POPULATION DOSE EVALUATION AND STANDARDS FOR MAN AND HIS ENVIRONMENT

Proceedings of a Seminar, 1974

PROCEEDINGS SERIES

POPULATION DOSE EVALUATION AND STANDARDS FOR MAN AND HIS ENVIRONMENT

PROCEEDINGS OF THE SEMINAR
ON RADIOLOGICAL SAFETY EVALUATION
OF POPULATION DOSES AND
APPLICATION OF RADIOLOGICAL SAFETY STANDARDS
TO MAN AND THE ENVIRONMENT
ORGANIZED BY THE
INTERNATIONAL ATOMIC ENERGY AGENCY
AND THE WORLD HEALTH ORGANIZATION
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FOREWORD

Radiation protection practice for wastes produced during the uranium fuel cycle requires that almost all the wastes be contained. However, after careful assessment of the risks of exposure of man, or of accident, small amounts of low radioactive effluents are occasionally released to the environment from nuclear installations.

The basic principles and criteria involved in such releases to the environment can be summarized as follows: (1) to avoid all unnecessary and unjustifiable exposure; (2) to justify any necessary exposure and to keep it as low as reasonably possible in the light of the economic and social factors, ensuring at the same time that the exposure in no case exceeds the dose limits prescribed by the ICRP and other international and national competent authorities.

Radioactive material released to the biosphere can reach man through a variety of pathways; consequently the justifiable exposure, in accordance with principle (2) above, should be kept as low as is readily achievable. This requirement can be met by the process of optimization of exposure. Optimization of exposure can be rationally achieved by the process of differential cost-benefit analysis, and this was the main subject of a Seminar on Population Dose Evaluation and Standards for Man and his Environment organized by the International Atomic Energy Agency and the World Health Organization with the support of the United Nations Environment Programme and held at Portorož, Yugoslavia, from 20 to 24 May 1974. The Seminar also examined some of the possible ecological effects of the operation of a nuclear installation on the balance of nature in the environment of man. The Seminar provided a valuable forum for the exchange of experience in Member States relating to the exposure of populations or individuals as well as to environmental studies.

The Agency gratefully acknowledges the invitation for this Seminar from the Government of the Socialist Federal Republic of Yugoslavia, and the assistance and co-operation of the staffs of the Jožef Stefan Institute, Ljubljana, and the Zavod za Turizem, Portorož.

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Invited Review Paper

BASIC CONCEPTS AND PRINCIPLES OF ASSESSMENT
A review of the Advisory Committee Report on the Biological Effects of Ionizing Radiation

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Abstract

BASIC CONCEPTS AND PRINCIPLES OF ASSESSMENT: A REVIEW OF THE ADVISORY COMMITTEE REPORT ON THE BIOLOGICAL EFFECTS OF IONIZING RADIATION.

The present concepts of a single upper limit for individual and population doses, with the understanding that the risks should be kept as low as practicable, may not be adequate for the future uses of nuclear radiation. This is because of the potential for exposing large populations from the uses of nuclear power and medical radiation. There is a need to compare the biological risks and benefits of radiation applications and its alternatives. The recommendations of the US National Academy of Sciences — National Research Council's Advisory Committee on the Biological Effects of Ionizing Radiation (BEIR) are presented. The Committee estimates of the genetic, somatic and ill health risks from population exposures of 170 mrem are included.

INTRODUCTION

The potential effects of ionizing radiation on human populations have been a concern of the scientific community for several decades. The oldest of the scientific bodies now having responsibility in this area is the International Commission on Radiological Protection (ICRP), formed in 1928. The ICRP has maintained continuing studies of radiation protection problems that are of special relevance to the radiation control programs of many nations.

In the 1940's with the establishment of the U.S. Atomic Energy Commission and its program, there was recognition of possible radiation problems and large-scale animal experiments were initiated. In the early 1950's, as a result of the testing of nuclear weapons, public concern arose about the potential effects of ionizing radiation on human populations. In 1955, as a response to this concern, the President of the National Academy of Sciences (NAS) appointed a group of scientists to conduct a continuing appraisal of the effects of atomic radiation on living organisms. That study, entitled "Biological Effects of Atomic Radiation," led to a series of reports by six committees issued from 1956-1963 and which are generally referred to as the BEAR reports.

The BEAR reports led to a basis for public understanding of the expected effects of the testing of nuclear devices that had occurred to that date and introduced the important concept of regulation of average population doses on the basis of genetic risk to future generations. These reports also emphasized medical-dental x rays as the greatest source of man-made radiation exposure of the population.

Also, in 1955, the General Assembly of the United Nations established the UN Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), which, among other tasks associated with monitoring and assembling reports of radiation exposure throughout the world, was "to make yearly progress reports and to develop a summary of reports received on radiation levels and radiation effects on man and his environment..." (UNSCEAR 1969). The periodic reports issued by UNSCEAR (the latest in 1972), in accordance with its objective, have served as a review of worldwide scientific information and opinion concerning human exposure to atomic radiation [1].

In the United States in 1959, the Federal Radiation Council (FRC) was formed to provide a Federal policy on human radiation exposure. A major function of the FRC was to "advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States..."

In the late 1960's, concern arose that developing peacetime applications of nuclear energy, particularly the growth of a nuclear power industry for production of electricity, could cause serious exposure of the human population to radiation. Thus, in February 1970, the FRC asked the NAS-NRC Advisory Committee[1] to consider a complete review and re-evaluation of the existing scientific knowledge concerning radiation exposure to human populations. This request from the FRC came about because of: (1) a naturally developing sequence of the Advisory Committee's concern that there had been no detailed overall review since the BEAR reports; (2) new factors that might need to be considered, such as optional methods of producing electrical energy and types of environmental contamination different from those previously encountered; and (3) a growing number of allegations made in the public media and before Congressional committees that the existing radiation protection guides were inadequate and could lead to serious hazard to the health of the general population. The following sections summarize the results of the NAS-NRC Advisory Committee review [2].

QUANTIFICATION OF RISK

Deleterious effects in individuals and populations of living organisms cannot be attributed to exposure to ionizing radiation at levels near that of average natural background except by inference. Such effects are not directly observable. It has been taken for granted by many that exposure to additional radiation near background levels, and especially within variations of natural background, represents a risk so small compared with other hazards of life that any associated nontrivial benefit would far offset any harm caused. The effects of such radiation exposures have been variously regarded as insiginificant, negligible, tolerable, permissible, acceptable. But if in fact any level of radiation will cause some harm (no threshold), and if in fact entire populations of nations or of the world are exposed to additional man-made radiation, then for decisions about radiation protection, it becomes necessary to quantify the risks; that is, to estimate the probabilities or frequencies of effects.

Such estimates are fraught with uncertainty. However, they are needed as a basis for logical decision-making and may serve to stimulate the gaining of data

1 The NAS-NRC Advisory Committee, on March 25, 1970, accepted the task proposed by the FRC, as a part of the contract agreement between NAS and the Department of Health, Education, and Welfare, signed September 1, 1970. On December 2, 1970, the activities and functions of the FRC were transferred to the Environmental Protection Agency because the FRC had ceased to exist as a specific body.

for assessment of comparative hazards from technological options and development, at the same time promoting better public understanding of the issues.

The present U.S. Radiation Protection Guide for the general population was based on genetic considerations and conforms to the BEAR Committee recommendations that the average individual exposure be less than 10 R (Roentgens) before the mean age of reproduction (30 years) [3]. The FRC did not include medical radiation in its limits and set 5 rem as the 30-year limit (0.17 rem per year).

Present estimates of genetic risk are expressed in four ways: (a) *Risk Relative to Natural Background Radiation.* Exposure to man-made radiation below the level of background radiation will produce additional effects that are less in quantity and no different in kind from those that man has experienced and has been able to tolerate throughout his history. (b) *Risk Estimates for Specific Genetic Conditions.* The expected effect of radiation can be compared with current incidence of genetic effects by use of the concept of doubling dose (the dose required to produce a number of mutations equal to those that occur naturally). Based mainly on experimental studies in the mouse and *Drosophila* and with some support from observations of human populations in Hiroshima and Nagasaki, the doubling dose for chronic radiation in man is estimated to fall in the range of 20-200 rem. It is calculated that the effect of 170 mrem per year (or 5 rem per 30-year reproduction generation) would cause in the U.S. in the first generation between 100 and 1800 cases of serious, dominant or X-linked diseases and defects per year (assuming 3.6 million births annually in the U.S.). This is an incidence of 0.05 percent. At equilibrium (approached after several generations) these numbers would be about fivefold larger. Added to these would be a smaller number caused by chromosomal defects and recessive diseases. (c) *Risk Relative to Current Prevalence of Serious Disabilities.* In addition to those in (b) caused by single-gene defects and chromosome aberrations are congenital abnormalities and constitutional diseases which are partly genetic. It is estimated that the *total* incidence from all these including those in (b) above, would be between 1100 and 17,000 per year at equilibrium (again, based on 3.6 million births). This would be about 0.75 percent at equilibrium or 0.1 percent in the first generation. (d) *The Risk in Terms of Overall Ill-Health.* The most tangible measure of total genetic damage is probably "ill-health" which includes but is not limited to the above categories. It is thought that between 5 percent and 50 percent of ill-health is proportional to the mutation rate. Using a value of 20 percent and a doubling dose of 20 rem, we can calculate that 5 rem per generation would eventually lead to an increase of 5 percent in the ill-health of the population. Using estimates of the financial costs of ill-health, such effects can be measured in monetary units if this is needed for cost-benefit analysis.

Until recently, it has been taken for granted that genetic risks from exposure of populations to ionizing radiation near background levels were of much greater import than were somatic risks. However, this assumption can no longer be made if linear nonthreshold relationships are accepted as a basis for estimating cancer risks. Based on knowledge of mechanisms (admittedly incomplete), it must be stated that tumor induction as a result of radiation injury to one or a few cells of the body cannot be excluded. Risk estimates have been made based on this premise and using linear extrapolation from the data from the A-bomb survivors of Hiroshima and Nagasaki, from certain groups of patients irradiated therapeutically, and from groups occupationally exposed. Such calculations based on these data from irradiated humans lead to the prediction that additional exposure of the U.S. population of 5 rem per 30 years could cause from roughly 3,000 to 15,000 cancer deaths annually, depending on the assumptions used in the calculations. The Committee considers the most likely estimate to be approximately 6,000 cancer deaths annually, an increase of about 2 percent in the spontaneous cancer death rate which is an increase of about 0.3 percent in the overall death rate from all causes.

Given the estimates for genetic and somatic risk, the question arises as to how this information can be used as a basis for radiation protection guidance.

Logically the guidance or standards should be related to risk. Whether we regard a risk as acceptable or not depends on how avoidable it is, and, to the extent not avoidable, how it compares with the risks of alternative options and those normally accepted by society.

COST-BENEFIT ANALYSIS

When the risk from radiation exposure from a given technological development has been estimated, it is then logical for the decision-making process that comparisons be made and consideration given to (a) benefits to be attained, (b) costs of reducing the risks, or (c) risks of the alternative options including abandonment of the development. The concept of always balancing the risk of radiation exposure against the expected benefit has been well-recognized and accepted, but it was not until the publication of ICRP Publication 22 that an attempt has been made to evaluate both sides of the equation in any way that could lead to operational guidance. Offical recommendations call for radiation exposure to be kept at a level "as low as practicable," a policy that emphasizes and encourages sound practice. However, risk-estimates and cost-benefit analysis are needed for decision-making. An additional important point, often overlooked, is that even if the benefit outweighs the biological cost, it is in the public interest that the latter must still be reduced to the extent possible providing the health gains achieved per unit of expenditure are compatible with the cost-effectiveness of other societal efforts.

It appears logical to attempt to express both risks and benefits in comparable terms - monetary units. To a limited degree, risks can be estimated in such terms. For example, the statement of risk can be expressed in terms of cost to an individual or to his family and society since there are specific expenses attributable to an effect. ICRP Publication 22 summarizes a number of published estimates of the monetary value of avoiding the detriment possibly associated with a population or collective dose of 1 man-rem [4]. In spite of the intuitive nature of these estimates, they all fall within the range of $10 to $250 per man-rad. Similarly, estimates can be made of expenses required to effect given reductions of exposure to harmful agents. In some instances, it may not be necessary to use absolute monetary costs: that is, one can compare the cost of different ways of producing the same desired objective. Given the need for additional electrical power, one might compare nuclear plants and fossil fuel plants directly in terms of total biological and environmental costs per unit of electricity produced. Often however, there will be need for information on absolute costs. This will occur when decisions have to be made on whether the public interest is better served by spending our limited resources on health gains from reducing contamination or by spending for other societal needs.

Cyril Comar, Chairman of the Advisory Committee on the Biological Effects of Ionizing Radiation, stated in his analysis of the implications of the BEIR Report that it is obvious that any risk can be decreased at an increased financial cost [5]. In a resource-limited society the allocations must be made where they will do the most good. It is a misuse of resources and a disservice to society to add costs for the purpose of decreasing the risks of any one system greatly below acceptable levels, when other societal activities with unacceptable risks are not being attended to. For examples of some choices that could be made: a national program to persuade people to use seat belts is estimated to cost less than $100 for each death averted; a program of early cancer detection and treatment is estimated to cost up to about $40,000 for each death averted. At the height of fallout, it was calculated that the removal of ^{90}Sr from milk, while costing 2 to 3 cents per quart, would cost about $20 million for each case of cancer averted. It has been estimated that money spent on improved collimation of x-ray machines would be 1,000 to 10,000 times more effective in reducing radiation dosages than money spent on improving present reactor waste systems.

It must be emphasized that there are many inherent problems in cost-benefit analysis that will prevent rigorous application in the very complex systems of present concern to society. These include the implication of assigning a monetary value to human life, suffering or productivity; the difficulty in assessment of factors related to the quality of life such as recreational water and land resources; the fact that the costs and benefits may not accrue to the same members of the population, or even to the same generation; and the virtual impossibility of establishing a single cost system that would be socially acceptable and still take into account differences in individual willingness to accept various types of risks. An illustration of the latter points is the observation that health and environmental effects from power plants would be reduced by their location in relatively unpopulated areas. Yet the people in such areas generally are not the ones who need the additional electrical energy.

Despite these uncertainties, there are important advantages in attempting cost-benefit analyses. There is a focus on the biological and environmental cost from technological developments and the need for specific information becomes apparent. Thus, for example, we find relatively little data available on the health risks of effluents from the combustion of fossil fuels. Furthermore, it is becoming increasingly important that society not expend enormously large resources to reduce very small risks still further, at the expense of greater risks that go unattended; such imbalances may pass unnoticed unless a cost-benefit analysis is attempted. If these matters are not explored, the decisions will still be made and the complex issues resolved either arbitrarily or by default since the setting and implementation of standards represent such a resolution.

STANDARDS

The present radiation standards used by the U.S. Federal Government are based on the recommendations of the Federal Radiation Council (FRC). The FRC developed the Radiation Protection Guide that is defined as "the radiation dose which should not be exceeded without careful consideration of the reasons for doing so, every effort should be made to encourage the maintenance of radiation doses as far below this guide as practicable." The FRC also indicated that "there should not be any man-made radiation exposure without the expectation of benefit resulting from such exposure."

The present status of Radiation Protection Guides for the U.S. general population is presented from FRC Report No. 1 [3]:

"5.2. We believe that the current population exposure resulting from background radiation is a most important starting point in the establishment of Radiation Protection Guides for the general population. This exposure has been present throughout the history of mankind, and the human race has demonstrated an ability to survive in spite of any deleterious effects that may result. Radiation exposures received by different individuals as a result of natural background are subject to appreciable variation. Yet, any differences in effects that may result have not been sufficiently great to lead to attempts to control background radiation or to select our environment with background radiation in mind.

"5.3 On this basis, and after giving due consideration to the other bases for the establishment of Radiation Protection Guides, it is our basic recommendation that the *yearly radiation exposure to the whole body of individuals in the general population (exclusive of natural background and the deliberate exposure of patients by practitioners of the healing arts) should not exceed 0.5 rem.* We note the essential agreement between this value and current recommendations of the ICRP and NCRP. It is not reasonable to establish Radiation Protection Guides for the population which take into account all possible combinations of circumstances. Every reasonable effort should be made to keep exposures as far below this level as practicable. Similarly, it is obviously appropriate to exceed this level if a careful study indicates that the probable benefits will outweigh the potential risk. Thus, the degree of control effort does not depend solely on whether or not this Guide is being exceeded. Rather, any exposure of the population may call for some control effort, the magnitude of which increases with the dose.

"5.4 Under certain conditions, such as widespread radioactive contamination of the environment, the only data available may be related to average contamination or exposure levels. Under these circumstances, it is necessary to make assumptions concerning the relationship between average and maximum doses. The Federal Radiation Council suggests the use of the arbitrary assumption that the majority of individuals do not vary from the average by a factor greater than three. *Thus, we recommend the use of 0.17 rem for yearly whole-body exposure of average population groups.* (It is noted that this guide is also in essential agreement with current recommendations of the NCRP and the ICRP.) It is critical that this guide be applied with reason and judgment. Especially, it is noted that the use of the average figure as a substitute for evidence concerning the dose to individuals, is permissible only when there is a probability of appreciable homogeneity concerning the distribution of the dose within the population included in the average. Particular care should be taken to assure that a disproportionate fraction of the average dose is not received by the most sensitive population elements. Specifically, it would be inappropriate to average the dose between children and adults, especially if it is believed that there are selective factors making the dose to children generally higher than that for adults.

"5.5 When the size of the population group under consideration is sufficiently large, consideration must be given to the contribution to the genetically significant population dose. The Federal Radiation Council endorses in principle the recommendations of such groups as the NAS-NRC, the NCRP, and the ICRP concerning population genetic dose, and recommends the use of the Radiation Protection Guide of 5 rem in 30 years (exclusive of natural background and the purposeful exposure of patients by practitioners of the healing arts) for limiting the average genetically significant exposure of the total U.S. population. The use of 0.17 rem per capita per year, as described in paragraph 5.4 as a technique for assuring that the basic Guide for individual whole-body dose is not exceeded, is likely in the immediate future to assure that the gonadal exposure Guide is not exceeded. The data ..... indicates that allocation of this population dose among various sources is not needed now or in the immediate future."

A major difficulty has been the misinterpretation of these standards, particularly in the public mind. The intent as stated is that no individual in the general population should receive whole-body exposure of more than 0.5 rem/year and that the average exposure of population groups should not exceed 0.17 rem/year. What is often not realized is that one or the other of these limits may be governing depending on the nature of exposure. For example, if the exposure were to arise from specific locations such as nuclear power plants or reprocessing plants and it were assured that no individual at the boundaries of the installations could be exposed to more than 0.5 rem/year, it would be physically impossible for the U.S. population averages to approach anywhere near the level of 0.17 rem/year from such sources. Accordingly, the Committee felt that both individual and average population guidelines should be maintained but that clarification should be included as an integral part of the regulatory statement.