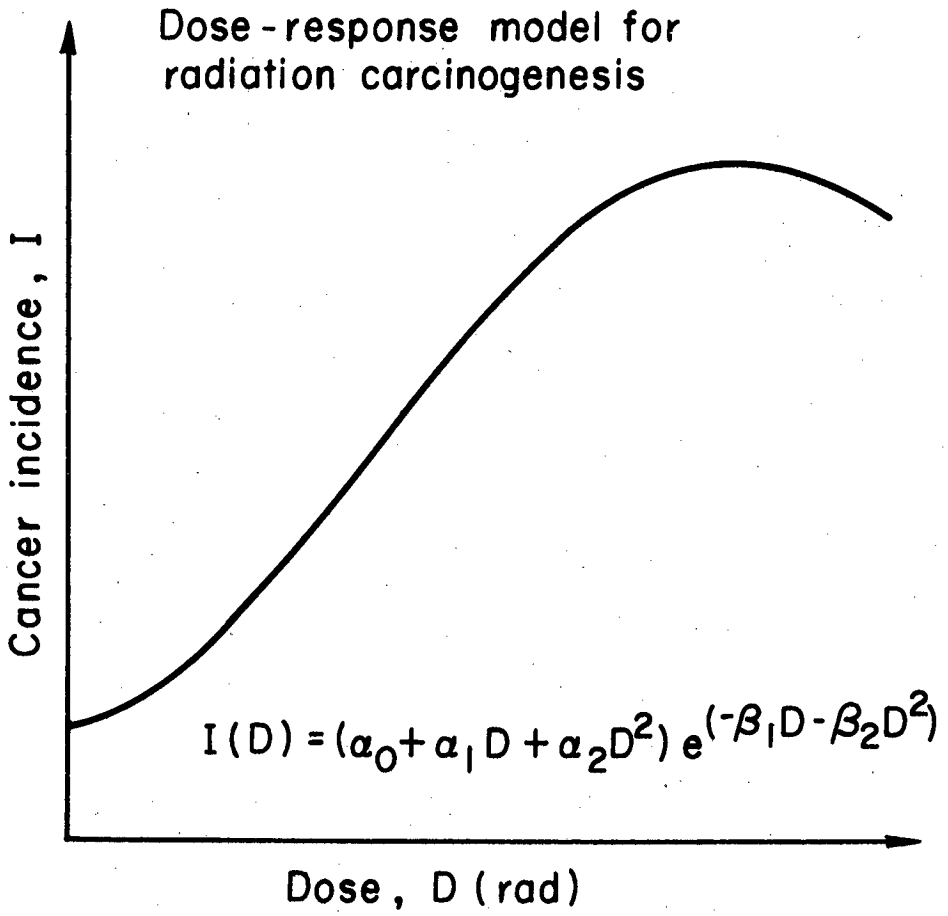

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Figure 1

in Figure 1 encompasses all these parameters and is necessarily complex, but certain of the parameters can be theoretically determined. α_0, the control or natural incidence of cancer in the population, is the ordinate intercept at 0 dose of the dose response curve. α_1 is the initial slope at 0 dose, defining the linear component in the low dose range. α_2 is the curvature near 0 dose at the upward-curving quadratic function of dose. β_1 and β_2 are the slopes defining the cell killing function, that is, the downward-curving function in the region of high dose (21).

Review of a large number of the available dose-incidence curves for carcinogenesis in irradiated populations has demonstrated that for different radiation-induced cancers, whether in man or in animals, the extent of variations in the shapes of the curves does not permit determination of any of these values with precision, or of assuming their values, or of assuming any fixed relationship between two or more of these parameters. In the case of the available epidemiological data on irradiated populations, this general dose-response mathematical form cannot be universally applied. It has become necessary to simplify the model by reducing the number of parameters or by eliminating those parameters which will have the least effect on the form of the curve in the dose range at low levels of radiation. Such simpler models with increasing complexity are illustrated in Figure 2, e.g., linear, quadratic, linear-quadratic, and finally, the linear-quadratic form with an exponential modifier due to the effects of cell killing similar to the general form in Figure 1.

There has been much concern among radiation scientists centering on one particular form of radiation-dose cancer-incidence relationship, generally a linear, no threshold dose-response relationship, that is, where the effect

SHAPES OF DOSE RESPONSE CURVES

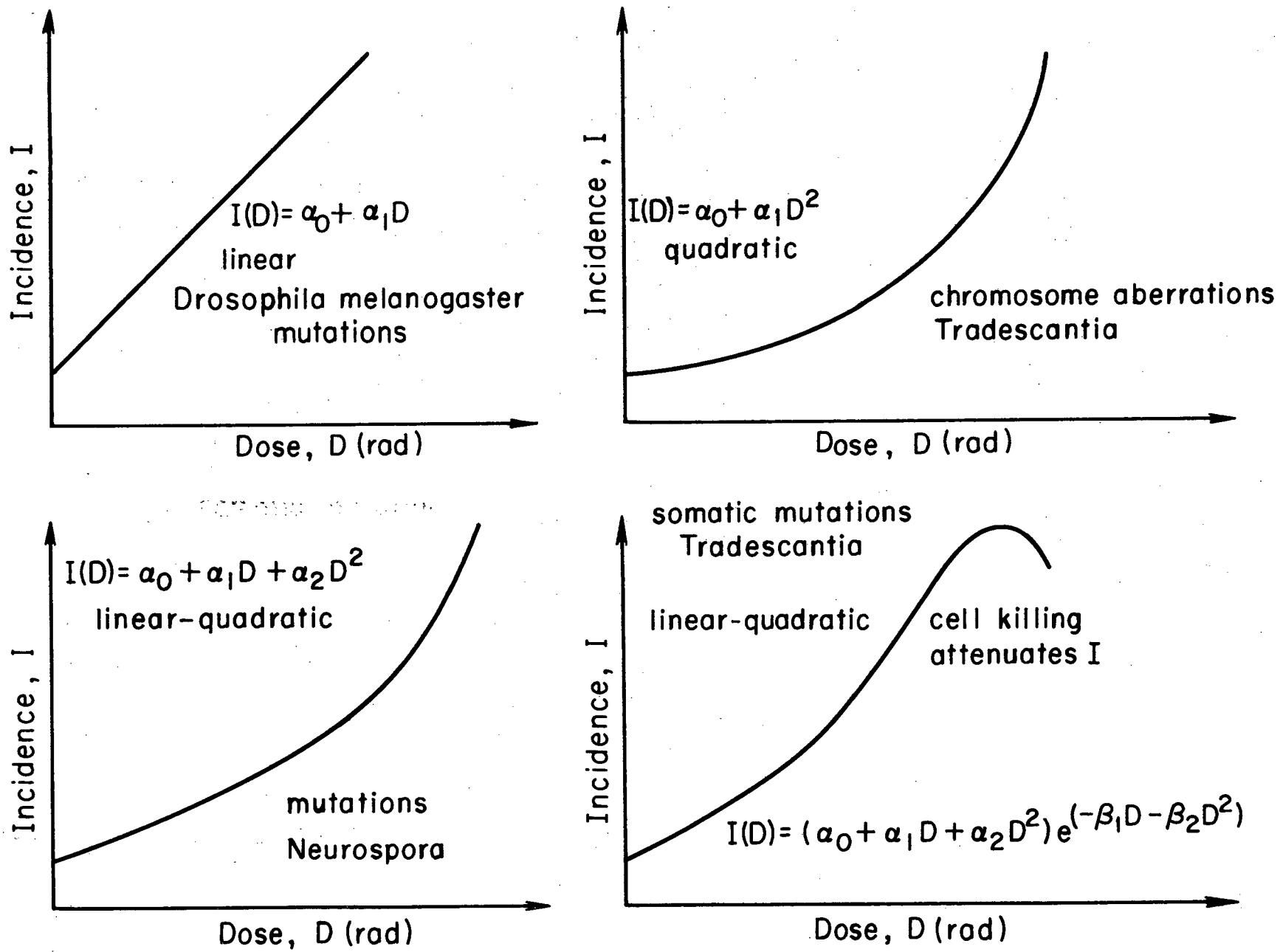

Figure 2

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observed is linearly related to dose (Figure 2) (18-20). There is no reason to assume that the linear form, or any form of dose-response relationship, is the inflexibly correct, or the appropriate function either for cells in tissue culture, or for animals in cages, or for man in his society, to warrant universal application in determining public health policy on radiation protection standards. The lack of our understanding of the fundamental mechanisms of radiation-induced cancer in man, and the recognition that the dose-response information from human data is highly uncertain, particularly at low levels of dose, does not relieve decision-makers of the responsibility for determining public health policy based on radiation protection standards. What has emerged from the committee rooms is that estimates of risk, particularly at low doses, must depend more on what is assumed about the shape of the mathematical form of the dose-response function than on the available epidemiological data. In considering the many mathematical functions of increasing complexity, the linear form has emerged by default as the simplest, but not necessarily the correct form. We are aware of experimental and theoretical considerations which suggest that various and different mathematical forms of dose-repsonse relationships may exist for different radiation-induced cancers in exposed human populations, indeed for different somatic and genetic mutations (18-21). It is therefore essential that very precise explanations and qualifications of the assumptions and procedures involved in determining such risk estimates are provided, and this has been done explicitly in the BEIR Committee Report containing the estimates of risk. Thus, given all the limitations, it appears that radiation risk estimates for cancer induction by radiation based on linearity are not necessarily spurious, but are estimates only--based solely on what is known. For low LET radiations, such as x-rays and gamma rays, at

low doses, risk estimates based on linearity could be high, and thus regarded as an upper limit. For high LET radiations, such as neutrons and alpha particles, at low doses, risk values may be overestimates or underestimates.

Whatever the case may be made for a particular mathematical form chosen for a dose-response relationship at very low doses, the inclusion of risk estimates thus derived appears not only appropriate, but essential, if the deliberations of the BEIR Committee are to be used for determining public health policy. Until much more information is available on the mechanisms of radiation carcinogenesis, however, the epidemiological data alone do not help in estimating the precise risk at low doses from data obtained at high doses. The problem, therefore, which must face every expert advisory committee on radiation, is not whether it should include numerical risk estimates, however crude and imprecise, for official documentation, but how it should improve the accuracy of the numerical risk estimates based on epidemiological surveys and laboratory experiments. This is particularly important, since it is now very well known that no matter how carefully the imprecise risk estimates are to be qualified in the text of any official committee report, these numbers are invariably used and quoted by others in and out of context. In such matters of responsible scientific policy, the governmental agencies, the legislative bodies, the regulatory bodies, the radiation-related industries, the consumer advocate groups, and the public media, do not necessarily enjoy the privilege to act irresponsibly, as may be accorded the average uninformed, but concerned, citizen. In spite of these inevitable consequences, nevertheless, the 1979 BEIR Report accepted the responsibility to assess the need to establish the most reliable estimate of range of health effects possible in human populations to exposure of low levels of ionizing radiation, in the light

of all available knowledge. This decision was necessary, and mainly because certain numerical risk estimates will be used freely in arguments and counter-arguments, and often used irresponsibly, in the public forum.

From the dose-response relationships used, and if it is assumed that there is no appreciable effect of dose rate or fractionation of dose, an estimate can be made of the absolute risk of radiation-induced cancer, the major risk of radiation to man. The overall figure derived is about one to five excess cancer cases per million exposed persons per year per rad, depending on the organ or tissue site, with evidence of age-, sex-, and time-dependencies. There are no good reasons to assume, in the determination of risks to health, that each exposed human population is identical, and thus, the risks estimated derived should be the same. Each cohort population in the human experience has a widely identifiable set of variables; there are no identical control populations. In the case of the human epidemiological surveys on cancer induction by radiation, such biological and physical factors as initiating and promoting mechanisms, damage to vital biologically-active macromolecules, hormonal and immunological imbalances, cellular proliferation, genetically-selected susceptible subpopulations, dose, dose-rate, duration of exposure, physical factors of radiation quality to name just a few, all interact to result in a clinical entity in man which we call cancer (Table 8). The margin for error is large in every case, primarily because of the uncertain nature of the limited data available. Thus, in the estimation of such radiation risks for man, it follows that comparisons of all populations should be made, but only with those data that are considered reliable, and not apt to change significantly over the coming years. However, any generalized summing-up to arrive at a total numerical index of harm based on such limited epidemiological and experimental

Table 8

Human Radiation Carcinogenesis

Some Uncontrolled Variables

1. Initiating and promoting mechanisms
2. Damage to DNA
3. Cellular proliferation
4. Hormonal and immunological imbalance
5. Genetically-predetermined susceptibility
6. Radiation dose and dose rate
7. Duration of exposure
8. Physical factors of radiation quality
9. Lack of controls

information without exercising cautious judgement can compound errors inappropriately, and destroy the credibility of the limited interpretation of the reliable epidemiological data that are available.

How Should We Quantitate Our Radiation-Induced Cancer Risk Estimates?

The tissues and organs involved in radiation-induced cancer in man about which we have the most reliable epidemiological data from a variety of sources from which corroborative risk estimates have been obtained include the bone marrow (16,22-28), the thyroid (22,23,28-30), the breast (22,23,28,31-39), and the lung (22,40-42). The data on bone (22,28,43-46) and the digestive organs (22,23,25-27) are, at best, preliminary, and do not approach the precision of the others. In several of these tissues and organs, risk estimates are obtained from very different epidemiological surveys, some followed for over 25 years, and with adequate control groups. There is impressive agreement when one considers the lack of precision inherent in the statistical analyses of the case-finding and cohort study populations, variability in ascertainment and clinical periods of observation, age, sex and racial structure, and different dose levels, and constraints on data from control groups.

By far, the most reliable and consistent data have been those of the risk of leukemia, which come from the Japanese A-bomb survivors (22,42), the ankylosing spondylitis patients treated with x-ray therapy in England and Wales (25-27,47,48), the metropathia patients treated with radiotherapy for benign uterine bleeding (51-53), and the tinea capitis patients treated with radiation for ringworm of the scalp (30,49,50) (Table 9). There is evidence of an age-dependence and a dose-dependence, a relatively short latent period of a matter of a few years, and a relatively short period of expression, some 10 years.

Table 9

Risk Estimates of Lifetime Incidence

Radiation-Induced Leukemia and Thyroid Cancer

Tissue-Organ Population	Absolute Risk Estimate of Lifetime Incidence (Cases/10^6/rad)		Dependence
LEUKEMIA			age and dose
Japanese A-bomb Survivors	Males	28	
Ankylosing Spondylitis Patients			
Tinea Capitis Radiotherapy Patients	Females	19	
Pelvic Radiotherapy Patients			
THYROID CANCER			age and sex
Neck and Mediastinum Radiotherapy Patients	Males	55	
Tinea Capitis Radiotherapy Patients			
Marshallese Islanders	Females	162	
Japanese A-bomb Survivors			

The lifetime risk is of the order of 19 to 28 excess leukemia cases per million exposed persons per rad. This cancer is uniformly fatal (1,9,22,27,28,55).

The data available on thyroid cancer are more complex; the surveys include the large series of children treated to the neck and mediastinum for enlarged thymus (28,29), children treated to the scalp for tinea capitis (30,49,50), and the Japanese A-bomb survivors (22) and Marshall Islanders (54) exposed to nuclear explosions (Table 9). Here, there is an age-dependence and sex-dependence--children and females are more sensitive. The lifetime risk is approximately 55 to 162 excess thyroid neoplasms per million exposed persons per rad. Although the induction rate is high, the latent period is relatively short, and it is probable that no increased risk will be found in future follow-up. In addition, most tumors are either thyroid nodules, or benign or treatable tumors, and only about 5 percent of the radiation-induced thyroid tumors are fatal (55).

In very recent years, much information has become available on radiation-induced breast cancer in women (22,31-39) (Table 10). The surveys include primarily women with tuberculosis who received frequent fluoroscopic examinations for artificial pneumothorax, post-partum mastitis patients treated with radiotherapy, and the Japanese A-bomb survivors in Hiroshima and Nagasaki. Here, there is an age- and dose-dependency, as well as a sex-dependency, and the latent period is long, some 20 to 30 years. The estimated lifetime induction rate is about 141 excess cancers per million women exposed per rad. Perhaps about half of these neoplasms are fatal (20,22,27,28,55).

Another relatively sensitive tissue, and a complex one as regards radiation dose involving parameters of the special physical and biological characteristics of the radiation quality, is the epithelial tissue of the

bronchus and lung (Table 10). The information from the Japanese A-bomb survivors (22-24,42), and uranium miners in the United States and Canada (40-41), and the ankylosing spondylitis patients in England and Wales (25-27) provide a risk estimate of lung cancer of approximately 39 to 45 excess cancers per million persons exposed per rad. There is some evidence of age-dependence from the Japanese experience and a relatively long latent period. This cancer is uniformly fatal (1,9,22,27,28,55).

The lifetime risk of radiation-induced bone sarcoma (Table 10), based primarily on radium and thorium patients who had received the radioactive substances for medical treatment, or ingested them in the course of their occupations (43-46) is low, possibly only 0.05 excess cancer deaths per million exposed persons per rad. For all other tumors arising in various organs and tissues of the body, values are extremely crude and preliminary estimates and probably less than 10 to 20 excess cancers per million exposed persons per rad (Table 11).

There is now a large amount of epidemiological information from various comprehensive surveys from a variety of sources; the most extensive, perhaps, include the Japanese A-bomb survivors (22), the patients treated to the spine for ankylosing spondylitis (25-27,47-78), the metropathia patients (51,52), and the early radiologists (56,57). These data indicate that leukemia is now no longer the major cancer induced by radiation, and that solid cancers are exceeding the relative incidence of radiation leukemia by a factor as high as five (55). That is, in view of the long latent periods for certain solid cancers to become manifest, it can be estimated that perhaps after some 30 years following radiation exposure, the risk of excess solid cancers may prove to be some five times the risk of excess leukemia. This does not necessarily imply that we can readily sum up all the radiation malignancies of the body and neglect the obvious lack of precision of certain of the

Table 10

Risk Estimates of Lifetime Incidence

Radiation-Induced Breast, Lung and Bone Cancer

Tissue-Organ Population	Absolute Risk Estimate of Lifetime Incidence (Cases/10^6/rad)		Dependence
BREAST CANCER TB-Fluoroscopy Patients Mastitis Radiotherapy Patients Japanese A-bomb Survivors	Females	141	age and dose
LUNG CANCER Japanese A-bomb Survivors	Males	39	age
Uranium Miners Ankylosing Spondylitis Patients	Females	45	
BONE CANCER Ra-226 Ingestion Workers Ra-224 Treatment Patients Tinea Capitis Radiotherapy Patients		0.05	age and duration of exposure

Table 11

Risk Estimates of Lifetime Incidence

Radiation-Induced Cancer - Other Cancers

Tissue-Organ Population	Absolute Risk Estimate of Lifetime Incidence (Cases/10^6/rad)		Dependence
Brain, Salivary Glands Stomach, Liver, Colon	Males	21	unknown
	Females	27	
Scalp, *in utero*, neck, spine, Japanese survivors, and pelvis irradiation			
Esophagus, Small Intestine, Rectum, Pancreas, Ovary, Paranasal Sinuses, Lymphoid Tissue Irradiation	Males	39	unknown
	Females	45	

epidemiological studies, particularly as regards radiation dose distribution, ascertainment, latency periods, and other important physical and biological parameters. The BEIR (1,3), the UNSCEAR (8,9) and the ICRP (10-13) Reports have done this in different ways and based primarily on the studies of the Japanese A-bomb survivors (22), and to a much lesser extent, from data on the ankylosing spondylitis patients (25-27), the metropathia patients (51,52), the tinea patients (30,49,50), and similar epidemiological surveys carefully followed, many of which now have adequate control study populations, a very crude figure of the total lifetime excess absolute risk of radiation-induced cancer deaths can be derived ($\sim$75 to 125 excess cancer deaths/10^6/rad). This figure for all malignancies from low LET radiation, i.e., x-rays and gamma rays, delivered at low doses would be a considerable overestimate of the true risk, and the more accurate value would be less than 100. The actual figure may be as low as 70 excess cancer cases per million persons exposed per rad total lifetime risk, a large fraction of which would not necessarily be fatal (55). This estimated figure remains very unreliable, but it does provide a very rough figure for comparison with other estimates of avoidable risks, or voluntary risks, encountered in everyday life.

What Can We Conclude?

The present scientific evidence and the interpretation of available data can draw very few firm conclusions on which to base scientific public health policy for radiation protection standards. The setting of any permissible radiation level or guide remains essentially an arbitrary procedure (60,61). Based on the radiation risk estimates derived, any lack of precision does not minimize either the need for setting public health policies

nor the conclusion that such risks are extremely small when compared with those available of alternative options, and those normally accepted by society as the hazards of everyday life (2,55,60,62). When compared with the benefits that society has established as goals derived from the necessary activities of energy production and medical care, it is apparent that society must establish appropriate standards and seek appropriate controlling procedures which continue to assure that its needs and services are being met with the lowest possible risks (2,55,63). This implies continuing decision-making processes in which risk-benefit and cost-effectiveness assessments must be taken into account (2,58,61,62).

The gap between our scientific knowledge and our societal needs appears to be continually widening. In a third of a century of inquiry, embodying among the most extensive and comprehensive scientific efforts on the health effects of an environmental agent, much of the practical information necessary for determination of radiation protection standards for public health policy is still lacking. It is now assumed that any exposure to radiation at low levels of dose carries some risk of deleterious effects. However, how low this level may be, or the probability, or magnitude of the risk, still are not known. Radiation and the public health, when it involves the public health, becomes a broad societal problem and not solely a scientific one, and to be decided by society, most often by men and women of law and government. It is not an exercise in statistical theory or laws of chance. Our best scientific knowledge and our best scientific advice are essential for the protection of the public health, for the effective application of new technologies in medicine and industry, and for guidance in the production of nuclear energy. Unless man wishes to dispense with those activities which

inevitably involve exposure to low levels of ionizing radiations, he must recognize that some degree of risk to health, however small, exists. In the evaluation of such risks from radiation, it is necessary to limit the radiation exposure to a level at which the risk is acceptable both to the individual and to society. A pragmatic appraisal of how man wishes to continue to derive the benefits of health and happiness from such activities involving ionizing radiation in times of everchanging conditions and public attitudes in our resource-limited society is the task which lies before each expert advisory committee on the biological effects of ionizing radiation, now and in future years.

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