ENVIRONMENTAL PROTECTION AGENCY

[FRL-5126-7]

RIN 2060-AE61

Federal Radiation Protection Guidance for Exposure of the General Public

AGENCY: U.S. Environmental Protection Agency.

ACTION: Proposed recommendations, request for written comments, and notice of public hearings.

SUMMARY: The Agency is proposing to make recommendations to the President for new guidance to Federal agencies on radiation protection which would have two effects: it would cause a five-fold reduction in the maximum allowable risk of cancer from any Federally regulated activity involving nuclear materials or other sources of radiation; and it would decrease the cost of Federal regulation of radiation by promoting uniform treatment of radiation by all Federal agencies, and reducing costly duplicative and conflicting requirements.

The new guidance would replace those portions of previous recommendations that apply to protection of the general public, approved by Presidents Eisenhower and Kennedy in 1960 and 1961, respectively. New Federal guidance issued in 1987 replaced those portions of the 1960 and 1961 guidance that applied to protection of workers.

These proposed recommendations are based on a review of existing guidance in light of current scientific understanding of the risks of exposure to ionizing radiation and of the experience of Federal agencies in its control. They include both qualitative guidance on radiation protection and numerical guides for limiting radiation doses to the general public. The most significant proposed changes are that: the Radiation Protection Guide (RPG) be expressed in terms of a single weighted sum of doses to organs, and the separate RPGs for individual organs deleted; the current RPGs limiting the average genetic dose to members of the U.S. population to 5 rems in 30 years and the annual whole body dose to 500 millirem dose equivalent be replaced by a single RPG of 1 millisievert (100 millirem) effective dose equivalent received by or committed in a single year to any individual from all sources combined; doses from individual sources normally be limited to a fraction of the RPG, and increased emphasis be given to the principle that all exposure should be maintained as low as reasonably achievable, within the RPG.

The Agency invites written comments on these proposals and shall also hold a public hearing, as discussed below. All written and oral comments will be considered carefully in preparing our final recommendations to the President.

DATES: Written comments in response to this notice of proposed guidance must be received on or before February 21, 1995, to be ensured full consideration. A public hearing will be held in Washington, D.C., on February 22 and 23, 1995. Requests to participate should be received on or before January 23, 1995. The schedule, location, and procedures for this hearing will be published in the **Federal Register** shortly.

ADDRESSES: Written comments (in duplicate if possible) should be submitted to: Central Docket Section Section (6102), Attn.. Docket No. A-83-41, U.S. Environmental Protection Agency Washington, DC 20460. Written comments, the public hearing record, and other documents related to this rulemaking will be filed under the above docket number in Room M1500 at Waterside Mall, U.S. Environmental Protection Agency 401 M Street, S.W., Washington, DC. The docket may be inspected between 8:00 a.m. and 4:00 p.m. on weekdays. A reasonable fee may be charged for copying.

Requests to participate in the public hearing should be submitted to Allan C. B. Richardson, Deputy Director for Federal Guidance, Criteria and Standards Division, Office of Radiation and Indoor Air (6602J), U.S. Environmental Protection Agency Washington, D.C. 20460. Requests to participate in the public hearing should include an outline of the topics to be addressed, the amount of time requested, and the names of the participants. EPA may allow testimony to be given at the hearing without prior notice, subject to time constraints at the discretion of the hearing officer.

FOR FURTHER INFORMATION CONTACT: Allan Richardson at the above address (telephone (202) 233-9213; FAX (202) 233-9629) concerning these proposed recommendations or the public hearing.

SUPPLEMENTARY INFORMATION:

Introduction

The Administrator of the Environmental Protection Agency (EPA) has the responsibility 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 authority stems from Executive Order 10831, the Atomic Energy Act of 1954, as amended; and Reorganization Plan No. 3 of 1970. Guidance to Federal agencies has historically consisted of both qualitative and quantitative recommendations expressed as "Federal Radiation Protection Guidance. The guidance proposed here would replace those portions of existing Federal Radiation Protection Guidance, adopted in 1960 (25 FR 4402) and 1961 (26 FR 9057), that apply to protection of the general public.

The purpose of Federal guidance is to provide a common framework to help ensure that the regulation of exposure to ionizing radiation is carried out by Federal agencies in a consistent and adequately protective manner. Although the individual Federal agencies have determined, and will continue to determine, the details of specific regulations, it is intended that they adhere to these proposed recommendations as basic, minimum requirements. It should be recognized, however, that in some situations application of these recommendations may be superseded by specific statutory requirements.

These proposed recommendations have been developed by EPA in cooperation with the Departments of Agriculture, Commerce, Defense, Energy Health and Human Services, Housing and Urban Development, Interior, Justice, Labor, and Transportation; the National Aeronautics and Space Administration; and the Nuclear Regulatory Commission. In addition, the Conference of Radiation Control Program Directors of the States contributed to the development of this proposal. This cooperation was carried out through an extensive series of interagency meetings carried out between 1986 and 1992, and agency reviews conducted in 1993.

Previous Relevant Actions by the FRC and EPA

On May 13, 1960, President Eisenhower approved the first recommendations of the former Federal Radiation Council (FRC) for guidance to Federal agencies on the protection of workers and the general public from radiation (25 FR 4402). This guidance was extended by further recommendations approved by President Kennedy on September 26, 1961 (25 FR 9057).

Following a lengthy review by Federal agencies of those portions of the 1960 and 1961 guidance that applied to

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occupational exposure the Administrator of EPA made new recommendations for protection of workers which were approved by President Reagan on January 27 1987 (52 FR 2822). Those recommendations motivated a number of the changes now proposed here for protection of the general public.

During the period since the current guidance was issued, EPA, alone and in concert with other Federal agencies, has sponsored major reviews of the health risks from exposure to low level ionizing radiation by the Committee on the Biological Effects of Ionizing Radiation (BEIR), National Academy of Sciences—National Research Council. These reviews, which were published in 1972, 1980, 1988, and 1990, each incorporated new scientific information that had become available since the preceding review and contributed directly to the deliberations which have resulted in these proposed recommendations.

Scope of the Proposed Guidance

These recommendations would apply to most exposure of the general public to sources of ionizing radiation that are created or influenced by human activities, the principal exceptions being exposure of workers, of patients for medical purposes in the practice of the healing arts, and of the general public from accidents. They would apply, for example, to exposure of members of the general public due to: (a) emissions of radioactive materials or radiation from industrial, defense-related, and scientific operations; (b) use of radiation and radionuclides in consumer products and medicine (except for beneficial exposure of patients); (c) mining and processing of ores that contain naturally-occurring radioactive materials; (d) disposal of wastes generated by any of the above operations; and (e) transportation of radioactive materials involved in any of the above operations.

Specific examples include, but are not limited to: nuclear installations, including mines, mills, and processors of uranium and thorium, nuclear fuel fabrication plants, nuclear reactors (nuclear power plants, critical and subcritical facilities, and research reactors), spent fuel storage and processing facilities, and weapons production, testing, and storage facilities; x-ray generators and radioactive sources; irradiation installations, such as particle accelerators and large irradiators for teletherapy radiosterilization, and commercial product irradiation; inspection devices in airports; consumer products such as static electricity elimination devices, ion generating tubes, smoke detectors, and devices for producing light or an ionized atmosphere, such as for dials and laboratory measurements; and radioactive waste installations where radioactive wastes are handled, treated and conditioned, temporarily stored, or permanently disposed of.

These proposed recommendations also address most terrestrial sources of exposure arising from human activities (these principally involve naturally-occurring radioactive materials), but *not* exposure due solely to background radiation or due to globally-dispersed effects of past activities and accidents. Excluded, for example, is consideration of variations in exposure which result from geographic location, as well as the small annual dose increment from past weapons tests and residual global contributions of past nuclear accidents, like that at Chernobyl in 1986, because it is not practicable to contemplate their control. For the purpose of these recommendations, "background radiation" includes radiation of cosmic and solar origin at the surface of the earth and radiation from naturally-occurring primordial and cosmogonic radionuclides found in the earth s crust or produced in the upper atmosphere by cosmic or solar radiation (including radioactivity normally ingested in food and water) that is not enhanced by human activities.

By technological means, however, exposure to naturally-occurring radionuclides that might otherwise be considered sources of "natural background" may be enhanced. Technologically-enhanced exposure to natural radiation may be defined as exposure to natural sources of radiation which is increased by (or would not occur without) a human activity Examples of such sources include radon and its progeny accumulated in buildings; wastes from mineral ores, including ores which are mined for uses or purposes other than for their radioactive isotopes; wastes and/or emissions from the burning of coal, oil, and natural gas; ion exchange resins and sludge from drinking water treatment; scale in oil- and gas-field piping; articles made from naturally-occurring radioactive materials, such as thorium in lantern mantles and in certain optical glasses, and uranium in certain ceramic glazes; and cosmic rays experienced during high altitude airplane flights.

To the extent that exposure to such sources is controllable, they are addressed by these recommendations. However, the guidance does not recommend that all situations that could lead to increased exposure should necessarily be regulated. For example, there is no readily applicable means to reduce the small increase in radiation exposure while in flight. In addition, it would require many circumnavigations of the globe by airline on non-business matters to approach the recommended limit for dose to individuals. Similarly, we believe it is also not appropriate to regulate, for example, exploration of caves, mountain climbing, or residence in high altitude locations because of technologically-enhanced radiation. Decisions on what exposures are appropriate candidates for reduction through regulation have been and will continue to be based on legislative mandates and decisions by regulatory agencies.

The largest single source of exposure of the general public is radon. Radon, a naturally-occurring radioactive gas, can accumulate in any structure that limits the free exchange of indoor and outdoor air. There are two general categories of sources that can generate significant amounts of radon within a building: radium-bearing soil or rocks naturally situated beneath or near the building and radium-bearing materials used in construction or as fill beneath or near the building. Although exposure to radon from sources of the first kind may be enhanced or reduced by building location, design, or construction, these factors usually are not subject to direct Federal or State control. Exposure to the second category of sources (radium-bearing materials placed in or near a building) may be subject to direct regulatory control or alleviation through Federal or State programs.

The numerical limits for individual dose proposed in this guidance do not include the contribution from indoor radon produced by either of the above categories of sources. EPA and the Centers for Disease Control have provided separate advice to the public for protection against exposure to indoor radon in A Citizen's Guide To Radon (EPA document 402–K92–001, May 1992, and subsequent editions) and EPA has published a series of other technical publications, pursuant to Pub. L. 100–551 (Oct. 28, 1988, 102 Stat. 2755, amending the Toxic Substances Control Act, 15 U.S.C. §§ 2601–2692). That advice is consistent with this proposed guidance, where applicable.

Finally these recommendations apply only to the management of normal operations of facilities and devices that may expose members of the public to radiation: that is, to controllable exposure to radiation and releases of radionuclides that may expose the general public. Normal operations

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include both those conditions that are expected to occur with certainty as well as those that may be predicted to occur with a reasonably large probability (e.g. anticipated operational occurrences at nuclear reactors), but not conditions with a very low probability of occurrence, such as the unintended re-entry of a satellite containing radioactive materials. These recommendations also do not apply to nuclear incidents, such as a major accident at a nuclear facility or the result of terrorist activity, or to exposure resulting from acts of war. Guidance for establishing radiological emergency response plans and for making radiation protection decisions during nuclear incidents has been provided by EPA in the Manual of Protective Action Guides and Protective Actions for Nuclear Incidents (EPA-520/1-75-001-A), pursuant to regulations issued by the Federal Emergency Management Agency (47 FR 10758, March 11, 1982). Additional guidance has been provided by the Food and Drug Administration on the prophylactic use of potassium iodide during radiological emergencies (47 FR 28158, June 29, 1982) and on the use of food and animal feed contaminated by an incident (47 FR 47073, October 22, 1982, and, jointly with the Department of Agriculture, 51 FR 23155, June 25, 1986).

Exposure to radiation as a medical patient, which may occur for diagnostic or for therapeutic purposes, is not covered by these recommendations. Recommendations of the Administrator of EPA and the Assistant Secretary for Health of the former Department of Health, Education, and Welfare concerning diagnostic use of radiation, approved by President Carter in 1978, are provided in Radiation Protection Guidance to Federal Agencies for Diagnostic X Rays (43 FR 4377). Additional specific recommendations and guidance on patient selection, evaluation of radiation exposure, quality assurance, and related topics have been published by the Department of Health and Human Services. However, decisions on the diagnostic or therapeutic use of radiation are the responsibility of individual patients and their physicians, and such decisions should be based on the benefits and risks of the use of radiation for the conditions specific to each patient. Since those decisions will involve considerations quite different from those addressed here—exposure of the general public to a variety of sources of general societal benefit—these recommendations do not apply to exposure of patients.

These recommendations also do not apply to occupational exposure. Federal agencies should normally regulate or manage the exposure of workers in accordance with Radiation Protection Guidance to Federal Agencies for Occupational Exposure (52 FR 2822), approved by President Reagan in 1987 [1] However, when workers can be exposed under conditions that also apply to members of the public (e.g., when the public has unlimited access to the work site), the source of such exposure should be controlled in conformance with these proposed recommendations for protection of the general public.

The Need for Revision of the 1960 Guidance

Since the current guidance was issued in 1960, knowledge of the effects of ionizing radiation on humans has increased substantially. The BEIR Committee of the National Academy of Sciences—National Research Council conducted major reviews of the scientific data on health risks of low levels of ionizing radiation in 1972 and again in 1980.[2] Portions of the information presented in the latter report were expanded in a 1988 publication on risks from exposure to alpha radiation.[3] A comprehensive, major new review was completed in 1990.[4] Similar reviews have been published by the United Nations Scientific Committee on the Effects of Atomic Radiation in 1977 1982, 1986, and 1988.[5] The most important results from these reviews, carried out over a period of more than two decades, are that, although estimates of the nature and general magnitude of the risks from radiation have not undergone fundamental revision, estimates of the principal risk, that of cancer, have increased roughly threefold and have become more certain.

While our knowledge of the effects of radiation has become more definitive, the extent of our use of radiation has increased and our policies for regulating it have evolved. Prior to 1960, major uses of radiation were limited, and the primary concern of radiation protection was to ensure that doses to those few individuals that were affected did not exceed limits on dose from all sources combined. Since then, the numbers and types of man-made radiation sources have greatly increased, and, at the same time, public concern about environmental contaminants of all kinds has become an important influence in their management. Of particular significance is that the focus of the many environmental policies and laws that have emerged during the past two decades has been more on improving the levels of control of individual sources of contamination than on establishing a single acceptable level of risk to individuals from all sources combined. This shift of concern has led to the development of new concepts for determining the appropriate level of control of specific kinds of sources. For radiation sources, it has meant that attention has been focused on assessing the potential impact of each source, or class of similar sources, on populations and on the capabilities and costs of controls to reduce that impact. The result has been the promulgation of a series of regulatory requirements that are based on the specific characteristics of particular classes of sources of public exposure to radiation. These requirements invariably have been more restrictive than those required to meet the existing Federal guidance on dose to individuals from all sources combined.

Concurrent with the improved understanding of the effects of ionizing radiation and the evolution of its regulation, international and national advisory groups have refined and revised their basic recommendations on radiation protection. In 1977 the International Commission on Radiological Protection (ICRP) published revised recommendations [6] that have since been adopted, in whole or substantial part, in most developed countries. In 1990, the ICRP issued revised general recommendations [7] that, for control of exposure of the general public, expanded on those issued in 1977 notably in the areas of policy for

In some situations the distinction between members of the public and workers will have to be carefully considered. A useful test for determining whether individuals should be considered workers or members of the public is whether or not their presence in the exposure situation in question is within the scope of their employment.

[2] *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation*, National Academy of Sciences, Washington, D.C., 1972; *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation; 1980*, National Academy Press, Washington, D.C., 1980.

The Health Risks of Radon and Other Internally Deposited Alpha-Emitters, National Academy Press, Washington, D.C., 1988.

Health Effects of Exposure to Low Levels of Ionizing Radiation, National Academy Press, Washington, D.C., 1990.

Sources and Effects of Ionizing Radiation, United Nations, New York, 1977; *Ionizing Radiation: Sources and Biological Effects*, United Nations, New York, 1982; *Genetic and Somatic Effects of Ionizing Radiation*, United Nations, New York, 1986; *Sources, Effects, and Risks of Ionizing Radiation*, United Nations, New York, 1988.

[6] *Recommendations of the International Commission on Radiological Protection*, ICRP Publication 26, Pergamon Press, Oxford, 1977

1990 Recommendations of the International Commission on Radiological Protection, ICRP Publication 60, Pergamon Press, Oxford, 1991.

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control of individual sources and the methodology for expressing doses and risks from radiation. National bodies have also contributed to the evolution of radiation protection practice. In the U.S., the most recent (1993) recommendations of the National Council on Radiation Protection and Measurements (NCRP)[8] are, in most cases, consistent with those of the ICRP The changes in the recommendations of these organizations reflect the improved understanding of effects on health of ionizing radiation, new methodologies for evaluating doses and risks from ionizing radiation, developing public policy on acceptable levels of risk, and refinements in the application of basic radiation protection principles to the regulation of individual sources of exposure of members of the public.

All of the above developments—improved estimates of radiation risk, experience in regulating the constantly expanding complex of applications of ionizing radiation, and the evolution of improved basic concepts and methodology for radiation protection—have contributed to the need for this proposed revision of the 1960 guidance.

Effects of Radiation on Human Health

Effects on human health of concern from exposure to low levels of ionizing radiation may be divided into three categories.[9] The first of these encompasses all forms of cancer (including leukemias). Cancers associated with radiation are not distinguishable from those associated with other causes. Although radiogenic cancers are observed in humans over a range of higher doses,[10] it is necessary to infer the risk of cancer at the exposure levels normally encountered by members of the public because there is insufficient information to draw direct conclusions based on observations of cancer at these levels.

The second category encompasses hereditary effects (mutations) induced in the reproductive cells of exposed individuals and transmitted to their descendants. The severity of hereditary effects ranges from inconsequential to debilitating or fatal. Although such effects are observed in studies of animals at high doses, excess hereditary effects have not yet been confirmed in epidemiological studies of the descendants of exposed human populations.

Both cancer and hereditary effects are postulated to be caused by "stochastic" (i.e. random) direct or indirect interactions of ionizing radiation with the genetic materials in living cells. In view of the extensive, albeit incomplete, scientific evidence supporting this view including much theoretical and experimental radiobiology it is commonly assumed that at low levels of exposure the probability of incurring either cancer or most serious hereditary effects increases linearly with dose, without a threshold. The severity of such effects is not believed to be related to the amount of dose received. That is, it is the probability of occurrence of a cancer or an hereditary effect, not its severity once it has been induced, that is assumed to be dependent upon the size of the dose.

The risks to health from exposure to low levels of ionizing radiation have been reviewed by the National Academy of Sciences, as noted earlier, in a series of reports published between 1972 and 1990. Regarding cancer, there continues to be divided opinion on how to interpolate between the absence of radiogenic cancers at zero dose and the observed effects of radiation (mostly at higher doses than those normally encountered) to estimate the most probable effects of the doses actually encountered by members of the public.[11] A preponderance of scientists believe that the available data best support the use of a linear model for estimating the effect of such doses. Some scientists, however, believe that other models provide better estimates. These differences of opinion have not been totally resolved by studies of the effects of radiation in humans, the most important of which are those of the Hiroshima and Nagasaki atom bomb survivors. Over the last decade an extensive reevaluation of the doses and effects in these survivors has been carried out. With respect to cancer, this reevaluation has strengthened the evidence for use of the linear model at doses near background levels.

These studies have also resulted in increased estimates (roughly threefold between 1972 and 1990) of the most probable risk of cancer from environmental levels of radiation. Nonetheless, the estimated number of health effects induced by incremental doses of radiation comparable to natural background levels remains small enough, relative to the number that already occur from other causes, that in all likelihood it will never be possible to detect them in human epidemiological studies. This lack of detectability does not mean, however, that such effects on health do not occur. In the absence of reliable evidence to the contrary, the Agency believes that it is appropriate, for radiation protection purposes, to assume that at and just above the level of natural background the risk of cancer and most serious hereditary effects increases linearly with increasing dose, without a threshold. That is, we assume that any increase in exposure to ionizing radiation carries the potential for causing harm to health. This assumption has been employed in the development of this guidance, and is consistent with current as well as historical practice for radiation protection world-wide.

The third category of health effects involves those exposed *in utero*. It has long been believed that the unborn are more sensitive than are adults to the induction of cancer by radiation. The unborn are also subject to various radiation-induced physical malformations.[12] Recent studies, however, have drawn renewed attention to the apparently greater risk of severe mental retardation from exposure of the unborn. These studies indicate that the sensitivity of the fetus is greatest during the period from 8 weeks to 15 weeks after conception, and continues at a lower level during the period 16 to 25 weeks.[4] The risk of less severe mental retardation—manifested as a lowered Intelligence Quotient—is similarly elevated during these periods. Although it is not clear to what extent the occurrence and degree of retardation are proportional to the dose (or whether there is a threshold dose for these effects), it is prudent to assume, for regulatory purposes, that there is a linear, non-threshold relationship

[8] *Limitation of Exposure to Ionizing Radiation*, NCRP Report No. 116, National Council on Radiation Protection and Measurements, Bethesda, MD, 1993.

A fourth category of effects, designated "non-stochastic," occurs at dose levels higher than those addressed by these recommendations. They are of importance for managing the response to nuclear accidents (see EPA-520/1-75-001-A, op. cit.).

[10] We use the general term "dose" to mean the dose equivalent, effective dose equivalent, committed dose equivalent, or committed effective dose equivalent, with the precise meaning to be inferred from the text. When precision is important, we use the full term. In 1990 the International Commission on Radiological Protection adopted new terminology (and definitions) for these quantities: equivalent dose in place of dose equivalent, and effective dose in place of effective dose equivalent. Although these terms are simpler and are acceptable for use, we use the older, more explicit terms.

[11] The risk of interest is not that at or near zero dose, but that due to small increments of dose above the pre-existing background level. Background in the U.S. is typically about 3 mSv (300 mrem) effective dose equivalent in a year, or 0.[illegible] Sv (20 rem) in a lifetime. Approximately two thirds of this dose is due to radon, and the balance comes from cosmic, terrestrial, and internal sources of exposure.

[12] These include small head circumference (microcephaly), brain size (microencephaly), eye malformations, and intrauterine growth retardation.

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between these effects and the dose delivered to the fetus during these periods.

For radiation protection purposes EPA assumes, using a linear, non-threshold model, an estimated risk to an average member of the U.S. population of 5×10^{-2} fatal cancers per sievert[13] (5×10^{-4} fatal cancers per rem) delivered at low dose rates.[14] (That is, we estimate that if 100,000 people chosen at random from the U.S. population were each given a uniform dose of 1 mSv (0.1 rem) to the entire body at a low rate of exposure, five cases of fatal cancer, on average, would occur during their remaining lifetimes, in addition to the roughly 20,000 cases that normally would occur from other causes.) The risk of inducing severe hereditary effects in their offspring is estimated to be smaller than that for cancer, namely on the order of 10^{-2} per sievert (10^{-4} effects per rem).[15] The risk of severe mental retardation from doses to a fetus is estimated to be greater per unit dose than the risk of cancer in the general population—5×10^{-1} per sievert (5×10^{-3} per rem)[16]—but the period of susceptibility is very much shorter.

The National Academy of Sciences has judged the 90% confidence limits for their most recent estimates of the risk of cancer to be about a factor of three greater and a factor of two less than their estimate of the most probable value. They also observe that, at the low doses and dose rates of concern in this guidance, the possibility that there may be no risk cannot be ruled out, since epidemiological data cannot rigorously exclude the existence of a threshold. The numerical values of risks of genetic abnormalities and mental retardation are somewhat less well established. In spite of uncertainties in the data and its analysis, however, estimates of the risks from exposure to low levels of ionizing radiation are better characterized than those for virtually any other environmental carcinogen.

Basic Principles

In recommending the 1960 Federal guidance, the Federal Radiation Council said: "Fundamentally setting basic radiation protection standards involves passing judgment on the extent of the possible health hazard society is willing to accept in order to realize the known benefits of radiation" (25 FR 4402). The need to make this judgment led to three basic principles that have governed radiation protection for many decades in the United States and in most other countries. Although the precise formulation of these principles has evolved over the years, their intent has remained essentially unchanged.

The first principle is that any activity involving the exposure of people to ionizing radiation should be sufficiently beneficial to society to warrant the exposure; i.e., a finding should be made that an activity causing exposure is "justified."

The second is that, for justified activities, exposure of people should be "as low as reasonably achievable." This principle commonly has been designated by the acronym ALARA in the United States, and is called "optimization" of radiation protection in international practice.

The third is that, even for justified and optimized exposures, the maximum dose to any individual should be limited so as not to exceed an acceptable level of risk. This is referred to as "limitation."

The objective of the first two principles is to minimize (consistent with benefits and costs) the estimated total harm (i.e. health detriment) in the entire population from each source of exposure; they do not, however, limit the way that harm is distributed among individuals. They are, in this sense, "source-related" radiation protection requirements. The purpose of the third principle, that of limitation of the maximum allowed dose, is to provide an upper bound on risk to individuals. This principle, which is an "individual-related" requirement, may be carried out in two ways: first, through limitation of the potential dose from all sources of exposure combined, and second, through additional more specific limitations on the doses from individual sources.

The following seven proposed recommendations directly express, expand upon, and implement these three basic principles in light of current improved knowledge of the risks of radiation and of the variety and extent of uses of radiation. In particular, they reflect lower upper limits on dose to individuals from all sources combined, they make explicit the need for further limitation of doses from individual (or classes of) sources of exposure that is more restrictive than that for all sources combined, and they introduce improved methods for assuring that all of the various components of risk associated with radiation exposure are accounted for in radiation protection requirements for limiting exposure of the public.

Recommendation 1

There should be no exposure of the general public to ionizing radiation unless it is justified by the expectation of an overall benefit from the activity causing the exposure. Justified activities may be allowed, provided exposure of the general public is limited in accordance with these recommendations.

The principle that activities causing exposure of the general public should produce a net societal benefit has long formed a cornerstone of radiation protection policy even though the judgment of net benefit is not easily made. The 1960 Federal guidance states: "There should not be any man-made radiation exposure without the expectation of benefit resulting from such exposure* " and "It is basic that exposure to radiation should result from a real determination of its necessity

Other advisory bodies have used language which has essentially the same meaning. In its 1990 revision of international guidance, the ICRP said "* *no practice* *should be adopted unless it produces sufficient benefit to the exposed individuals or society to offset the radiation detriment it causes. When it addressed this issue in 1975, the NCRP said, "* *all exposures should be kept to a practicable minimum; *this principle involves value judgments based upon perception of compensatory benefits commensurate with risks, preferably in the form of realistic numerical estimates of both benefits and risks from activities involving radiation and alternative means to the same benefits."[17]

These recommendations would continue the requirement for justification in terms of an overall benefit. An obvious problem in making this judgment is the difficulty of

[13] The traditional special unit for dose equivalent has been the rem. The special unit sievert (Sv) in the International System of Units, adopted in 1979 by the General Conference on Weights and Measures, is now in general use throughout the world. The RPGs recommended here may be expressed in either of these units. One sievert is equal to 100 rem. The prefix "milli" (m) means one thousandth.

[14] "Low dose rates" here means dose rates on the order of or less than those from background radiation (see footnote 11). This value for the risk from such doses incorporates a dose rate effectiveness factor of two.

[15] The risk of severe hereditary effects in the first two generations, for exposure of the reproductive part of the population, is estimated to be 5×10^{-3} per Sv (5×10^{-5} per rem). For all generations the risk is estimated to be 1.2×10^{-2} per Sv (1.2×10^{-4} per rem). For exposure of the entire population, which includes individuals past the age of normal child-bearing, each estimate is reduced to 40% of the cited value.

[16] The risk for mental retardation during the 8th through 15th week [estimated to be 4×10^{-1} per Sv (4×10^{-3} per rem)] plus the risk during the 16th through 25th week [estimated to be 10^{-} per Sv (10^{-} per rem)].

[17] *Review of the Current State of Radiation Protection Philosophy*, NCRP Report No. 43, National Council on Radiation Protection and Measurements, Bethesda, MD, 1975.

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assessing, in comparable terms, costs (including risks) and benefits. Given this situation, informed value judgments may be necessary and, in fact, are usually all that is possible.

The determination that a particular activity involving exposure of the general public is justified is often a complex process. Commonly it is not made by those directly responsible for radiation protection decisions. For a few activities, like the x-ray examination of feet for shoe-fitting practiced many years ago, agreement that there is not a net benefit was easy to achieve. The decision was simplified in that example because the risks and benefits accrued to the same individuals. This is usually not the case. In extreme cases the determination can be far more complex. For a major industrial application of radiation, for example, the determination may involve not only the benefits and the costs (direct, health, and environmental) of construction, operation, waste disposal, accidents, and eventual decommissioning, but also the tradeoffs between the activity and the economic, societal, environmental, and resource implications of alternative means to achieve the same result.

In any case, for a major activity the analysis should make a reasonable demonstration that the benefit associated with the proposed activity clearly outweighs the risks associated with the use of ionizing radiation, including those associated with normal operations, reasonably possible incorrect operation or management, and disposal of wastes over the life cycle of the activity. When the consequences can be significant, the analysis should include low probability events and exposure pathways.

The process of balancing these factors may eventually involve congressional, executive, and judicial inputs. One vehicle for assisting such decision-making is the National Environmental Policy Act of 1969 which, in effect, requires Federal agencies to assess and consider the above factors for any major Federal action that could significantly affect the quality of the human environment. Others include the regulatory analysis process pursued by Federal agencies (Executive Order 12866; 58 FR 51735, October 4, 1993), and decision processes of public and professional bodies, such as public utility commissions and professional medical groups. However, in making these recommendations EPA does not propose to specify how or by whom justification should be determined, but simply that the detrimental effects of radiation, as well as other detrimental effects, should be considered along with the benefits in any situation where an initial decision is being made that involves significant exposure of the general public to radiation.

Recommendation 2

A sustained effort should be made to ensure that doses to individuals and to populations are maintained as low as reasonably achievable.

The idea that exposure to radiation should be kept to a practical minimum became a basic requirement in radiation protection early in the century shortly after the recognition that harm from radiation is not limited to the skin damage that occurs at relatively high doses. The concept was first applied to exposure of individual workers, primarily in medical and research applications, since early uses of radiation did not involve large populations. Later, after the commencement of nuclear weapons testing and introduction of the widespread use of nuclear power, it was applied to the exposure of populations—first to safeguard the genetic pool and, later, after the assumption that cancer induction is a stochastic process became accepted as a prudent premise, also to reduce the presumed incidence of cancer. The requirement is now taken to be the logical and necessary consequence of the assumption of a linear relationship between exposure to radiation and the risks of cancer and hereditary effects at the dose levels addressed by these recommendations.

The phrase "as low as reasonably achievable" (ALARA) is used to designate a general principle that exposure to radiation should be controlled so as to achieve the lowest level reasonably attainable. The 1960 FRC guidance applied the concept to keeping dose to the *individual* as low as practicable, and expressed it as a responsibility to be carried out by the user of radiation. In these proposed recommendations the ALARA principle is broadened to apply to collective doses in *populations* as well, and in this broader application serves as a principal basis for the implementation of ALARA through regulatory practice. This use of the ALARA principle is customarily designated "optimization" of radiation protection. Optimization may be carried out through regulatory determinations for whole classes of similar sources, as in the establishment of standards for environmental releases from nuclear power facilities, or, more directly in the determination of operating requirements for a specific facility. Depending on the nature of the source, optimization may involve use of simple or complex decision tools for balancing public health and economic concerns to determine the optimal level of control. The basic elements required for optimization are the values placed on avoiding the estimated health detriments and the direct costs of control, as a function of various levels of protection. In reaching a final optimization determination, however, a variety of other economic and societal factors may also have to be considered, such as the distribution of health detriment over populations and over time, and the technical feasibility and overall economic impact of controls. In rare cases, the optimization process could result in the need to make tradeoffs between larger doses to a few individuals (within the limits specified in Recommendations 3 and 4) and many small doses in large populations.

At the dose levels involved in the comparison of alternatives for determining ALARA levels, linearity is assumed, and effects on public health may be estimated from the collective dose in populations. In cases where it is necessary to estimate the total public health detriment from long-lived radionuclides, collective dose will often have to be projected into the future, or in distant populations. Regulatory decisions on ALARA levels should take into account such projections when their contribution is both a significant part of the total collective dose from the activity under examination and its uncertainty is not large compared to the differences in collective dose among the alternatives being examined. In some cases, it may be appropriate to estimate effects on public health as a function of time or distance, and to take their distribution in time or distance into account in decisionmaking. However, it will never be appropriate to apply an arbitrary cutoff to such projections based solely on the level of dose to individuals, or on the distance from the source or in time; such cutoffs would have the effect of preempting the decision-making process before the magnitude and distribution of the avoidable impact on health has been estimated.

In some situations, a decision to refrain from applying controls may be the appropriate outcome of an ALARA determination. Such a finding for an individual practice, or for a group of practices meeting specified requirements, may be used as one criterion for exemption from regulatory control. However, in addition to a finding that the total health detriment in populations is not large enough to justify control, it is also necessary to ensure that individual exposures are

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sufficiently small, in view of the stipulations of Recommendation 4, not to warrant regulation. Exemptions that satisfy each of these criteria would be consistent with these proposed recommendations.

Although the ALARA principle is relevant to a wide variety of radiation protection activities, these tend to fall into two general categories. The first is that emphasized above, the establishment of regulatory levels of control over individual sources or categories of sources by Federal (or State) agencies. The second, and equally important, is making management decisions in day-to-day operations at facilities where ionizing radiation or radioactive materials are present. The selection of regulatory limits for facilities, as well as the day-to-day management of sources, in a manner consistent with the ALARA principle are discussed further in connection with Recommendation 4.

Recommendation 3

The preceding recommendations address the need for justification and optimization of activities that involve exposure of the general public. The third basic radiation principle, limitation of maximum dose to individuals, is addressed by the next two recommendations. Recommendation 3 limits the sum of doses to any individual from all radiation sources combined, through the Radiation Protection Guide (RPG) for the general public; and Recommendation 4 addresses limitation of doses from individual sources, through the establishment of source-specific authorized limits.

The RPGs established in 1960 and 1961 consist of separate limits on dose to the whole body and bone marrow (0.5 rem in a year, each), the thyroid and bone [18] (1.5 rem in a year, each), and the gonads (5 rem over 30 years, average in the U.S. population). Those recommendations (except that for the gonads) were based on the concept of limiting the dose to the most critically exposed organ of the body.[19] That is, it was assumed that if dose to the critical organ was limited to an acceptable level, then doses to other parts of the body would also be acceptably low. One consequence of this approach is that exposure of the body to external sources of radiation and exposure to internal radioactivity are addressed by separate limits, and therefore the risks from such exposures can be additive. Further, when several different organs are exposed to internal radiation simultaneously only the part of the body receiving the highest dose relative to its RPG is decisive for limiting the dose. That is, the risks associated with exposure of other parts of the body are not considered in applying a dose limit based on the critical organ approach. The 1960 limit for dose to the gonads was based on an entirely different consideration, that of limiting the incremental rate of mutation in the entire genetic pool of the U.S. population. The incremental level of mutation deemed unacceptable was on the order of a few per cent.

These recommendations would replace the system described above with the risk-weighted dose limitation system introduced by the ICRP in 1977 [6] The ICRP system takes into account the individual contribution of each exposed part of the body to total risk. It does so by assigning to each organ or tissue of the body a weighting factor that is proportional to the risk per unit dose of inducing cancer or, for the reproductive organs, to the risk per unit dose of inducing hereditary effects in offspring. The risk limit is then expressed in terms of the sum of weighted dose equivalents to all parts of the body, a quantity called the "effective dose equivalent" (EDE).[20] A limit in terms of the EDE therefore reflects both the distribution of doses among the various organs and tissues and their assumed relative sensitivities to cancer and hereditary effects. Further, the EDE does not differentiate exposures from external and internal sources; it includes both.

The effective dose equivalent is defined formally in footnote (b) to Recommendation 3 and proposed weighting factors are listed in Notes 5 and 6, in the formal statement of proposed recommendations at the end of this notice. These factors reflect the organ-specific risks of lethal cancer, and, for the reproductive organs, the risk of serious hereditary effects in the first two generations of offspring. They are the same weighting factors as those adopted in Federal guidance on radiation protection for workers in 1987 Although our current best estimates for these effects on health would lead to somewhat different values, the differences are sufficiently small that new weighting factors are not proposed as part of these recommendations. The Agency has made this choice for several reasons. First, it should be noted that changes in the weighting factors, based on new estimates for mortality would have no effect on the level of risk represented by a given dose to the *whole* body, since the sum of the weighting factors is, by definition, normalized to unity. (If these factors were adjusted to take into account non-lethal cancers or other factors such as age at incidence the risk level could change, but, for the same reason, this change would be small.) Thus, the general level of risk achieved would not be affected. Second, the ICRP has recently published revised weighting factors that, in addition to incorporating updated information on risks of mortality also consider other factors such as morbidity i.e., the risk of non-lethal cancer (but do this without changing the recommended dose limit).[7] We are reviewing those weighting factors, as well as our own estimates of organ-specific risk factors. Finally extensive new tabulations, for each of over 700 radionuclides, of dose factors for various chemical forms and routes of exposure have recently been completed using the existing weighting factors.[21] Regulations using these dose factors are being implemented by EPA, NRC, and DOE. Changing the weighting factors for many of these regulations will require formal rulemaking. EPA will keep these considerations under review will continue to review the choice of weighting factors as new information becomes available, and will issue guidance on improved weighting factors from time to time, following review by and consultation with affected Federal agencies.

Recommendation 3, which specifies the proposed new RPG for the general public, consists of three parts. We first set forth the text of the recommendation and some explanatory details, and then discuss the basis for the choice of the value of the RPG and other related matters. The first part of Recommendation 3 reads:

> The combined radiation doses incurred in any single year from all sources of exposure covered by these recommendations should not normally exceed a Radiation Protection Guide of 1 mSv (100 mrem) effective dose equivalent to an individual. The Radiation Protection Guide applies to the sum of the effective dose equivalent resulting from exposure to external sources of radiation during a year and the committed effective dose equivalent incurred from the intake of radionuclides during that year

[18] The guidance also included an approximately equivalent RPG for bone in terms of radium-226 in the adult skeleton (0.003 micrograms).

[19] This was an incomplete set for this scheme of protection, since many relevant parts of the body were not assigned RPGs. The 1960 RPGs for workers, by contrast, did comprise a complete set, and, for the general public, the missing values for other parts of the body were generally taken as 1/10 of the corresponding occupational values.

[20] The weighting factors are normalized so that the risk associated with a given EDE is equal to that from a uniform dose of the same magnitude to the whole body

[21] These are specified in Note 7 to the Recommendations.

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This recommendation would replace the 1960 and 1961 RPGs for dose equivalent to the whole body and specified parts of the body by a single RPG of 1 mSv (100 mrem) effective dose equivalent in a year. In so doing, it would create a single limit for combined dose from external and internal radiation.

Certain radionuclides, if inhaled or ingested, may remain in and continue to irradiate the body for many years. This proposed recommendation incorporates the use of "committed" dose into guidance for the general public (this concept was introduced into Federal radiation protection guidance for workers in 1987). It provides that Federal agencies should base control of annual intake of such radionuclides upon the future dose that may result over time (that is, the committed dose), not just the "annual" dose accrued during the first year following intake. This would assure that, in regulating annual intake of such materials by members of the public, account is taken of the additional risks committed from doses that will be delivered in future years. The standard period for which committed dose is calculated is proposed to be taken as 50 years, as in the Agency's previous recommendations for workers. Although there are a few radionuclides from which doses can accrue for longer periods, the risk associated with intake of such radionuclides will be conservatively estimated, compared to the risk from a comparable external dose, because of the combined effect of the distribution over time of committed dose and the latency period for expression of cancer.

The proposed RPG is expressed in terms of both the new special SI unit "sievert" and the historically-used special unit "rem." It is not the intent of these recommendations to express a preference for either system of units, but merely to recognize the existence and acceptability of both. Federal agencies would be free to use either unit under these recommendations, but should specify conversion factors between the two systems in new regulations.

The second part of Recommendation 3 reads:

> The Radiation Protection Guide may not be reasonably achievable in some unusual situations. It may be exceeded temporarily in situations that are not anticipated to recur chronically and when Recommendations 1 and 2 are satisfied, provided that the radiation dose incurred in any year does not exceed 5 mSv (500 mrem) effective dose equivalent.

It is not anticipated that this provision would be used frequently In the past, doses to members of the public at or near such levels have been uncommon, and the Agency expects this to continue to be true. We have identified two examples of situations in which such doses are known to occur now, and might reasonably be permitted to exceed the RPG. The first is through the incidental exposure of a family member, household member, or friend to a patient being treated (or diagnosed) using radioactive materials, for certain medical procedures (primarily in the treatment of thyroid cancer using ^{131}I). The second involves the exposure, in some unusual cases, of individuals living near radioactive contamination that has not yet been cleaned up. This almost invariably involves naturally-occurring materials, often from mining or milling operations. In situations where temporary relocation is not an acceptable alternative it may not be practical to complete such cleanup without exposing a few members of the public to doses exceeding 1 mSv (100 mrem) in a year. This provision is not intended for use as a limit in dealing with short-term emergency situations arising from nuclear accidents; these are governed by the Protective Action Guides for nuclear incidents (EPA-520/1-75-001-A).

The third part of Recommendation 3 reads:

> Continued exposure of an individual over substantial portions of a lifetime at or near the level of the Radiation Protection Guide should be avoided. This will normally be achieved through conformance of individual sources to Recommendations 2 and 4.

In recommending an RPG of 1 mSv (100 mrem) in a single year, it has been necessary to balance the practical regulatory need for an RPG expressed in terms of *annual* dose against the public health objective of adequately limiting *lifetime* risk. We anticipate that satisfying the criteria specified in Recommendations 2 and 4 will almost invariably achieve this objective. However, in the unlikely event that circumstances were such that continued exposure at or near the RPG over substantial portions of a lifetime could occur, this portion of Recommendation 3 explicitly expresses the criterion that chronic exposure at such levels should be avoided.

Basis for the Radiation Protection Guide

In the latter part of the twentieth century society has become increasingly unwilling to accept risks imposed by activities that produce environmental pollutants. Many of the benefits of industrialized society however, are brought about by activities that carry with them some unavoidable elements of risk. This is especially the case for so-called "non-threshold" pollutants like radiation, for which it is assumed that there are no risk-free levels. The risk to an individual from exposure to ionizing radiation, as discussed above, is assumed to depend linearly upon the radiation dose, without a threshold. Under current guidance the average member of the public now receives, from all the sources to which that guidance has consistently been applied, only a very small dose—less than 0.01 mSv (1 mrem) in a year.[22] The average risk of fatal cancer incurred from such an exposure is estimated to be somewhat less than 5 in ten million.

The cumulative risk to society associated with the variety of current uses of radiation is now governed by the dual requirements that *each* use be justified and that its effect on public exposure minimized by optimizing radiation protection. These requirements would be continued and strengthened under proposed Recommendations 1 and 2. Typically this would result in a distribution of annual doses from each source of radiation exposure ranging from zero for most members of the population to a maximum value (established under Recommendation 4) accruing to a small number of individuals. The RPG serves as an upper bound on the highest doses resulting from the sum of all such distributions. As such, it acts as a limit on the annual increment of risk, now and in the future, to the theoretically most exposed individual with typical consumption and other relevant behavior habits.

In selecting the proposed value for the RPG the Agency has had to consider a number of judgmental factors: the relation between a limit on annual dose and the implied lifetime risk; the degree of protection achieved through the application, by regulatory authorities, of optimization to the derivation of source limits, as well as their consideration of the various possibilities for multiple exposure to current and future sources, under Recommendation 4; and, finally the record to date on the operational

[22] During the period 1960 to the present, the current RPG has not consistently been applied to exposure due to natural sources. The primary examples are building materials and radon in domestic groundwater supplies; these contribute *additional* average effective dose equivalents to the U.S. population of 0.035 mSv (3.5 mrem) and 0.01-0.06 mSv (1-6 mrem), per year, respectively. Tobacco smoke contributes a further, at present incompletely characterized, dose. (These estimates are derived from *Ionizing Radiation Exposure of the Population of the United States*, National Council on Radiation Protection and Measurements Report 93, Bethesda, MD (1993).)

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application of ALARA (i.e., the difference between source limits and the doses actually experienced).

It is anticipated that the proposed RPG, applied in the context of these proposed recommendations, would, under most circumstances, result in lifetime risks to the most exposed members of the public from man-made radiation in the environment of less than one in ten thousand. This expectation is based on past experience under current radiation protection guidance, cited above, coupled with the improvements in protection proposed here—most particularly those proposed under Recommendations 2, 3, and 4. Recommendation 2 strengthens the requirement that doses be maintained as low as reasonably achievable; Recommendation 3 reduces the RPG, and Recommendation 4 requires source-specific limits that take into account the present and future potential for doses from other sources (and are therefore normally only a fraction of the RPG). EPA has, in a number of previous actions, concluded that a lifetime risk level no greater than about one in ten thousand provides an acceptable level of protection. These include the National Emission Standards for Hazardous Air Pollutants (NESHAPs), the National Primary Drinking Water Standards, and the Agency's guidelines for site-specific risk management under the Comprehensive Environmental Response, Compensation, and Liability Act ("Superfund"). These recommendations propose that this level of protection is also appropriate for application in this Federal Radiation Protection Guidance for Exposure of the General Public and would be achieved through the cumulative application of these recommendations.

In addition, the proposed five-fold reduction in the RPG and the accompanying requirement that it be applied to the sum of external and committed internal doses would assure that maximum risks permitted to even the most highly exposed individuals are greatly reduced, compared to those permitted under the current RPGs. Although not many people are exposed near the RPG, a few cases of such high risks do now exist. These are usually associated with technologically enhanced exposure to natural radioactive materials. Examples include phosphate mining residues in Idaho and Florida, radium processing wastes in New Jersey, Illinois, and Colorado, and uranium mill tailings at publicly accessible locations in a number of western states. Under the current RPGs, annual doses due to external exposure up to 5 mSv (500 mrem) are permitted, in addition to organ doses from internal exposure up to 15 mSv (1500 mrem), depending on the organ and the radionuclide. Such doses imply lifetime risks up to 250 in one million for each year of external exposure, and up to 40 in one million for each year of internal exposure. The proposed RPG of 1 mSv effective dose equivalent would limit the incremental lifetime risk associated with each year of combined external and internal exposure to 50 in one million, a significant reduction in risk.

Finally, the Agency notes that the proposed RPG is consistent with levels found acceptable and in use by the international community. A value of 1 mSv per year is recommended as the upper bound on doses to members of the public by both the ICRP and the International Atomic Energy Agency, and is in common use throughout the world.

To provide a perspective on the above levels of risk, it may be noted that the average American is exposed annually to an effective dose equivalent of about 3 mSv (300 mrem) from natural background radiation, including an average contribution of about 2 mSv (200 mrem) from radon in homes. This exposure is three times the proposed RPG, and each year's exposure corresponds to an incremental lifetime risk of 150 in one million. Although the average level of exposure to natural background provides perspective, it does not, however, provide a justification for the RPG, since it represents an uncontrollable source of risk, and the RPG applies to controllable sources.

The levels of risk assumed to be associated with radiation exposure may also be compared to involuntary and voluntary risks actually incurred in common activities. For example, the essentially involuntary risk of dying of a household accident averaged about 110 in a million per year, between 1980 and 1990, and the average probability of dying of an automobile accident in the same decade, a voluntary risk, was 240 in a million per year. We emphasize that all of these examples are provided for perspective only, and that the existence of other risks, voluntary or involuntary is not a justification for any particular incremental radiation risk.

EPA recognizes that some of the assumptions that underlie the proposed RPG are not readily quantified, or are based on experience that may not accurately predict the future. We will continue to review exposure of the general public, with a view to initiating recommendations for any further modification of these recommendations that may be warranted to ensure that low risks to individuals are maintained.

Other Matters Related to the Radiation Protection Guide

In developing these recommendations, EPA also considered risk to the unborn from exposure of pregnant women. It is clear that, in general, the fetus is more sensitive to many environmental carcinogens, mutagens, and teratogens than are adults, because the rate of cell division in their developing organs is far greater. This appears to be the case for radiation as well, which can act in any of these three ways. Of these risks, the most important at the levels of exposure addressed by these recommendations is mental retardation due to exposure to radiation during the eighth to fifteenth weeks of gestation, as discussed earlier.

In considering the importance of the risk of mental retardation to the choice of the RPG, we note that the sensitive period for inducing this effect represents a very small part (0.2%) of a normal lifetime, the time span addressed by the risk limitation contemplated by these recommendations. This sensitive period should be considered in conjunction with the observation that sources governed by these recommendations typically yield exposure that is uniformly distributed in time, and almost never yield high-level, short-duration doses. (Accidents are not addressed by this guidance.) Based on these two observations, coupled with the numerical values for radiation risks cited earlier, EPA concludes that the risk of mental retardation from the relatively small exposure of the unborn that would accumulate during the short period of sensitivity before birth will be smaller than the risk of cancer associated with the very much longer period following birth, during which time a relatively much larger exposure to sources governed by these recommendations could accumulate. EPA believes, further, that it is not appropriate to base a general limit for members of the public on the highly unlikely circumstance that the entire RPG is delivered during the short period of significantly elevated susceptibility of the unborn. We conclude, therefore, that these proposed recommendations would provide adequate protection of the unborn without specifying a separate limit specifically for this purpose.

An opposite situation is posed in considering the risk to members of the population who are within one or two decades of the end of a normal lifetime. In this case the risk, instead of being higher, is lower. The risk of cancer in

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this population approaches being an order of magnitude smaller than the risk to an average member of the population, and the risk of genetic consequences is normally no longer present. EPA has not proposed a higher RPG for this population because, as noted for the case of the unborn, these recommendations are based on limiting the risks that accrue over a lifetime, not on a yearly basis. The RPG is expressed as an annual limit simply for ease of implementation. We also note that a limit that was different for different ages of members of the public would pose severe implementation difficulties.

Implementation of measures for assessment and control of internal exposure to radionuclides commonly makes use of intake-to-dose conversion factors. EPA has previously tabulated such values for use in implementing the Federal Guidance for Protection of Workers, in Federal Guidance Report No. 11, Limiting Values of Radionuclide Intake and Air Concentration, and Dose Conversion Factors for Inhalation, Submersion, and Ingestion (EPA-520/1-88-020). The dose conversion factors in this report and its subsequent editions also apply to intake of radionuclides by members of the general public. For external sources, exposure-to-dose conversion factors are tabulated in Federal Guidance Report No. 12, External Exposure to Radionuclides in Air, Water, and Soil (EPA 402-R-93-081).

These dose conversion factors are appropriate for application to any population adequately characterized by the set of values for physiological parameters developed by the ICRP and collectively known as "Reference Man." [23] The actual dose to a particular individual from a given intake is dependent upon age and sex, as well as other characteristics. As noted earlier, implementing limits for the general public expressed as age and sex dependent quantities would be difficult. (Clearly it would be impracticable to conduct an annual survey of age and sex at every location of a potential source of public exposure.) More importantly the variability in dose due to these factors is comparable in magnitude to the uncertainty in our estimates of the risks which provide the basis for our choice of the RPG. For this reason EPA believes that, for the purpose of providing radiation protection under the conditions addressed by these recommendations, the assumptions exemplified by Reference Man adequately characterize the general public, and a detailed consideration of age and sex is not generally necessary. The most obvious exception is for large doses delivered in a short period of time, as in an accident, for which case the appropriate response is addressed by separate EPA recommendations (EPA-520/1-75-001-A).

The proposed RPG is sufficiently small that the dose any organ might receive will be far below threshold levels for non-stochastic health effects (i.e. effects on health, such as burning of the skin, cataracts, impairment of fertility and more serious effects which can lead to early death, all of which only occur when threshold levels of dose that are greater than 0.5 Sv (50 rem) are exceeded). That is, adequate protection of every organ from non-stochastic health effects is automatically ensured by the proposed RPG. These recommendations therefore do not include separate limits to prevent the occurrence of non-stochastic effects.

The sum of weighted organ doses that comprises the effective dose equivalent does not include an allowance for cancers induced by irradiation of the skin. In some circumstances, however, in the assessment of total health detriment in populations, dose to the skin may be large enough to warrant consideration of fatal cancers due to skin dose. These proposed recommendations provide for adding to the effective dose equivalent a term that is the product of the dose equivalent to skin (averaged over the entire skin surface) and a weighting factor of w_{skin}=0.01 in such cases.

Recommendation 4

Recommendation 4 consists of two parts. The first reads:

> Authorized limits for sources should be established to ensure that individual and collective doses in current and future populations satisfy the objectives of this guidance. These limits may be developed for categories of sources or for specific sources. Authorized limits for sources should normally limit doses to a fraction of the Radiation Protection Guide for all sources combined.

Authorized limits are standards, regulations, technical specifications, or other requirements established by a responsible authority to ensure that the objectives of this guidance with respect to limitation of doses will be satisfied. Implementation of the ALARA requirement (Recommendation 2) will involve consideration of collective doses to populations,[24] of control mechanisms, and of other factors that will differ for each category of sources, and will usually lead to control levels that result in doses to individuals less than the RPG (Recommendation 3). However, there are many different categories of activities using radiation that can lead to exposure of members of the public. These currently include medical uses of radiation and their supporting activities; nuclear electric power facilities and their supporting fuel cycle facilities; research and industrial users; weapons production, storage, and disposal facilities; technologically-enhanced exposure to natural radiation sources; consumer products; space applications; disposal sites for radioactive wastes; and decommissioned sites at which radioactive materials were formerly used. It is therefore also necessary to ensure that total doses to individuals, who may be exposed not only to more than one source in a given category in a few cases, but more often to a number of different categories of sources at one time, are not likely to exceed the RPG. It is not intended that this objective be implemented through apportionment of the RPG among categories of sources; this would be impracticable. Rather, this consideration, which must encompass the potential for doses to the general public both now and in the future, will necessarily be a broad judgment, based on general observations of the characteristics of existing activities, projections for their use in the future, and the potential for presently unidentified future uses.

To implement these objectives, authorities responsible for limiting exposure of the public should govern sources through use of "authorized limits" established either for categories of similar sources or for specific sources. In establishing these authorized limits, since the ALARA process considers actual costs and capabilities of controls, it is important that assessments of doses to individuals and populations be carried out realistically and comprehensively. Such assessments should contain neither unnecessarily unrealistic assumptions that overestimate doses nor omit any significant contributions to risk or detriment, since either of these would invalidate the ALARA determination. Further, authorities should consider, in addition to the design capabilities of

[23] ICRP No. 23 *Report of the Task Group on Reference Man*, 1974.

[24] These recommendations are not intended to require numerical limits for collective dose. Although the determination of ALARA levels necessarily involves optimization of the collective dose, the regulations that implement these levels can be expressed in terms of individual or collective dose, total or concentration of activity released, installation and use of specified controls, or any other specification that the regulatory authority finds appropriate.

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facilities for control of releases, expected departures from anticipated design performance. Finally, in the case of authorized limits established for broad categories of sources, the judgments will often necessarily be broad and may lead to somewhat higher values, with further implementation of the ALARA process left to management of the individual sources within a category.

Authorized limits currently exist for a wide variety of sources, at levels that are fractions of the proposed RPG. For example, in 1977 EPA established general limits for dose received from all radionuclides, combined, via all exposure pathways, combined, from most facilities involved in the nuclear fuel cycle combined, including power reactors, in 40 CFR Part 190. The principal limit, 25 millirem (0.25 mSv) per year to the whole body, is 25% of the proposed RPG. Additional site specific limitations are established, for example, by the Nuclear Regulatory Commission in license conditions for individual commercial reactor sites, or in requirements for specific types of facilities, such as low level waste sites in 10 CFR Part 61. EPA has recently established source-specific limits for doses from all radionuclides, combined, via all air pathways from individual sources of radionuclide emissions, including all Federal facilities, in 40 CFR Part 61. These generally require limiting doses to 10 millirem (0.1 mSv) per year effective dose equivalent, or 10% of the proposed RPG. Finally, the national drinking water standards at 40 CFR Part 141 limit doses from water at the tap to 4 millirem (0.04 mSv) per year whole body or organ dose from all man-made radionuclides, or 4% or less of the proposed RPG. In each of these cases, the regulatory process, under the current recommendations, supplemented in some cases by additional statutory requirements, has resulted in requirements ensuring that maximum dose to individuals from a specific source or category of sources is a small fraction of the proposed RPG for dose from all sources combined. Although this situation is anticipated to continue, we believe it is prudent to note explicitly that authorized limits should normally satisfy this condition.

Once such authorized limits are established, it will no longer be necessary to further evaluate contributions to doses from any other source as part of the management of the operations of a specific source. These requirements thus serve to avoid the need to perform detailed, and in some cases very difficult to validate, evaluations of the combined incremental doses from other sources at individual sites. Conversely, if these requirements are exceeded (or are absent), then such evaluations may be necessary to assure conformance to the RPG (Recommendation 3).

The second part of Recommendation 4 reads:

> Sources should be designed not to exceed authorized limits, and should be operated so as to maintain doses to members of the general public as low as reasonably achievable within such limits.

The ALARA principle applies not only to the establishment of authorized limits, but also to detailed management of facilities where sources of radiation are prepared, employed, stored, or transported. This is necessary and appropriate because authorized limits must usually provide flexibility for anticipated deviations from design performance, and controls usually can perform better than their design limits. Thus, exposure of the general public, even if a source conforms to authorized limits, will not be ALARA when lower exposures are reasonably achievable.

As exemplified by the performance of many facilities over the past two decades, doses to the public usually can be maintained far below authorized limits through responsible and skillful control of radiation sources. This has required careful management and supervision of radiation protection activities, including the choice and implementation of radiation control measures for sources of exposure of members of the public, training in procedures to control such exposure, and monitoring, assessment, and reporting of exposure levels and doses at appropriate on-site and off-site locations. The routine management of a facility and decisions on how, or whether, particular actions should be carried out can, in the aggregate, be as (or more) significant for radiation protection of the public as the design of the facility and choice of its authorized limit.

The selection of authorized limits and the application of the ALARA principle to operations requires technically informed judgments. Thus, the practice of ALARA must be the responsibility primarily of those persons who control and manage sources of radiation under the oversight of the responsible public authorities; that is, it should not be the responsibility of individual members of the public, who are not familiar with radiation protection practices. For example, consumer products containing radioactive materials, and instructions for their use and disposal, should be designed to maintain radiation doses that are ALARA, and members of the public who use them should not have to rely upon their own judgment on this issue. The ALARA principle must be implemented by those who are directly responsible for radiation protection, or who are otherwise professionally responsible for health, safety, and environmental protection aspects of radiation sources.

Recommendation 5

> Risks associated with exposure of the general public to radiation that may occur due to Federal agency decisions, and the policies upon which these decisions are based, should be made known to the public in a timely fashion as part of the decision process. The degree of detail and type of information made available should be appropriate to the potential radiation exposures involved. Information on risks should encompass estimates of the risks of effects on health over time, and of the uncertainties in such estimates. Information on policies should include reference to this Federal radiation protection guidance for the general public and other relevant Federal policies.

To judge the validity and acceptability of decisions about Federal activities which not only bring benefits but also pose risks, the public requires clear and, to the extent possible, quantitative information. In the case of proposed Federal actions involving exposure to radiation, this includes information on the biological effects of radiation, on the levels of risk associated with exposures that may result from the actions, and on the Federal policies that underlie the action.

Requirements for the development and presentation of these kinds of information may be found in the National Environmental Protection Act (NEPA), 42 U.S.C. §§ 4231 et seq., Title III of the Superfund Amendments and Reauthorization Act (SARA), 42 U.S.C. §§ 9601 et seq., the Administrative Procedure Act, 5 U.S.C. §§ 551 et seq., and in other legislation. Such information serves to assist the public in becoming constructively involved in the decision process and in influencing the public policy issues that affect them.

It is the purpose of this recommendation to ensure that, when Federal agencies formulate policies and make decisions that influence the exposure of the general public, information that will adequately inform the public during the decision-making process is made available by them in a timely manner. Although it is not intended to require general dissemination of information concerning ongoing operations, nor to require major public information distribution efforts, such activities are

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encouraged whenever it is reasonable to carry them out.

Recommendation 6

Assessments and records appropriate to the origin and magnitude of expected doses and the exposed population should be performed and maintained to demonstrate conformance with requirements which implement these recommendations. The types and accuracy of methods and procedures used in these assessments should be reviewed periodically to ensure that they are appropriate and are being competently applied.

Control of exposure of the public is normally ensured through analysis of releases from sources and modeling of environmental transport to hypothetical "critical groups" of the general public assumed to receive the greatest exposure. Unlike the situation for workers exposed occupationally it is usually neither appropriate nor feasible to physically monitor doses to individual members of the public. Such dose rates and concentrations may be determined by measurement of radioactive effluents, mathematical modeling of the dispersal of radionuclides in the environment, or both.

Assessments and records required to ensure conformance with these recommendations will vary depending upon the nature of the source of exposure. Responsible authorities will have to determine what is needed to ensure that exposures of members of the public actually are maintained within authorized limits and are ALARA. In some cases, comprehensive radiation assessment programs will be needed which include trained personnel, facility and environmental measurements, audit procedures, and maintenance of records. In many cases conservative assumptions, such as the assessment of doses to a hypothetically most exposed individual, may be used to simplify the demonstration of compliance. In still others, simple operational procedures will suffice.

This recommendation intentionally allows flexibility with respect to what should be assessed and recorded, so that the responsible authorities will be able to design optimal programs for each situation. This is intended to avoid, in particular, burdensome requirements for situations in which individual doses and detriments to populations are very low. At the same time, assessments and recordkeeping must be adequate to document that requirements which implement these recommendations have been satisfied.

Recommendation 7

Exceptions to Recommendation 3 for planned exposure to radiation should be made only for highly unusual circumstances, and only when the Federal agency having jurisdiction has carefully considered the reasons for making them in light of these recommendations. If Federal agencies authorize any exception to these values, they should make it a matter of public record.

This proposed guidance applies to emissions and exposure of the general public under normal circumstances. In developing these recommendations, EPA has considered situations that might normally arise. It is not possible to foresee all contingencies, however, and highly unusual situations may occur when exceptions to the limiting values of Recommendation 3 are appropriate. This recommendation provides that if such circumstances should arise, Federal agencies should carefully consider the balance of the guidance, including the information requirements of Recommendation 5, and make a public record of any authorized exception to Recommendation 3 (e.g., by publishing a notice in the **Federal Register** or in a local newspaper of general circulation).

Implications of these Recommendations

It is expected that these proposed recommendations could be implemented relatively easily, since most of them are already in large part, in effect. For example, most sources are already regulated in such fashion that exposures of members of the public are a small fraction of the proposed Radiation Protection Guide of 1 mSv (100 mrem) in a year, and we are aware of no regulated sources that exceed the proposed RPG. Perhaps the most significant implication of these recommendations would be to promote consistency between Federal agencies by clarifying the basic considerations to be taken into account in the development of new standards and regulations, and in their implementation. The recommendations modernize the methodology for expressing dose, and clarify the relationship of the RPG to standards and regulations for sources, as well as the various applications of the principle that doses should be maintained "as low as reasonably achievable," and they provide, for the first time as a part of their basis, numerical estimates of the various risks from low levels of ionizing radiation.

Implementation of the proposed recommendations would require only minimal changes in Federal regulations, and should be achievable over a short period of time. Many of the changes called for are largely already well under way major examples being the revisions recently made by the Department of Energy in their Order No. 5400.5, and those recently promulgated by the Nuclear Regulatory Commission in 10 CFR Part 20. It is expected that Federal agencies will have little difficulty in identifying and correcting any remaining problem areas, and in providing necessary flexibility and transition periods, to avoid undue impacts that might inhibit prompt implementation of new guidance.

We note in passing that in some cases (notably in the regulation of exposure of the public from the transportation of radioactive materials) conformance to existing guidance is based upon the assumption of "reasonably foreseeable" scenarios for the spatial and temporal relationship between radioactive materials and members of the public, and that because of this assurance the RPG will never be exceeded cannot be given with absolute certainty. These recommendations do not propose any changes in this regard, and EPA expects that in such cases the same approach to protection would continue to be employed to achieve conformance to these new recommendations.

The anticipated costs of implementing these recommendations are primarily those that would be incurred by the various agencies in modifying their own regulations. These are not expected to be substantial, since most of the necessary methodological changes have already been implemented in connection with the revised Federal guidance for occupational exposure issued in 1987 Unlike the situation for occupational exposure, where the need to reduce the doses received by a few highly exposed workers to conform to lower limits may lead, in some cases, to the hiring and training of additional workers, there are few direct implementation costs involved here, since most sources are already regulated to well within the proposed new requirements.

This guidance would not supersede any statutory responsibilities of the agencies that would implement these recommendations, and in some situations application of these recommendations could be superseded by specific statutory requirements. In addition, it does not create any new authority As noted earlier, it is the purpose of this Federal guidance to provide a common framework to help ensure that the management of exposure to radiation in the United States is consistent and adequately protective. This can be carried out through regulations applicable to the public sector, through orders applicable to the internal operations of Federal agencies, through guidance, or by any other

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practicable means. The individual Federal agencies, based on their statutory and administrative mandates, have determined, and would continue to determine, the details of specific regulations, orders, guidance, or other actions, the parties responsible for implementing them, and the means to do this.

The proposed recommendations differ from current guidance in significant ways. The Radiation Protection Guide for maximum radiation dose to a member of the public in a year is reduced by a factor of five, from 500 mrem to 1 mSv (100 mrem). The concept of risk-based weighting of doses to different parts of the body is adopted, and the committed dose is introduced as the primary basis for control of internal exposure. The RPG now applies to the sum of external and internal exposure. Increased emphasis is placed on keeping justified exposure as low as reasonably achievable (ALARA), and on the comprehensive consideration of doses in populations near and distant, now and in the future. The establishment of authorized limits for sources or categories of sources that are derived giving consideration to the wide variety of potential sources and their future implications for exposure that, combined, must be maintained within the RPG, and from the comprehensive application of ALARA, is recommended. The proposed recommendations recognize, for the first time in this Federal guidance, the importance of public information and of assessing and recording public exposures. Finally, these recommendations would bring U.S. radiation protection policy into conformance with that in general international use. EPA expects these changes would strengthen the overall system for radiation protection of the members of the public in the United States.

These recommendations would replace those portions of current Federal Radiation Protection Guidance (25 FR 4402) that apply to protection of the general public from ionizing radiation. It is expected that individual Federal agencies, on the basis of their knowledge of specific sources of exposure of the general public, would use this new guidance as the basis upon which to revise or develop detailed standards or regulations, to the extent that they have regulatory or administrative jurisdiction. Pursuant to my responsibilities under Executive Order 10831, the Atomic Energy Act of 1954, as amended, and Reorganization Plan No. 3 of 1970, I would propose to keep informed of Federal agency actions to implement this guidance and to interpret and clarify these recommendations, and, in consultation with affected Federal agencies, from time to time amend the clarifying notes to reflect new technical information, as necessary to promote a consistent and effective Federal program of protection of the public from radiation.

Request for Comments

EPA requests comments on any and all aspects of these proposed recommendations. We would, for example, appreciate comment on the overall approach to protection of the public embodied by these proposals, which would continue and expand upon the approach recommended for protection against the effects of exposure to radiation by national and international professional advisory bodies, and which has formed the basis for previous guidance to Federal agencies. In addition to general comments, we are also particularly interested in commenter's views on the following specific matters:

1. Should EPA consider a lower or higher value for the Radiation Protection Guide (RPG); e.g., 0.3, 0.5, or 1.5 mSv (30, 50, or 150 mrem)? What would be the rationale for such a value? If a lower value is adopted would it be necessary to modify Recommendation 4, and, if so, how could it be modified to retain flexibility to provide for possible future beneficial uses?

2. Is it necessary to provide, in Recommendation 3, for temporary exposures as high as 5 mSv (500 mrem). What specific examples of situations that justify this proposed provision currently exist, or have a high probability of occurring in the future?

3. Should the guidance recommend a single maximum risk (or dose) level for individual sources, under Recommendation 4, which would serve as an upper bound on all ALARA determinations? If this approach were adopted, would the RPG in Recommendation 3 become superfluous?

4. Should the recommendations provide guidance on the kinds of situations under which it would be appropriate for a Federal agency to invoke Recommendation 7 Are there foreseeable situations that require the existence of this proposed provision?

5. Should EPA initiate proposals to update the weighting factors for effective dose now. If so, what basis or values for these factors should we consider?

6. Has EPA correctly characterized the cost of implementing these recommendations. If not, what specific costs have we not identified, what is their estimated magnitude, and what is the basis for this estimate?

7 These proposals do not express a preference between historical radiation units, commonly used in health physics practice, and the new system of units (SI) now in scientific and international health physics use. Should they?

8. These proposed recommendations do not address protection of animals and plants. Are the proposed levels adequate to protect all plant and animal species? If not, what level would provide adequate protection? Is protection at the level of species the appropriate choice?

EPA will carefully consider all written responses to this request for comments, and we encourage interested parties to present their views at the public hearing that will be held on these proposals. Following these hearings we will, after consulting with affected Federal agencies, formulate and transmit final recommendations to the President for revisions to Federal radiation protection guidance for exposure of the general public.

Dated: December 14, 1994.

Carol M. Browner,

Administrator.

Proposed Recommendations

The following recommendations are made for the guidance of Federal agencies in the formulation of regulations and conduct of programs for the protection of the general public from ionizing radiation. Their objective is to ensure that exposure to ionizing radiation is restricted to levels that will not produce undue risk to individuals or undue harm in populations. The recommendations apply to radiation exposure other than that from background radiation or received as a patient in the practice of the healing arts, as a worker, or as the result of an accident. (See Notes 1 and 2.)

1. There should be no exposure of the general public to ionizing radiation unless it is justified by the expectation of an overall benefit from the activity causing the exposure. Justified activities may be allowed, provided exposure of the general public is limited in accordance with these recommendations.

2. A sustained effort should be made to ensure that doses to individuals and

*The term "risk, as used here, means the statistical probability of harm to the health of an individual from exposure to radiation. "Harm in populations" from exposure to radiation, called the radiation "detriment" means the mathematical expectation of harm in the population, taking into account the probabilities and the severities of different deleterious effects.

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to populations are maintained as low as reasonably achievable. (See Note 3.)

3. The combined radiation doses incurred in any single year from all sources of exposure covered by these recommendations should not normally exceed a Radiation Protection Guide of 1 mSv (100 mrem) effective dose equivalent[b] to an individual. The Radiation Protection Guide applies to the sum of the effective dose equivalent resulting from exposure to external sources of radiation during a year and the committed effective dose equivalent incurred from the intake of radionuclides during that year. (See Notes 4 through 7.)

The Radiation Protection Guide may not be reasonably achievable in some unusual situations. It may be exceeded temporarily in situations that are not anticipated to recur chronically and when Recommendations 1 and 2 are satisfied, provided that the radiation dose incurred in any year does not exceed 5 mSv (500 mrem) effective dose equivalent.

Continued exposure of an individual over substantial portions of a lifetime at or near the level of the Radiation Protection Guide should be avoided. This will normally be achieved through conformance of individual sources to Recommendations 2 and 4.

4. Authorized limits[d] for sources should be established to ensure that individual and collective doses in current and future populations satisfy the objectives of this guidance. These limits may be developed for categories of sources or for specific sources. Authorized limits for sources should normally limit doses to a fraction of the Radiation Protection Guide for all sources combined. (See Note 8.)

Sources should be designed not to exceed authorized limits, and should be operated so as to maintain doses to members of the general public as low as reasonably achievable within such limits.

5. Risks associated with exposure of the general public to radiation that may occur due to Federal agency decisions, and the policies upon which these actions are based, should be made known to the public as part of the decision process. The degree of detail and type of information made available should be appropriate to the potential radiation exposures involved. Information on risks should encompass estimates of the risks of effects on health over time, and of the uncertainties in such estimates. Information on policies should include reference to this Federal radiation protection guidance for the general public and other relevant Federal policies.

6. Assessments and records appropriate to the origin and magnitude of expected doses and the exposed population should be performed and maintained to demonstrate conformance with requirements which implement these recommendations. The types and accuracy of methods and procedures used in these assessments should be reviewed periodically to ensure that they are appropriate and are being competently applied.

7 Exceptions to Recommendation 3 for planned exposure to radiation should be made only for highly unusual circumstances, and only when the Federal agency having jurisdiction has carefully considered the reasons for making them in light of these recommendations. If Federal agencies authorize any exception to these values, they should make it a matter of public record.

Notes

The following notes are provided to clarify application of the above recommendations:

1. Background radiation includes natural sources of background radiation, such as cosmic radiation and radiation from naturally-occurring radionuclides undisturbed by human activities, as well as radiation from certain other sources of exposure beyond Federal regulatory control, such as residual fallout from past nuclear accidents and weapons tests.

2. People may by technological means, enhance their exposure to natural radiation sources that might otherwise be considered sources of background radiation. Technologically-enhanced exposures to natural radiation are usually controllable, in that they may be avoided or reduced by taking reasonable actions. Unless specifically noted, these recommendations apply to controllable technologically-enhanced exposure to such natural radiation sources.

3. The admonition to maintain doses "as low as reasonably achievable" includes consideration of economic and societal factors, and applies to radiation exposure that may occur now or in the foreseeable future. In making this judgment for doses to populations, any incremental doses to individuals that are avoidable and which make a significant contribution to collective dose should be considered.

4. Although indoor radon from proximate natural sources is considered technologically-enhanced exposure to natural radiation, Recommendations 3 and 4 of this guidance do not apply to such exposure. Specific advice for protection against exposure to indoor radon is provided in *A Citizen's Guide To Radon* (EPA document 402–K92–001 and subsequent editions) and in other EPA technical publications.

5. The following values of the weighting factors w_T may be used to implement these recommendations:

Gonads	0.25
Breasts	0.15
Red bone marrow	0.12
Lungs	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30

("Remainder" applies to the five other organs with the highest doses (of the liver, kidneys, spleen, brain, thymus, adrenals, pancreas, stomach, small intestine, and upper or lower large intestine, but excluding skin, lens of eye, and extremities). The weighting factor for each such organ is 0.06.)

6. The sum of weighted organ doses that comprises the effective dose equivalent does not include an allowance for the induction of fatal cancers in skin. In cases where dose to skin is large enough to consider such effects, this may be done by adding to the effective dose equivalent a term[e]

[b] Effective dose equivalent is a derived quantity defined as the risk-weighted sum of dose equivalents to specified organs and tissues.

Dose equivalent is the product of the absorbed dose and a quality factor which varies with the energy and type of radiation. In the system of quantities of ionizing radiation historically in use in the United States, the unit of dose equivalent is the "rem. In the international system (S.I.), the corresponding unit is the "sievert" (Sv). One sievert equals 100 rem.

The effective dose equivalent, H_E, incurred in a given period of time is the sum of the effective dose equivalent, $H_{E,ext}$, received from external exposure in that period and the committed effective dose equivalent, $H_{E,50}$, incurred from the intake of radionuclides during that period. That is,

$$H_E = H_{E,ext} + H_{E,50} = \Sigma_T w_t (H_{,ext} + H_{T,50}),$$

where w_T is a weighting factor for organ or tissue T; $H_{T,ext}$ is the dose equivalent from external irradiation averaged over organ or tissue T; and $H_{T,50}$, the committed dose equivalent, is the sum of all dose equivalnts, averaged over organ or tissue T, that may accumulate over an individual's anticipated remaining lifetime (taken as 50 years) from radionuclides retained within the body. The weighting factors satisfy the condition $\Sigma_T w_t = 1$.

The word "dose" when used alone in these recommendations, is intended to carry the specific dose unit implied by the surrounding text.

[c] The term "individual" means a typical member of any critical group of most highly exposed members of the general public; it refers to persons with typical consumption and other relevant behavior habits.

Authorized limits are standards, regulations, or other requirements established by responsible authority for categories of sources or for a specific source.

[e] Since the sum of the weighting factors is normalized to unity, addition of a further factor would strictly require adjustment of the other

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that is the product of the skin dose equivalent (averaged over the whole body) and a weighting factor w_{skin} = 0.01.

7 The exposure-to-dose conversion factors tabulated in *Federal Guidance Report No. 11* (EPA–520/1–88–020), *Federal Guidance Report No. 12* (EPA 402–R–93–081), and their subsequent editions should be used for determining conformance to these recommendations. In addition, dosimetric models and conventions and models for reference persons specified by the International Commission on Radiological Protection (ICRP) may be used. Under special circumstances, other factors may be used when such factors are more appropriate on the basis of well-established scientific evidence.

8. To ensure that specific sources or categories of sources, including their installed control capability, are designed and operated to achieve as low as reasonably achievable levels of exposure, a variety of quantitative and qualitative analysis and decision methods may be used to determine authorized limits. These, in addition to considering radiation detriment and risk, and direct costs, may also take into account societal and other economic factors. Statutory requirements may impose additional constraints on the selection of authorized limits.

factors. In practice, the addition of this small factor for skin does not warrant any change.

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