REPORT NO. 1

background material for the development of radiation protection standards

May 13, 1960

Staff Report of the

FEDERAL RADIATION COUNCIL

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SECTION I.–INTRODUCTION

1.1 It was recognized soon after discovery of x-rays that exposure to large amounts of ionizing radiation can produce deleterious effects on the human body so exposed. More recently, because of increased scientific knowledge and widespread use of radiation, additional attendon has been directed to the possible effect6 of lower levels of radiation on future generations. Various scientific bodies have made recommendations to limit the irradiation of the human body. Probably the oldest of such scientific bodies are the International Commission on Radiological Protection (ICRP) and the U.S. National Committee on Radiation Protection and Measurements (NCRP). Initially, these bodies were interested primarily in the irradiation of those exposed occupationally, but recently they have been concerned with those who are non-occupationally exposed.

1.2 The ICRP was formed in 1928 under the auspices of the International Congress of Radiology. It is now a Commission of the International Society of Radiology. This Commission has published recommendations about every three years except for the period 1938-49.

1.3 The NCRP was initially organized as the "Advisory Committee on X-ray and Radium Protection." The initial membership included representatives from the medical societies, x-ray equipment manufacturers, and the National Bureau of Standards. After the reorganization in 1946, the name was changed to the National Committee on Radiation Protection and Measurements, and additional representatives from other organizations having scientific interest in the field were included. The recommendations of this group have generally been published as National Bureau of Standards handbooks. Since 1947, 15 such handbooks have been made available on different aspects of the protection problem.

1.4 In 1956, the National Academy of Sciences-National Research Council published reports of its Committees on the Biological Effects of Atomic Radiation. For genetic protection this group recommended a maximum gonadal dose up to age 30 both for individual radiation workers and for the entire population. These committees published a revised report in 1960.

1.5 The recommendations of the NCRP, ICRP, and NAS-NRC are in rather close agreement, The recommendations of the NCRP have received wide acceptance in the United States.

1.6 In 1955, The United Nations established a Scientific Committee on The Effects of Atomic Radiation (UNSCEAR). The report of this group (UNSCEAR, 1958) summarized the current knowledge on effects of radiation exposure and on human exposure levels. The report also contained predictions on exposures from testing of nuclear devices under various assumptions.

1.7 The Joint Committee on Atomic Energy of the Congress held public hearings in 1957 on "The Nature of Radioactive Fallout and Its Effects on Man." The same committee held hearings in 1959 on "Industrial Radioactive Waste Disposal;" on "Employee Radiation Hazards and Workman's Compensation;" on "Fallout from Nuclear Weapons Tests;" and on "Biological and Environmental Effects of Nuclear War." In all these hearings, questions of the biological effects of radiation and of protection against excessive exposure to radiation received attention.

1.8 The Federal Radiation Council was formed in 1959 (Public Law 86-373) to provide a Federal policy on human radiation exposure. A major function of the Council is 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…" This staff report is a first step in carrying out this responsibility. As knowledge of the biological effects of radiation increases, and as factors making exposure to radiation desirable undergo change, modifications and amplifications of the recommendations of this staff report probably will be required.

Scope

1.9 This staff report seeks to provide some of the required radiation protection recommendations. These recommendations are of an interim nature. Periodic review will be necessary to incorporate new information as it develops. This staff report includes recommendations for additional research which will provide a firmer basis for the formulation of radiation standards.

1.10 Only peacetime uses of radiation which might affect the exposure of the civilian population are considered at this time. The staff report also does not consider the effects on the population arising from major nuclear accidents. Only that portion of the knowledge of the biological effects of radiation that is significant for setting radiation protection standards is considered. Published information by the groups indicated above is summarized in this staff report; details may be found in the original reports.

1.11 Certain of the classes of radiation sources are now regulated by various Federal agencies. There are some which are not so regulated but which should be considered as aspects of the overall exposure of the population to radiation. Therefore, this staff report will consider exposure of the population from all sources except those excluded above.

Preparation of the Staff Report

1.12 In preparation of this staff report, a series of meetings was arranged with staff members of various Federal agencies concerned with radiation protection. The objectives of this first phase in the preparation were (1) to determine the problems unique to these agencies; (2) to define problem areas not adequately covered by current radiation protection recommendations of the National Committee on Radiation Protection and Measurements or the National Academy of Sciences; and (3) to discuss the implications of the above recommendations.

1.13 A second phase in the preparation of this staff report consisted of a series of consultations with Governmental and nongovernmental scientists in the various fields involved in the development of radiation protection standards. The purposes of these consultations were (1) to discuss the bases upon which recommendations on radiation protection standards are formulated; (2) to obtain the most up-to-date information on the biological effects of radiation; and (3) to elucidate some of the physical and chemical problems involved in the establishment and implementation of radiation protection standards.

1.14 These consultations and the reports of the groups indicated above provided a basis for the present staff report,

Definitions[1]

1.15 The activity of a radioactive source is the number of nuclear disintegrations of the source per unit of time. The unit of activity is the curie. The weight of a radionuclide corresponding to one curie is directly proportional to the half-life and to the atomic weight of the nuclide. For example, uranium-235 with a half life of 7.07×10^8 years requires about 4.65×10^5 grams to obtain an activity of one curie. The mass-activity relationship for iodine - 131 with a half life of 8.0 days is about 8.05×10^{-6} grams to produce a curie.

1.16 Any biological effect produced by radiation depends on an absorption of energy from the radiation. For many years the roentgen (r)[1] has been used as a measure of x- and gamma-ray absorption in body tissue. Conceptually, the roentgen is only a measure of the ability of x- or gamma-rays to produce ionization in air and not of the absorption of these rays in tissue. More recently (ICRU H62, 1957, the absorbed dose of any radiation has been defined as "the energy imparted to matter by ionizing particles per unit mass of irradiated material at the place of interest." The unit of absorbed dose is the rad. However, under most conditions and to the accuracy required for radiation protection purposes, the number of roentgens is numerically equal to the number of rads in soft tissues.[2]

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[1]For detailed definitions see ICRU, H62, 1957.

[2]For the accuracy of this approximation and the conditions for its applicability, see the International Commission Radiological Units (ICRU) Report (1957).

1.17 The same absorbed dose of different kinds of radiation does not, in general, produce the same biological effect. Different kinds of radiation have a different relative biological effectiveness (RBE). It is well known that the RBE for a particular kind of radiation may be dependent upon such factors as the specific biological effect under consideration, the tissue irradiated, the radiation dose, and the rate at which it is delivered. Recommendations on radiation protection have generally assumed a specific RBE for each kind of radiation.[3] The RBE dose is equal numerically to the product of the dose in rads and an agreed conventional value of the relative biological effectiveness. The unit of RBE dose is the rem, considered to be that dose which is biologically equivalent to one roentgen of x- or gamma-radiation. For example, one rad of neutrons is conventionally considered to be equivalent to 10 roentgens of gamma radiation, and this equivalence is expressed by saying that the RBE dose is 10 rem. However, it has been found experimentally that the same RBE dose of different radiation sources in the bone does not always produce the same biological effect. A numerical factor called the relative damage factor is introduced to take care of this difference. Thus, in the case of bone, the biological effect is represented by the product of the RBE dose and the relative damage factor.

1.18 Radiation Protection Guide (RPG) is 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.

1.19 Radioactivity Concentration Guide (RCG) is the concentration of radioactivity in the environment which is determined to result in whole body or organ doses equal to the Radiation Protection Guide.

Contents of the Staff Report

1.20 The following sections of this staff report provide information on human exposure from radiation sources, the present state of our knowledge on the genetic and somatic effects of radiation, the problems of formulating radiation protection standards from available scientific data, the basic and derived radiation protection guides, recommendations for further work by the Federal Radiation Council, and indications as to areas in which research is needed in order to fill gaps in our basic knowledge.

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[3]Currently used values of RBE (relative to x-rays) are one for x-rays, gamma rays and electrons, 10 for neutrons and protons up to 10 Mev, and alpha particles, and 20 for heavy recoil nuclei. These are for chronic irradiation and should be used only for protection purposes.

SECTION II.–KNOWLEDGE OF RADIATION EFFECTS

Introduction

2.1 This section includes general summaries of knowledge of the biological effects of ionizing radiation on animals and man particularly pertinent to the problem of defining radiation protection standards. As noted in Section I (paragraph 1.13), this staff report was developed following a series of consultations with scientists who provided recent information on the genetic and somatic effects of radiation. The consultations included the experimental evidence in animals and the observations on humans, as well as the assumptions, hypotheses, and unknowns in the relationships of radiation dose and effects.

Definitions of General Biological Factors

2.2 Radiation exposure can be described in terms of the part of the body exposed, the total dose delivered, the dose rate, and the duration of the exposure. Acute exposure is usually considered an exposure to a single event of irradiation or a series of events in a short period of time. Continuous or fractionated exposures over a long period of time are considered chronic exposures.

2.3 Acute exposure can result in both immediate and delayed biological effects. Chronic exposure is usually considered to produce only delayed effects. The acute radiation syndrome will not be discussed in detail since it is applicable primarily to accidental or emergency exposures. The literature documents this effect (refer to Table 2.1).

2.4 The available data describing immediate effects on humans include:

(1) Medical data on effects following the therapeutic use of external sources such as x-rays, and of radionuclides such as radium, iodine, etc.;

(2) Occupational data on exposure of radiologists, cyclotron workers, and workers in nuclear industry as a result of certain accidents; and

(3) Population observations on atomic bomb survivors and on persons irradiated by heavy fallout in the vicinity of the Marshall Islands.

2.5 Most delayed effects, in man, are inferred from consideration of experimental knowledge in animals, from available epidemiological statistical observations, and from a limited number of medical and industrial case observations. Delayed effects are those effects observable at some time following exposure. The effects cornsidered are: (1) genetic effects; and (2) somatic effects, including the appearance of leukemia, skin changes, precancerous lesions, neoplasms, cataracts, changes in the life span, and effects on growth and development. The delayed effects produced by ionizing radiation in an individual are not unique to radiation and are for the most part indistinguishable from those pathological conditions normally pres - ent in the population and which may be induced by other causes.

2.6 External radiation exposure: refers to that exposure resulting from sources outside the body. Classifications of external radiation exposure are made on the basis of the portions of the body irradiated: whole body or partial body.

2.7 Internal radiation exposure is that which comes from radioactive materials incorporated within the body following their ingestion, inhalation, injection, or absorption.

2.8 A critical organ is defined as that organ of the body whose damage by a given radiation source results in the greatest impairment to the body. Criteria appropriate to the determination of critical organs for external or internal exposure are: (1) the radiosensitivity of the organ, i.e., the organ damaged by the lowest dose; (2) the essentialness or indispensability of

TABLE 2.1

SUMMARY OF EFFECTS RESULTING FROM ACUTE WHOLE BODY EXTERNAL EXPOSURE OF RADIATION TO MAN[1]

0 - 25 r	25 - 100 r	100 - 200 r	200 - 300 r	300 - 600 r	600 or more
No detectable clinical effects.	Slight transient reductions in lymphocytes and neutrophils.	Nausea and fatigue, with possible vomiting above 125 r.	Nausea and vomiting on first day.	Nausea, vomiting and diarrhea in first few hours.	Nausea, vomiting and diarrhea in first few hours.
			Latent period up to two weeks or perhaps longer.	Latent period with no definite symptoms, perhaps as long as one week.	Short latent period with no definite symptoms in some cases during first week.
Delayed effects may occur.	Disabling sickness not common, exposed individuals should be able to proceed with usual duties.	Reduction in lymphocytes and neutrophils with delayed recovery.	Following latent period symptoms appear but are not severe: loss of appetite, and general malaise, sore throat, pallor, petecheae, diarrhea, moderate emaciation.	Epilation, loss of appetite, general malaise, and fever during second week, followed by hemorrhage, purpura, petecheae, inflammation of mouth and throat, diarrhea, and emaciation in the third week.	Diarrhea, hemorrhage, purpura, inflammation of mouth and throat, fever toward end of first week.
	Delayed effects possible, but serious effects on average individual very improbable.	Delayed effects may shorten life expectancy in the order of one per cent.	Recovery likely in about 3 months unless complicated by poor previous health, superimposed injuries or infections.	Some deaths in 2 to 6 weeks. Possible eventual death to 50% of the exposed individuals for about 450 roentgens.	Rapid emaciation and death as early as the second week with possible eventual death of up to 100% of exposed individuals.

[1]Adapted from "The Effects of Nuclear Weapons," U.S. Government Printing Office, 1957.

the organ to the well-being of the entire body; (3) the organ that accumulates the greatest concentration of the radioactive material; and (4) the organ damaged by the radionuclide enroute into, through, or out of the body. For a given situation, determination of the criteria chosen for internal emitters is subject to judgment based on various factors: physical (particle size), chemical (solubility; the compound form of a given chemical element), ecological (the environmental balance of calcium or iodine) and physiological (differential uptake by age and the metabolic condition of the organism).

2.9 On the basis of comparisons with known effects of x-rays in humans and animals, radioisotope experiments in animals, and the radium and other radioisotope observations in man, certain organs in the body appear to be the critical organs under various conditions of irradiation. These organs, and examples of the delayed effect of irradiation upon these organs are: (1) gonads: genetic alterations; (2) bone marrow and other blood forming organs; the leukemias, aplastic anemia; (3) whole body: life span shortening; (4) single organs (bone, skin, thy-

roid, etc.): neoplasms, and other pathological effects; and, (5) the lens of the eye: cataracts. These are the effects ordinarily considered when assigning guides for external and internal exposure.

2.10 A body burden of a radionuclide is that amount present in the body. The organ burden is the amount present in an organ.

2.11 Multiple exposures may occur from diverse sources, e.g., from several sites of deposition and from several routes of entry into the body. Sources may be external or internal. An external source may irradiate the whole body or a portion of the body. An internal source or sources may produce radiation exposure in several ways: (1) a single radionuclide may produce whole body exposure or a single organ exposure; or (2) single nuclides may affect different body organs simultaneously; or lastly, (3) multiple radionuclides may be absorbed thereby producing whole body, or single, or several organ exposures.

Biological Variability

2.12 Variations of effect with age depend upon metabolic, cellular, and organ differences. Some factors of significance are:

(1) Radiation sensitivity of a cell in terms of chromosomal aberration depends on the stage of mitosis when radiation is delivered. Damage becomes manifest when cell division takes place; the more divisions that occur, the greater the probability of manifestation.

(2) During fetal life there is a greater sensitivity to radiation and the median lethal dose (LD_{50}) of fetuses is less than that of adults. After birth, in certain strains of mice the radiosensitivity decreases until maturity is reached, and then remains relatively constant until late in life when radiosensitivity again rises sharply.

(3) Gross malformations may result from small amounts of radiation delivered to the developing embryo. The production of clinically evident malformations in fetal life depends on the stage of embryonic organ development when the radiation is delivered.

2.13 Although few data are available on human populations it is presumed from the analogy of other stresses that undernourishment and strain may affect radiosensitivity. Anemia renders mice more sensitive to radiation. However, from the evidence on radiobiological studies in tissue culture, and on the induction of mutations and biochemical effects, it has been shown that a reduction in oxygen tension produces a lowered response to radiation.

2.14 There is a scarcity of information on the effect produced by the simultaneous presence of bone-seeking nuclides (radium, strontium) and bone infection or bone conditions in which the mineral states are altered due to aging.

2.15 The minimum doses causing biological effects detectable by current methods differ among species. However, for most mammals the LD_{50} dose varies by less than an order of magnitude.[1] Comparison of genetic effects between the fruit fly and the mouse can be cited. The x-ray induced mutation rate per r per average gene locus varies by a factor of 15 between fruit fly and mouse. For mouse spermatogonia the sensitivity of the mutation rate per locus (at 90 r per min.) from least to most sensitive locus may vary by a factor of 30; while in the fruit fly the specific locus sensitivity varies by a factor of two. Our ability to extrapolate confidently the data from animal experience to man depends on whether there is sufficient evidence of similarity between humans and the experimental animals.

2.16 Within an individual, the range of tissue sensitivity varies by more than an order of magnitude from the more sensitive (blood forming organs) to the more resistant (the adult nervous system).

2.17 The apparent sensitivity of a tissue to damage depends on the index of measurement used, e.g., the biochemical effect, the mitotic effect, the cellular effect, or states of tissue derangement, tumor production, or life span changes. As examples, (1) for changes in the lens of the eye, one may measure the clinical appearance of cataracts years after radiation injury, or one may measure the immediate biochemical changes; (2) lymphocyte damage may by measured

[1]The term, an order of magnitude, as used in this staff report refers to a factor of ten.

by the reduction in the number of lymphocytes, or by the structural changes in the cell nucleus, or by the chemical change in nuclear DNA content; and (3) the effect on bone marrow may be measured by the appearance of immature cells in the blood stream or by the rate and amount of Fe-59 incorporated in the cells.

2.18 In an individual adult it is difficult or in some cases impossible to detect effects from a single external exposure of less than 25 to 50 r, and from continuing exposure to levels even about two orders of magnitude greater than natural background. It should be noted, however, that changes in the nucleus of lymphocytes have been described in some adult radiation workers after two weeks of exposure to levels as low as 0.20 r per week.

2.19 Man's Sensitivity to radiation depends on his age at the time of exposure. Considering his long life, the time periods of importance are: for genetic considerations, the interval from conception to the end of the reproductive period; and for somatic effects, the total lifetime during which delayed effects may become manifest.

(1) Embryonic neuroblasts in vitro are sensitive to a dose of radiation of orders of magnitude smaller than the dose which kills adult nerve cells.

(2) In fetal organ systems, effects (e.g., delayed effects on blood forming tissues) may be evident with 2-1.0 r acute exposure, and skeletal effects with 24 r.

(3) The child's thyroid is more sensitive than the adult thyroid. Cancer of the thyroid has been observed in children after an acute external exposure of approximately 150 r. In adults the same effect has been observed only after exposures of more than several hundred r.

(4) A study of the differential sensitivity for induction of skin tumors by x-ray (used in the treatment of hemangiomas) showed that children were 3-4 times more sensitive than adults.

(5) In adults, the presence of disease states may be correlated with the later appearance of neoplasms, apart from the effects of radiation. This has been reported in ankylosing spondylitics who later developed leukemia.

2.20 In addition to differential sensitivity there are important factors of differential uptake between adults and children. Some of these are:

(1) The rate of deposition of skeletal calcium and the fractions of equilibrium Sr-90/Ca ratio for accretion and for remodeling of bone are each a complex function of age; each may vary by a factor of at least 10 from newborn to age twenty.

(2) The uptake of iodine per gram of tissue by the normally functioning thyroid gland differs widely between children and adults.

(3) Different age groups are exposed to different environmental radiation conditions. For example, because of differences in dietary intake an infant may be exposed to different total amounts of Sr-90 radiation than an adult.

2.21 There is a current definition for the "average" adult–"Standard Man." The "Standard Man" is defined in such terms as organ size, distribution of elements in the body organs, fluid intake and excretion, and air balance. Each of these factors differs between adults and children, and also differs among various age groups of children. Therefore, there is a need for a comparable definition of "Standard Children" to be used in developing Radioactivity Concentration Guides.

Dose-Effect Relations for Genetic and Somatic Effects

2.22 Among the possible dose -effect relationships at least three possibilities have been considered in the literature: (1) a linear, no threshold concept; (2) a nonlinear, no threshold concept; and (3) a nonlinear, threshold concept. Among the parameters which must be considered in the relationships are the total dose, the dose rate, the biochemical or clinical manifestation of effect, and the period of time in which the effect becomes manifest.

2.23 The evidence for linearity and no threshold for induction of mutations in the genetic material is based on work with fruit flies and mice. The method consists in the scoring of the

occurrence of specific traits in progeny of irradiated animals. In studying irradiated males, the experimenter can determine the generic manifestations in the progeny corresponding to the stages of development of spermatogonia and spermatozoa in the parent. This can be accomplished by selecting suitable time intervals between irradiation and mating. Experimentally one measures visible traits in the offspring (such as coat color changes in the mouse or failure of pupal development in the fruit fly). These traits are then attributed to specific gene mutations in the parent germ cell. The effect is therefore considered to be directly proportional to the number of genetic changes induced in the parental germ cell. It is well demonstrated that the curve showing effect against dose in experimental animals is linear within the range of 37 r to 1,000 r total acute dose, and geneticists believe that there is no threshold for the genetic effect. The finding of a dose-rate dependence effect (chronic exposure is approximately one-fourth as effective in inducing mutations as is acute exposure) probably represents partial recovery at low dose-rates and does not conflict with the no threshold concept.

2.24 For somatic effects, unlike genetic mutation effects, there is no general agreement among scientists on the dose-effect relationships. It is known, for example, that the nature of the dose-response curve can be altered drastically by changes in the external environment of the organism. In addition, although radiation may be the initiating event, there may be other promoting factors operating before the manifestations are evident. Such factors mentioned in the literature include cocarcinogens: hormones, chemicals, and viruses.

2.25 Because of the complexities of animals and man, there may be many mechanisms by which radiation produces effects. One of the mechanisms may be the induction of a primary effect by radiation which, after a sequence of secondary events over a period of time, leads to a clinical manifestation such as neoplasia. In this hypothesis, the induction of the primary effect could be consistent with a linear no threshold concept of dose-effect relationship, yet the successive manifestations of the damage could be nonlinear and not consistent with a threshold concept. Therefore, in the case of neoplasia, the demonstration of linearity or nonlinearity for the gross effect does not predict the presence or absence of a threshold dose for the primary insult.

2.26 There are some somatic effects in animals which do not support a linear no threshold concept (e.g., acute mortality; splenic, thymic and testicular atrophy, incidence of lens opacity, duration of depression of mitotic activity, and incidence of heterologous tumor implants). However, the experiments demonstrating these effects were not performed primarily to examine threshold theory and were done at high dose ranges above 100 r. Considering the diversity of results in different species of animals, extrapolations to man for these effects at low doses should be made with caution.

2.27 In man, the chief evidence for a linear dose-effect relationship for somatic effects comes from some of the leukemia studies (see Table 2.2). Data are available for acute exposures above 50 rads in adults. Predictions of the incidence of leukemia in the general population per rad of exposure have been made by extrapolations from these data. Certain of these predictions have involved the assumption that the occurrence of radiation-induced leukemia per rad will remain constant for the life of the population, the assumption of no difference among effects of irradiation of various parts of the body and the assumption of a constant probability of occurrence of leukemia per rad of acute and chronic exposure. There is no direct evidence that justifies extrapolation from the condition of acute exposure to one of a low dose chronic external exposure, or to the radiation from internal emitters.

2.28 In summary, the evidence is insufficient to prove either the hypothesis of a damage threshold or the hypothesis of no threshold in man at low doses. Depending on the assumptions used, forceful arguments can be made either way. It is therefore prudent to adopt the working principle that radiation exposure be kept to the lowest practical amount.

Genetic Effects

2.29 The following working assumptions have been derived from the evidence considered in this staff report: (1) radiation induced mutations, at any given dose rate, increase in direct

linear proportion to the genetically significant dose;[2] (2) mutations, once completed, are irreparable; (3) almost all the observed effects of mutations are harmful; (4) radiation-induced mutations are, in general, similar to naturally occurring mutations; and, (5) there is no known threshold dose below which some effect may not occur.

2.30 The linearity is established in fruit flies down to 25 r and is confirmed in mouse spermatogonia down to 37 r, but there is no direct evidence for linearity below these doses. Although the studies in animals do not involve a period comparable to the 30-year period of chronic irradiation in humans, the hypothesis used in this staff report is that the mutations induced by small dose rates of radiation to human reproductive cells are cumulative over long periods of time. Under this assumption, irradiation of the whole population from any source is expected to have genetic consequences.

2.31 In addition to genetic effects in the progeny of an exposed individual, attention must be given to the total genetic effect on the population. Within the working assumptions above, the total genetic load is independent of the distribution of the exposure within the population. Therefore, when radiation protection standards are established for large numbers of exposed persons, limitations may be imposed by considerations of population genetics (the effects on population as a whole).

2.32 Major areas of uncertainty in genetic information for man, with regard to both population and individual genetics, are the estimations of the spontaneous and induced mutation rates; the genetic load of mutations; the influence of man-made factors (mortality reduction brought about by health protection, for example) operative in natural selection; and the influence of synergism of gene interaction.

2.33 Formulation of radiation protection standards has been based in part on estimates of genetic hazards to man. These in turn have been based chiefly on data from mice and from acute rather than chronic irradiation. Results of recent experiments considered pertinent to the evaluation of genetic effects are:

(1) The genetic effects under some radiation conditions may not be as great as those estimated from the mutation rates obtained with acute irradiation. It has been shown in mice that fewer specific locus mutations are produced in spermatogonia and oocytes by a low dose rate (chronic gamma radiation at 90 r per week) than by a high dose rate (acute irradiation at 90 r per minute) for the same total accumulated dose above 100 r. A similar effect has been reported for sex-linked lethal mutations in the oogonia of fruit flies. The number of mutations induced in spermatogonia by chronic irradiation is smaller (about one-fourth) than that induced by acute irradiation.

(2) Studies being planned may define quantitatively the dose-effect relationship with fractionated, low doses delivered at high dose rates. These data may be of direct significance to medical practice using fluoroscopy and radiography.

(3) Life shortening has been demonstrated in the offspring of male mice irradiated at high doses.

(4) Radiation doses of 25 r appear to produce chromosomal breakage in human cells grown in tissue culture.

Items (1) and (2) above indicate that in the preparation of radiation protection standards based on the genetic effects, consideration should be given to dose rate as well as total dose.

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[2]The genetically significant dose to the individual is considered to be the accumulated dose to the gonads weighted by a factor for the future number of children to be conceived by the irradiated individual. The genetically significant dose for the population is defined as the dose which, if received by every member of the population, would be expected to produce the same total genetic injury to the population as do the actual gonad doses received by the various individuals.

Leukemia

2.34 Information useful for study of the risk of leukemia among exposed persons is based on experimental data on animals, some observations on humans, and the rise in crude leukemia mortality rates observed in many countries. There is more information available on the correlation between radiation exposure and leukemia incidence in man than there is for other radiation effects.

2.35 Most of the reported investigations indicate that the incidence of leukemia among irradiated persons increases with the exposure dose. A definitely increased incidence of leukemia occurs after one large whole body dose or a large accumulated dose. The available evidence applicable to the general population under the assumptions listed in paragraph 2.27 indicates a linear correlation of dose to incidence down to about 50 rads of whole body acute exposure. The specific findings in other studies vary with the type of exposure and are speculative at lower doses. There have been reports that, during prenatal life, fetal doses as low as 2-10 r may double the incidence of leukemia, although other studies have not confirmed this finding. Prenatal exposure may be quite different from exposure of adults and there is no evidence that these low dose levels may be effective later in life. There is also no satisfactory evidence that chronic lymphatic leukemia is produced by radiation although this is the form of leukemia primarily responsible for the rising crude leukemia rate in the general population.

2.36 Past studies of leukemia-radiation correlations in human populations have limitations imposed by retrospective epidemiological techniques as well as factors inherent in the nature of leukemia. Epidemiological techniques which are retrospective in type are limited by the:

(1) difficulty of determination of the radiation dose;

(2) absence of uniform radiation recording methods;

(3) difficulty of associating medical and vital statistical records: i.e., such studies introduce biases inherent in the techniques of interview, questionnaire, or manual searching;

(4) statistical selection of cases which may be weighted with those cases having a disease related in some way to leukemia; and

(5) the fact that the numbers of persons in the population groups studied are usually small.

2.37 The following factors produce difficulties in the evaluation of the findings on possible radiation produced leukemia:

(1) Although leukemia has the advantage of the use of simpler procedures for the diagnosis of the disease than are available for other neoplastic diseases, it has the disadvantage that the classification of various types of leukemia is subject to debate. It is thus difficult to compare statistics of different origins.

(2) The hematological effects such as are seen in leukemia can also be observed in other diseases which may or may not be radiation induced.

(3) Leukemia ascribed to radiation cannot be distinguished from leukemia due to other causes.

(4) Leukemia in humans is a rare disease whose crude annual incidence in the population-at-large is about 5 per 100,000 persons.

(5) The various forms of leukemia have different clinical courses and the relative incidence of cytologic types varies with age. Not all the various forms of leukemia can be placed in one category since it does not appear that the chronic lymphatic form may be induced by radiation.

2.38 Considerations of the above factors require that epidemiological studies include large samples of exposed subjects, provide mechanisms for follow-up over long periods of time, provide adequate control groups, and provide ascertainable exposure and outcome.

2.39 Conclusions drawn from the studies listed in Table 2.2, indicate that:

(1) Under certain conditions, there is a clear association between leukemia and prior radiation exposure. This association has been demonstrated only where the exposures are high. The effect may be discerned at doses of the order of several thousand r for prolonged intermittent exposure over many years in normal adults; or, doses of the order of 500 r for bone marrow exposure in adult males with pre-existing disease; or, doses of the order of 50-100 r for acute whole body exposure in a general population of all ages; or at acute dose possibly as low as 2-10 r to the fetus;

(2) Long follow-up periods are required to assess cancer experience following irradiation.

(3) Little data exist on leukemia incidence among women exposed to therapeutic doses of radiation from radium or x-rays;

(4) It is unlikely that retrospective studies will definitely solve the question of the shape of the dose-response curve at low levels of exposure or the existence of a threshold. Additional retrospective studies on population groups receiving high doses of radiation may provide refined quantitative knowledge. There are only a few prospective studies reported that can provide information on both the quantitative and qualitative effects of chronic low doses received over many years;

(5) The risk of any one individual developing leukemia is small even with relatively large doses. However, when large populations are exposed, the absolute number of people affected may be considerable.

2.40 The leukemogenic effect of internally deposited isotopes requires special mention.

Strontium: We have no documented evidence that bone depositions of strontium in humans have produced leukemia. Statements that radiostrontium is leukemogenic are based solely upon studies in mice. Since leukemia is a common disease spontaneously occurring in certain strains of mice, one cannot accept this observation as necessarily applicable to man.

Thorium: Only a few cases of leukemia following thorium injections for medical diagnosis have been reported in the literature. The leukemias have occurred with latent periods up to 20 years. However, the dose calculations for irradiation of the bone are complicated by the presence of thorium daughters.

Radium: No cases of leukemia have been reported in those persons who have had radium deposited in their bones, even though some persons developed bone cancers. This is not unexpected in view of the fact that radium deposited in bones results in a relatively small dose to the bone marrow.

Iodine: Only a few cases of leukemia have been reported in patients receiving iodine-131 for the medical treatment of hyperthyroidism and cancer of the thyroid. It would seem that well planned large population studies on persons who received radioiodine medically would contribute to the knowledge of the leukemogenic and carcinogenic effect at the levels used.

2.41 The possibility of the detection of low doses of radiation by hematological techniques is deserving of high priority. The most sensitive indicator available at present may be the counting of binucleated lymphocytes, but the technique is not now practical for wide applications because of the need to examine large numbers of cells on hematology slides. The development of practical electronic devices to screen these cytologic blood specimens should be encouraged. The prognostic significance of the observations of morphological changes in the lymphocytes will be elucidated by long term follow-up of selected study and control groups.

Other Neoplasms and Premalignant Changes

2.42 Clinical evidence indicates that irradiation in a sufficient amount to most parts of the body may produce cancer as a delayed effect although no inference of an incidence-dose relationship should be drawn. Some of the evidence in humans is based on:

(1) Skin cancers among radiologists in the early history of the use of x-ray;

(2) Thyroid cancers in children irradiated in the neck region;

(3) Leukemia among children who were exposed in utero to x-ray for pelvimetry of the mother;

(4) Bone sarcomas in radium dial painters and other persons exposed to radium-226;

(5) Liver sarcomas in medical patients given thorotrast; and

(6) Bronchogenic cancer in miners occupationally exposed to radon and its daughters.

2.43 The bulk of the evidence lies in the work done on animals with external whole and partial body doses, as well as with internally absorbed radionuclides. Both benign and malignant lesions have been produced, although the evidence is incomplete and there is no simple relationship between carcinogenesis and dose. Mice are more sensitive to all modalities of radiation exposure than man for the induction of skin and ovarian tumors and leukemia.

TABLE 2.2

TYPES OF STUDIES THAT HAVE BEEN DONE IN HUMANS ON LEUKEMIA AND RADIATION

I. Occupational

1. Cases not reported in the literature.
2. Scattered reports in the literature.
3. Radiologists.
4. Uranium miners.

II. Therapeutic and Diagnostic

1. Children receiving partial body exposure to x-rays.
   a. Infants treated for thymus gland enlargement.
   b. Infants similarly treated who had normal size thymus glands.
   c. Children treated for pertussis and lymphoid hyperplasia.
   d. Children treated for other benign conditions of many different types.
   e. Children treated for neuroblastoma.
2. Adults
   a. Patients with ankylosing spondylitis given x-ray treatment to the spine.
   b. Radiologists receiving partial body x-ray radiation over many years.
   c. Patients treated for hyperthyroidism with x-ray; and radioiodine.
   d. Patients treated for polycythemia with radiophosphorus.
3. Prenatal

   Maternal prenatal exposure to diagnostic doses of x-rays.

III. General Population

Japanese people who received whole body irradiation from A-bomb explosion.

IV. Internal Emitters

1. Thorotrast
2. Radium
3. Iodine
4. Phosphorus

2.44 It is pertinent to the discussion of a threshold dose or dose rate dependence for carcinogenesis to describe two theories of radiation carcinogenesis: the direct somatic mutation effect and the theory of indirect effect.

2.45 The direct theory postulates that the incidence of tumors induced by radiation in a population is proportional to the dose. This theory states, by direct analogy with genetic theory, that the somatic cell may incur chromosomal changes which become evident on cell division and lead to a neoplastic change. So far it is impossible to test this on human populations. Animal experiments show that the effect is much more complicated. The theory of indirect effect considers that there are tissue and hormonal factors which mediate the occurrence and site of development of tumors following irradiation.

2.46 The evidence bearing on the two theories may be summarized as:

(1) The long latent period for development of tumors may indicate that they develop only after a series of premalignant changes or states of tissue alteration have taken place. As yet unknown is the sequence of events and how the events are correlated with dose or dose rate. For example, the deposition of radium in bone may produce slight changes in the bone at lower levels, necrosis at increasing levels, and bone tumors at high levels.

(2) In man, the latent period for cancer induction by radiation is often from 10 to 20 years, although for leukemia the period may be from 5 to 10 years after a single whole body irradiation. For chronic exposure at low dose rates, it would appear that the latent period is longer.

(3) Tissue changes induced by radiation need not occur at the site of injury. There are indications that the critical factors may include responses of the whole body to the radiation, rather than the radiation effect upon a single cell exclusively; examples of this principle are:

(a) The primary cause of tumors such as mouse lymphomas or mouse ovarian and pituitary tumors may be disturbances of an endocrine gland.

(b) Mouse experiments how that shielding of a part of the body will prevent the appearance of radiation leukemia, or that shielding one ovary will prevent a tumor from developing in the other.

(c) Cells grown in tissue culture (where growth inhibitory factors which may be present in the body are lacking) have a tendency for malignant variance entirely apart from considerations of radiation. Under certain conditions, attempts to transplant a tumor to an animal are unsuccessful until the animal has developed an autogenous metastatic malignancy.

(d) The presence, in an animal or man, of a cancer is associated with an increased probability of occurrence of a second cancer, in a similar or other tissue.

2.47 At chronic low levels of radiation the combination of varying susceptibility with age and the long latent period for tumor induction complicates an analysis of dose-effect relationships. Experimental animals must be maintained for long periods of time and there must be large numbers of animals to achieve statistically significant results.

2.48 In man, the data seem to show that one must be exposed to relatively high external exposure levels to show a carcinogenic effect in certain tissues. For example, available information indicates that cancers have been observed in persons receiving doses in the range of 500 to 2,500 r to the skin. The thyroid carcinogenic dose has been shown to vary greatly with age and may be one of the most sensitive indices in children of the carcinogenic property of radiation.

Bone Tumors From Internal Emitters

2.49 The two sets of crucial data on the problem are the human radium experience and the animal experiments, now underway, on comparative toxicity of radium, strontium, plutonium, and thorium.

2.50 Historically, the evidence leading to the first establishment of a radium body burden limit, for occupational workers only, was based on physical data and a small amount of bio-medical information on a few dozen adults. Summaries of new data on several hundred living persons have been reviewed for this report. Persons studied were workers who absorbed pure radium (or radium plus mesothorium and radiothorium) in the course of radium dial painting, or were patients treated medically with radium waters, or were persons drinking public water supplies relatively high in radium. The information permits the comparison of effect on bone with body burden estimates of radium-226-equivalent present after periods as much as 35 years of prolonged exposure. Present physical techniques of estimation of body burden are based on radon breath analysis, whole body gamma counting, excreta analysis, and the assay of teeth and bone. The complications of dosimetry in some of the dial painters arising from the presence of both radium and mesothorium are partially resolved, but the exact equivalence of radium to mesothorium is not well established.

2.51 The clinical evaluation of the living persons studied includes a history, physical examination, and radiographic and pathological studies. The criteria of effect are based on the differential diagnosis of x-ray evidence of bone changes, the presence of pathological fractures, bone tumors, changes in teeth or signs of other findings.[3] The period between exposure and observation of skeletal changes by x-ray examination is usually determined by the date of examination rather than the date of onset of skeletal changes. Rarely are serial radiographs available over a period during which the changes first appear. In other than special microradiographic studies, there is no evidence available of cellular or biochemical effects.

2.52 A major problem in evaluation of the hazard of radium exposure is the definition of a clinically significant effect. If clinically significant effect is defined in terms of significant injury to the person, it may include only the symptomatic factors which impair the person's daily living, energy or longevity (tumors and pathological fractures). If clinically significant effect is defined in terms of detectable changes, the index may be radiographic evidence discernable to a competent physician. In either case the changes indicate varying degrees of late effects and are observed after many years of exposure.

2.53 It can be hypothesized that, on a cellular level, the effect is linearly proportional to body burden. Gross demonstrable changes plotted against dose could follow a normal distribution even though the effect at the cellular level were linear.

2.54 In attempting to define effects which can be extrapolated to the general population the following unknowns are apparent:

(1) the sequence of events during the latent period, as a function of dose;

(2) the radiobiological effect on small volumes of tissue;

(3) the site of injury and the degree of recovery from injury;

(4) the elapsed period of time from cellular injury to the evidence of the effect and the possible interrelationships among bone osteitis, necrosis, pathological fracture, and bone tumors;

(5) the variance in biological sensitivity with age; also, the variance in bone physiology at all ages in humans, the structure of the organic matrix, the crystalline and vascular structure, and the differences in homogeneity of distribution of the bone seeking nuclides;

(6) the variations of body burden with time in the individual after a single or fractionated intake; more radium retention data are needed in humans to permit determination of body burdens at times less than the 35 years after initial intake;[4]

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[3]The indices used are: absence or presence of x-ray evidence of localized areas of bone rarefaction, areas of increased density, abnormal trabecular pattern, severe aseptic necrosis, pathological fracture; abnormal tooth structure; sarcoma; carcinoma at other sites; leukemia; anemia.

[4]Some recent data suggest that, for oral intake of radium waters, the measured body burden of humans drinking the waters is about one-sixth of the body burden predicted by currently used biological models.

(7) information from large populations on the correlation between the average background body burden of radium and the natural population incidence of osteogenic sarcoma; and

(8) uncertainties in the RBE for alphas on chronic exposure.

2.55 There is no evidence to establish definitely the presence or absence of a threshold for the effects of radium deposition in bone. However, the first appearance of minimal radiographic changes in boner; of adults exposed to radium occurs with a residual body burden (measured several decades after exposure) of the order of 0.2 microgram. Whether this effect is attributable to radium is in doubt because of the absence of matched age group controls. There seems to be no doubt that, at 0.5 microgram burden, changes in adult bones, shown by radiographs, are manifest in some individuals. Radiographic changes are always seen above 0.8 microgram, and there is agreement that bone tumors begin to occur at about a burden of 0.8 to 1.0 microgram. Teeth changes were noted in a young person with a body burden of 0.15 microgram. Within the limits of the time duration for the effect and the relatively small numbers of individuals studied, there is a range of radium body burdens within which any specific clinically significant effect occurs. The body burdens among individuals with a given effect appear to be statistically normally distributed At increasing burdens the curve of body burden against effect follows a steeply rising slope. At body burdens below 0.1 microgram, which is the are of our interest, prediction is hazardous.

2.56 It would appear- that current radium studies (among the groups described in paragraph 2.50) may have a maximum number of about 2,000 persons available for body burden measurements. These numbers may be insufficient on a statistical basis to assure extrapolation of the probability of occurrence of an effect to the general population. It remains to be demonstrated whether or not, on an individual basis, the diagnostic methods used on humans can show "damage" below 0.1 microgram. This is true even if one studies a larger number of individuals, particularly if the group is composed of children with differential sensitivity or of older persons with intercurrent infections or increased bone fragility. It is hoped that pertinent data on the question of threshold will be forthcoming from animal studies. There is suggestive evidence that the length of the latent period for the development of "clinically significant findings" may increase as the body burden decreases. If this be true, depending on the age of the animal, the latent period may be greater than the remaining lifetime of the animal.

2.57 With other bone seeking radionuclides there are not as extensive data in man on biological effects as for radium. Therefore, it has become the custom to relate the biological effects of other bone seeking radionuclides to those of radium. Evidence for the relationships has been obtained at high doses in animals. For example, mouse experiments showed the ratio of body burden of radiostrontium to radium for the same tumor induction to be approximately 10 to 1. However, newer biological data in man on the skeletal escape and excretion of the radium daughter radon require further adjustment in the ratio when it is applied to man. Although bone tumors have been produced by radiostrontium in animals, it should be noted that no cases of bone tumors have been demonstrated in man as due to strontium-90.

Life Span Shortening

2.58 Radiation exposure does not produce in the individual a pattern of effects specific to radiation. Life span shortening has been demonstrated in animals by comparisons of mean life span between exposed and nonexposed groups. This involves observations continued to death of the cohorts of the irradiated individuals while controlling the intercurrent factors which might affect the study groups.

2.59 The experimental evidences of radiation effect on life span in animals includes:

(1) Exposure of animals to chronic high doses, in general, decreases their life span. A plot of the percentage survival vs. time yields an S shaped curve in both the exposed group and the unexposed controls. The mean survival time, however, is shortened in the exposed group to the total dose. While the evidence is not conclusive, it appears that in mice the mean life span is lengthened at very low dose rates, at a total dose of about 100 r. However, in every piece of experimental evidence (except at about the 100 r level in animals described above) there is life span shortening at dosages above approximately 100-300r total bodydose. At such dosages the life span shortening in mice is in the order of 1 to 1.5 percent of total life

span per 100 r total dose. The evidence for linearity of the dose-effect curve in other species (dogs) rests on only a few animals and, again, at doses greater than 100 r. There is suggestive evidence that protracted doses above 200 r have a lesser effect than a single acute dose. For protracted radiation, in some experimental animals, it appears that there is some life shortening from the range of 200 to 1000 r, but that the chronic radiation is about 4 to 5 times less effective per r than a single very large dose. For radiations other than x- or gamma-rays the RBE for this effect is uncertain.

(2) A decrease in the median lethal dose is observed when pre-irradiated animals are exposed to a second course of irradiation in comparison to controls not previously irradiated. This decrease in the LD_{50} depends upon the elapsed time between first and second exposure.

2.60 The facts concerning acute injury and delayed effects described above might lead to the following assumptions; viz:

(1) The total injury produced by radiation varies linearly with the dose.

(2) Partial recovery from acute injury occurs, but an irreparable effect remains.

(3) Recovery from reparable injury is an exponential process. The recovery rate varies with the dose rate and whether the exposure is whole body or partial body. The exponential rate of recovery following acute exposure is the cumulative expression of the fact that different parts of the body repair at different rates.

(4) Irreparable injury is accumulated in proportion to the total dose. It may be measured by life shortening, or, for experimental purposes, by a reduction in the median lethal dose. Residual injury of irradiation occurs irrespective of the age of the animal when irradiation is begun.

2.61 Examination of the specific causes of death shows that the same causes of death, apart from tumors, occur generally in the same proportion but sooner in the irradiated than in the unirradiated individuals. It is to be noted that observations are sometimes made of some vascular impairment or accumulation of connective tissue, but these cannot be quantitated. Studies of performance tests may shed more light on this.

2.62 The effects from large acute exposure may conform to the assumptions outlined above but all of these assumptions may not be applicable to the effects of a chronic daily dose of 1 r. Lacking in our knowledge is a formulation of indices of recovery following irradiation at these low levels. The experimental use of the median lethal dose to measure recovery requires pre-irradiation doses of at least 40-50 r to yield definitive data with reasonable numbers of animals.

2.63 Little is known of the nature of the pathological process responsible for life shortening. One theory considers, by analogy to genetic mutations, that the accumulation of radiation injury to the somatic cell chromosomes leads to reproductive death of a somatic cell. This process occurring in a large number of cells may be responsible for the aging of an organism. In the present state of knowledge it is premature to attribute the complex processes of aging to somatic mutations. It seems that extensive studies of the causes of death shown by animal experiments and human surveys may further our knowledge of chronic radiation effects in man.

2.64 In humans the evidence for life span shortening is limited. Mortality studies among U.S. physicians, comparing the effects of occupational exposure of radiologists with other physicians and with the general male population, have not produced definitive answers to the question of whether a decrease in life span occurred in the radiologists. For the general population, estimations of a non-specific life shortening effect from whole body radiation continues to be based on experiments on animals exposed to large doses. There are as yet no data in man to answer the questions of quantitative estimates of life shortening effect per rad of whole body exposure. Equally in question are the existence of a threshold dose, or the dose fractionation effect for exposures commonly experienced by the general population.

Growth and Development

2.65 Only a portion of developmental defects are attributable to genetic origins. It is necessary to distinguish within the totality of congenital defects, those attributable to changes in the genetic material; and of the latter, those which may be due to environmental causes, including radiation. Some geneticists estimate that 10 percent of fertilized ova have some congenital defect (malformation) detectable during that generation. Of this 10 percent, about 0.1 are ascribed to an environmental insult to the developing fetus (such as rubella and other viruses, toxic chemicals, maternal nutritional disturbances, radiation, etc.); about 0.1 are clearly due to simple mendelian genetic systems; and about 0.1 are due to chromosomal aberrations of a particular type. The great bulk of the remaining 0.7 are believed to be due to complex genetic systems whose expression depends on environmental variables operating on alterations of the homeostatic balances of life. Radiation may be one of a myriad of possible causes of congenital defects.

2.66 In animals, effects of radiation on prenatal embryonic development have been demonstrated from 25 r to several hundred r or more, and are closely correlated with the time of gestation at which radiation is given. The prenatal effects include (1) failures of uterine implantation leading to a maternal missed period, or to miscarriages and stillbirths; (2) alterations induced in the varying stages of development of fetal organs which lead to a high neonatal death rate and abnormalities at term; and (3) late stage manifestations, such as subtle changes in physiological states.

2.67 Parts of the human brain and eye are probably susceptible to injury until the last months of gestation. In mice, acute doses of 25-30 r (whole body x-rays) to the fetus produce discernible skeletal defects. It is known from bone studies on human stillbirths that radiostrontium may pass through the placental barrier and become fixed in the skeleton and other organs. It is presumed that exposure of this type may in the early stages of the growing embryo resemble whole body exposure.

2.68 Effects of irradiation on postnatal development are also described. Although it is known that regeneration and repair processes are sensitive to radiation, more quantitative studies under conditions of whole or partial body exposure are needed. In rats, quantitative studies show that growth in body weight is decreased as a result of about 24 r per week whole body irradiation. Localized irradiation of the epiphysis of bones at high doses in humans and animals will cause measurable shortening of the bones. Studies on children exposed to the atomic bomb in Japan indicate that there may be depression of growth rates after irradiation as has been observed in animals. However, little is known in either animals or humans of the after-effects of whole or partial body irradiation in the young in comparison to mature animals, and of the subtle changes induced in their physiological efficiency.

Skin Effects

2.69 Knowledge of effects to the skin of localized exposure to radiation of low penetrating power has accumulated since the discovery of x-rays. The early promulgation of a "tolerance dose" of x-radiation was established by quantitating skin reactions (erythema) with dose. Among early radiologists the chronic radiation produced erythema, dermatitis, and skin cancers. Under modern practices, these conditions should no longer be seen.

Eye Effects

2.70 Injury to the lens serves as a sensitive detecting index of the effect of radiation on the eye. Lens opacities (cataracts) have occurred following exposure of the eye in animals (exposed to neutrons and x-rays), and cyclotron workers, nuclear physicists, and Japanese survivors at Hiroshima and Nagasaki. In man, the minimal single dose producing cataracts is estimated to be approximately 200 rads acute exposure of x- or gamma-rays. In animals the production of cataracts depends on the age and health of the animal, the exposed lens area,

and the RBE of the source of radiation. There are no quantitative dose-effect data relating the incidence of cataracts late in life in humans or animals to the acceleration of aging processes.

Summary

1. Acute doses of radiation may produce immediate or delayed effects, or both.

2. As acute whole body doses increase above approximately 25 rems (units of radiation dose), immediately observable effects increase in severity with dose, beginning from barely detectable changes, to biological signs clearly indicating damage, to death at levels of a few hundred rems.

3. Delayed effects produced either by acute irradiation or by chronic irradiation are similar in kind but the ability of the body to repair radiation damage is usually more effective in case of chronic than acute irradiation.

4. The delayed effects from radiation are in general indistinguishable from familiar pathological conditions usually present in the population.

5. Delayed effects include genetic effects (effects transmitted to succeeding generations), increased incidence of tumors, life span shortening, and growth and development changes.

6. The child, the infant, and the unborn infant appear to be more sensitive to radiation than the adult.

7. The various organs of the body differ in their sensitivity to radiation.

8. Although ionizing radiation can induce genetic and somatic effects (effects on the individual during his lifetime other than genetic effects), the evidence at the present time is insufficient to justify precise conclusions on the nature of the dose-effect relationship especially at low doses and dose rates. Moreover, the evidence is insufficient to prove either the hypothesis of a "damage threshold" (a point below which no damage occurs) or the hypothesis of "no threshold" is man at low doses.

9. If one assumes a direct linear relation between biological effect and the amount of dose, it then becomes possible to relate very low dose to an assumed biological effect even though it is not detectable. It is generally agreed that the effect that may actually occur will not exceed the amount predicted by this assumption.

III. – SOURCES OF RADIATION EXPOSURE

3.1 For convenience, the exposure of persons to radiation will be divided into three classes: (a) exposures from natural sources; (b) exposures from man-made sources other than environmental sources; and (c) exposures from environmental contamination. Where data are available, the exposures of various critical portions of the body are indicated separately. Of special interest are the gonadal dose because of its genetic significance and the bone marrow dose because of possible leukemogenesis. Therefore, the following discussions center their attention on the genetically significant and hone marrow doses as examples of the general problem.

Natural Sources

3.2 Table 3.1 lists the doses received by persons in the United States from natural sources. The principal exposures from radiation sources outside of the body (external sources) and from sources inside of the body (internal sources) are listed separately.

3.3 The dose from cosmic rays for 38 principal cities in the United States was determined from data on the variation of cosmic ray dose with altitude[1] (Solon et al--1959). As most of the large centers of population are near sea level, the mean dose to the population of the United states from cosmic rays is nearer the lower than the upper limit.

3.4 The dose from terrestrial external gamma rays was estimated by subtracting the cosmic ray component from measurements of the sum of the two components (Solon et al, 1959) and applying an approximate correction (0.6) for the average shielding of the outer tissues of the body. The resulting range of values includes mean values for 38 of the principal cities of the United States. However, it should be noted that doses obtained at different locations within a city varied in several cases by a factor of 2 or 3 for the limited data available. In part, this may be due to shielding of heavy structures or the proximity of structures whose building materials contained small quantities of gamma emitting nuclides.

3.5 When doses from internal sources are added, it appears (Table 3.1) from the limited data available that the radiation dose to soft tissue from all natural sources varies by at least a factor of 2 in the United States.

Man-Made Sources Other Than Environmental Contamination

3.6 Exposure of persons to man -made radiation other than environmental contamination arises principally from (1) exposures received during medical procedures, (2) exposures received by radiation workers during their working hours, (3) exposures to persons in the vicinity of medical and industrial radiation sources (environs), and (4) exposure produced by other sources, such as radium dialed watches, television sets, etc. Table 3.2 summarizes the estimated per capita mean marrow doses and genetically significant doses to the population from man-made sources other than environmental contamination. The per capita dose is the sum of all of the doses received by the population divided by the number of individuals in the population. The annual genetically significant dose to the population is the average of the gonadal doses received by the individuals each weighted for the expected number of children to be conceived subsequent to the exposure.

3.7 For the occupational exposure it is assumed that as much as a half of one per cent of the population might be exposed in the future to as much as an average annual dose of 4 rems. Both estimated figures are high because the fraction of the population occupationally exposed to

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[1]Variation of the dose from cosmic rays with latitude is small compared to that with altitude.

radiation and the annual. dose they receive at the present time is considerably less than that assumed in Table 3.2. 'There are presently only about 66,000 radiation workers out of a total employment approximating 120,000 in the Atomic Energy Commission and its contractors (see Table 5.1) and perhaps 250,000 persons occupationally exposed to x-rays in medical applications. Persons in these two areas plus the industrial radiography field probably do not constitute more than 0.2 percent of the population at the present time. Morgan (1959) indicates that the average annual exposure of radiation workers at Oak Ridge National Laboratory is 0.4 r, and at Hanford, 0.2 r (see Table 5.1). In the fields of medical applications and industrial radiography, the annual doses received by most radiation workers falls within the range of 0.5 to 5 rems. Most of them probably receive doses in the lower half of this range but a few possibly receive more than 5 and some less than 0.5 rems. Thus, the average annual dose for all radiation workers is probably much less than the 4 rems assumed for the calculation at the present time.

3.8 For exposure of persons in the environs it is assumed that one per cent of the population might be involved and they would have an annual dose of as much as 0.5 rems. This assumption concerning per capita dose from the exposure of environs is probably larger than will be obtained in the foreseeable future. The fraction of the population assumed is quite large and it is unlikely that the average individual will receive as much as 0.5 rem per year.

3.9 Unfortunately, there are no data on the mean marrow dose from medical therapy, but it is obvious that diagnostic x-rays contribute considerably to the total exposure from man-made sources other than environmental contamination. While diagnostic x-rays are an important clinical tool, the practitioner of the healing arts should always attempt to balance the risk against the gain for each exposure. He should also assure himself that the most modern techniques are being used in order that the dose is reduced as much as practicable. Current recommendations of the NCRP (H54, 1954 and H60, 1955) indicate methods by which the gonadal dose can be minimized. If these recommendations are observed the bone marrow dose will also be minimized.

Man-Made Environmental Contamination

3.10 Sources of environmental contamination may result from fallout after the explosion of nuclear devices and during the use and processing of fuels for reactors. There are other sources which contribute relatively smaller amounts to environmental contamination.

3.11 Environmental contamination from fallout has received considerable attention over the past decade. When there is a nuclear explosion in the megaton range, the gases cool so slowly that a major portion of the fission products enter the stratosphere where they are distributed widely. Some fission products drift back into the troposphere before losing their radioactivity and are deposited in patterns which depend at least in part upon meteorological conditions. This final fallout, however, takes a long time to drift back to earth so that the fission products from this stratospheric source consist mainly of the long-lived nuclides. For nuclear explosions in the kiloton range:, the heat of the fireball is considerably less so that the fission products do not reach the stratosphere but stay in the troposphere. About half of the radioactive material from the troposphere comes back to the earth in about three weeks and most of the fallout reaches the earth in about three months (UNSCEAR p. 99, 1958). From such a fallout, many of the nuclides are of short half-life.

3.12 According to reported estimates,[2] the genetically significant per capita dose in the United States from both external and internal radiation from fallout of cesium-137 will be about 53 millirem in 30 years providing nuclear weapons testing in the atmosphere is not resumed after the cessation at the end of 1958. It was also reported that the per capita mean marrow dose in the United States would be, under the same conditions, about 331 millirem in 70 years from cesium-137 and strontium-90. For continued testing at the same rate as in the previous 5 years, it was estimated that the above numbers should be multiplied by a factor of 8. Other estimates (UNSCEAR 1958 and Feeley 1960) are somewhat lower.

[2]W. Langham and E. C. Anderson, Fallout from Nuclear Weapons Tests, Hearings of the Joint Committee on Atomic Energy, Congress of the United States, May 1959, p. 1061 ff.

3.13 Under normal operating conditions, most industries in the nuclear engineering field, including the use of reactors, do not now release activity which will give significant contributions to the population dose.

3.14 It is usually considered very unlikely that the core of a reactor would melt down accidentally and release fission products. This possibility, however remote, is considered in designing a reactor. Modem reactors are designed with a containment shell which would permit only a very small portion of the fission products, from a melt-down, to contaminate the environment. However, according to the best engineering estimates, this and other containment provisions will not trap all of the activity. An additional major reduction in the activity released by the shell would substantially increase the cost of the reactor.

3.15 Plants used for the processing of spent fuel elements have a larger potential for contaminating the environment. Here the fuel element is dissolved and the radioactive material is liberated from the fuel element. However, the amount of material treated at any one time is much less than the material present in a reactor. In this process, fission product gases, such as radioactive iodine, bromine, xenon, and krypton are released from the fuel element. Most of the other radionuclides remain in the solutions. Some nuclides, such as cesium-137 and strontium-90, may be separated out for other uses. The remainder of the radionuclides are now stored in huge tanks. Such storage is, of course, expensive.

Summary

3.16 From a limited survey it appears that the human annual gonadal, soft tissue, and bone marrow doses from natural sources may be from 80 to 170 millirem (see Table 3.1).

3.17 The estimated annual genetically significant dose from all man-made sources except environmental contamination probably is about 80 to 280 millirem. The per capita annual mean marrow dose is probably greater than 100 millirem, although no data are available on the contribution from medical .radiation therapy. The genetically significant dose and the mean marrow dose are each of the order of the dose received from natural sources. Diagnostic x-rays provide a substantial contribution to these totals (see Table 3.2).

3.18 It has been estimated[3] that fallout will contribute about 53 millirem to the genetically significant per capita dose of the population in 30 years if nuclear weapons testing in the atmosphere is not resumed after the cessation at the end of 1958. If testing were to continue at the same rate as in the previous 5 years, it was estimated that the above number should be multiplied by a factor of 8. The estimated corresponding per capita mean marrow doses for 70 years are 331 millirem and 2648 millirem respectively.

3.19 Under normal operating conditions, most industries in the nuclear engineering field, including the use of nuclear power plants do not now release activity which will give a significant contribution to the population dose.

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[3]W. Langham and E. C. Anderson, Fallout From Nuclear Weapons Tests, Hearings of the Joint Committee on Atomic Energy, Congress of the United States, May 1959, p. 1061 ff.

TABLE 3.1

ANNUAL RADIATION DOSES[1] FROM NATURAL SOURCES

Irradiation	Millirem
By external sources:	
Cosmic rays	32-73
Terrestrial gamma rays	25-75
By internal sources:	
K^{40}	[2]19
C^{14}	[2]1.6
Ra^{226}	[3]?
Total	[4]80-170

[1]Doses to the gonads and other soft tissue including bone marrow.

[2]Report of United National Scientific Commission on the Effects of Atomic Radiation (UNSCEAR, p. 58, 1958).

[3]Unconfirmed research of Muth et al, Brit. J. of Radiol. Suppl. No. 7, 1957, indicates that the dose may be of the order of 2 millirem per year to the gonads and 5 to 15 millirem per year to other soft tissue.

[4]The lungs may receive an additional dose of from 125 to 1570 millirem per year from radon given off by building structures. The spread is caused by variations in ventilation and differences in building materials (UNSCEAR, p. 58, 1958).

TABLE 3.2

ESTIMATED EXPOSURE FROM MAN-MADE SOURCES (OTHER THAN ENVIRONMENTAL CONTAMINATION)

Irradiation	Average annual genetically significant dose to the population	Per capita annual mean marrow dose
	(millirem)	(millirem)
Medical (exposure of patients):		
Diagnostic x-rays	[2] [3]40-240	[4]50-100
Therapy	[5]12	Not available
Internal (radionuclides)	[5]1	10
Occupational	20	20
Environs	5	5
Other (luminous dials, TV, etc.)	[6]2	[6]1-3
Total	80-280	.....

[1]Fallout from tests of nuclear weapons is not included (see sub-section on environmental contamination).

[2]International Commission on Radiological Protection (ICRP) and International Commission on Radiological Units and Measurements (ICRU) Joint Study Group Report. Physics in Med. and Biology, 2 107 (1957).

[3]These are probable values.

[4]Report UNSCEAR, p. 66.

[5]Clark, S. H., Bull. of the Atomic Scientists 12 14 (1956). The 12 millirem per year may be an underestimate because patients treated for malignances are not included. Martin (1958), who assumed that these patients might procreate after treatment, obtained a value of 28 for Australia.

[6]Report of UNSCEAR, p. 11.

SECTION IV.–THE DERIVATION OF RADIATION PROTECTION STANDARDS

4.1 Shortly after the discovery of x-rays and natural radioactivity in the late 19th century, it became apparent that exposure to sufficiently large doses could produce both acute manifestations and serious later sequelae in man. Based on relatively limited observations on a rather small number of individuals, attempts were made to define a level at which these obvious deleterious effects would not be seen. With increasing scientific knowledge, based on observations of larger numbers of individuals and laboratory animals and a better understanding of radiation damage, these suggested levels have undergone continuous downward revision. For some time, however, the underlying basic philosophy remained unchanged, and radiation protection standards were based on the premise that there was a dose ("tolerance dose") below which damage would not occur. The validity of this basic assumption was subject to increasing question, first in the field of genetic damage, and later in connection with somatic effects. Thus, by 1954, the National Committee on Radiation Protection and Measurements included the following statement in Handbook 59 (NCRP, H59, 1954):

> "The concept of a tolerance dose involves the assumption that if the dose is lower than a certain value—the threshold value—no injury results. Since it seems well established that there is no threshold dose for the production of gene mutations by radiation, it follows that strictly speaking there is no such thing as a tolerance dose when all possible effects of radiation on the individual and future generations are included. . . " and " . . . the concept of a permissible dose envisages the possibility of radiation injury manifestable during the lifetime of the exposed individual or in subsequent generations. However, the probability of the Occurrence of such injuries must be so low that the risk would be readily acceptable to the average individual. Permissible dose may then be defined as the dose of ionizing radiation that, in the light of present knowledge, is not expected to cause appreciable bodily injury to a person at any time during his lifetime. As used here, 'appreciable bodily injury' means any bodily injury or effect that the average person would regard as being objectionable and/or competent medical authorities would regard as being deleterious to the health and well-being of the individual. . ."

4.2 With the accumulation of even more quantitative information concerning radiation effects in both animals and humans, and some increased understanding of the mechanisms of radiation injury, the possibility that somatic effects as well as genetic effects might have no threshold appeared acceptable, as a conservative assumption, to increasing numbers of scientists. In discussing its recommendations for additional downward revision of the maximum permissible occupational radiation exposure, the NCRP in 1958 stated (2):

> "The changes in the accumulated MPD (maximum permissible dose) are not the result of positive evidence of damage due to the use of earlier permissible dose levels, but rather are based on the desire to bring the MPD into accord with the trends of scientific opinion; it is recognized that there are still many uncertainties in the available data and information . . . ," and, "The risk to the individual is not precisely determinable but, however small, it is believed not to be zero. Even if the injury should prove to be proportional to the amount of radiation the individual receives, to the best of our present knowledge, the new permissible levels are thought not to constitute an unacceptable risk. . . "

4.3 Thus, over the past decade or two, there has been an increasing reluctance on the part of knowledgeable scientists to establish radiation protection standards on the basis of the existence of a threshold for radiation damage and on the premise that this threshold lies not too distant from the point at which impairment is detectable in an exposed individual. Although many scientists are prepared to express individual opinions as to the likelihood that a threshold does or does not exist, we believe that there is insufficient scientific evidence on which to base a definitive conclusion in this regard. Therefore, the establishment of radiation protection guides, particularly for the whole population, should take into account the possi-

bility of damage, even though it may be small, down to the lowest levels of exposure. This involves considerations other than the presence of readily detectable damage in an exposed individual. It also serves as a basis for such fundamental principles of radiation protection as: there should not be any man-made radiation exposure without the expectation of benefit resulting from such exposure; activities resulting in man-made radiation exposure should be authorized for useful applications provided the recommendations set forth in this staff report are followed.

4.4 If the presence of a threshold could be established by adequate scientific evidence, and if the threshold was above the background level and sufficiently high to represent a reasonable working level, a relatively simple approach to the establishment of radiation standards would be available.

4.5 On the assumption that there is no threshold, every use of radiation involves the possibility of some biological risk either to the individual or hi6 descendents. On the other hand, the use of radiation results in numerous benefits to man in medicine, industry, commerce, and research. If those beneficial uses were fully exploited without regard to radiation protection, the resulting biological risk might well be considered too great. Reducing the risk to zero would virtually eliminate any radiation use, and result in the loss of all possible benefits.

4.6 It is therefore necessary to strike some balance between maximum use and zero risk. In establishing radiation protection standards, the balancing of risk and benefit is a decision involving medical, social, economic, political, and other factors. Such a balance cannot be made on the basis of a precise mathematical formula but must be a matter of informed judgment.

4.7 Risk can be evaluated in several different ways before it is balanced against benefit. A logical first step is the identification of known or postulated biological effects. The uncertainty of our present knowledge is such that the biological effects of any given radiation exposure cannot be determined with precision, so it is usually necessary to make estimates with upper and lower limits.

4.8 It is helpful to compare radiation risk to other known hazards in order to maintain perspective or a sense of proportion with respect to the risk. For example, attempts have been made to compare the relative biological risks of various radiation exposure levels to such other industrial hazards as traumatic injuries and to toxic agents employed in industrial processes. Likewise, the possible hazards from various radiation levels have been reviewed in relation to such everyday risks to the general population as the operation of motor vehicles, the possibility of home accidents, and the contamination of our environment with industrial wastes.

4.9 Effects can also be evaluated in terms of the normal incidence of disease conditions usually present in the population which may also be caused by radiation. In a given instance, the portion of the total number of cases of a given disease which might be attributed to radiation may be quite small. Therefore, the significance of a given radiation exposure can appear superficially to be quite different depending upon whether the data are expressed in terms of the absolute numbers of cases of a given condition which will possibly result, or be expressed as percentages of the normal incidence. However, it is extremely difficult to assign any numerical value to the increase which should be permitted in a given abnormal condition. It is also important to remember that at the present time, any numerical predictions of the number or percentage increase in any given condition anticipated as a result of radiation exposure are based on inadequate data and have extremely limited reliability, even though upper and lower limits can be stipulated.

4.10 The biological risk attributable to man-made radiation may also be compared with that from natural sources. This approach is also important in maintaining perspective. Man and lower forms of life have developed in the presence of such natural sources in spite of any radiation damage that may have been present. Perhaps one of the more important advantages to this approach is that it makes due allowance for qualitative as well as quantitative ignorance of yet unrecognized radiation effects, if such exist. Weighing for various somatic as well as genetic effects is also inherently included. It automatically includes a consideration of the largest body of human and subhuman data on radiation effects. One disadvantage is the degree

of conservatism introduced by this approach, since it is likely that only a small fraction of the total incidence of disease results from background radiation.

Summary

4.11 Two factors need to be considered in the formulation of radiation protection standards: biological risk, and the benefits to be derived from radiation use. Maximum benefits cannot be obtained without some risk, and risk cannot be eliminated without foregoing benefits. Therefore some balance must be struck between risk and benefit.

4.12 Since an accurate delineation of risk is impossible, a number of approaches can usefully be employed to aid in the evaluation of risk, and to put risk in reasonable perspective. Each has merit, but such approaches are not mutually exclusive and should be used in combination. An evaluation of benefits in addition to an evaluation of risk is also necessary.

SECTION V.–BASIC GUIDES

5.1 The philosophical bases for derivation of radiation protection standards have been discussed in Section IV, with the conclusion that they are not mutually exclusive, and that consideration should be given to all in the final selection of numerical values. We believe, however, that there are reasons why the relative emphasis placed on the various bases may appropriately be different for the radiation worker and the general population. Additionally, there appear to be a number of reasons why the exposure to the general population should be less than that for occupationally exposed groups, For example:

(1) There is reason to believe that the child and the infant may be particularly sensitive to radiation damage. Children and infants are not included in occupationally exposed groups.

(2) The number of years of exposure to radiation in the course of employment will be less than the average total life span. Therefore, the total accumulated dose will be less for an individual exposed only during a working life than for an individual exposed at the same level from birth through a normal life span to death.

(3) There is considerable evidence that, at least for certain effects, there is a latent period between the time of exposure and the time at which effects are first detectable. The effects of exposure late in life may not become manifest during the normal remaining life span. Whereas, the effects of exposure early in life may well become manifest during the longer remaining life span.

(4) Industrial workers undergo at least some degree of preplacement selection. It is thus possible to exclude from exposure those individuals with intercurrent disease who might be more susceptible to injury.

(5) Insofar as an individual has a choice of occupations, there is, at least in principle, a voluntary acceptance of the small risk potentially involved.

(6) Considerations of population genetics make it desirable to limit gonadal exposure of the whole population.

Radiation Protection Guides for the General Population[1]

6.2 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. Simi-

[1]See Section VII for applicability of these guides.

larly, 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-NCR, 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 in Section III indicates that allocation of this population dose among various sources is not needed now or in the immediate future.

Radiation Protection Guides for Occupational Exposure[2] [3]

5.6 Extrapolation from experience with background radiation to the exposure of the relatively small percentage of the population in the radiation industry is rather unsatisfactory. The difficulties inherent in a careful mathematical balancing of the biological risk against the tota1 gain have been outlined previously. It is possible to estimate the maximum biological damage which could be reasonably expected to result from a given radiation exposure. Using such estimates, a numerical value can be selected at which the radiation risk appears so small as to be justified by even a relatively minor benefit. The NCRP recommend6 that, for occupational exposure, the radiation dose to the whole body, head and trunk, active blood forming organs, a. gonads, accumulated at any age, shall not exceed 5 rems multiplied by the number of years beyond age 18, and that the dose in any 13 consecutive weeks shall not exceed 3 rems. The Federal Radiation Council agrees with the opinion of the NCRP that this dose of ionizing radiation is not expected to cause appreciable body injury to a person at any time during his lifetime. Thus, while the possibility of injury may exist at this dose, the probability of detectable injury is almost certain to be extremely low. Even the use of the more pessimistic assumptions would indicate that the small risk involved is acceptable if the gain is of any significance. Fortunately, this level also appears to be one which is not unduly restrictive in ordinary working circumstances.

5.7 There will be individual circumstances under which compliance with this guide would not be feasible. For example, accidents will occur, but the dose received will usually be de-

[2] See Section VII for applicability of these guides.

[3] In the formulation of Radiation Protection Guides for occupational exposure. special consideration has not been given in this staff report to the possible existence of pregnancy among female workers..

termined by the nature and conditions of the accident and consequently, the dose does not lend itself to prior planning. In addition to accidents, emergency situations will almost certainly arise, but here too, the dose should be determined by the nature of the emergency.

5.8 It is recognized that, even though small, there is a possibility of biological damage to the individual or his progeny from exposures of less than 5 rem per year. For this reason, radiation exposures should always be maintained at the minimum practicable level. Thus, it seems inadvisable to expose man to radiation if no benefit is anticipated.

5.9 It is to be noted that these recommendations are expressed in terms of rem. While the rad is the basic unit in physical dosimetry, some adjustment for the relative damage produced, even in the same individual, by one rad of gamma-rays as compared to one rad of alpha-rays, for example, must be included. (For a definition of terms and a list of RBE conversion factors, refer to Section I.) Because the value for the RBE may change with newer scientific knowledge, and in view of the relative importance of the total accumulated dose throughout a worker's lifetime, agencies and departments may wish to consider the desirability of maintaining exposure records in such a fashion that recalculation of the accumulated dose in rem can be made at any time when changes in the RBE are justified. One technique would be to keep primary exposure records in terms of rads with a stipulation as to the type of radiation involved.

5.10 One can examine the difficulties arising if the average yearly dose of 5 rems for occupational exposure is increased or decreased. Immediately, it is seen from the information in Section II that one cannot increase this level by as much as a factor of 10 without materially increasing the possibility of biological harm, for this is close to the level at which biological damage has been observed (see paragraphs 2.18 and 2.19).

5.11 Fortunately, it appears that there is no necessity for setting the level this high because the doses actually received are generally much less at the present time. It also appears that these recommended levels do not unduly restrict the beneficial use of radiation. In this connection, it is interesting to examine the distribution of doses received by radiation workers. Figure 5.1 shows the dose distribution for all AEC radiation workers. Each of these persons was supposed to receive less than 12 r yearly and not more than 5 r when averaged over a number of years. It appears that about 3 persons per 10,000 were involved in accidents, so they received more than 12 r. Only about 3 per 1,000 received more than 5 r and only about 1 per 100 received more than 3 r. Thus, if there is some assurance that those receiving the high doses in any year are not those who receive them every year, the accumulated dose received by each worker during 50 years of radiation employment will be considerably less than 250 r or 50 x 5r.

5.12 On the other hand, for economic and other operational reasons, one cannot set the level too low. This is not only because of the cost of extra radiation shielding and other radiation protection measures, but even more because of the difficulty of radiation measurements in regions where the radiation levels vary widely in both time and space.

Measurability of External Exposure

5.13 After the selection of Radiation Protection Guides, it is necessary to examine the numbers so selected for their measurability. Measurability here is used in the sense of both sample selection and sample measurement.

5.14 The radiation worker who has a reasonable chance of receiving radiation as a result of his employment can be monitored essentially for the entire time he is on the job. There are instruments available to make measurements with acceptable precision and accuracy at the levels recommended in the Radiation Protection Guides.

5.15 The problem of sampling the human population in the vicinity of an operation which might expose people to radiation may be a very simple one or a very complex one depending on the operation and the distribution of people around the operation. The actual measurement of 0.5 rem per year is usually a difficult one to make. This number is near or below the accuracy level of many widely used monitoring instruments. It will take special methods on the part of the monitoring group to measure this number with sufficient accuracy.

TABLE 5.1

DOSE DISTRIBUTION, AEC RADIATION WORKERS, 1958[1]

Oper. Office	Total employees monitored EXTERNAL	Number of annual accumulated exposures in ranges reported														
		0-1	1-2	2-3	3-4	4-5	5-6	6-7	7-8	8-9	9-10	10-11	11-12	12-13	13-14	14-15	15+
1.....	3,411	3,359	47	5													
2.....	3,288	2,785	260	143	47	24	11	9	4	4	1						
3.....	11,377	10,825	383	97	32	16	9	6	0	1							8
4.....	8,089	7,672	373	44													
5.....	15,018	12,152	1,845	697	198	78	26	5	4	2	1	1	1	3	2	0	3
6.....	1,647	1,533	61	26	9	3	3	0	3	1	3						
7.....	3,332	2,867	198	117	67	37	9	4	9	15	6	3					
8.....	10,758	9,774	573	405	6												
9.....	3,670	3,479	96	49	21	11	6	5	3								
10.....	1,394	1,279	82	25	5	1	1										1 (15 rem ± 40 percent)
11.....	3,838	3,645	118	44	22	1	1	2	4								
12.....	85	80	5														
Totals.....	65,907	59,455	4,041	1,652	407	171	67	31	27	23	11	4	1	3	2	0	12

[1]Data supplied by the Atomic Energy Commission.

Organ Doses

5.16 The recommendations of this staff report include (paragraph 7.10) recommendations for organ doses to the radiation worker which are believed to carry a biological risk not greater than that represented by 5 rem of whole body exposure. These organ doses may also represent a starting point for the derivation of Radioactivity Concentration Guides for the worker.

5.17 The establishment of individual organ doses for the general population involves additional considerations which preclude the possibility of relating them to the Guides for the radiation worker by a simple mathematical relationship that is applicable to all situations. An extension of the recommendations contained in this document in order to provide guidance in the derivation of Radioactivity Concentration Guides for the population is recognized as an important responsibility of the Federal Radiation Council. The complexities are such that a detailed study is required. In order to make our basic recommendations known as soon as possible, it was deemed advisable not to delay the release of our initial recommendations pending the completion of our studies of this and certain other important problems. It appears that there will be no undue risk nor undue hardship if the Federal agencies and departments continue their present practices concerning organ doses for the general population during this interim period.[4]

Summary

5.18 It appears feasible to establish a Radiation Protection Guide for the general population with primary relationship to background radiation levels. For radiation workers a Guide can be established which appears to be generally practicable in its application, and for which even pessimistic predictions of biological damage would be so small as to warrant acceptance if any appreciable bene fit results.

5.19 It is not reasonable to establish Radiation Protection Guides which take into account all possible combinations of circumstances. Every reasonable effort should be made to keep exposures below any level selected. Similarly, it is obviously appropriate to exceed the level if 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 may call for some control effort, the magnitude of which increases with the dose.

5.20 There are many pertinent reasons why the Radiation Protection Guide for the general population should be lower than that for the radiation worker. Although it is feasible to monitor essentially all exposure to radiation workers, a similar approach to exposure of the general population is not generally feasible. As an operational technique, where the individual whole body doses are not known, a suitable sample of the exposed population should be developed whose protection guide for annual whole body dose will be 0.17 rem per capita per year. It is emphasized that this is an operational technique which should be modified to meet special situations.

5.21 The complexities of establishing guides applicable to radiation exposure of all body organs for the population preclude their inclusion in the staff report at this time. However, current concentration guides now used by the Federal agencies appear appropriate on an interim basis.

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[4]For one approach to this problem, see Recommendations of the International Commission on Radiological Protection, (Sept. 9, 1958), page 16, paragraph 68.

SECTION VI.–DERIVED GUIDES

6.1 This section is concerned with the amount of radioactive material, deposited internally in the body or its organs ("body burdens" and "organ burdens"), which results in a certain physical radiation dose; the amount of environmental contamination with radioactive material which produces a given body or organ burden (Radioactivity Concentration Guides): and accompanying levels in the body excreta.

Body and Organ Burdens

6.2 Calculation of the physical dose delivered to a given mass of material as the result of homogeneous distribution of a known quantity of radioactive material throughout a volume is rather straight-forward, and can be made with considerable precision and accuracy. This statement is especially valid if the volume involved is in some standard geometric arrangement, such as a sphere. Similar calculations regarding the physical dose to all or a part of the human body as a result of radioactive material deposited within it will yield data which diverge from the true value for several reasons, including the following:

(1) Distribution of the radioactive material may be nonhomogeneous because of selective distribution between organs or between portions of the same organ. For example, the thyroid gland has a high degree of selective uptake for radioactive iodine as compared to the body as a whole; various major portions of the same bone may contain differing amounts of radium, dependent, at least in part, upon relative growth rates.

(2) At the microscopic level there may be a significant degree of nonhomogeneity of deposition. For example, not only will the radium content of various major portions of the bone differ, but within a single major portion different cells or groups of cells may contain widely differing quantities of radionuclides. Likewise, colloidal thorium oxide in the liver may concentrate almost entirely in certain types of cells, leaving other cell types essentially free of contamination.

(3) The shape of the organ or whole body may differ from any simple geometric form. Few organs of the body are truly spherical, and the majority of body organs are not true simple geometric shapes, such as cylinders, cubes, and ellipsoids.

6.3 With highly penetrating radiation, such as energetic gamma rays, the lack of homogeneous distribution may introduce only a relatively small error. However, with radiations of very low penetrating power such as alpha emissions, nonhomogeneity can result in variations by several orders of magnitude (factors of ten) among different cells in the same organ. With regard to the shape of body organs or the whole body, calculations are most often made on the basis of an idealized geometry; this simplification does not introduce serious errors into the calculations. For example, the variations introduced by considering a body organ as a sphere or a cylinder do not introduce errors which are significant compared to the lack of quantitative knowledge concerning biological effects of irradiation.

6.4 Thus, for highly penetrating radiation the relatively straight-forward and comparatively simple calculation relating body or organ burden to physical dose provides relatively accurate answers. For less penetrating radiations such as beta rays, the distribution pattern becomes more important, but, giving due regard to this problem, the calculations should ordinarily not err by orders of magnitude. With even less penetrating radiation such as alpha particles, however, the potential errors in the calculations are such as to make the answers clearly suspect.

6.5 As an additional complication, assessment of the biological significance of internally deposited radioactive materials emitting particles with high linear energy transfer, such as

alphas, require the introduction of a factor for relative biological effectiveness. Thus, the computation of the body burden of beta or gamma emitting material which is biologically equivalent to a given amount of alpha emitting material is fraught with many pitfalls and inaccuracies.

Radioactivity Concentration Guides

6.6 The measurement of body burdens provides information regarding the extent to which an individual has accumulated radioactive materials. However, it is not always practical to monitor the body burdens resulting from environmental contamination solely by the use of direct measurements on the human body, its tissues, or excreta. Although certain supplemental information can be obtained by monitoring the organ and body burdens of animals, this approach also has significant practical limitations. Furthermore, it is usually desirable to predict the significance of environmental contamination without waiting until it has accumulated in humans or animals.

6.7 For these reasons, direct data on the levels of environmental contamination are being collected, and it is necessary to have guides or benchmarks against which these environmental contamination levels can be evaluated. The National Committee on Radiation Protection and Measurements and its international counterpart have been publishing, for many years, tables of "maximum permissible concentrations" of radionuclides in air and in water for radiation workers.

6.8 Our understanding of the basis used in the derivation of these values is:

For the majority of radionuclides, the body burden which would result in a specified average annual dose is calculated. The doses used for this purpose are 15 rems for most individual organs of the body, 30 rems when the critical organ is the thyroid or the skin, and 5 rems when the gonads or the whole body is the critical organ. For bone seekers, the estimation is based on the deposition of radioactive material, the relative biological effectiveness, and a comparison of the effective energy release in the bone with the effective energy release from a body burden of 0.1 microgram of radium-226 plus daughters. According to certain calculations, this bone limit may correspond to approximately 30 rems per year. However, the difficulties inherent in estimating the physical dose to organs from alpha emitting isotopes, together with the relatively large amount of direct information on the biological effects of various body burdens of radium, have led the NCRP to use this basis for its recommendations. Once the "permissible body burden" has been decided upon, calculations are made as to the daily intake which, continued over a SO-year period, would not result in an accumulation greater than the permissible body or organ burden. (COMMENT: It is to be noted that the limiting factor is a maximum annual dose rate by the end of the period of exposure. Within this limitation there can be differences in the total accumulated dose depending upon the time taken for the isotope to reach an equilibrium concentration in the body. For example, with the same maximum dose rate, the total accumulated dose with a short half-life bone-seeker could be approximately twice the accumulated dose from a long half-life bone-seeker.) While biological data are introduced where available, the basis of much of these calculations is the so-called "standard man" which provides representative constants for the many variables involved. With regard to the determination of permissible intake by ingestion, among the variables involved are:

(1) The fraction of the ingested material which is absorbed into the blood from the gastro-intestinal tract. (COMMENT: Even for a given radionuclide, this may be quite variable depending upon the individual, the chemical form in which the radionuclide is present and its relative solubility, and the influence of other materials also present in the gastro-intestinal tract.)

(2) The fraction of material present in the blood which becomes deposited in the critical organ. (COMMENT: Here again, there will be appreciable individual variations and, of course, major differences with various isotopes.)

(3) Rate of uptake and the time of retention of the material in the critical organ.

6.9 Available biological data were utilized in the NCRP-ICRP computations whenever available. In many cases, the available data are extremely meager, and for certain isotopes, essentially nonexistent. Thus, there is a rather high degree of uncertainty in the calculation of permissible daily intakes, especially for the less adequately studied radionuclides. Even ignoring individual variability, estimates of permissible intakes of ingested radionuclides might vary by factors of 10 to 100 if all of the errors worked in one direction. This, however, is a rather unlikely situation and it appears from the rather meager direct data that, for ingestion, the estimates may bo correct within a factor of less than 10.

6.10 Similar considerations are also involved for inhaled radioactive material, except that an estimate of the fraction of inhaled material which reaches the lungs and becomes absorbed into the blood stream is used, instead of the fraction absorbed from the gastro-intestinal tract for ingested material. Estimates and calculations of permissible intakes for inhalation appear much less reliable than for those for ingestion. This results primarily from our rather poor understanding of absorption from the lungs and such added complexities as the effect of particle size. The possible errors with regard to inhaled radionuclides being greater than for ingested radionuclides, it is possible that these intake values could be incorrect by even several orders of magnitude, especially if allowance is made for the existence of variations between individuals.

6.11 Once the NCRP has determined "permissible daily intake" by ingestion or inhalation, "maximum permissible concentrations" in air and water are derived by assuming that the total daily intake of water is 2.2 liters and that the water is uniformly contaminated; and that the total breathing rate is 2×10^7 milliliters per 24 hours and the air is likewise uniformly contaminated. These give values for the "168-hour week" which are then adjusted upward by a factor of 3 for ingestion and a factor of 3 for inhalation to allow for the shorter time exposure involved in a 40-hour week.

6.12 When lower Radiation Protection Guides are selected for the whole population as compared to the worker, this includes allowances for differential sensitivity between children and adults. However, in establishing Radioactivity Concentration Guides, consideration must also be given to the possibly different ratios of intake to uptake for adults and children. Whether this additional difference is sufficiently great to alter the final recommendation cannot be decided without thorough consideration of the specific radionuclide at hand.

6.13 It is also important to note that guides for continuous exposure are not readily converted to guides for short-term exposure by any simple mathematical relationship appropriate to all radionuclides. It is essential that detailed study of this problem be conducted as expeditiously and thoroughly as possible.

6.14 Taking the above factors into account, attention is being given to the establishment of numerical values for Radiation Concentration Guides applicable to the general population for the radionuclides of immediate practical importance to whole population exposure.

Determination of Body Burdens in the Intact Human

6.15 Because of the many complications inherent in attempts to establish Radioactive Contamination Guides for the environment, attempts to determine body burden in the intact human have been made both as a control measure and as a technique for refinement of our knowledge regarding the relationship of intake to body or organ burdens. Historically, the quantitative determination of the radon content of the exhaled air has been used for decades as a technique for estimating the body burden of radium, the radioactive parent of radon. This particular technique has proved to be an extremely valuable one and the relationship has been substantiated by direct determination of the radium consent of the skeleton of a few individuals. There are, however, relatively few radioactive materials which are deposited in body organs in a solid form and which decay to radioactive gaseous daughter products.

6.16 An additional approach has been to determine the radioactive content of the urine and feces in order to provide data to estimate the body or organ burden. This approach eliminates many of the uncertainties involved in converting intake to, uptake. It does not, however, provide a direct answer as the excretion rate or any given radioactive material will vary between

individuals and within the same individual from time to time. An important limitation in this technique arises from the fact that the excreta will contain not only a portion of the radioactive material which truly represents the organ burden, but also additional amounts may be present as a result of excretion of radioactivity which is not fixed in the tissues. Thus, measurements of excreta are particularly unreliable at relatively short times after an exposure, or during a continuing exposure. Additionally, the amounts in the excreta will usually be only a very small fraction of the body burden, and thus the quantities involved at levels of interest may be so small as to require extremely sophisticated radiochemical analytical techniques. In spite of these limitations, the relative directness of this approach as compared to the estimation of human exposure by analysis of environmental samples has led to its practical application in certain installations. It is to be noted, however, that the difficulties in the conduct of the procedures and interpretation of the data suggest that this method is not likely to be immediately useful for the study of problems related to exposure of large population groups.

6.17 One other approach to the determination of body or organ burdens is the use of "whole-body counters." This method can provide extremely useful information, but has several important limitations:

(1) The emissions of the radionuclide under consideration must have sufficient penetrating power to pass through intervening body tissues.

(2) The quantities involved must be sufficiently great to yield significant data in a reasonable period of time.

(3) For detection of very low levels, the equipment needed and the capabilities required for its operation can result. in practical limitations when attempts are made to apply this technique to large numbers of people.

Suitability and Measurability

6.18 At the present time the serious gaps in knowledge which exist with regard to factors involved in the establishment of derived standards make them unsuitable as exact standards. Occasional short-term excesses should not be cause for undue concern. Meanwhile, major effort should be expended to determine the various unknowns, particularly those which relate intake to uptake in the body, with greater accuracy.

6.19 It appears that techniques are available to detect and measure, with adequate accuracy, environmental contamination near the levels currently recommended by the NCRP at least for several of the more important radionuclides. Such measurements are not necessarily simple or inexpensive, but should be within the competence of routine laboratories. However, the procedures involved may be sufficiently complicated that sampling on only a representative portion of the environment is indicated.

Atmospheric Contamination in Uranium Mines

6.20 In addition to the current recommendations of the NCRP, the American Standards Association (ASA) has been active in the establishment of recommendations in this field concerning air contamination from radon and its daughter products. It appears that quite different approaches are used by these two groups, and the apparent differences are not readily explainable on a simple basis. Rather, there are differences as to whether primary emphasis is placed on dose calculations or on direct biological evidence and operational considerations. These recommendations are expressed in terms of different radionuclides, so that direct numerical comparison is not easily done. It is not immediately apparent that the measurements actually taken in the mines are directly applicable to the NCRP standard, It does appear prudent to assume, however, that significant numbers of individuals are being exposed to radiation in the mines that are in excess of the recommendations of either group. It is desirable, therefore, to make every reasonable attempt, on a continuing basis, to keep the exposures as low as practical. Reduction of the contamination to the recommended levels would be difficult and even unfeasible in some cases.

6.21 In the meantime, the exposed group is being kept under close medical surveillance. This program should be continued, and expanded if there appears to be any probability of securing additional significant information. In addition, major efforts should be made to better define the radionuclide of principal significance to this problem.

Summary

6.22 Reasonably accurate estimates can usually be made of the amount of internally deposited radioactive material equivalent to any given dose to a critical organ of the body. However, the establishment of guides as to the amount of material which, when taken into the body, will yield such organ burdens is fraught with many uncertainties. Further extension of the estimation to indicate the equivalent amount of environmental contamination is even more uncertain. The potential errors are greater with inhaled contamination than with ingested materials. Extension to individual portions of the environment further compounds the possible errors. The possibility of multiple radionuclides in the same critical organ must be considered, and appropriate allowances made to be certain that the total dose to that organ is not excessive. At the present time, it therefore does not seem appropriate to consider Radioactive Concentration Guides or other derived standards as anything more than guidance levels, to be applied with judgment and discretion.

6.23 It is critical to note that no single standard is applicable to all situations. For example, the level at which the release of radioactivity from normal operations of a nuclear energy plant should be restricted might be quite different from the levels at which a food or milk supply is destroyed or discarded.

SECTION VII.–SUMMARY AND RECOMMENDATIONS

7.1 To provide a Federal policy on human radiation exposure, the Federal Radiation Council was formed in 1959 (Public Law 86-373) 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 . . . ." The present staff report is a first step in carrying out this responsibility.

7.2 The scope of this staff report is limited to provide some basic radiation protection recommendations which are required. Some of these recommendations should be considered only of an interim nature. Periodic review will be necessary to incorporate new information as it develops. Only peacetime uses of radiation which affect the exposure of the civilian population are considered at this time. A further limitation of the staff report is that it does not consider the effects on the population arising from major nuclear accidents. Certain of the classes of radiation sources are now regulated by various Federal agencies. However, there are some which are not so regulated but which should be considered when dealing with the overall exposure of the population to radiation. Therefore, this staff report considers exposure of the population from all sources except those excluded above.

7.3 Only that portion of the knowledge of the biological effects of radiation that is significant for setting radiation protection standards is considered. Published information is summarized in this report; details may be obtained from reading the original documents. Among the items of most immediate interest to the establishment of radiation protection standards are the following:

1. Acute doses of radiation may produce immediate or delayed effects, or both.
2. As acute whole body doses increase above approximately 25 rems (units of radiation dose), immediately observable effects increase in severity with dose, beginning from barely detectable changes, to biological signs clearly indicating damage, to death, at levels of a few hundred rems.
3. Delayed effects produced either by acute irradiation or by chronic irradiation are similar in kind, but the ability of the body to repair radiation damage is usually more effective in the case of chronic than acute irradiation.
4. The delayed effects from radiation are in general indistinguishable from familiar pathological conditions usually present in the population.
5. Delayed effects include genetic effects (effects transmitted to succeeding generations), increased incidence of tumors, life span shortening, and growth and development changes.
6. The child, the infant, and the unborn infant appear to be more sensitive to radiation khan the adult.
7. The various organs of the body differ in their sensitivity to radiation.
8. Although ionizing radiation can induce genetic and somatic effects (effects on the individual during his lifetime other than genetic effects), the evidence at the present time is insufficient to justify precise conclusions on the nature of the dose-effect relationship especially at low doses and dose rates. Moreover, the evidence is insufficient to prove either the hypothesis of a "damage threshold" (a point below which no damage occurs) or the hypothesis of "no threshold" in man at low doses.
9. if one assumes a direct linear relation between biological effect and the amount of dose, it then becomes possible to relate very low dose to an assumed biological effect even

though it is not detectable. It is generally agreed that the effect that may actually occur will not exceed the amount predicted by this assumption.

7.4 To clarify the most critical problem areas concerning quantitative relationships of the effects of irradiation on man, it is recommended that special attention be given to the following research efforts:

1. Increasing epidemiological studies on humans who have been exposed to radiation especially in doses sufficient to offer some probability that deleterious effects can be found.
2. Continuing studies on the mechanism of radiation damage and of the interaction of radiation with matter at the cellular level and at the molecular level.
3. Studies designed to determine more adequately the relationship between damage and dose at low total dose and low dose rates. Included should be more precise information at higher levels from which the relationships at lower levels may be inferred.

7.5 The various current sources of radiation exposure to the U.S. population are discussed in Section III. It should be noted that the radiation exposure to patients by practitioners of the healing arts is in the same order as natural background, when averaged over the population. The average exposure to the U.S. population from activities of the nuclear energy industry, under current practices, is less than that from background by a substantial factor.

7.6 If the presence of a threshold for radiation damage could be established by adequate scientific evidence, and if this threshold were above the background level and sufficiently high to represent a reasonable working level, it would serve as a relatively simple basis for the establishment of radiation protection standards. However, with the accumulation of quantitative information concerning radiation effects in both animals and humans, and some increased understanding of the mechanisms of radiation injury, the possibility that somatic effects as well as genetic effects might have no threshold appeared acceptable, as a conservative assumption, to increasing numbers of scientists. On the basis of this conservative assumption, radiation protection standards must be established by a process of balancing biological risk and the benefits derived from radiation use. Such a balance cannot be made on the basis of a precise mathematical formula but must be a matter of informed judgment. Several approaches towards the evaluation of the risk are discussed in Section IV. These approaches, together with the evaluation of benefits and useful applications by the agencies, have been used in the formulation of the recommendations in this staff report.

7.7 Under the working assumptions used, there can be no single "permissible" or "acceptable" level of exposure, without regard to the reasons for permitting the exposure. The radiation dose to the population which is appropriate to the benefits derived will vary. widely depending upon the importance of the reason for exposing the population to a radiation dose. For example, once weapons testing in the atmosphere has taken place, the dose to be permitted in lieu of such alternatives as depriving the population of essential foodstuffs might also be quite different Prom levels used in the planning phases. As another example, for radiation workers, emergency situations will almost certainly arise which make exposures in excess of those applicable to normal operations desirable.

7.8 Also, under the assumptions used, it is noted that all exposures should be kept as far below any arbitrarily selected levels as practicable. There should not be any man–made radiation exposure without the expectation of benefit resulting from such exposure. Activities resulting in man-made radiation exposure should be authorized for useful applications provided the recommendations set forth in this staff report are followed. Within this context, any numerical recommendations should be considered as guides, and the need is for a series of levels, each of which might be appropriate to a particular action under certain circumstances.

7.9 The term "maximum permissible dose" is used by the NCRP and ICRP for the radiation worker. However, this term in often misunderstood. The words "maximum" and "permissible" both have unfortunate connotations not intended by either the NCRP or the ICRP. This report introduces the use of the term Radiation Protection Guide (RPG). This term 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.

7.10 There can, of course, be quite different numerical values for the Radiation Protection Guide, depending upon the circumstances. It seems useful, however, to recommend Guides which appear appropriate for normal peacetime operations. It is recognized that our present knowledge does not provide a firm basis within a factor of two or three €or the selection of any particular numerical value in preference to another value. Nevertheless, on the basis set forth in Section V, the following Radiation Protection Guides are recommended for normal peacetime operations:

Type of exposure	Condition	Dose[1] (rem)
Radiation worker:		
(a) Whole body, head and trunk, active blood forming organs, gonads, or lens of eye.	Accumulated dose	5 times number of years beyond age 18
	13 weeks	3
(b) Skin of whole body and thyroid	Year	30
	13 weeks	10
(c) Hands and forearms, feet and ankles.	Year	75
	13 weeks	25
(d) Bone.....	Body burden	0.1 microgram of radium-226 or its biological equivalent
(e) Other organs.....	Year	15
	13 weeks	5
Population[2]		
(a) Individual[3]..... ...	Year	0.5 (whole body)
(b) Average[3].....	30 years	5 (gonads)

[1]Minor variations here from certain other recommendations are not considered significant in light of present uncertainties.

[2]See Section V for reasons why these values differ from those applicable to radiation workers.

[3]See Paragraph 5.4 for app1icability of these levels.

7.11 Recommendations are not made concerning the Radiation Protection Guides for individual organ doses to the population, other than the gonads. Unfortunately, the complexities of establishing guides applicable to radiation exposure of all body organs preclude their inclusion in the report at this time. However, current protection guides used by the agencies appear appropriate on an interim basis.

7.12 These guides are not intended to apply to radiation exposure resulting from natural background or the purposeful exposure of patients by practitioners of the healing arts.

7.13 The Federal agencies should apply these Radiation Protection Guides with judgment and discretion, to assure that reasonable probability is achieved in the attainment of the desired goal of protecting man from the undesirable effects of radiation. The Guides may be exceeded only after the Federal agency having jurisdiction over the matter has carefully considered the reason for doing so in light of the recommendations in this staff report.

7.14 This staff report also introduces the term Radioactivity Concentration Guide (RCG) defined as: the concentration of radioactivity in the environment which is determined to result in organ doses equal to the Radiation Protection Guide. Within this definition, Radioactivity Concentration Guide can be established only after the Radiation Protection Guide is decided upon. Any given Radioactivity Concentration Guide is applicable only for the circumstances under which use of its corresponding Radiation Protection Guide is appropriate.

7.15 As discussed in Section VI, reasonably accurate estimates can be made of the amount of internally deposited radioactive material resulting in any particular organ dose. However, the establishment of guides as to the amount of material which, when taken into the body, will yield such organ doses is fraught with many uncertainties. Further extension of the estimation to indicate the equivalent amount of environmental contamination is even more uncertain. The potential errors are even greater with inhaled contamination than with ingested materials. Extension to individual portions of the environment further compounds the possible errors.

7.16 This staff report, therefore, does not contain specific numerical recommendations for Radioactivity Concentration Guides. However, concentration guides now used by the agencies appear appropriate on an interim basis. Where appropriate radioactivity concentration guides are not available, and where Radiation Protection Guides for specific organs are provided in this staff report, the latter Guides can be used by the Federal agencies as a starting point for the derivation of radioactivity concentration guides applicable to their particular problems. The Federal Radiation Council has also initiated action directed towards the development of additional Guides for radiation protection.

7.17 Particular attention is directed to the possibly different ratios of intake to uptake for adults and children. There is no simple numerical relationship between Radioactivity Concentration Guides for the worker and for the general population, even if such a simple relationship is adopted for Radiation Protection Guides.

7.18 With particular relationship to the establishment of Radioactivity Concentration Guides, the following research needs (in addition to those listed in paragraph 7.4) are pointed out:

1. Efforts to design design better and less expensive radiation monitoring instruments and methods.
2. Extensive studies to determine the relationship between concentration of radioactivity in food, air and water, and the ultimate disposition of these by the body.
3. Studies designed to elucidate the relationship between the intake of radionuclides in various chemical forms and their subsequent uptake. Presently, many compounds of a given radionuclide are treated as though they were the same compound.
4. Studies to elucidate the difference between children and adults in their uptake and disposition of radioactivity and their radiation sensitivity.

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