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PERSPECTIVES OF DECISION-MAKING AND ESTIMATION OF RISK IN POPULATIONS EXPOSED TO LOW LEVELS OF IONIZING RADIATIONS

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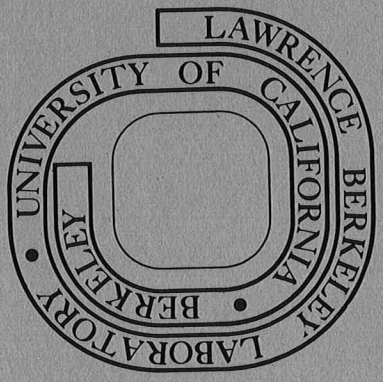

Perspectives of Decision-Making and Estimation of Risk In Populations Exposed to Low Levels of Ionizing Radiations[1,2]

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INTRODUCTION

My assignment this morning is to try to give some sort of general background on the implications certain of the national and international committee reports on radiation risks may have on societal decision-making in the regulation of activities involving man-made radiation (Table 1). I shall try to center on how certain of the areas addressed by such committee reports attempt to deal with the scientific basis for establishing appropriate radiation protection guides, and how such reports 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 any Committee, and particularly I do not speak for the BEIR Committee[1] whose present deliberations are soon to be published. It would be difficult for me not to be somewhat biased and directed by the past BEIR Reports (1,2), and particularly the 1972 and 1977 Reports, since as an individual, I was, nevertheless always sufficiently close to the ongoing scientific deliberations of agreement and disagreement as they developed over the past 8 years.

To speak as an individual under such circumstances is a chary business, and so I think the best thing for me to do is to describe very briefly some of the characteristics of certain aspects of the published BEIR Reports (1,2) which may apply to societal decision-making as regards present and future energy needs and health care delivery services 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

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

Table 1

Introduction

1. The BEIR Reports
2. Societal Decision-Making
3. Energy Needs and Health Care Services
4. Public Acceptance
5. Epidemiological and Experimental Studies
6. Concept of Risks to Health
7. Risk Estimates, Risk/Cost-Benefit, Cost-Effectiveness Analyses
8. 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 will have 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 energy needs and medical care, but with minimum, and wherever possible, negligible risks to its health and to its environment.

At the same time, I want to raise a number of questions relating to the need and wisdom for inclusion of numerical risk estimates in unofficial and official documents. 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 man-made risk estimates for assessment of risk-benefit relationships, and cost-effectiveness analysis, and particularly those areas of my own interests in regard to medical radiation and to energy production. And lastly, I would like to conjecture with you on the importance of keeping in proper perspective those pragmatic responsibilities of 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 Have Committees?

Man enjoys a passionate need to record his scientific experiences, to discuss and to debate them, and to question them. The response to public concern about the possible health effects of 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, effectively, and responsibly, 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 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 Committee--such as the ICRP[2], the UNSCEAR[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

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

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

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

Table 2

Why Have Committees?

1. Extent of harm to health; perspectives
2. Quantitative indices of harm
3. Societal activities involving radiation
4. The BEIR Reports
5. Changing societal conditions and public attitudes

particular report. I would submit that the main difference of the BIER Reports (1, 2) in the past and possibly to be expected in the future (3), is not so much from any 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.

Are the BEIR Reports of Value?

The BEIR Reports of 1972 (1) and 1977 (2), the Report of the 1955 BEAR Committee (4,5), the parent Committee, and I would anticipate that the forthcoming 1979 BEIR-III Report (3) all differ from one or more of the other Committee Reports of the UNSCEAR (6,7,8,9), the ICRP (10,11,12,13), the NCRP (14,15) and of other national councils and committees (16,17), in five important ways (Table 3). First, the BEIR Reports (1,2) were never 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 control programs involving radiation in the United States. There has been no intent, that I can perceive in the 1972 and 1977 BEIR Reports (1,2), nor would I anticipate any change in philosophy in the 1979 Report (3) to be published, to make the task any easier or to set the direction for those decision-makers who must take into account those considerations of science and technology and those sociological and economic matters which must be taken into account in the development of such regulatory programs. The past BEIR Committees have seriously deliberated these issues, and have responsibly addressed them to a greater or lesser extent.

Second, the cogent experimental data and epidemiological surveys are carefully reviewed and assessed for their value in estimating numerical risk values for 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 even among committee members. But such disagreements center not on

Table 3

Are the BEIR Reports of Value?

1. Useful document for decision-makers
2. Estimation of numerical risk values
3. Do not set radiation protection standards
4. Consideration of medical-dental radiation
5. Risk-assessment, benefit-risk assessment, cost-effectiveness assessment

the scientific facts or the epidemiological data, but rather on the assumptions and interpretations of the available facts and data. Therefore, the BEIR Reports (1,2) used a format unlike the others, viz., the numerical risk estimates derived are presented logically after the compilations of data and the scientific assumptions on which they are based.

Third, the past BEIR Reports (1,2) carefully and loudly pronounce that they do not set radiation protection standards. However, they suggest 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, and for the first time in 1972 (1), medical and dental radiation exposure is considered of significant concern to the health of the public. Although the 1955 BEAR Committee (4,5) emphasized the significance of medical-dental exposure, it had fallen to the 1972 BEIR Committee (1) to assess this factor in the light of new epidemiological surveys since that time. And in view of the enormous growth of radiological health care delivery in the United States, the Committee recommended 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 (1,2).

Perhaps no other advisory committee on radiation had so consistently and repeatedly recommended the need to assess the benefits from radiation to be derived in perspective with the risks from radiation to be incurred (1,2). However difficult, tedious and pedestrian that task may be, the BEIR Committees recognized that in any society with limited resources, risk assessment would be an academic exercise without some form of benefit-risk assessment to which

it can relate. Cost-effectiveness assessment is essential for societal decision-making. 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 to society through a comparison of the costs to human health and to the environment (2).

Should Radiation Risk Estimates be Determined?

Radiation is now recognized as a firmly-established 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. 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 (1,2). It is logical that to a large extent such guidance and regulation of population doses should be based on the estimation of risk (1). And here we have a quantitative approach. Indeed, this was the concept introduced by the original 1955 BEAR Committee (4,5), and at that time, the 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 in those societal activities in which radiation exposure however small, is nevertheless unavoidable? Thus, it is not surprising that including numerical estimates of absolute or relative risk 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 (18,19,20). Here, there is a very large literature, but very little quantitative information with which to work in order to make broad and fundamental societal decisions.

A general hypothesis for estimating excess cancer risk, based on theoretical

considerations, extensive experimental animal studies and epidemiological surveys, suggests a complex relationship exists between radiation dose and cancer incidence (18,19,20). Land (21) has described perhaps the most widely accepted unifying model, based on the available information and consistent with both knowledge and theory which 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 (21). The multicomponent curve contains an initial upward-curving quadratic function of dose which represents 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 α and β parameters introduce important concepts, and in no epidemiologic surveys are they available in the dose ranges of interest. α_0 is the spontaneous incidence of cancer in a population in the absence of irradiation; it is above this incidence that excess risk is determined. α_1 is the excess cancer incidence per unit radiation dose (here, per rad) at low doses; this parameter is among the most difficult to determine. α_2 represents the additional carcinogenic effect of multiple-hit kinetics, here, two-hit ionizing events as compared with one-hit events. This results in a greater effect per rad at high doses as compared with lose-dose exposure. The exponential modifying factors β_1 and β_2 represent the cell killing effect at low dose and high dose exposures, respectively; here, too, there is a greater effect per rad at high dose exposure than at low doses. The dose-response function illustrated in Figure 1 encompasses all these parameters and is necessarily complex, but certain of the parameters can be theoretically determined. α_0, the control 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).

Land (21) has reviewed a large number of the available dose-incidence curves for carcinogenesis in irradiated populations and has demonstrated that for different cancers, whether in man or in animals, the extent of variations in the shapes of the curves preclude determination of any of these values with precision, or assuming their values, or assuming any fixed relationship between two or more of these parameters. In the case of the available epidemiological data on irradiated populations, the general mathematical form in Figure 1 cannot be universally applied. It has become necessary, for estimation of the parameters available by curve-fitting, to simplify the model, insofar as possible, by reducing the number parameters or by eliminating those parameters which will have the least effect on the form of the curve in the dose range of interest. 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 relationship, that is, where the effect observed is linearly related to dose (Figure 2) (18, 19, 20). There

is no reason to assume that the linear form, or any form of dose-response relationship, is the inflexibly correct, or appropriate function either for cells in tissue culture, or for animals in cages, or for man in his society, to warrant use in determining public health policy on radiation protection standards. The lack of our understanding 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. Thus, we are all very much aware of those experimental and theoretical considerations which suggest that various and different mathematical forms may exist for different radiation-induced cancers in irradiated populations, indeed for different somatic and genetic mutations (18,19,20,21). 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 must be done explicitly in such committee reports containing 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 at low doses, risk estimates based on linearity could be high, and thus regarded as an upper limit, whereas for high LET radiations at low doses, risk values may be overestimates or underestimates.

Whatever the case may be made for a particular mathematical form chosen for a particular dose-response relationship at very low doses, the inclusion of risk estimates thus derived would appear not only appropriate, but essential, if these deliberations of an advisory 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, is whether it should include numerical risk estimates, however crude and imprecise, for official documentation. This is particularly important, since it is now very well established that no matter how carefully such crude risk estimates are to be qualified in the text of an official committee report, the precise numbers are inevitably 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 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 previous 1972 BEIR Report (1), and I anticipate the forthcoming one (3), as well, accepted the responsibility to assess the need to establish the most reliable estimate of range of effects possible on human populations to exposure of low levels of ionizing radiations, 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 counterarguments, and often used irresponsibly, in public discussion.

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 figure derived is about one to five excess cancer cases per million persons irradiated 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 absolute risk, that each exposed human population is identical, and thus, the risks estimated derived should be the same. Each subpopulation in the human 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, LET, RBE, to name just a few, all interact to result in a clinical entity in man which we call cancer (Table 4). Would we dare design a laboratory experiment with such callous disregard for Cartesian scientific method? The margin of 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 relatively reliable, and not apt to change significantly over the coming years. However, any summing-up to arrive at a total numerical index of harm based on such limited epidemiological and experimental information without exercising cautious judgement is not only compounding our errors inappropriately, but it is destroying the credibility of the limited interpretation of the reliable epidemiological data that are available.

Table 4

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. LET and RBE
9. Lack of controls
10. Clinical cancer in man

Should We Quantitate Our Risk Estimates?

The tissues and organs about which we have the most reliable 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, even within factors of 3 to 5 at most, when one considers the lack of precision inherent in the statistical analyses of the 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, now also available for the ankylosing spondylitis patients (47-48), the tinea capitis patients (30,49,50), the tuberculosis and mastitis patients (31-39), and the metropathia patients (51, 52).

By far, the most consistent data are those of the risk of leukemia, which come from the Japanese A-bomb survivors (22), the ankylosing spondylitis patients (25-27,47,48), the metropathia patients (51-53), and the tinea capitis patients (30,49,50) (Table 5). There is evidence of an age-dependence and a dose-dependence, and a lifetime risk of the order of 10 to 60 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 tend to be somewhat 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

Table 5

Risk of Radiation-Induced Leukemia and Thyroid Cancer[1]

Tissue-Organ Population	Absolute Risk Estimate (Cases/10^6/rad)	Dependence
LEUKEMIA	10 - 60	age and dose
Japanese A-bomb Survivors		
Ankylosing Spondylitis		
Tinea Capitis Radiotherapy		
Pelvic Radiotherapy		
THYROID CANCER	20 - 150	age and sex
Neck and Mediastinum Radiotherapy		
Tinea Capitis Radiotherapy		
Marshallese Islanders		
Japanese A-bomb Survivors		

[1]Modified from Pochin (55). See text.

tinea capitis (30,49,50), and the Japanese A-bomb survivors (22) and Marshall Islanders (54) exposed to nuclear explosions (Table 5). Here, there appears to be an age-dependence and sex-dependence--children and females are more sensitive--and a lifetime risk of approximately 20 to 150 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 neoplasms are either benign or treatable, and only about 3 percent of the radiation-induced thyroid tumors are fatal (55).

In very recent years, much information has now become available on radiation-induced breast cancer in women (22,31-39) (Table 6). The surveys include primarily the women with tuberculosis who received frequent fluoroscopic examinations for artificial pneumothorax, the mastitis patients, and the Japanese A-bomb survivors. Here, there appears to be an age- and dose-dependency, as well as a sex-dependency, and an estimated lifetime induction rate of about 30 to 200 excess cancers per million women exposed per rad. Only about one-third 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 RBE and LET, is the epithelial tissue of the lung (Table 6). The information from the Japanese A-bomb survivors (22-24,42), the uranium miners (40-41), and the ankylosing spondylitis patients (25-27) provide a risk estimate of lung cancer of approximately 20 to 100 excess deaths per million persons exposed per rad, with some evidence of age-dependence from the Japanese experience (1,9,22,27,28,55).

The lifetime risk of radiation-induced bone sarcoma (Table 6), based primarily on radium and thorium patients (43-46), and of other tumors arising in various organs and tissues, are extremely crude and probably less than 5 to

Table 6

Risk of Radiation-Induced Breast, Lung and Bone Cancer[1]

Tissue-Organ Population	Absolute Risk Estimate (Cases/10^6/rad)	Dependence
BREAST CANCER	30 - 200	age and dose
TB-Fluoroscopy Patients		
Mastitis Patients Radiotherapy		
Japanese A-bomb Survivors		
LUNG CANCER	20 - 100	age
Japanese A-bomb Survivors		
Uranium Miners		
Ankylosing Spondylitis		
BONE CANCER	5	age and duration
Ra-226 Ingestion		
Ra-224 Treatment		
Tinea Capitis Radiotherapy		

[1]Modified from Pochin (55). See text.

15 excess cancers per million exposed persons per rad (Table 7).

There is now a large body 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, 47-48), 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 has been estimated that perhaps after some 30 years following radiation exposure, the ratio of the excess of solid cancers to the excess of leukemia may prove to be as high as 3-5 to 1. This does not 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 epidemiological studies, particularly as regards dose distribution, ascertainment, latency periods, and other important physical and biological parameters. The ICRP (10-13) and the UNSCEAR (8,9) Committees have done this, and based on the precision of the leukemia studies (lifetime absolute risk of radiation-induced leukemia, low LET, low dose: 15 to 25 excess deaths/10^6/rad) from the Japanese A-bomb survivors (22), almost exclusively, and to a much lesser extent, from the ankylosing spondylitis patients (25-27), the metropathia patients (51,52), and the tinea patients (30,49,50), all of which now have adequate control study populations, a very crude figure of the total lifetime excess risk of radiation-induced cancer (deaths) was derived (< 50 to 100 excess cancer deaths/10^6/rad).

Table 7

Risk of Radiation-Induced Cancer - Other Cancers[1]

Tissue-Organ Population	Absolute Risk Estimate (Cases/10^6/rad)	Dependence
Brain, Salivary Glands, Stomach, Liver, Colon	10 - 15	unknown
Scalp, *in utero*, neck, spine, Japanese survivors, pelvis irradiation		
Esophagus, Small Intestine, Rectum, Pancreas, Ovary, Paranasal Sinuses, Lymphoid Tissue Irradiation	$\leq$ 5	unknown

[1]Modified from Pochin (55). See text.

This figure for all malignancies from low LET radiation delivered at low doses would be an overestimate of the risk by far, and certainly considerably less than 100 and perhaps as low as 20 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 figure for comparison with other estimates of avoidable risks, or voluntary risks, encountered in everyday life. This approach has been provided by Sir Edward E. Pochin in an objective way in the ICRP Report No. 27 as regards occupational risks (58). In 1975, the U.S. Government report on Accident Facts published by the National Safety Council (59) (Table 8) indicated that the estimated risk from occupational exposure to radiation would be at the very lowest end of the scale, indeed very much less than 100 fatal cancers per million persons per rad lifetime risk. If occupational exposure in industries listed in Table 8 is considered for workers 20 to 65 years of age, the safety margin for lifetime occupational risk from radiation carcinogenesis would approach a safety factor of over 50-100 compared with that expected each year in the hazards of dying in government and service occupations (55,60)! A lifetime safety factor of over 500-1000 obtains in comparison with that of fatal mining accidents each year (55,60).

As regards the risk of radiation carcinogenesis in the general population, even very crude quantitation of radiation risk estimates provides some method for intercomparison with other objective risks, both voluntary and involuntary experiences. The evidence, for example, for the magnitude of risk of dying from malignancy induced by radiation as a result of exposure from nuclear power generation providing 1 kilowatt of energy per person year in the general population has been estimated at less than 0.5 excess cancer

Table 8

Occupational Accident Rates - U.S. (59)[1]

(Deaths/10^6/year in 1975)

Industry	Deaths	(Mean, 1955-1975)
Trade	60	83
Manufacturing	80	103
Service and Government	115	131
Transport and Public Utilities	330	373
Agriculture	580	613
Construction	610	717
Mining and Quarrying	630	994
All Industries	150	200

[1]Modified from Pochin (55,58,60).

deaths per million persons per year (55). If one wishes a familiar comparison for a comparable risk of dying in the population, this has been estimated to be equal to smoking one cigarette every two years (55,60)!

Should Radiation be Compared with Other Risks?

It is tempting to establish qualitative or even semi-quantitative levels of risk for various societal activities, then make those comparisons which would appear appropriate in an attempt to develop a method for comparative indices of risk and benefit (2,58,60,61). However, such comparisons are easily made, and such comparisons must be biased, since they assume both, that no avoidable risk is acceptable, and that acceptability of unavoidable risk depends on comparisons with existing alternatives or with other existing risks accepted by society. Both assumptions can be proven spurious. Comparison could be justified, however, not on the basis of existing risks, but on the basis of existing alternatives provided the activity were desired or could be abandoned. It is just not possible in the complexities of modern medicine to dispense with medical radiation exposure in diagnosis and treatment of disease at the present time, and it is not possible nor practical to lower the population dose by the delivery of fewer exposures to each individual radiodiagnostic or radiotherapeutic patient. It is possible, on the other hand, not to build a nuclear energy plant or a coal-burning plant, and thereby providing less energy to the population by delivering less, or making available less energy to each individual. It follows, therefore, that health protection standards do not necessarily have to be related directly to risk. Two natural boundary conditions of comparative population risks in the United States can be discerned. The high risk boundary of 1:100 is the statistical risk of death from all causes (risk of death per year, $1:10^2$ to $1:10^3$). The medium level risk of death per year would encompass the range of $1:10^3$ to $1:10^5$. This would include the risk of death per year from exposure to 170 mrem per year. The low risk boundary of 1:1,000,000 is the risk of death

from natural disasters and catastrophies such as floods, earthquakes, lightning and snakebites (2,61). These negligible risks tend to be readily accepted by society without much that can be done to avert them, so-called "acts of God" (risk of death per year, $1:10^5$ to $1:10^7$). This would include the risk of death per year from exposure to 1 mrem per year. However, the high risk boundary can often be controlled by society in most circumstances, since they invariably involve individual decision-making, such as mode of transportation (e.g., auto travel, plane travel) and sports (e.g., hunting, skiing, mountain climbing) (2,55,58,60,61). And finally, the perception of risk does not necessarily lead to a logical response to avoid them. At the height of the radioactive fallout deliberations in the early 1960s, it was estimated that the removal of traces of radiostrontium from milk at the cost of a few pennies per quart would ultimately cost some 20 million dollars for each case of bone cancer averted (61).

Any attempt at assessing a cost-benefit relationship for any societal activity involving ionizing radiation implies that an identifiable benefit exists, and can be identified (2,58). Furthermore, unless society needs the associated benefit, any associated man-made risk may be regarded as avoidable. Thus, if one benefit of nuclear energy lies in the avoidance of injurious health from fossil fuel combustion, it does not necessarily follow that the benefits from nuclear energy exceed those of alternative options, or that the risks are less. And finally, an assessment of cost-effectiveness is necessary not only to determine how avoidable a defined risk can be, but it provides insights into decision-making on how societal resources may be allocated to decrease existing risks at an increased financial cost (2,58,61).

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 (61,62). 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 (2,55,61,63). When compared with the benefits that society has established as goals derived from the necessary activities of medical care and energy production, it is apparent that society must establish appropriate standards and seek appropriate controlling procedures which continue to assure that its needs are being met with the lowest possible risks (2,55,64). This implies continuing decision-making processes in which risk-benefit and cost-effectiveness assessments must be taken into account (2,58,62,63).

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 societal and political problem and not solely a scientific one, and to be decided by society, most often by men and women of business and law. 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 for guidance in the production of energy in industry. 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, 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 radiation now and in future years.

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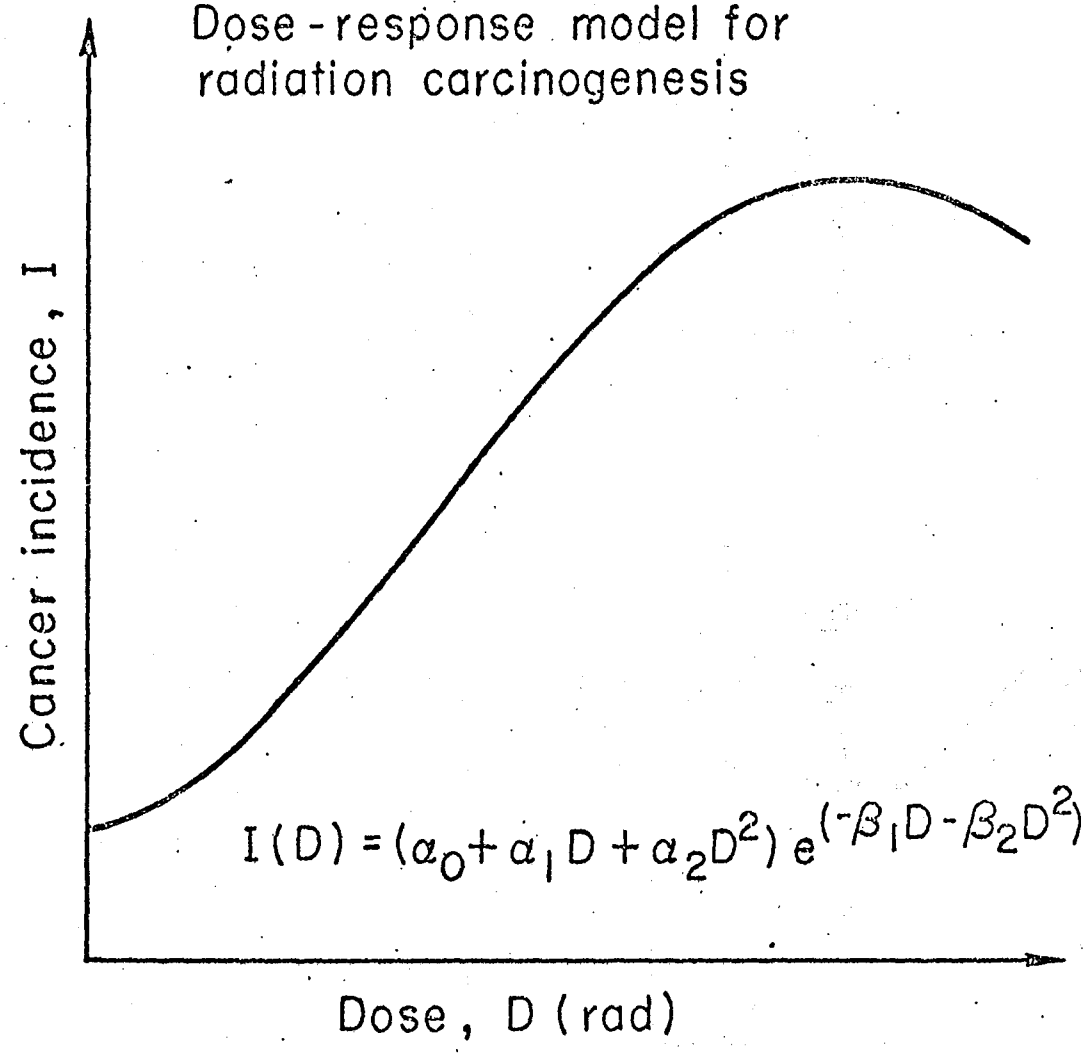

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Figure 1

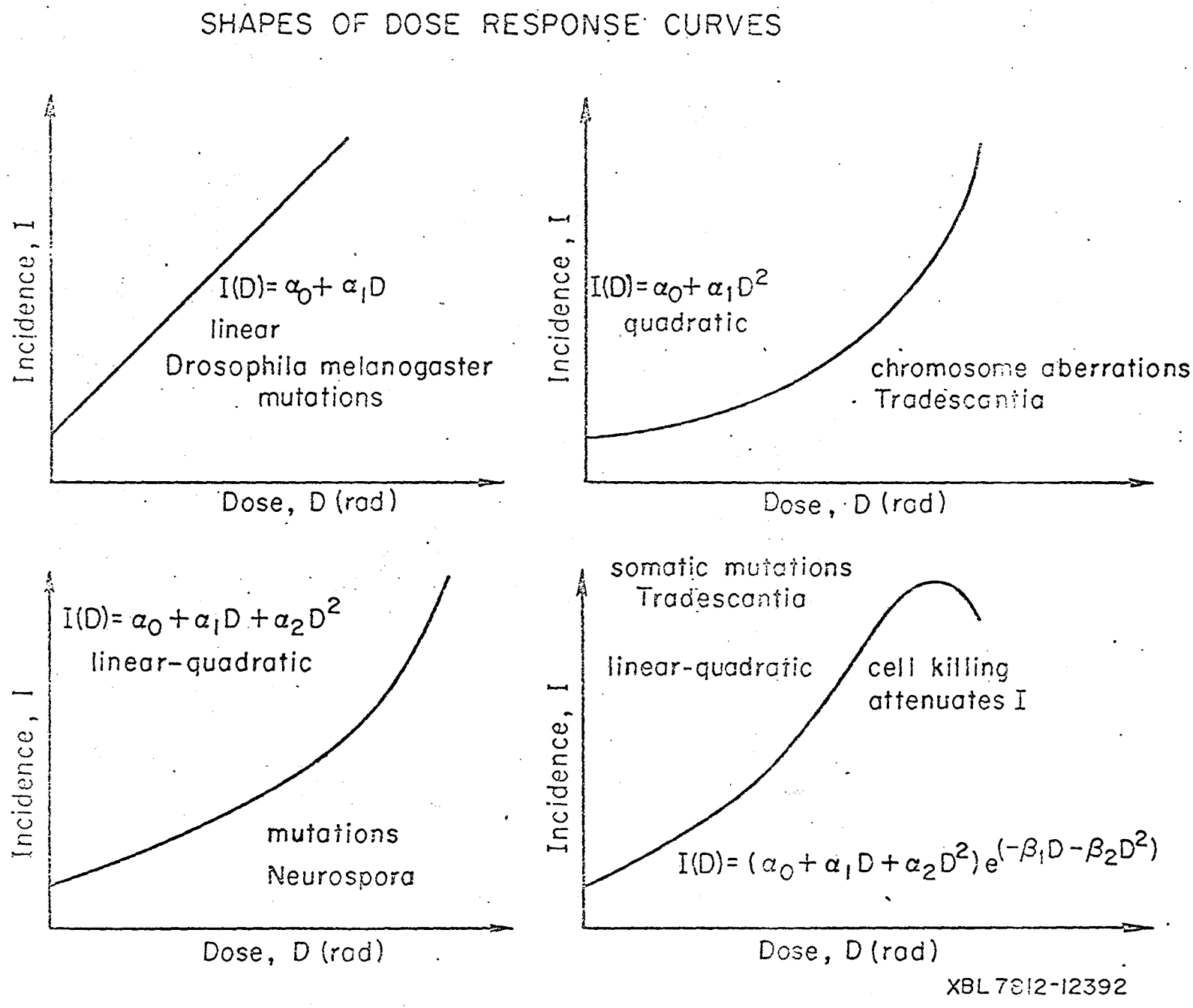
SHAPES OF DOSE RESPONSE CURVES
Incidence, I
Dose, D (rad)
I(D)= α0+ α1D
linear
Drosophila melanogaster
mutations
I(D)= α0+ α1D2
quadratic
chromosome aberrations
Tradescantia
I(D)= α0 + α1D + α2D2
linear-quadratic
mutations
Neurospora
somatic mutations
Tradescantia
linear-quadratic
cell killing
attenuates I
I(D)= (α0 + α1D + α2D2) e(-β1D -β2D2)
XBL 7812-12392

Figure 2

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