UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 28 1980

COPY

Mr. James B. Martin
Director, Division of Waste Management
Nuclear Regulatory Commission
Washington, D.C. 20555

Dear Mr. Martin:

We last asked you to review and comment on draft disposal standards for the uranium mill tailings remedial action program under PL 95-604 on January 24, 1980. We now request your comments on the enclosed revised documents:

1. Draft Federal Register notice - "Proposed Disposal Standards for Inactive Uranium Processing Sites" (August 25, 1980).

2. Draft Environmental Impact Statement (EIS) - "Remedial Action Standards for Inactive Uranium Processing Sites" (August 25, 1980).

Please note that, although the EIS covers both cleanup and disposal standards, you should attend only to the latter because the cleanup standards have already been published (45 F.R. 27366-75, April 22, 1980). The draft disposal standards are designated as Subpart A of 40 CFR 192. Subpart C, "Exceptions," was published with the cleanup standards in April 1980, but parts of it also apply to disposal.

Only a few parts of the disposal standards documents have been substantially changed, since you reviewed them last January. Specifically, a surface water protection standard has been added (40 CFR 192.03(c)) -- surface water is discussed in the Federal Register notice and in Chapters 5, 6, and 8 of the EIS -- and the "Exceptions" sections of the Federal Register (pages 20, 21) and the EIS (Sec. 9.2) have been changed significantly.

Please send me your comments by September 17, 1980. If you or your staff have any questions regarding the enclosed material, please contact Stanley Lichtman (557-8927) of our General Radiation Standards Branch.

Sincerely yours,

David M. Rosenbaum
Deputy Assistant Administrator
for Radiation Programs (ANR-458)

2 Enclosures

cc: Mr. D.G. Hawkins (ANR-443)

DRAFT (August 25, 1980)

FEDERAL REGISTER NOTICE

PROPOSED DISPOSAL STANDARDS

FOR

INACTIVE URANIUM PROCESSING SITES

Title 40 - Protection of the Environment

Chapter 1 - Environmental Protection Agency

Subchapter F

Part 192 - Environmental Protection Standards for Uranium Mill Tailings

Subpart A - Environmental Standards for the Disposal of Residual Radioactive Materials from Inactive Uranium Processing Sites

PROPOSED DISPOSAL STANDARDS

FOR INACTIVE URANIUM PROCESSING SITES

Invitation for Comment

AGENCY: U.S. Environmental Protection Agency

ACTION: Proposed Disposal Standards

SUMMARY: The Environmental Protection Agency (EPA) requests comments on proposed standards for disposal of residual radioactive materials (mainly tailings) from inactive uranium processing sites. EPA has developed these standards pursuant to Section 275(a) of the Atomic Energy Act, as added by Section 206(a) of PL 95-604, the Uranium Mill Tailings Radiation Control Act of 1978. PL 95-604 requires the Department of Energy to conduct remedial actions for designated inactive uranium processing sites in accordance with standards promulgated by EPA.

The proposed standards apply to disposal of tailings which qualify for remedial actions under Title I of PL 95-604, and set limits on their radon release to the atmosphere and on water contamination. The standards also require tailings to be disposed of in a way that provides a reasonable expectation that these limits will be satisfied for at least one thousand years.

We have already proposed standards for the cleanup of open lands and buildings contaminated with residual radioactive materials from inactive uranium processing sites (45 F.R. 27370-27375, April 22, 1980). The cleanup standards were also made immediately effective as interim standards pending public review and promulgation of final standards (45 F.R. 27366-27368, April 22, 1980).

Additional background material for the proposed cleanup and disposal standards is given in a Draft Environmental Impact Statement which EPA is issuing simultaneously with this notice. In addition to this request for written comments, the Agency will shortly announce the time and place of hearings at which interested persons may present comments on both the previously proposed cleanup standards and these disposal standards.

ADDRESS: We are hereby extending the comment period for the cleanup standards we proposed earlier so that it will coincide with the comment period for the disposal standards. Comments should be submitted by (60 days) to Docket No. A-79-25, which is located in the Environmental Protection Agency, Central Docket Section, Room 2902, 401 M Street, S.W., Washington, D.C. 20460. Single copies of the Draft Environmental Impact Statement (EPA Report 520/4-80-011) may be obtained by writing to the address given below.

FOR FURTHER INFORMATION CONTACT: Dr. Stanley Lichtman, Criteria & Standards Division (ANR-460), Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, D.C. 20460; telephone number 703-557-8927.

SUPPLEMENTARY INFORMATION:

I. INTRODUCTION

The proposed standards were developed by EPA at the direction of Congress in order to protect public health, safety, and the environment from uranium mill tailings produced at processing sites which are now inactive. There are two major parts of the remedial actions necessary for this protection: cleanup and disposal. The cleanup process reduces the potential health consequences of tailings which have been dispersed from their original location on a tailings pile, or used in construction. Disposal is the operation which places the tailings themselves in a condition which will be safe for a long time. The disposal site may be at the original location of the tailings, or a new one. Standards are proposed here for the disposal aspects of the remedial actions.*

In order to carry out our responsibility under PL 95-604 to set generally applicable standards for uranium mill tailings, we have examined

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* The cleanup standards (Subpart B and Subpart C) were proposed earlier (45 F.R. 27370-27375, April 22, 1980), and simultaneously also were declared immediately effective as interim standards (45 F.R. 27366-27368, April 22, 1980). We issued interim cleanup standards in order to have standards in effect as soon as possible, because some buildings have been found where tailings are causing radiation levels that are very hazardous to anyone exposed to them for long times. Public Law 95-604 precludes undertaking remedial action before EPA has promulgated standards. The interim cleanup standards permit the Department of Energy to clean up open lands and buildings under PL 95-604 to alleviate these problems. In addition to having issued interim cleanup standards, however, we are following the public review process contemplated by PL 95-604 for promulgating final cleanup standards.

In this notice we propose disposal standards and invite the public to comment on them. For the convenience of the reader, we are restating here some background material from our earlier notice proposing cleanup standards.

their potential public health and environmental impacts. This examination established the radiological and nonradiological characteristics of tailings which require control.

Tailings are hazardous primarily because: 1) breathing radon and its decay products exposes the lungs to alpha particles; 2) the body may be exposed to gamma rays; 3) radioactive materials and nonradioactive toxic elements from tailings may be swallowed with food and water. The radiation hazard from tailings lasts for many thousands of years, and nonradioactive toxic elements persist indefinitely. The longevity of these hazards played a major role in determining the proposed standards.

Although the available data are consistent with many models, we believe that a linear, nonthreshold dose-effect relationship is a reasonable basis for deriving estimates of radiation risk to the general public and for establishing regulations. This model assumes that any radiation dose presents some risk to humans and that the risk is directly proportional to the damage demonstrated at higher doses. We recognize, however, that the data preclude neither a threshold for some types of radiation below which there is no damage to people, nor the possibility that low doses may do more damage to people than the linear model implies.

The alpha particles from inhaled radon decay products can cause lung cancer. Also, gamma rays can cause cause cancers, teratogenesis, and genetic damage. Our health risk estimates are based on our review of epidemiological studies conducted in the United States and other countries of underground miners of uranium and other metals who have been exposed to radon decay products, and on three reports: The Effects on Population of Exposure to Low Levels of Ionizing Radiation (1972), Health Effects of

Alpha Emitting Particles in the Respiratory Tract (1976) by the Advisory Committee on the Biological Effects of Ionizing Radiation of the National Academy of Sciences (the BEIR Committee), and the report of the United Nations Scientific Committee on the Effects of Atomic Radiation entitled Sources and Effects of Ionizing Radiation (1977). Details of our risk estimates are provided in Indoor Radiation Exposure Due to Radium-226 in Florida Phosphate Lands (EPA 520/4-78-013) and in the Draft Environmental Impact Statement (EIS) (EPA 520/4-80-011).

Data from studies of underground miners lead to uncertain risk estimates. This uncertainty is increased when the data are used to estimate the risk to the general population. Nevertheless, we believe the information is sufficient to give a basis for public health standards. For gamma ray exposure standards the data base is very large and good, but again involves extrapolation for application to tailings.

Oftentimes it is not possible to remove all the risk to people exposed to radiation or many other hazardous materials. In deciding how much we should attempt to reduce the risk, we considered the longevity, efficacy, and costs of remedial action methods for uranium mill tailings as well as the level of risk. We also considered things which are not easily quantified, such as equity of risk, and administrative difficulties. Finally, we considered the overall implementation costs and protection offered by alternative standards to determine those which are most reasonable.

EPA's mandate is to set standards which apply to any site and method of control. Therefore, our analyses of technology, costs, risk, and other pertinent factors emphasize the general characteristics of uranium mill

tailings and their control. The law gives other agencies of Government the authority to decide how these standards will be satisfied at particular locations.

The information, reasoning, and judgments which lead us to issue these particular proposed disposal standards for tailings piles at inactive uranium processing sites are summarized below. Additional background information is contained in the Draft Environmental Impact Statement.

II. DISPOSAL OF TAILINGS

In PL 95-604, the Congress stated its findings that tailings "...may pose a potential and significant radiation health hazard to the public,... and...that every reasonable effort should be made to provide for stabilization, disposal, and control in a safe and environmentally sound manner of such tailings in order to prevent or minimize radon diffusion into the environment and to prevent or minimize other environmental hazards from such tailings." The Environmental Protection Agency was directed by Congress to set "...standards of general application for the protection of the public health, safety, and the environment..." for such materials. The legislative record also shows Congress intended that these standards not be site-specific.

The Committee report on the Uranium Mill Tailings Radiation Control Act expressed the intention that the technologies used for remedial actions should not be effective for only a short period of time. "The Committee does not want to visit this problem again with additional aid. The remedial action must be done right the first time," it stated (House

of Representatives Report 95-1480, Part 2). Our proposed disposal standards are meant to ensure this long-lasting solution for those tailings piles at inactive processing sites that are covered by PL 95-604.

PATHWAYS AND HEALTH EFFECTS

Uranium mill tailings can affect people's health through four basic pathways. These are:

1. Diffusion of radon-222, the noble gas decay product of radium-226, from the tailings to the air. Breathing radon-222 and its short half-life decay products (principally polonium-218, bismuth-214, and polonium-214) exposes the lungs to alpha particles. Smaller additional doses to the lungs and other organs result from swallowing and breathing the long-lived radon-222 decay products (lead-210 and polonium-210).

2. Small particles of tailings material in the air. Wind erosion of unstabilized tailings piles results in airborne tailings material. Intake of thorium-230, radium-226, and lead-210 are the principal concerns from this pathway. The predominant doses are to the lungs from breathing these radionuclides and to the bones from eating foods containing them.

3. Waterborne material. Both wind and water flowing over or through the tailings can carry radioactive and other toxic materials to bodies of water. This could cause long-term contamination of surface and underground water, and human intake of toxic substances.

4. External gamma radiation exposure from tailings. A tailings pile emits gamma radiation, since many of the radioactive nuclei in it produce gamma rays along with their other decay products. The most important gamma emitters are lead-214 and bismuth-214.

The increase in cancer possibly caused by airborne substances from a pile can be estimated reasonably well by using general environmental transport models. However, the levels of waterborne contaminants and their effects are highly site-specific and we can only discuss them in general. The possible effects of direct gamma radiation from the piles are easy to estimate. They are small, except very close to the tailings piles.

EPA's analysis of the exposure pathways for uranium mill tailings piles relies on existing information provided by NRC and DOE and their contractors, and on earlier studies by EPA.* To significantly enhance this knowledge would require several years of intensive investigation. We believe this is unnecessary and that such a delay in promulgating standards would not be in the public interest.

Radiation Effects from Air Pathways

Based on the current U.S. population, we estimated the air-transmitted hazards of uranium mill tailings piles for people close to the pile (within several miles), in the surrounding region (within 50 miles, but not "close to the pile"), and in the remainder of the nation. Four sources of exposure were considered: inhaled short-lived radon decay products, the most important source of potential cancers; the long-lived radon decay

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* We analyzed 22 of the 25 tailings piles at inactive processing sites DOE has designated for remedial actions under PL 95-604. The other 3 piles were determined to be eligible for remedial actions only after our assessment was nearly completed. However, based on general descriptions of the 3 piles, we believe that including them in the assessment would not cause us to change our proposals for disposal standards that apply to all the designated sites.

products, principally lead-210; airborne tailings particulates; and direct gamma radiation. Estimating the risk from exposure to the short-lived radon decay products and the gamma radiation is relatively straightforward. However, the pathways and dose calculations for long-lived radon decay products and airborne tailings depend very heavily on assumptions about the use and preparation of locally grown foodstuffs. Dose estimates for these pathways are given in the NRC Draft Generic Environmental Impact Statement on Uranium Milling (DGEIS). These estimates are likely to be high because of the assumptions made in regard to local foods. Nevertheless, the risks are small compared with those due to the short-lived radon decay products.

From our analysis we conclude:

1. Lung cancer caused by radon's short-lived decay products is the dominant radiation hazard from untreated uranium mill tailings piles on local, regional, and national scales. Effects of long-lived radon decay products, of windblown tailings, and of direct gamma radiation from the piles are much less significant.

2. Individuals near a pile bear much higher radiation risks than those far away. For example, we estimate that individuals living continuously one mile from a large pile would have about 200 times as great a chance of a fatal lung cancer caused by radon decay products as persons living 20 miles away (7 in 10,000 versus 3 in 1,000,000). People even closer to some of the piles at inactive processing sites bear increased lifetime lung cancer risks as high as 4 chances in 100.

3. The total number of cancer deaths estimated to be caused by a uranium mill tailings pile depends strongly on the size and locations of the local populations.

4. Based on present population data, all the 22 piles at inactive sites we studied, taken together, may cause about 40 to 90 deaths from lung cancer per century among persons living 50 miles or more away from a pile. When local and regional rates are added to these, the estimated total national effect of all the 22 piles is about 200 premature deaths from lung cancer per century; i.e., about 2 deaths each year.

Part of the uncertainty in these estimates is due to necessary approximations in estimating the environmental radiation levels a tailings pile produces, and what dose people will receive. Additional uncertainty comes from our incomplete knowledge of the effects on people of these generally low exposures.

Our estimates are based upon current population sizes and geographical distributions. Overall increases in national population would raise the estimated national effects in approximate proportion. Development of new population centers near currently remote piles, and substantial growth of cities already near one, would increase these estimates proportionately to this growth.

Water Pathways

The water-transmitted hazards of uranium mill tailings are due both to radionuclides and to nonradioactive toxic substances, such as arsenic, lead, selenium, and molybdenum. Uranium, thorium, radium, and nonradioactive toxic substances can contaminate water resources, and affect crops,

animals, and people. A theoretical analysis of a model pile performed for NRC's DGEIS on Uranium Milling showed that ground water contamination by selenium, sulfate, managanese, and iron might exceed current drinking water standards over an area 2 kilometers wide and 8 to 30 kilometers long.

Tailings piles at inactive mill sites already have lost much of the water deposited in them during mill operation. The water either evaporated, went underground, or ran out on the surface. Any future water contamination by the pile would be from erosion, rain, snow, or flooding. The quality of streams and lakes could be degraded by contaminated seepage from a pile, or by tailings which are carried to them by wind or water.

The movement of contaminants to ground water depends on a combination of complex chemical and physical properties of the underground environment, and on conditions such as precipitation and evaporation. Chemical and physical processes in the subsoil partly remove contaminants from water passing through it. However, some contaminants, such as selenium, arsenic, and molybdenum, can occur in forms which are not removed.

Future ground water contamination could be caused by either past or future releases of toxic substances from the piles. These substances are likely to move slowly through the ground. Ground water itself can move slower than a few feet per year, and only in coarse or cracked materials does the speed exceed one mile per year. For these reasons, pollutants from tailings may not affect the quality of nearby water supply wells for decades or longer after they are released. However, once polluted, the quality of such water supplies can not be quickly restored by eliminating

the source. Even if a pile is covered so that there is no further run-off or seepage, it may take longer to restore the original water quality throughout the affected area than the time from the start of the pile to the first contamination of water supplies.

In the draft EIS for these proposed standards, we review the health problems that could arise from using water containing nonradioactive toxic substances from uranium mill tailings.

Control of Tailing Piles

Only recently have several States and the NRC had regulations for tailings control at active mills. Several attempts to stabilize tailings piles at inactive sites by applying thin covers on them have had only limited and short-term control objectives. The growing awareness of the hazards of uranium tailings and passage of PL 95-604 in 1978 have led to increasing research on effective long-term control methods.

We analyzed several levels of control. For each control level, we estimated the health and environmental protection benefits and the likely range of costs, assuming a variety of potential control methods. No method of control has been tested sufficiently to establish its practicality or effectiveness over very long periods of time. However, we believe the basic principles of effective long-term control methods are understood.

SELECTION OF PROPOSED DISPOSAL STANDARDS

Proposed Radon Emission Standards

From several perspectives, we find it reasonable to reduce radon emission rates from tailings at inactive processing sites from their

current values of several hundred pCi/m2-sec* to a range more characteristic of ordinary land. Typical natural emission rates are from 0.5 to 1 pCi/m2-sec, with variations up to several times these values not unusual.

After considering the alternatives, we have concluded that the numerical limit on pile flux, following disposal, should be chosen in a range of about 0.5 to 2.0 pCi/m2-sec. When this flux is added to the flux of a normal earth covering, the disposal site flux would still be within natural variations.

Several analyses** of controlling radon emission by covering piles with soil suggest that the required covering thickness rises sharply*** near a flux of about 1 pCi/m2-sec. However, there has been no opportunity to test these analyses against full-scale field experience. If soil coverings should be less efficient in controlling radon than the analyses indicate, achieving a standard at the low end of the range could be much more difficult and expensive than we estimate. Yet, the health benefit so gained would be marginal. We therefore propose an allowed tailings flux

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* pCi/m2-sec stands for picocuries per square meter per second, a measure of the release rate of radioactivity from a surface ("flux"). A curie is the amount of radioactive material which produces 37 billion nuclear transformations per second. A picocurie is a trillionth of a curie. One picocurie produces a little more than two nuclear transformations per minute.

** These studies are cited in the draft EIS.

*** Reducing flux from 10 to 9 pCi/m2-sec (a 10% reduction) requires about 1 cm of added soil; the same size flux reduction from 2 to 1 pCi/m2-sec (50%) takes about 50 cm of added soil.

of 2 pCi/m2-sec, rather than a slightly lower figure, to allow for more technical flexibility in implementing the standard.

Higher control levels, say 10-40 pCi/m2-sec, appear unjustified, because emission rates of that size can be lowered to 2 pCi/m2-sec for about 10% additional cost.* With such elevated radon emissions, the probable need for land-use restrictions adjacent to the disposal site would place a continuing administrative burden on future generations.

We also find almost total control of radon release from the tailings unjustified. Incremental costs for achieving long-term emission rates lower than 2 pCi/m2-sec rise rapidly relative to radon emission reduction and any health benefits that might be achieved. There is no need to restrict the use of land near the disposal site because of radon releases from the tailings for flux levels near 2 pCi/m2-sec. We have not found any administrative or esthetic advantages in further reductions.

We believe our approach is appropriate for a new and large-scale undertaking. Typically, the proposed standard would reduce radon emissions and their possible effects by 99%. Measures which will cut down radon emissions this much for at least 1000 years (see below) will also eliminate

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*This assumes that covering the tailings with soils and clay is a feasible method for radon control to a flux level of about 2 pCi/m2-sec. Tailings piles vary widely in their size and radioactivity content. Therefore, costs of applying the burial method or any other adequate disposal technique will vary greatly among the piles. We estimated potential disposal costs for a variety of methods. For example, assuming the tailings would be taken to a new site and buried in a shallow pit, we estimated the disposal cost for an average pile as 6-13 million (1978) dollars. Costs for some piles may be partially off-set by the value of residual uranium that may be recovered by reprocessing the tailings before disposing of them.

blown tailings ... excess gamma radiation. Therefore, implementing the radon control standard will virtually eliminate all the potential hazards except wa' pollution.

Proposed Water Protection Standards

The proposed ground water protection standards for uranium mill tailings are patterned after criteria adopted for solid wastes (44 F.R. 53438, September 13, 1979; 40 CFR Part 257) under Sec. 4004 of the Resource Conservation and Recovery Act (RCRA). EPA deems violation of these criteria in disposing of the solid wastes to which they apply to pose a reasonable probability of adverse effects on health or the environment.

Except as noted below, the proposed ground water protection levels are the same as the maximum contaminant levels of the National Interim Primary Drinking Water Regulations (NIPDWR). Our standards have no legal tie to the NIPDWR or the RCRA criteria, however, and need not be altered if the latter are changed. The proposed standards provide that after tailings piles are disposed of, the piles will not cause ground water concentrations to exceed the specified levels. If the ground water already exceeds these concentrations for causes other than tailings, then no further degradation is allowed. Though fluoride levels are given in the NIPDWR, we are omitting them from the proposed standards because fluorides have not been found in tailings. Levels for molybdenum and uranium are not given in the NIPDWR, but we believe they are needed for adequate tailings disposal standards. We base the proposed molybdenum standard on its toxicity for humans. The proposed standard for uranium is

the level for which our estimate of bone cancer risk is about the same as the estimated bone cancer risk from radium under the NIPDWR. The toxicity of these substances is discussed in the draft EIS.

None of these levels were developed originally as general water quality standards. Since no water quality standards specifically applicable for disposal of uranium tailings are available, we chose to base our proposed standards on levels adequate for public drinking water supplies. We believe they provide enough protection in a wide variety of circumstances.

The proposed ground water protection standards apply only to releases from tailings which may occur after disposal of the piles. It is probably not practical to prevent substances which have already been released from reaching ground water. Moreover, while it may sometimes be possible to improve the quality of an already-contaminated aquifer, we believe a generally applicable requirement to do so is not feasible. There is evidence of limited ground water contamination at some of the inactive sites, but the long-term prospects have not been fully assessed. We believe that disposal methods which satisfy the standards will avoid any ground water problems caused by future releases from the piles. However, if tailings should be found to be contaminating water that is being used, then we would expect DOE to provide alternate water sources or other appropriate remedies. We note, however, that PL 95-604 will terminate DOE's authority to do so seven years after we promulgate standards, unless Congress extends the period. Therefore, we cannot be sure whether anyone will remedy problems that may arise in the more distant future.

The actions necessary to avoid future ground water contamination may increase disposal costs up to double the cost of radon control alone. Available information suggests that such measures often will not be needed at inactive processing sites. Moreover, where the standards might be exceeded only in the immediate neighborhood of a pile, we don't believe the substantial costs and disruptions necessary to avoid the violation would be warranted. Therefore, when existing tailings sites are used for disposal, we propose that the ground water protection standards be applied 1.0 kilometer from the pile. If tailings are moved to a new disposal site, for whatever reason, then new opportunities for site selection and preparation become available; we propose that the standard for a new site be applied 0.1 kilometer from the pile.

Wind, rain, or floods can carry tailings into rivers, lakes, and reservoirs. Pollutants may also seep out of the piles and contaminate surface waters. However, implementing the radon emission limits and the ground water protection requirements will greatly reduce this. A pile with severely restricted radon releases will not be able to release particulates to wind or water. Similarly, the ground water protection requirements imply limited water flow through the pile, which limits flow to the surface as well as under the ground. Thus, we expect that the radon emission and groundwater standards will protect surface water, and explicit surface water protection standards may not be necessary. However, to assure adequate protection, we propose to require that surface water not be degraded by tailings after disposal of the piles. This means that after tailings are disposed of they should not increase the concentration of any hazardous substances in surface water.

Longevity of Disposal Standards

Congress recognized that uranium mill tailings are hazardous for a long time, and directed EPA to set reasonable standards for their long-term disposal. We propose requiring a reasonable expectation that the radon emission and water protection standards for disposal of tailings piles will be satisfied for at least 1000 years.

Institutional control methods such as recordkeeping, maintenance, monitoring, and land-use restrictions are useful adjuncts to an adequate disposal system, to provide greater protection than the standards require, and to regulate deliberate disruptions of the tailings by people.* However, we do not believe they should be relied upon for periods longer than a century, and are inappropriate for long-term control. They should not replace use of adequate long-term physical disposal methods.

The choice of a 1000-year period of application results from practical considerations. We believe 1000 years meets the congressional criterion that "the remedial action must be done right the first time." A 1000-year standard does not mean our concern for the future is limited to 1000 years, but does reflect our judgment that the disposal standards must be practical. Technically and economically reasonable disposal methods may, in some instances, be expected to protect for longer than 1000 years. However, based on existing knowledge of control methods and natural

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* For example, Sec. 104(h) of PL 95-604 anticipates that subsurface minerals at a tailings disposal site may be used. However, it provides that any tailings disturbed by such use "will be restored to a safe and environmentally sound condition." Therefore, we propose to apply the disposal standards to any subsurface mineral rights acquired under the provisions of Sec. 104(h).

processes, we believe it is unreasonable to generally require longer protection under this remedial action program.

III. IMPLEMENTATION

PL 95-604 requires the Secretary of Energy to select and perform remedial actions for uranium mill tailings from inactive processing sites in accordance with EPA's standards, with the full participation of any State which shares the cost. Remedial actions will be selected and performed with the concurrence of the Nuclear Regulatory Commission and in consultation, as appropriate, with affected Indian tribes and the Secretary of the Interior. The costs of the remedial actions will be borne by the Federal Government and the States as prescribed by law.

The disposal standards will be implemented by showing that the disposal method provides a reasonable expectation of satisfying the radon emission limits and water protection provisions of the standards for at least 1000 years. We intend for this expectation to be founded upon analyses of the physical properties of the disposal system and the potential effects of natural processes over time. Computational models, theories, and expert judgment will be major tools in deciding that a proposed disposal system will satisfy the standard. Post-disposal monitoring can serve only a minor role in confirming that the standards are satisfied.

Exceptions

We believe that our proposed standards are the strictest that are justified for general application at all the inactive uranium processing

sites covered by PL 95-604. However, providing greater protection may be reasonable at specific sites. Therefore, we urge the implementers to lower the residual risk as far below the required level as is reasonably achievable.

On the other hand, the standards could be unreasonably strict for certain circumstances. Because the scale of material-moving activity is so great, the possibility of serious harm to both workers and the general public from accidents associated with transporting an entire tailings pile to a new disposal site deserves particular consideration. Relocating a pile should be considered whenever it may not be practical to satisfy all the disposal standards at the original location. However, circumstances might be such that one would not expect the standards to be greatly exceeded within a thousand years, and that substantial human exposure to any resulting pollution would not necessarily occur. If all practical transport methods would probably cause serious harm to people from accidents, and if the risk from producing the energy used in the transport and building and maintaining the transportation system is large enough, the near-term endangerment may outweigh the additional long-term benefits of full rather than partial compliance with the standards. By carefully considering all these factors for each tailings pile where the issue arises, exceptions to the disposal standard could be justified because of the degree of unavoidable endangerment in attempting full compliance.

We do not consider the current remoteness of a pile from population centers sufficient by itself to justify relaxing the standards. Even small numbers of people nearby require protection, and the population of an area could increase considerably over the one thousand year period the

standards apply. Furthermore, radon released from tailings piles propagates over long distances.

In order to allow for reasonable implementation of PL 95-604, we are proposing criteria which may be used to determine whether particular circumstances justify exceptions to the disposal standards. In such exceptional cases, DOE, with the concurrence of NRC, may select and perform remedial actions which come as close to meeting the disposal standards as is reasonable. When doing so, DOE shall also inform EPA.

NOTE: The costs and benefits of these standards are discussed in the Draft Environmental Impact Statement. However, our program to set remedial action standards for PL 95-604 does not require preparation of an economic analysis under Executive Order 12044. We expect the costs of the remedial action program in any calendar year to be less than the $100 million criterion EPA has established (44 F.R. 30988-30998, May 29, 1979) for requiring an economic analysis.

DATED:

Douglas M. Costle
Administrator

NOTE: Subparts B and C of the following were proposed earlier (45 F.R. 27370-27375, April 22, 1980) and are repeated here for the convenience of the reader.

The Administrator of the Environmental Protection Agency hereby proposes to add a Part 192, Subpart A, to Title 40 of the Code of Federal Regulations as follows:

Part 192 - ENVIRONMENTAL PROTECTION STANDARDS FOR URANIUM MILL TAILINGS

Subpart A -- Environmental Standards for the Disposal of Residual Radioactive Materials from Inactive Uranium Processing Sites

Subpart B - Environmental Standards for Cleanup of Open Lands and Buildings Contaminated with Residual Radioactive Materials from Inactive Uranium Processing Sites

Subpart C -- Exceptions

192.20 Criteria for exceptions

192.21 Remedial actions for exceptional circumstances

(Authority: Section 275 of the Atomic Energy Act of 1954, 42 U.S.C. 2022, as amended by the Uranium Mill Tailings Radiation Control Act of 1978, PL 95-604.)

Subpart A -- Environmental Standards for Disposal of Residual Radioactive Materials from Inactive Uranium Processing Sites

192.01 Applicability

This subpart applies to the disposal of residual radioactive material at any designated processing site or depository site as part of any remedial action conducted under Title I of the Uranium Mill Tailings Radiation Control Act of 1978 (PL 95-604), or following any use of subsurface minerals at such a site.

192.02 Definitions

(a) Unless otherwise indicated in this subpart, all terms shall have the same meaning as in Title I of the Uranium Mill Tailings Radiation Control Act of 1978.

(b) Remedial action means any action performed under Section 108 of the Uranium Mill Tailings Radiation Control Act of 1978.

(c) Disposal means any remedial action intended to assure the long-term, safe, and environmentally sound stabilization of residual radioactive materials.

(d) Disposal site means the region within the smallest practicable boundaries around residual radioactive material following completion of disposal.

(e) Depository site means a disposal site selected under Section 104(b) or 105(b) of the Uranium Mill Tailings Radiation Control Act of 1978.

(f) Aquifer means a geologic formation, group of formations, or portion of a formation capable of yielding usable quantities of ground water to wells or springs.

(g) Ground water means water below the land surface in the zone of saturation.

(h) Underground drinking water source means:

(1) an aquifer supplying drinking water for human consumption, or

(2) an aquifer in which the ground water contains less than 10,000 milligrams/liter total dissolved solids.

(i) Curie (Ci) means the amount of radioactive material which produces 37 billion nuclear transformations per second. One picocurie (pCi) = 10^{-12} Ci.

(j) Surface waters means "waters of the United States, including the territorial seas" ("navigable waters") as defined in the Federal Register, Volume 44, page 32901, June 7, 1979. (Comment: This definition is taken from the Regulations for the National Pollutant Discharge Elimination System, 40 CFR 122.3(t). In essence, it includes all U.S. surface waters which the public may traverse, enter, or draw food from.)

192.03 Standards

Disposal of residual radioactive materials shall be conducted in a way that provides a reasonable expectation that for at least one thousand years following disposal --

(a) The average annual release of radon-222 from a disposal site to the atmosphere by residual radioactive materials will not exceed 2 pCi/m2-sec.

(b) Substances released from residual radioactive materials after disposal will not cause

(1) the concentration of that substance in any underground drinking water source to exceed the level specified in Table A, or

(2) an increase in the concentration of that substance in any underground drinking water source, where the concentration of that substance prior to remedial action exceeds the level specified in Table A for causes other than residual radioactive materials. This subsection shall apply to the dissolved portion of any substance listed in Table A at any distance greater than 1.0 kilometer from a disposal site which is part of an inactive processing site, or greater than 0.1 kilometer if the disposal site is a depository site.

(c) Substances released from residual radioactive materials after disposal will not cause an increase in the concentration of any toxic substance in any surface waters.

192.04 Effective date

The standards of this Subpart shall be effective 60 days after promulgation of this rule.

Subpart B -- Environmental Standards for Cleanup of Open Lands and Buildings Contaminated with Residual Radioactive Materials from Inactive Uranium Processing Sites

192.10 Applicability

This subpart applies to open lands and buildings which are part of any processing site designated by the Secretary of Energy under PL 95-604, Section 102. Section 101 of PL 95-604, states that "processing site" means --

(A) any site, including the mill, containing residual radioactive materials at which all or substantially all of the uranium was produced for sale to any Federal agency prior to January 1, 1971 under a contract with any Federal agency, except in the case of a site at or near Slick Rock, Colorado, unless --

(i) such site was owned or controlled as of January 1, 1978, or is thereafter owned or controlled, by any Federal agency, or

(ii) a license (issued by the (Nuclear Regulatory) Commission or its predecessor agency under the Atomic Energy Act of 1954 or by a State as permitted under section 274 of such Act) for the production at such site of any uranium or thorium product derived from ores is in effect on January 1, 1978, or is issued or renewed after such date; and

(B) any other real property or improvement thereon which --

(i) is in the vicinity of such site, and

(ii) is determined by the Secretary, in consultation with the Commission, to be contaminated with residual radioactive materials derived from such site.

Any ownership or control of an area by a Federal agency which is acquired pursuant to a cooperative agreement under this title shall not be treated as ownership or control by such agency for purposes of subparagraph (A)(i).A license for the production of any uranium product from residual radioactive materials shall not be treated as a license for production from ores within the meaning of subparagraph (A)(ii) if such production is in accordance with section 108(b).

192.11 Definitions

(a) Unless otherwise indicated in this subpart, all terms shall have the same meaning as defined in Title I of the Uranium Mill Tailings Radiation Control Act of 1978.

(b) Remedial action means any action performed under Section 108 of the Uranium Mill Tailings Radiation Control Act of 1978.

(c) Open land means any surface or subsurface land which is not a disposal site and is not covered by a building.

(d) Working Level (WL) means any combination of short-lived radon decay products in one liter of air that will result in the ultimate emission of alpha particles with a total energy of 130 billion electron volts.

(e) Dose equivalent means absorbed dose multiplied by appropriate factors to account for differences in biological effectiveness due to the type and energy of the radiation and other factors. The unit of dose equivalent is the "rem."

(f) Curie (Ci) means the amount of radioactive material which produces 37 billion nuclear transformations per second. One picocurie (pCi) = 10-12 Ci.

192.12 Standards

Remedial actions shall be conducted so as to provide reasonable assurance that --

(a) The average concentration of radium-226 attributable to residual radioactive material from any designated processing site in any 5 cm thickness of soils or other materials on open land within 1 foot of the surface, or in any 15 cm thickness below 1 foot, shall not exceed 5 pCi/gm.

(b) The levels of radioactivity in any occupied or occupiable building shall not exceed either of the values specified in Table B because of residual radioactive materials from any designated processing site.

(c) The cumulative lifetime radiation dose equivalent to any organ of the body of a maximally exposed individual resulting from the presence of residual radioactive materials or byproduct materials shall not exceed the maximum dose equivalent which could occur from radium-226 and its decay products under paragraphs (a) and (b) of this section.

192.13 Effective date

The standards of this Subpart shall be effective 60 days after promulgation of this rule.

Subpart C -- Exceptions

192.20 Criteria for exceptions

Exceptions to the standards may be justifiable under any of the following circumstances:

(a) Public health or safety would be unavoidably endangered in attempting to meet one or more of the requirements of Subpart A or Subpart B.

(b) The goal of environmental protection would be better served by not satisfying cleanup requirements for open land, Sec. 192.12(a) or the corresponding part of Sec. 192.12(c). To justify an exception to these requirements there should be a clearly unfavorable imbalance between the environmental harm and the environmental and health benefits which would result from implementing the standard. The likelihood and extent of current and future human presence at the site may be considered in evaluating these benefits.

(c) The estimated costs of remedial actions to comply with the cleanup requirements for buildings, Sec 192.12(b) or the corresponding part of Sec. 192.12(c), are unreasonably high relative to the benefits. Factors which may be considered in this judgment include the period of occupancy, the radiation levels in the most frequently occupied areas, and

the residual useful lifetime of the building. This criterion can only be used when the values in Table B are only slightly exceeded.

(d) There is no known remedial action to meet one or more of the requirements of Subpart A or Subpart B. Destruction and condemnation of buildings are not considered remedial actions for this purpose.

192.21 Remedial actions for exceptional circumstances

Section 108 of PL 95-604 requires the Secretary of Energy to select and perform remedial actions with the concurrence of the Nuclear Regulatory Commission and the full participation of any State which pays part of the cost, and in consultation, as appropriate, with affected Indian tribes and the Secretary of the Interior. Under exceptional circumstances satisfying one or more of the conditions 192.20(a), (b), (c), and (d), the Department of Energy may select and perform remedial actions, according to the procedures of Sec. 108, which come as close to meeting the standard to which the exception applies as is reasonable under the exceptional circumstances. In doing so, the Department of Energy shall inform any private owners and occupants of affected properties and request their comments on the selected remedial actions. The Department of Energy shall provide any such comments to the parties involved in implementing Sec. 108 of PL 95-604. The Department of Energy shall also inform the Environmental Protection Agency of remedial actions for exceptional circumstances under Subpart C of this rule.

TABLE A

Arsenic	0.05	milligram/liter
Barium	1.0	milligram/liter
Cadmium	0.01	milligram/liter
Chromium	0.05	milligram/liter
Lead	0.05	milligram/liter
Mercury	0.002	milligram/liter
Molybdenum	0.05	milligram/liter
Nitrate nitrogen	10.0	milligram/liter
Selenium	0.01	milligram/liter
Silver	0.05	milligram/liter

Combined radium-226 and radium-228	5.0	pCi/liter
Gross alpha particle activity (including radium-226 but excluding radon and uranium)	15.0	pCi/liter
Uranium	10.0	pCi/liter

TABLE B

Average Annual Indoor Radon Decay Product Concentration (including background)	0.015	WL
Indoor Gamma Radiation (above background)	0.02	milliroentgens/hour

BACKGROUND REPORT

PROPOSED
FEDERAL RADIATION PROTECTION GUIDANCE
FOR OCCUPATIONAL EXPOSURE

Working Draft
of
August 11, 1980

Criteria & Standards Division
Office of Radiation Programs
U.S. Environmental Protection Agency

SUMMARY OF PROPOSED CHANGES

IN OCCUPATIONAL RADIATION PROTECTON GUIDANCE

	Requirement	1960 Guides	Proposed New Guides
1.	Justification of exposure	required	required (also consider alternatives)
2.	Optimization of exposure	required	required (include collective dose)
3.	Limitation of exposure		
	a) Whole body	3 rems/quarter 5(N-18)cumulative	5 rems/year
	b) Partial body	individual critical organ limits*	summation of risk* (breast and lung added; forearms, feet, ankles, head and trunk deleted)
	c) Combined internal and external exposure	independent limits	combined limit
4.	Radiation Protection Requirements	not specified	in three ranges for instruction, supervision, monitoring, and recordkeeping (including lifetime dose)
5.	Regulatory limits lower than the RPGs for specific job categories	not addressed	recommended
6.	Intake guides	Radioactivity Concentration Guides (RCGs)	Radioactivity Intake Factors (RIFs)
7.	Exposure of minors	1/10 RPGs	1/10 RPGs
8.	Exposure of the unborn	not addressed	four alternative recommendations
9.	Exceeding the RPGs	permitted	permitted (disclosure now required)

*Some limits are raised and some lowered. See the specific guides for numerical values.

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INTRODUCTION

In 1975, the latest year for which comprehensive statistics are available, there were almost one and a quarter million people potentially exposed to ionizing radiation in their jobs or as students (En79). We estimate there are now about one and a half million. Workers exposed to radiation are engaged in a wide variety of medical, industrial, defense, research, and educational activities involving many kinds of radiation sources. These include x-ray emitting devices, a large number of naturally-occurring and man-made radioactive materials, nuclear reactors, and particle accelerators. Workers exposed to radiation in mining operations are not included in the above estimates; except for underground uranium miners, there is little information on their exposure.

No single agency regulates the exposure of workers in the United States. This responsibility is carried out by five Federal regulatory agencies with jurisdiction over exposure of workers or sources of radiation exposure in private industry, several Federal agencies who regulate exposure of their own (or their contractor's) employees, and various agencies of the fifty States (see Figure 1). Some of these State agencies regulate exposure of workers under agreements with one or more of the Federal regulatory agencies, and some regulate independently.

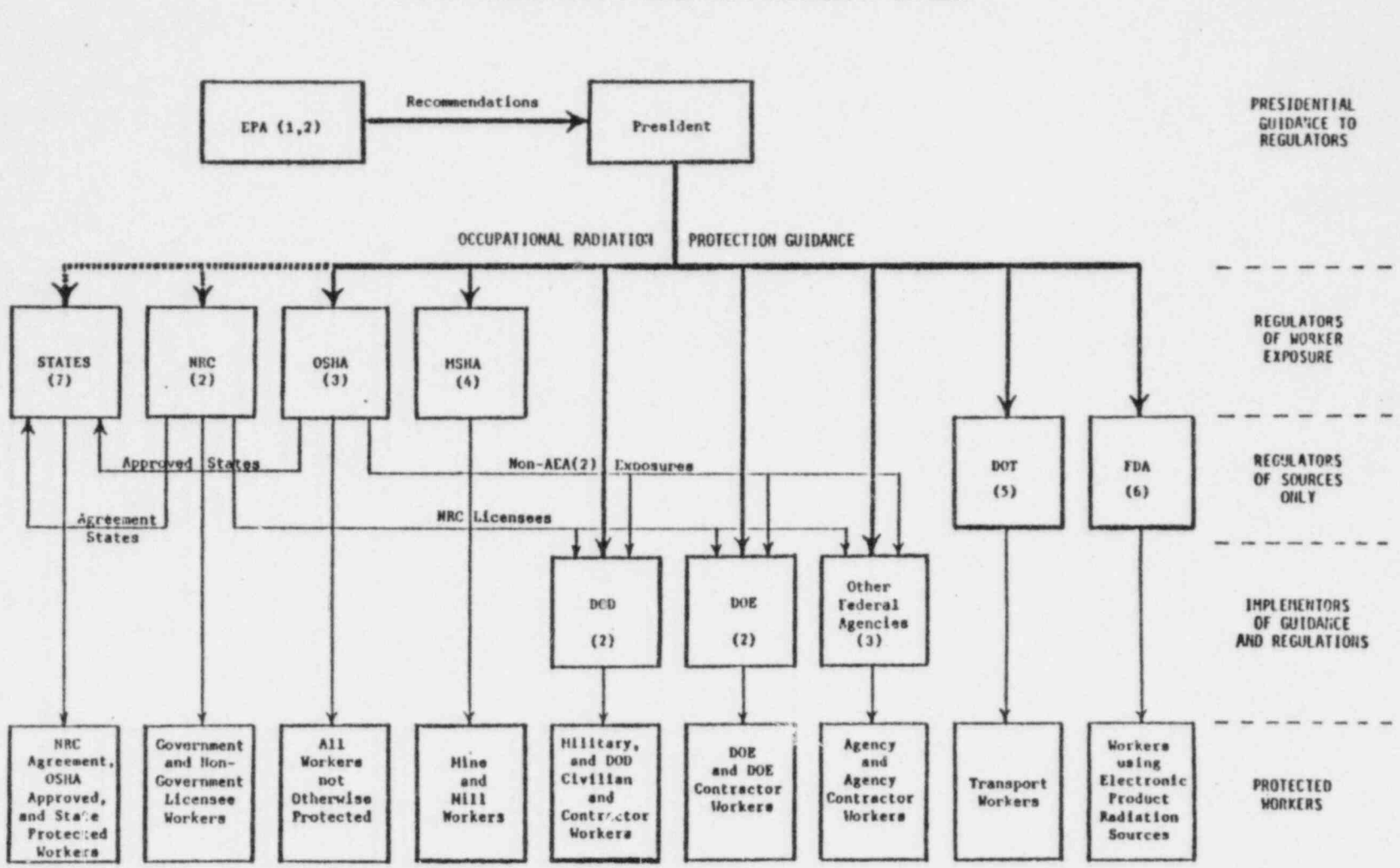

Figure 1. Occupational radiation protection guidance is binding on all major regulatory agencies except NRC and the States, in which case it is advisory. Heavy lines refer to Federal Radiation Protection Guidance; light lines indicate regulations. The authorities cited in parentheses are (1) Executive Order 10831; (2) Atomic Energy Act of 1954, as amended; (3) Occupational Health and Safety Act of 1970; (4) Federal Mine Safety and Health Act of 1977; (5) Department of Transportation Act of 1966; (6) Radiation Control for Health and Safety Act of 1968; (7) State enabling legislation and State laws.

During the three decades prior to 1960 two organizations of professionals in radiation protection and in related fields of research, the International Commission on Radiological Protection (ICRP) of the International Congress on Radiology and the National Council on Radiation Protection and Measurements (NCRP) and its predecessor, provided recommendations which served as the principal basis for the rules established by all of these regulators. However both of these are, in effect, private groups; they choose their own members and their recommendations are reached in private. In 1959 the President created a public body for the United States, the Federal Radiation Council (FRC), to provide recommendations to him on radiation matters affecting health. The recommendations issued by the FRC were promulgated by successive presidents as guidance to Federal agencies, and provided a uniform basis for both Federal and State regulation of many forms of public exposure to radiation.

The Federal radiation protection guidance now in effect for most occupational exposure (Fe60) was developed by the FRC and was promulgated by President Eisenhower on May 18, 1960. It was implemented through regulations of the former Atomic Energy Commission, the former Energy Research and Development Administration, the Nuclear Regulatory Commission, the Occupational Safety and Health Administration, the Departments of Defense and Energy, and the States, as well as by other Federal regulatory agencies with specialized responsibilities, such as the former Mining Enforcement and Safety Administration, the Mine Safety and Health Administration, and the Department of Transportation. Although additional Federal guidance was issued in 1971 for the special

case of exposure of underground uranium miners to radon decay products (En71), the basic guidance which governs the exposure of the vast majority of workers has not been reviewed or modified since it was established in 1960.

In 1970 the President abolished the FRC and transferred its functions to the Administrator of the Environmental Protection Agency (EPA) (Re70). EPA has developed these recommendations for new radiation protection guidance for workers pursuant to this responsibility to advise the President on radiation matters affecting health. This report contains the support for these new recommendations, which would replace the guidance now used by Federal agencies to regulate all occupational exposure to ionizing radiation except the exposure of miners to radon decay products.

We have based these recommendations on the assumption that risks to health should be considered in relation to the need for exposure. This approach is similar to that used by the FRC in 1960. As the FRC said (Fe60): "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." In this review we have also compared risks from occupational exposure to ionizing radiation with risks of accidental death and occupational diseases in industries and occupations in which workers are not occupationally exposed to radiation.

In forming these judgements we have considered current knowledge of how radiation affects health, the number of people now exposed, and the size of the radiation doses they receive. We have also considered recent reviews and recommendations of the National Academy of Sciences - National

Research Council (NAS-NRC) (NA72), the United Nations Scientific Committee on the Effects of Atomic Radiation (Un77), the NCRP (NC71-77), and the ICRP (IP73-80). Although our estimates of risk are based on more data and better understanding than existed in 1960, they are still uncertain. Nevertheless, we believe they provide an adequate basis for this new radiation protection guidance. In spite of the uncertainties involved, we have made numerical estimates of the harm from doses permitted by these recommendations because we believe that this information is essential to judgments by the public of the appropriateness and acceptability of these recommendations.

The primary changes from the 1960 guidance are structural, but we have also modified the numerical values of maximum allowed radiation dose levels. The recommendations place increased emphasis on eliminating unjustified exposure and on keeping justified exposure as low as is reasonably achievable, both long-standing tenets of radiation protection. A principal addition is the introduction of a graded set of minimum radiation protection requirements in three exposure ranges. We have tried to express these recommendations in terms that dispel any notion that the levels specified are dividing lines between "safe" and "unsafe," and that exposure within any of the recommended levels may be viewed as "acceptable" for any exposure situation without qualification.

Among the major issues we addressed in developing these recommendations are the following (sections of the report which contain principal discussions of each are indicated in parentheses):

1. Are the doses currently received by workers (II) and the maximum dose permitted under existing guidance adequately low? (VI) In this

regard, a) how adequate is the basis used for estimating risks to health from radiation exposure (III), and b) what are the appropriate bases for judging collective* and maximum individual radiation doses in the work force and the tradeoffs between these two indices of the risk from occupational exposure? (IV)

2. Should the same guides apply to all categories of workers (e.g., dental workers, nuclear medicine technicians, nuclear maintenance personnel, industrial radiographers)? (IV) Should specific guides be developed for pregnant women, female workers who could bear children, and/or men? (VI)

3. On what time basis should the guides be expressed? Quarterly? Annual? (VII) Should the lifetime occupational dose be limited? (VI) Should the age of the worker be a factor? (VI)

4. Should the guidance reflect or cover medical, accidental, and/or emergency exposures? (VII)

5. Is existing guidance for situations that involve exposure of less than the whole body adequate? In this respect, a) what organs and parts of the body should have designated limits, and b) on what basis should guidance be expressed for exposure of more than one organ or portion of the body? (VI)

6. How should the radiation protection principles requiring a) justification of any exposure, and b) reduction of the dose from justified exposures to the lowest practicable or as low as is reasonably achievable level be applied to exposure of workers? Should the concept of lowest feasible level be applied to exposure of workers? (IV and V)

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* Collective dose is numerically identical to the sum of all the doses received by the members of a group.

7. What, if any, relationship should be maintained between permissible levels of risk to health from radiation exposure and other regulated hazards of disease or accidents? (IV and VI)

8. Should the guidance include numerical values for the factors (called Quality Factors) used to convert dose (measured in rads) to dose equivalent (measured in rems)? If so, should this be developed now or issued later as supplementary guidance? (VII)

9. What guidance should apply to workers who do not use radiation sources, but who are exposed to radiation due to the activities of others? (VII)

10. Are there situations that may require doses higher than normally permitted? Should we provide special guidance for them? (VII)

The proposed recommendations for radiation protection of U.S. workers are contained in the first chapter. The report continues with a summary of the size, composition, and exposure of the work force exposed to radiation (Chapter II), followed by a summary of current knowledge of the harm from radiation exposure and estimates of the risks at the exposure levels experienced under and the maximum levels permitted by current Federal radiation protection guidance (Chapter III). In Chapter IV we discuss general radiation protection principles. Chapter V describes our proposal for graded Minimum Radiation Protection Requirements in three numerical ranges to help assure that workers get as small a dose as is reasonably achievable. In Chapter VI we justify the numerical values recommended as Radiation Protection Guides (RPGs) for the whole body and for individual organs and extremities of the body, and discuss alternative

proposals for protection of the unborn. In this chapter we also address some related matters, such as additivity of risk when several organs are irradiated and the factors used to relate intake of radioactive materials to the RPGs. Finally, in Chapter VII we briefly cover several special exposure situations, such as exposure of minors, emergency exposures, and overexposures; diagnostic x-rays; and some technical matters regarding implementation.

I. THE PROPOSED RECOMMENDATIONS

We propose nine recommendations as guidance to Federal agencies in the formulation of Federal radiation protection standards for workers, and in their establishment of programs of cooperation with States. In all cases but one we have made single recommendations for public comment. The exception, Recommendation 8, addresses protection of the unborn during gestation. Because this recommendation involves issues that go beyond simple radiation protection of workers, including equality of employment rights and the rights of the unborn, we have proposed four alternatives for public consideration. The recommendations follow:

1. All occupational exposure should be justified by the net benefit of the activity causing the exposure, including consideration of alternatives not requiring radiation exposure.

2. For any justified activity a sustained effort should be made to assure that the collective dose is as low as is reasonably achievable.

3. The radiation dose to individuals should conform to the numerical Radiation Protection Guides (RPGs) specified below. Every effort should be made to maintain individual doses as far below these RPGs as is reasonably achievable.

3. (Continued).

Radiation Protection Guides:

a. The sum of the annual dose equivalent* and the annual committed dose equivalent** to the whole body or to any organ shall not exceed the following values:

Whole body	5 rem
Gonads	5 rem
Lens of eye	5 rem —— ?
Hands	50 rem
Any other organ	30 rem

b. Non-uniform exposure of the body shall also satisfy the condition on the sum of annual weighted dose equivalents, H_w, that

$$H_w = \sum_i w_i H_i \leq 5 \text{ rem},$$

where w_i is a weighting factor, H_i is the annual committed dose equivalent to organ i, and the sum excludes the gonads, lens of eye, and hands. Recommended values of w_i are:

Breast	0.20
Lung	0.16
Red Bone Marrow	0.16
Thyroid	0.04
Bone Surfaces	0.03
Skin	0.01
Other Organs***	0.08
	0.68

* "Dose equivalent" means the quantity expressed by the unit "rem," as defined by the International Commission on Radiation Units (IU73).

** "Annual committed dose equivalent" applies only to dose equivalents from radionuclides inside the body. It means the sum of all dose equivalents that may accumulate over an individual's remaining lifetime (usually taken as 50 years) from radioactivity that is taken into the body in a given year.

*** Applies to each of the five other organs with highest doses, only.

3. (Continued).

c. In cases where both uniform whole body exposure and non-uniform exposure of the body are involved, the sum of the annual uniform whole body dose equivalent added to the sum of annual weighted dose equivalent from additional non-uniform exposure, H_w, shall not exceed 5 rem.

4. The following Minimum Radiation Protection Requirements should be established and carried out in the workplace by appropriate authorities, on the basis of the range of doses anticipated in individual work situations. The dose ranges specified may be adjusted to fit the needs of specific situations, as neccessary, by regulatory authorities.

Minimum Radiation Protection Requirements:

Range A (Doses less than 0.1 RPG)

a. Determine that exposures result only from justified activities and are as low as is reasonably achievable. These determinations may often be made on a generic basis, that is, by considering groups of similar work situations and protective measures.

b. Monitor or otherwise determine individual and/or area exposure rates to the extent necessary to give reasonable assurance that doses are within the range and are as low as is reasonably achievable.

4. (Continued).

c. Instruct workers on basic radiation hazards and radiation protection principles, the specific levels of risk from radiation in their work, and the radiation protection practices they should follow.

Range B (Doses 0.1 - 0.3 RPG)

The above requirements, plus:

d. Provide professional radiation protection supervision in the work place to assure that both individual and collective exposures are justified and are as low as is reasonably achievable.

e. Provide individual monitoring and annual recordkeeping.

Range C (Doses 0.3 - 1.0 RPG)

All of the above requirements, plus:

f. Justify the need for each work situation which is expected to result in exposure in Range C and provide professional radiation protection supervision before and while it is undertaken to assure that collective and individual exposures are as low as is reasonably achievable.

g. Carry out supplementary monitoring of individual workers for each work situation in which the dose rate is high enough to make a significant contribution to any worker's Range C exposure.

4. (Continued).

h. Once a worker has been exposed in Range C, maintain a lifetime record of subsequent annual doses in Ranges B and C.

i. Maintain lifetime doses as low as is reasonably achievable. The recorded lifetime accumulation of external whole body dose equivalent and weighted dose equivalent to organs of individual workers should be less than 100 rem.

5. Federal regulatory agencies should establish regulatory limits that are below the RPGs for specific types of work situations, when this is appropriate. These limits do not have to conform to the numerical values used to specify the ranges of applicability of the Minimum Radiation Protection Requirements.

6. "Radioactivity Intake Factors" (RIFs) should be used to regulate occupational radiation hazards from breathing, swallowing, or immersion in radionuclides. The RIF for a radionuclide is defined as the maximum annual intake (in curies) for which the committed dose equivalent to a reference person satisfies the Radiation Protection Guides in Recommendation 3, parts a) and b). RIFs may be derived for different chemical or physical forms, and for intake by breathing, swallowing, or for external exposure from air containing a radioactive gas. Exposure regulated through use of the RIFs should meet the same Minimum Radiation Protection Requirements as equivalent exposure under the Radiation Protection Guides.

7. In addition to any other Federal restrictions, the occupational exposure of individuals younger than eighteen should be limited to dose equivalents in Range A.

8. Exposure of the unborn* should be restricted more than that of workers. Women able to bear children should be fully informed of current knowledge of risks to the unborn from radiation. Due to the complexity of the issues involved, we propose four alternative recommendations for public comment. We would be glad to receive other recommendations for dealing with exposure of the unborn.

a. Both workers and employers are encouraged to keep doses to any unborn less than 0.5 rem during any known or suspected pregnancy; or

b. Both workers and employers are encouraged to avoid job situations involving whole body dose rates to women able to bear children greater than 0.2 rem per month, and to keep doses to any unborn less than 0.5 rem during any known pregnancy; or,

c. Women able to bear children should be limited to job situations for which the whole body dose rate is less than 0.2 rem per month. Doses to the unborn during any known period of pregnancy should be limited to 0.5 rem; or

d. The whole body dose to both male and female workers should not exceed 0.5 rem in any six month period. (This would eliminate use of Range C whole body exposures in Recommendation 4.)

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* "Unborn" here means the fertilized oocyte, the embryo, and the fetus.

9. In exceptional circumstances the RPGs may be exceeded, for cause, but only if the Federal agency having jurisdiction carefully considers and publicly discloses the specific reasons for doing so.

The following notes clarify application of the above recommendations:

1. Occupational exposure of workers does not include that due to a) normal background radiation and b) exposure as a patient of licensed practitioners of the healing arts.

2. When uniform external whole body exposure occurs in addition to exposure from radioactive materials in the body, the requirement of Recommendation 3, part c), that the sum of the annual whole body dose equivalent and the weighted dose equivalent from non-uniform exposure not exceed 5 rem may be satisfied by the condition that

$$\frac{H_{ext}}{RPG_{wb}} + \sum_j \frac{I_j}{RIF_j} \leq 1,$$

where H_{ext} is the external whole body dose equivalent, RPG_{wb} is 5 rems, I_j is the quantity of radionuclide j contributing to internal dose, and RIF_j is defined in Recommendation 6.

3. The values currently specified by the ICRP for quality factors and dosimetric conventions for measurement of the various types of radiation may be used for determining conformance with the RPGs. The model for a reference person and the metabolic models currently specified by the ICRP may be used to calculate the RIFs. We will recommend other factors, conventions, and models when and if they are more appropriate.

4. Numerical guides for emergency exposures are not provided by this guidance. Agencies should follow the general principles established by this guidance in dealing with such situations.

5. Overexposures are not addressed by this guidance. The equitable handling of such cases is the responsibility of the employer and the Federal agency having regulatory jurisdiction.

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6. Limits for periods other than one year may be derived by Federal agencies from the annual RPGs and RIFs when necessary. Such limits should be consistent with Recommendation 2 and the three ranges in Recommendation 4.

7. The existing guide for limiting exposure of underground uranium miners to radon decay products is not changed by these recommendations.

These proposed recommendations would provide general guidance for the radiation protection of workers. Individual Federal agencies, using their knowledge of specific worker exposure situations, would use this guidance as the basis upon which to develop detailed standards and regulations to meet their particular statutory obligations. We propose to follow the activities of the Federal agencies as they implement the final Guidance, to issue any necessary clarifications and interpretations, and to promote the coordination necessary for an effective Federal program of worker protection.

II. OCCUPATIONAL EXPOSURES IN THE UNITED STATES

The use of radiation in the work place has increased steadily since current Federal occupational radiation protection guidance was established in 1960. In a 1972 study we estimated that in 1960 about 460,000 people were exposed to radiation in their jobs (C172). This was 0.6 percent of all workers and about one quarter of one percent of the 1960 United States population. The mean annual occupational dose to that work force was roughly estimated as 300 millirem, based on data for only 30,000 workers from two of the larger facilities operated by the Atomic Energy Commission, the Hanford and Oak Ridge National Laboratories. In a study begun in 1975 (En79) we improved this estimate by using additional data; the result was a mean annual occupational dose of 170 millirem per person based on records for 130,000 workers in Federal and Federal contractor facilities.

The 1972 study also contains an analysis of the 1970 work force. The results are shown in Table 1. The total number of radiation workers was estimated to be about 770,000, with a mean annual occupational dose of 210 millirem per person. This was 0.9 percent of all workers and about one-third of a percent of the 1970 United States population. The number of radiation workers increased by two-thirds during this decade. However, the data bases are too different and too uncertain to tell whether there was a significant change in mean dose. The data indicate that the largest collective dose was received by medical workers and that medical workers who handled radium received the highest mean dose of any class of workers studied.

Table 1. Occupational Exposure Summary for 1970 (C172)*

Category	Number of Workers	Mean Whole Body Dose (millirem)	Collective Dose (person-rems)
Atomic Energy Commission			
Contractors	102,918	198	20,361
Reporting Licensees			
AEC	62,090	215	13,365
Agreement State	24,519	274	6,715
Non-reporting Licensees			
AEC	93,000	54	5,022
Agreement State	3,000	274	822
Department of Defense			
Army	7,445	100	744
Air Force	17,591	88	1,555
Navy	55,051	198	10,879
Other Federal			
PHS	508	129	65
Miscellaneous	2,000	129	258
Medical**			
Radium	37,925	540	20,480
Non-Federal			
Medical x ray	194,451	320	62,253
Dental x ray	171,226	125	21,403
All Workers	72,000	210**	164,000**

* Numbers of some workers, and the mean and collective dose to the entire work force have been rounded to the nearest 1000 workers, 10 millirem, and 1000 person-rems, respectively. Sources of values quoted to more significant figures are given in the original report.

** Values of doses to medical workers were based on limited data obtained from a few States. Based on data for comparable situations in government facilities, as well as more complete data for later years, doses to medical workers are probably overestimated.

The study begun in 1975 designs and tests a procedure to monitor trends in occupational exposure and provides a baseline for assessing the impact of any future changes in Federal occupational radiation protection guidance. This study was recently completed using 1975 records for over 450,000 people obtained from both governmental and commercial sources (En79).

Figure 2 shows the distribution of occupational doses projected from these data. We estimate that two-thirds of those exposed in their jobs received "no measurable dose" during any monitoring period. (This means that the dose received by these workers was not distinguishable from background radiation for any single monitoring period during the year, and therefore that their annual occupational dose was much less than 100 millirem, the nominal value for background radiation exposure in the United States.) About 95% of all workers are estimated to have received doses of less than 500 millirem. ~~Only~~ Approximately 0.1% of the work force ~~are~~ estimated to have received doses between 5 and 12 rem. Twelve rem is the maximum permitted under current guides.

Based on this study, we estimate that 1,106,900 workers were potentially exposed to ionizing radiation in their workplaces in 1975. (There were also an estimated 120,000 students and airline flight personnel who are not usually considered part of the radiation work force.) This was 1.2 percent of all workers and a little over one-half of one percent of the 1975 United States population. It is approximately two and one-half times the number in 1960 and one and one-half times that in 1970. The mean annual occupational dose to these workers was 120 millirem. This mean is computed assuming that those reported as receiving "no measurable dose"

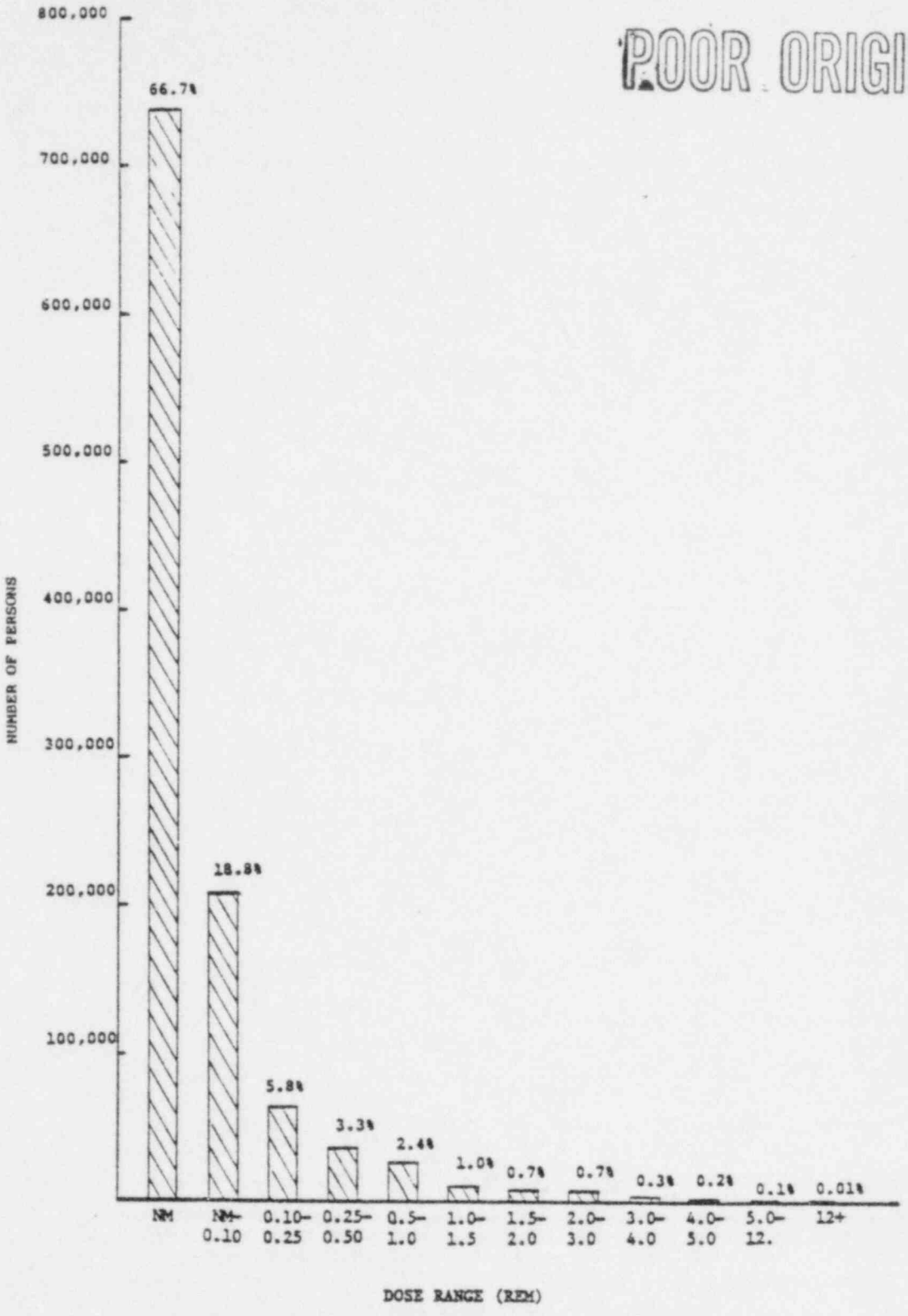
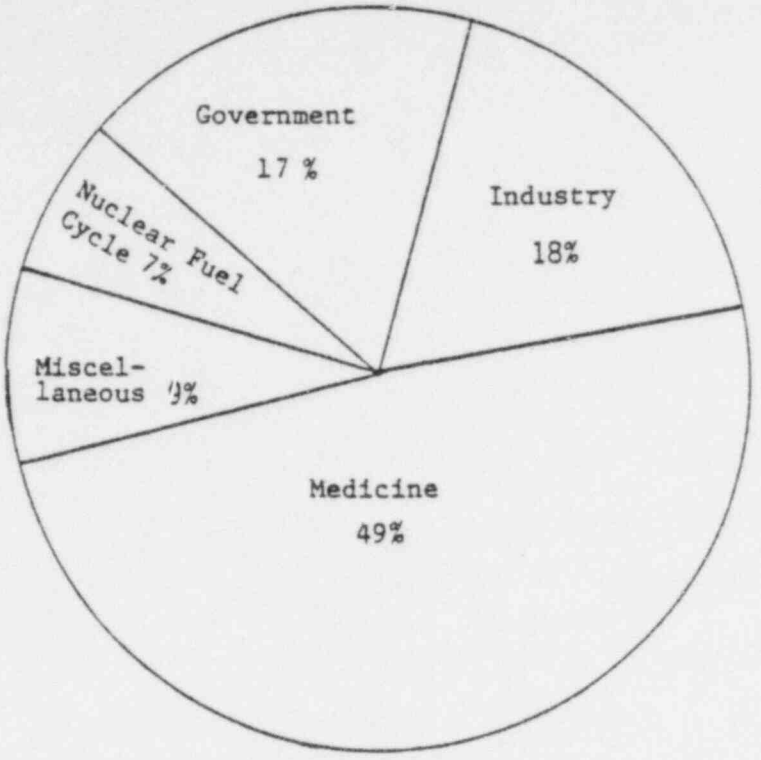


Figure 2. The distribution of persons versus dose range for U.S. workers in 1975 (En75). "NM" means that the dose was not measurable.

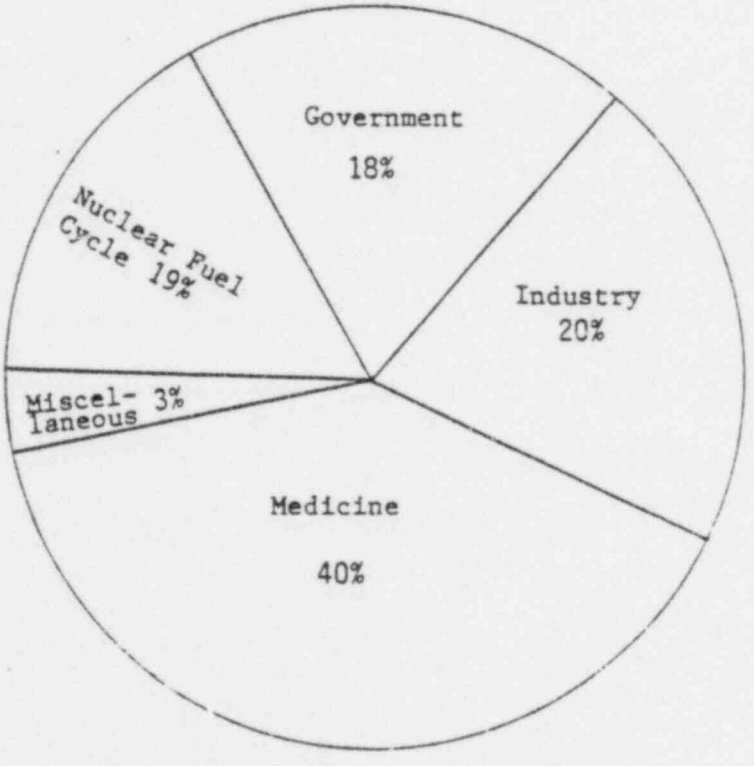
received zero dose. If only those who received a measurable dose during any reporting period of the year are counted (approximately 369,100 individuals), the mean becomes 350 millirem. Although it can be inferred from these data that the average dose has probably declined during the years 1960-1975 and that the collective dose to the entire work force may not have increased, definite conclusions cannot be drawn because we do not know how comparable the data from the earlier studies are.

We also estimated the number of workers, as well as mean and collective doses, in different parts of the work force. Figure 3 shows the distribution of workers among major occupational groups in 1975. Medical workers make up about one half of the work force, industrial workers 18%, and government (including defense) workers 17%. Nuclear fuel cycle workers are 7% of the work force. The Figure also illustrates the distribution of collective dose among these major occupational groups. Despite the significantly higher mean doses noted below for some types of nuclear fuel cycle and industrial workers, medical workers account for 40 percent of the national collective dose, more than all nuclear fuel cycle and industrial workers combined.

Table 2 summarizes the number of workers, the mean dose, and the collective dose in individual job categories. Mean doses are shown for all workers and for just those who received a measurable dose. Since we calculated mean doses to all workers and collective doses using the assumption that the dose to individuals receiving "no measurable dose" was zero, these calculated doses may be underestimated. If one assumes that a log-normal distribution, which fits measured doses above 100 millirem



(a)



(b)

Figure 3. Distribution of workers (a) and collective dose (b) in the 1975 work force (En75).

Table 2. National Occupational Exposure Summary For 1975[a] (En 79)

Occupational Subgroup	Number of Workers Total[b]	Number of Workers Exposed[c]	Mean Whole Body Dose (millirem) Total[b]	Mean Whole Body Dose (millirem) Exposed[c]	Collective Dose (person-rems)
MEDICINE					
Hospital/Clinic	100,000	55,100	220	400	22,000
Private Practice	137,800	53,300	160	410	21,700
Dental	265,700	41,400	20	140	5,800
Podiatry	10,100	2,100	10	30	100
Chiropractic	14,600	3,700	30	110	400
Veterinary	18,100	6,200	80	230	1,400
Entire Subgroup	546,300	161,800	90	320	51,400
INDUSTRY[d]					
Industrial Radiography Licensees	19,800	9,700	290	580	5,700
Other Industrial Users					
Licensees	114,100	18,800	100	610	11,400
Registrants	55,900	16,000	110	370	5,900
Source Manuf. & Distr.					
Licensees	7,000	3,900	350	630	2,500
Registrants	4,000	800	40	200	200
Entire Subgroup	200,800	49,200	130	520	25,600
NUCLEAR FUEL CYCLE					
Power Reactors	54,763	28,034	390	760	21,400
Fuel Fabrication and Reprocessing	11,405	5,495	270	560	3,100
Uranium Enrichment	7,471	5,664	50	70	400
Nuclear Waste Disposal	300	100	310	920	100
Uranium Mills	300	100	20	50	-
Entire Subgroup	74,200	39,400	340	630	24,900

Table 2. (Continued)

Occupational Subgroup	Number of Workers Total[b]	Number of Workers Exposed[c]	Mean Whole Body Dose (millirem) Total[b]	Mean Whole Body Dose (millirem) Exposed[c]	Collective Dose (person-rems)
GOVERNMENT					
Dept. of Energy	80,954	39,451	150	300	11,800
Dept. of Defense	92,500	55,800	110	180	10,100
Other Federal Govt.	13,400	4,400	90	280	1,300
Entire Subgroup	186,800	99,700	120	230	23,100
MISCELLANEOUS					
Education (Faculty):					
2-year Institutions	7,000	2,300	60[e]	170	400
4-year Institutions	14,800	4,900	80[e]	230	1,100
Transportation	77,000	11,800	30	200	2,300
Entire Subgroup	98,800	19,000	40	200	3,800
ALL WORKERS	1,106,900	369,100	120	350	128,800
ADDITIONAL GROUPS[f]					
Transportation (Flight attendants; radionuclides)	30,000	10,000	0	10	100
Education (Students):					
2-year Institutions	35,000	11,700	60[e]	170	2,000
4-year Institutions	54,800	18,300	80[e]	230	4,200
All Additional Groups	119,800	40,000	50	150	6,100

[a] Extrapolated numbers of workers are rounded to the nearest 100, mean doses to the nearest 10 millirem, and collective doses to the nearest 100 person-rems.

[b] All monitored and unmonitored workers with potential occupational exposure.

[c] Workers who received a measurable dose in any monitoring period during the year.

[d] "Licensee" means NRC and NRC agreement state licensees for use of radionuclides. Doses from electronic (e.g., x-ray) sources are also included. "Registrant" means state registrants, who have electronic sources only.

[e] These estimated doses are based on small samples that may not be representative.

[f] Persons who are only incidentally exposed or not normally considered workers; the estimates listed are very uncertain.

well, holds also for lower doses that are not measurable, then assuming "no measurable dose" was zero dose would under-estimate the collective dose for all workers by less than 3 percent. However, dosimeter readings are corrected by subtracting an average value for background radiation. When negative values result these are reported as zero. This creates an upward bias in reported values that could more than compensate for assuming that "no measurable dose" is zero. Since the number of monitored but not exposed workers in any job category is also a highly variable quantity, depending upon the degree of conservatism in administering radiation protection programs as well as other difficult to assess factors, we consider that the mean dose of those workers with measurable doses only is a more reliable value to use for comparing risks in various parts of the work force.

A recent study of personnel dosimetry services for the U.S. Nuclear Regulatory Commission indicates that a significant number of individual dosimetry records are not accurate (Nu80). In two rounds of tests, 22% and 14% of dosimeters were in error by more than 50%. However, despite the poor performance of individual dosimeters, the same study showed that the mean value for a large number of dosimeters gives close to the correct average and collective doses. The study showed, for example, that in samples of more than 1000 dosimeters the mean value of measured dose was 28% high for low-energy x rays (15-30 kev), 17% high for medium-energy x rays (30-300 kev), 3% high for cobalt-60 gamma rays (1.2-1.3 Mev), and 21% low for californium-252 neutrons (thermal to several Mev).

We do not know to what extent the choice and calibration of personnel dosimeters is tailored to the various kinds of radiation to which workers

are exposed. In addition, different methods are used to adjust dosimeters for background radiation. These factors, along with the results of the above study, lead us to conclude that mean and collective values of dose to most categories of workers, as well as to the entire work force, are probably known to within no better than 20-30%.

Counting only those who received measurable doses, nuclear fuel cycle workers had the highest mean annual dose. In 1975 these nuclear workers averaged 630 millirem and included three of the six job categories with the highest mean dose -- 920 millirem for waste disposal workers, 760 millirem for power reactor workers, and 560 millirem for fuel fabrication and reprocessing workers. Industrial workers with measurable doses had the second highest mean dose -- 520 millirem. This group, which contains the job categories with the third, fourth, and fifth highest mean dose, are all NRC and Agreement State licensees principally exposed in work involving the use of radionuclides -- industrial radiographers at 580 millirem, source manufacturing and distribution workers at 630 millirem, and other industrial workers at 610 millirem. Mean measurable doses to workers in jobs in the remaining parts of the work force, which include 82% of all exposed individuals, were in most cases significantly below 500 millirem.

One can divide workers receiving measurable doses into two major groups: 1) a group of about 66,000 in the above six highest dose job categories who received mean doses in the neighborhood of 600-900 millirem, and 2) a much larger group of about 303,000, primarily in medicine, government, and education, most of whom received mean doses of 100-400 millirem. Almost two-thirds of the collective dose in the entire

work force is received by workers in this latter group. That is, the majority of occupational exposure accrues to the 82% of exposed workers who are in the lower dose occupations.

The study also provides some information on the distribution of dose by age and sex. The mean dose for men is higher than that for women at any age, and is more than double averaged over all ages. Women average about 70 millirem per year during their childbearing years. Men average about 170 millirem per year prior to age 40. Women comprise 66% of all radiation workers of ages 18-24, but accumulate only 42% of the collective dose to workers in that age group. From age 30 on, men comprise about 70% of the work force, and accumulate 85% of the collective dose. Female workers are found mostly in the parts of the work force with lower mean doses, i.e. in medicine, government, and education. This explains in part why women contribute a lower proportion of collective dose than their numbers might imply. Within these occupations mean doses to women are generally only 25-50% of those to men in the same occupations.

To summarize: During the period 1960 - 1975, we estimate that the number of workers potentially exposed to radiation grew from 460,000 to 1,106,900, an average growth rate of about 6% per year during a period when the average growth rate of the general population was only 1.2% per year. The mean annual dose in 1960, based on exposure records for AEC workers, has been roughly estimated as a few hundred millirem. In 1975 the estimated mean dose to all 1,160,900 United States workers was 120 millirem. For the 369,100 workers receiving measurable doses it was 350 millirem. The largest group of workers and the largest contributors to collective dose are medical workers, who accumulated 40 percent of the

total dose for all workers. Mean doses for workers receiving measurable doses in a few specific occupations, such as nuclear power reactor workers and industrial radiographers, were twice as high as those to most other workers receiving measurable doses. The mean dose to males was significantly higher than that to women in all job categories. Finally, the distribution of doses among workers is heavily weighted toward low doses: two-thirds received no measureable dose, 95% received less than 0.5 rem, and ~~only~~ 0.1% received 5 rem or more.

III. HEALTH RISKS DUE TO OCCUPATIONAL RADIATION EXPOSURE

This chapter outlines the assumptions and methods we use to estimate the harm from occupational levels of radiation exposure. Section A discusses the units used to quantify radiation dose. Section B defines each type of harm and briefly describes the information on which our risk estimates are based. The last section describes the parameters and risk projection models we use and illustrates how these choices affect the risks calculated for different levels of occupational exposure.

The following discussion represents our current understanding of the risks from exposure to radiation. Our understanding has grown and changed over the years. Undoubtedly it will continue to grow and change. Some of what we now believe may, in the light of future knowledge, prove to be wrong and much of it is clearly incomplete. Nevertheless, the degree and mechanisms of harm from ionizing radiation are better understood than those of almost any other carcinogen or mutagen.

Biological effects caused by ionizing radiation may be divided into two general classes: somatic effects, which occur in exposed individuals; and hereditary effects, which appear in their descendants. Some somatic and all hereditary effects are generally believed to be "stochastic" effects (IP77). We use "stochastic effects" here to mean those for which the frequency of occurrence increases with dose, but the degree of impairment does not. This is in contrast to some somatic effects for which the kind or the severity of the impairment changes with dose so that, for small enough doses, the effects are negligible.

Cancer is the principal stochastic risk to the exposed worker. Radiation-induced cancers include leukemia and most commonly-occurring solid cancers. There is no known way to distinguish them from cancers due to other causes. Similarly, hereditary effects due to radiation are assumed to exhibit the same range of impairment as those due to other causes. Non-stochastic effects include cataract of the lens of the eye, non-malignant damage to skin, cell depletion in the bone marrow leading to hematological deficiencies, and gonadal cell damage causing impaired fertility.

Since the 1960 Federal Guidance (Fe60) was issued, quantitative estimates of ionizing radiation risks have been developed, particularly for cancer. These estimates are still uncertain. Making them involves choosing the most accurate and relevant information, because the reliability of available data varies.

Adverse effects in humans have been clearly shown only for doses and dose rates much higher than those to which most workers are exposed. Therefore, risks at occupational levels must be estimated on the basis of the data obtained at higher levels of exposure and an assumed response at lower levels. Our estimates of the stochastic effects from ionizing radiation are based on the assumption that the number of stochastic effects at low doses is directly proportional to the dose. The constant of proportionality is derived from the number observed at larger doses and the assumption that there is no level of radiation without some potential for harm. More exactly, we use the straight line which fits the data best and passes through the point representing no effect at zero dose.

A. Units

The amount of damage done to a tissue by ionizing radiation depends mostly on the amount of energy the tissue absorbs. Energy absorption is commonly measured in a unit called a rad. One rad is 100 ergs absorbed per gram of tissue. Thus, one rad to twice as much tissue means that twice as much energy has been absorbed. A person receives a "whole body dose" when the absorbed energy is distributed relatively evenly throughout the body.*

One rad is a very small amount of energy absorbed per gram, but a dose of a few rad to body tissues can be harmful. This is because the energy is in a form that can ionize molecules - that is, knock off their electrons. It requires little energy to ionize an atom. A 160-pound person who receives a whole body dose of one rad absorbs enough energy to ionize 7 billion billion molecules; this is about 100,000 ionizations per cell. Fortunately, very few of these ionizations interact with DNA.

Ionizations can cause fundamental changes (either directly or indirectly) in the body's chemical constituents, including DNA molecules. Our genes, which regulate much of our cellular activity, are made of DNA. Cancer is probably due, in part, to certain types of changes in cellular DNA. Mutations are inheritable changes in DNA molecules.

All ionizing radiation is not the same. Some consists of particles such as protons (hydrogen nuclei), beta particles (electrons), and

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*A 160-pound person who has received a whole body dose of one rad has absorbed enough energy to light a 75 watt bulb for only one-hundredth of a second. A person absorbs from a milk shake, French fries, and large cheeseburger enough energy to light a 75 watt bulb for about 21 hours; 125,000 times as much.

neutrons, or combinations of these, e.g., an alpha particle is composed of two neutrons and two protons. Electromagnetic radiation of high enough energy per photon - x rays and gamma rays - can also ionize molecules. For doses of the same size, different types of ionizing radiation act differently. Some, like x rays, beta rays, and gamma rays, ionize molecules which are far apart, like this:

PHOTOGRAPH

Some, like alpha particles, make very dense tracks like this:

PHOTOGRAPH

Alpha particles and protons are examples of "high-LET" radiation. LET stands for linear energy transfer, the amount of energy deposited per unit track distance. High LET means that the particle gives up large

amounts of energy along a short, densely ionized track. Low-LET radiation, such as gamma rays and x rays, produces a long, sparsely ionized track. "High LET" and "low LET" are broad and rather imprecise categories. For example, some particles have sparse ionization at the beginning of their tracks and dense ionization at the end. Also, the electrons that high-LET particles knock off atoms themselves act largely as secondary, low-LET radiation. In general, doses of the same size from high-LET radiation are more dangerous than from low-LET radiation.

The biological effects of ionizing radiation can depend, among other factors, on: the type of radiation; the size of the dose and the rate at which it is received; the mass and type of tissues irradiated; and the age, sex, race, genetic makeup, and other characteristics of the exposed person. Because all the relevant factors and their precise effects are usually not known, for radiation protection purposes we only consider the amount and type of radiation, the tissues irradiated, and in some cases, age and sex.

The ability of different types of radiation to cause harmful effects is related by "quality factors." The quality factor for x rays and gamma rays is defined as one. If the quality factor for another type of radiation is five, this means that in some general way this type of radiation is likely to cause five times as much harm as the same dose absorbed from x rays. The International Commission on Radiation Units and Measurements publishes tables listing quality factors as a function of [illegible] (IU71-76). In this general review of occupational guidance we have not re-evaluated the specific quality factors in current use.

The dose measured in rad from a particular type of radiation multiplied by its quality factor gives a quantity called "dose-equivalent." Dose-equivalent is measured in a unit called the rem. For simplicity, in this document we call "dose-equivalent" just "dose." The dose in rem is a rough measure of health risk. This is why most radiation protection limits, including ours, are expressed in terms of rem.

B. The Present State of Knowledge

In this section, we discuss the risk of cancer caused by radiation (radiogenic cancer) first, followed by hereditary risks and then risks to the unborn following exposure in utero. Finally, risks of nonstochastic effects are described.

1. Radiogenic Cancer

A number of long-term epidemiological studies to evaluate the consequences of exposure to radiation are in progress. Almost all of these studies have been reviewed in the 1972 National Academy of Sciences report, The Biological Effects of Ionizing Radiation, commonly called the BEIR report, and the 1977 report of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), Sources and Effects of Ionizing Radiation (NA72,Un77). More recently, the Interagency Federal Task Force on the Health Effects of Ionizing Radiation has published a report describing the health effects associated with radiation exposures, Report of the Work Group on Science (In79). The General Accounting Office is close to publishing a report, The Cancer Risks of Low-Level Ionizing Radiation Exposure (Ge80). The National Academy of Sciences has recently finished a revision of their 1972 report (NA80).

A particularly important source document for any review of radiation risk is the Life Span Study, Report No. 8 - Mortality Experience of Atomic Bomb Survivors 1950-1974 (Be78), which provides the most recent results from the long-term study of persons exposed at Hiroshima and Nagasaki. This study is particularly valuable because it has continued for a long time, contains a large number of persons, and has been carefully documented. Moreover, the population at risk was exposed on a known date so that follow-up studies give some insight into when radiogenic cancers appear and how long exposed persons are at risk following exposure. Even so, the Life Span Study has many limitations.

The population studied contains 82,000 A-bomb survivors, of whom over 62,000 persons were still alive in 1974. Thus, even the most recent results are based on far from a lifetime follow-up. Of the 3,842 cancer deaths observed by 1974 in this population, only about 200 are thought to be due to radiation. These cancer deaths can be grouped into broad intervals according to the dose received to obtain rough estimates of the cancer risk per unit dose. Further subdivision of these data to obtain an estimate of the risk for a particular kind of cancer or by age at exposure usually results in a small sample size and, therefore, a relatively unreliable estimate. It follows that more is known about the total risk of solid cancers and leukemia from the A-bomb survivor study than about individual cancers. In addition, the type of radiation thought to be important at Hiroshima, neutrons, is different from the major source of exposure at Nagasaki, gamma rays. In many cases, but not all, this makes combining the data from two cities a possible source of error. Moreover, both of these populations were exposed almost instantaneously at very high

dose rates. The consequences of prolonged exposures at low dose rates, such as occur in most occupational situations, may be different.

In spite of the limitations of the study of Japanese survivors and other exposed groups, scientists are reasonably sure about which kinds of cancers follow radiation exposures at high doses. Even though there is less certainty on when cancers appear, how long the excess cancer risk persists, and the magnitude of this risk per unit dose, some quantitative estimates can be made. This is in marked contrast to the situation when the 1960 guides were prepared and direct knowledge of radiogenic cancer risks was quite limited. Table 3 indicates the kinds of cancer that have been identified as radiogenic in the Life Span Study and in some other epidemiological studies of persons exposed to high levels of radiation (In79). The number of persons at risk in these other studies is quite small compared to the number of A-bomb survivors and we cannot be sure all types of radiogenic cancers have been identified yet.

As important as the number of persons in an epidemiological study is the length of time they have been followed for excess cancer. This is because most radiogenic cancers begin to appear only after a rather lengthy "latent period" and radiogenic cancers usually occur late in life. People in major exposed groups have not been followed long enough to observe the full extent of their cancer risk. This must be estimated by projecting the excess risk observed to date over the rest of the expected lifetime of the members of the groups.

The "risk period"* for leukemia appears to be about 25 years (Be78), but this is not true for most cancers. Current results from the Life Span

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* The risk period means the time from the end of the minimum latent period until the exposed persons no longer have an excess risk.

Type of Cancer	Atom Bomb Radiation		Medical Radiation									Occupational Radiation		
	Japanese atom bomb survivors	Marshall Islanders	Ankylosing spondylitis (x-ray)	Ankylosing spondylitis (radium)	Benign pelvic disease	Benign breast disease	Multiple chest fluoroscopy	Tinea capitis (children)	Enlarged thymus (infants)	Thorotrast	In utero x-ray	Radium dial painters	Radiologists	Uranium & other miners
Leukemia	**		**		*				*	**	**		**	
Thyroid	**	*						*	**					
Female Breast	**					**	**							
Lung	**		**							*				**
Bone				**								**		
Stomach	*		*											
Esophagus	*		*											
Bladder	*													
Lymphoma (incl. mult. mycloma)	*		*										*	
Brain								*					*	
Liver										**				
Skin								*	*				**	*
Salivary Gland								*	*					
Colon					*									
Rectum					*									

TABLE 3. Cancers Linked to Radiation in Particular Populations. Strong associations are indicated by **, and meaningful but less striking associations by *.

Study indicate that for most cancers the person exposed has an excess risk for the rest of their life. Fortunately, the numerical risk estimates for adults we use are not very sensitive to the assumed length of the risk period.

Ideally, estimates of lifetime risk would be based on a person's age at the time of exposure and the observed chance of excess cancer as a function of age. For most cancers the available data are too incomplete to make this a feasible approach. Instead, two different kinds of projection models are commonly used. These were developed by the NAS-BEIR Committee for their 1972 report. To the extent that the dose response is independent of dose rate and increases linearly with the dose, the different numerical results obtained with these models may indicate the possible range of the future risk.

The two projection models are called the absolute risk model and the relative risk model. The risk coefficient for the absolute model is found by dividing the observed number of excess total cancers by the total dose to the population and the number of person-years at risk. We have used this risk coefficient, the number of excess fatal cancers per rem per person-year at risk, to estimate the number of excess fatal cancers in adults exposed at various annual dose rates and having the life expectancy predicted by 1970 mortality statistics (see Section C below)(Bu80,Na75).

The relative risk model is not based on the absolute number of observed excess fatal cancers, but on the percentage increase of excess fatal cancers per unit dose relative to the expected normal incidence. Relative risk coefficients, percent increase per rem, are used in Section C to calculate the numerical increase in fatal cancer after a

given latent period on the basis of age-specific U.S. cancer mortality in 1970 (Na73). The two models yield different numerical results when the data are extrapolated to years beyond those not yet covered by follow-up of the study group. For most, but not all, fatal cancers the relative risk model projects a larger number of radiogenic cancers because for most cancers the normal incidence increases rapidly with age. However, the relative risk model predicts that death will occur at an older age, on the average. Thus, the two models tend to predict a similar total number of years of life lost in an exposed population.

Section C includes only estimates of fatal cancers, not estimates of the total of fatal and nonfatal cancers. The risk of nonfatal radiogenic cancers is not calculated because little information is available on their incidence. Almost all of the epidemiological studies are based on mortality. In the absence of specific data on nonfatal radiogenic cancers, the total risk of radiogenic cancer can be roughly estimated from State and national health statistics on cancer incidence and mortality in the general population. One way to do this is to compare the ratio of the incidence of fatal cancers to the incidence of all clinically observed cancers. Such estimates are not too satisfactory, not only because of the possibility of differences in the relative frequency of cancer types between radiogenic cancers and those caused by other factors, but also because cancer incidence statistics are incomplete and not directly related to cancer mortality statistics. Studies of survivorship following treatment are another possible source of mortality to incidence ratios. However, most of these studies are from exemplary medical centers and may not accurately reflect the national situation.

The 1972 BEIR Committee estimated the probability of a nonfatal cancer to be about the same as the probability of a fatal cancer (NA72). While this ratio is reasonable for breast cancer and many other cancers, there are exceptions. Skin and thyroid cancer have very low fatality, probably less than 6% (Un77). On the other hand, the mortality for lung cancer, and leukemia in adults, approaches 100%. We estimate that the total number of discovered radiogenic cancers, excluding skin cancer, is one and one half to two times the number of fatal cancers estimated in Section C.

Because breast cancer is one of the most common radiogenic cancers, the total risk to men and women following whole body exposure is probably not the same. On the basis of the absolute risk projection model, breast cancer makes the total radiation risk of fatal cancer for women about twice that for men. On the other hand, because of prevalence of lung and some other cancers among men, the relative risk model projection of mortality due to all cancers is 7% greater for men than women. The recent trend of increased lung cancer in women will reduce this margin. Male A-bomb survivors have a higher mortality risk from radiogenic cancer than comparably exposed women, particularly at older ages (Mo78). In view of the ambiguity in the available data, the estimated risks of cancer fatality in Section C have been calculated using averaged risk coefficients for both sexes. However, even if cancer mortality is about the same for both sexes, there will be more nonfatal cancers observed in women because they have more curable breast and thyroid cancers.

The numerical estimates of fatal radiogenic cancer that are listed in Section C cannot be compared directly to general cancer mortality for U.S.

population. The latter reflects the age distribution of the whole U.S. population while our calculations assume a cohort of workers who were 18 years old at the start of their exposure to radiation. Calculations based on 1970 age-specific cancer mortality rates indicate st a worker in this cohort has a 16% chance of dying of a cancer unrelated to occupational radiation exposure. Use of more recent cancer mortality data would increase this percentage by a small amount.

In Section C we have used the risk coefficients listed in the 1972 BEIR Report to prepare numerical estimates of the potential number of fatal cancers from occupational exposures to radiation.* While there is little controversy about doing so for high-LET radiations, there is considerable controversy about how well a linear extrapolation estimates the cancer risk for low doses of low-LET radiation. Because of this, our numerical estimates may be considered too high by some and too low by others. We believe our estimates are the most reasonable possible, even though the available epidemiological evidence is insufficient to prove or disprove the linear, nonthreshold hypothesis used to derive these values.

Although exposures of animals and cultured cells sometimes give responses that are consistent with a nonlinear relation to dose, they are usually consistent with a linear relation as well. Moreover, it is unclear how these results apply to human populations which, unlike cultured cells and most laboratory animals, are highly heterogeneous. Even for a population of genetically identical individuals the shape of

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* For solid cancers due to adult exposures, these risk coefficients agree rather well with those in the 1980 BEIR Committee Report (NA80), certainly within their inherent uncertainty. A more definitive comparison will not be possible until the 1980 report is evaluated.

the dose response curve can be very different from the shape of dose response curve for their cells; and the shape of a dose response curve for a genetically diverse human population can be very different from the shape of the curve for any individuals in the population. Each of these points are briefly discussed below, and more complete statements may be found in the literature cited.

The risk estimates in Section C are for an imaginary cohort of radiation workers - all of the same age and receiving the same annual dose for a working lifetime. We then estimate the chance of fatal cancer occurring to a hypothetical "average" individual. This is not the same as estimating the risk to a particular real individual. In an inhomogeneous population some persons are more susceptible to cancer than others, either because of genetic predisposition, age, personal habits, or other factors. While the extent of such variability is currently unknown, it can have an important influence on the average response of a population to radiation. A recent General Accounting Office report explores this in some detail (Ge80).

Figure 4, taken from that report, shows the expected radiation response in a hypothetical group having a highly nonlinear dose response (response proportional to the dose squared) and various degrees of sensitivity to radiation among its members. Although the example is arbitrary, it illustrates that the overall response can be quite different from that of any subgroup. In particular, it shows that a linear extrapolation of the data can lead, over most of the dose range, to an underestimate of the risk to those who are most sensitive to radiation and an overestimate of the risk to most people. At low doses it can lead to an underestimate of

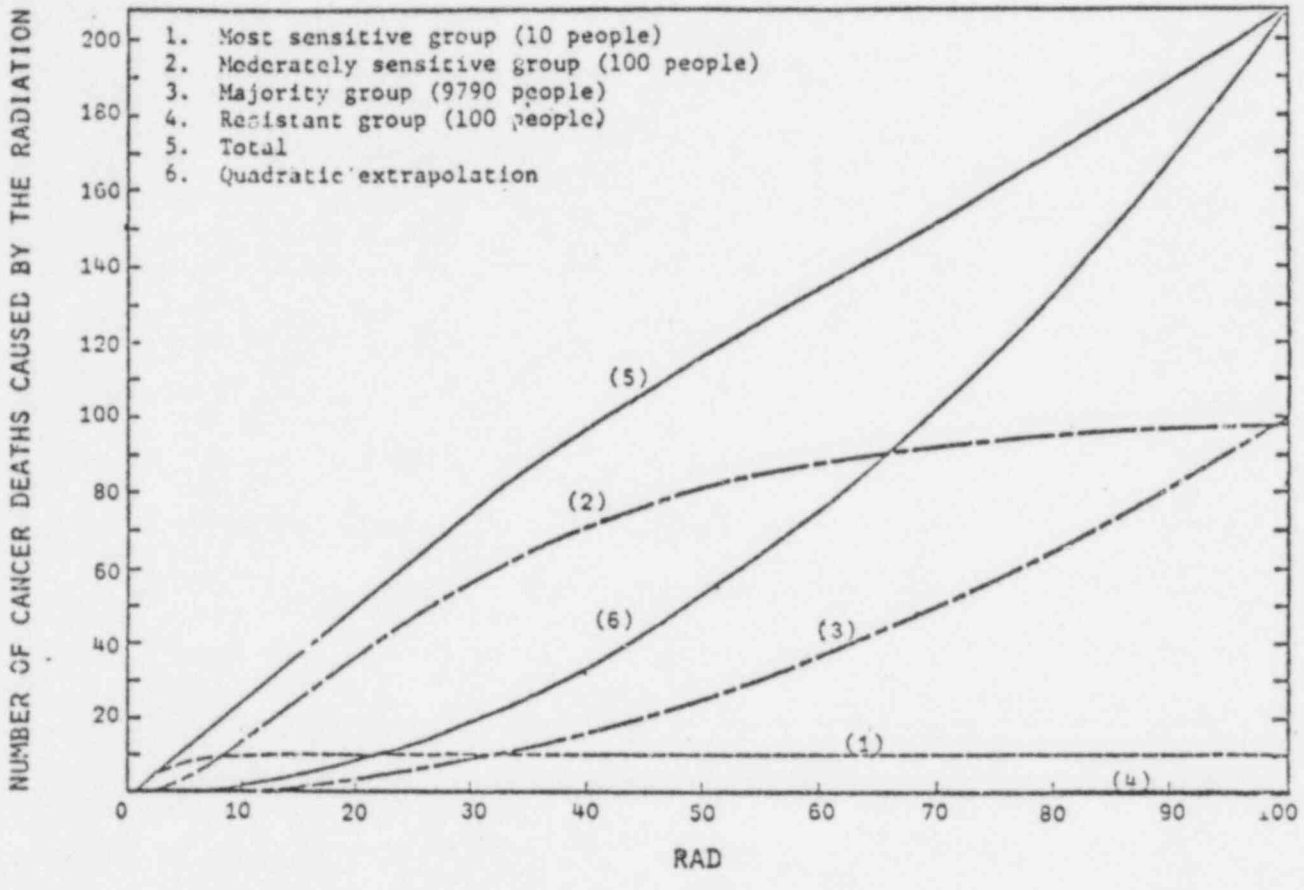

Figure 4. The presence of groups of people especially sensitive to radiation can cause the overall response of the entire population to differ from the dose-response of any one group. The figure, taken from Ge80, illustrates the effect of radiation on a hypothetical population of 10,000 people, each of which has a quadratic dose-response with saturation at some dose (i.e., at that dose the person is almost certain to die from the exposure): 10 people very sensitive to radiation-induced cancer, 100 people moderately sensitive, 100 people resistant, and a majority of 9790 people having typical (modal) sensitivity. In this example, the population dose-response curve is approximately linear even though the basic response of each group is quadratic, i.e., increases as the square of the dose. For this population, a quadratic extrapolation (curve 6) substantially underestimates the risk. Even a linear extrapolation can underestimate the risk in such examples.

the risk to the population as a whole. For this reason, we believe that the experimental induction of radiogenic cancers in inbred strains of rodents and other mammals does not provide a useful guide for predicting the dose response to radiation for a heterogeneous human population.

The risk estimates we have used are based on epidemiological studies which include persons exposed to relatively large amounts of radiation compared to occupational doses. The data from these studies is consistent with several different types of dose response functions. The functional form chosen for estimating risks can have a large effect on the degree of risk predicted at low doses. In Appendix A we discuss an example commonly cited as a non-linear dose response in an inhomogeneous human population - leukemias in the Life Span Study of Nagasaki survivors, - and why we do not find this evidence convincing. The risk estimates in Section C are based on a straight line fit through the data and an assumed zero risk at zero dose. We believe this is a reasonable regulatory position for predicting the dose response to radiation for human populations.

2. Hereditary Impairments From Occupational Exposures

A mutation is an inheritable change in the genetic material within chromosomes. We assume that ionizing radiation causes the same kinds of mutations as those that occur from other causes. Generally speaking, mutations are of two types, dominant and recessive, but these categories are rough and somewhat arbitrary. The effects of dominant mutations usually appear in the first and subsequent generations. The effects of recessive mutations do not appear until a child receives a similarly changed gene for that trait from both parents. This may not occur for many generations. It may never occur. Although mutations may

in time be eliminated from the population by chance or by natural selection, they can persist through many generations. The 1972 BEIR Committee estimated that radiation-induced recessive mutations are spread over 10 to 20 generations. Dominant mutations are usually expressed (and eliminated) in the first few generations.

Mutations can cause harmful effects which range from undetectable to fatal. In this report when we refer to mutational effects we mean only those heritable conditions which are usually severe enough to require medical care at some time in a person's lifetime. Even as limited by this definition the range of seriousness of mutational effects is large. The effect of one fairly common dominant mutation is extra fingers and toes. However, some other dominant mutations can have much more severe effects, such as increased susceptibility to cancer, severe mental retardation and muscular dystrophy. McKusick has classified over 55% of 583 "proven autosomal (not sex-linked) dominants as clinically important." (Mc75)

Most identified mutations are recessive, not dominant. The severity ranges from changes in hair and eye color (not a mutational effect as defined above), to such dangerous diseases as hemophilia, Tay Sach's disease, sickle cell anemia, and cystic fibrosis. The largest class of genetic impairments, classified by the 1972 BEIR Committee as diseases of complex origin, includes congenital malformations and constitutional degenerative diseases having a genetic component. These "diseases," which are thought to be caused by the cumulative effects of many mutations and environmental factors, can cause serious handicaps. Examples are anemia, diabetes, schizophrenia and epilepsy (NA72).

Risk estimates for mutational effects caused by radiation are almost wholly based on data from inbred strains of animals. There is no

completely satisfactory way to apply these data to genetically inhomogenous human populations. Nonetheless, the 1972 BEIR Committee estimated the dose needed to double the human mutation rate on the basis of the average increase of recessive mutations per rem in large populations of inbred mice. This average "doubling dose" could be determined only within broad limits, 20 to 200 rem for low dose rate, low-LET radiation. Using a very similar analysis, the 1977 UNSCEAR Committee arrived at 100 rad as their estimate of the doubling dose. Low LET radiation is about 3 times less effective per rem at low dose rates than at high dose rates in producing genetic damage in the progeny of male laboratory mice (NA72). For the progeny of female mice the effect of decreasing the dose rate on lowering the hereditary risk is even larger, a factor of twenty or more (NA72). Both the BEIR and UNSCEAR Committee concluded that radiation-induced genetic damage in humans would be similarly reduced at low dose rates.

In addition to an estimated doubling dose based on recessive mutations, the UNSCEAR Committee also made a second and more direct estimate of heritary risk. This estimate is based on the first direct measurement of radiation-induced dominant mutations, in this case, those affecting skeletal tissues in mice. This is important because these anomalies are due to rare dominant and irregularly expressed dominant mutations, types of mutations generally thought to be major contributors to mutational effects in humans. Moreover, the severity of the skeletal changes observed in these mice were related to similar skeletal defects in humans so that the extent of potential impairment to humans could be considered. Both of the UNSCEAR estimates are in substantial agreement with each other and with those proposed by the BEIR Committee in 1972.

The largest source of human data that can be used to estimate genetic risks are the records of children of A-bomb survivors. So far, there is little statistical evidence of genetic damage in these children (Ne74). While this does not contradict other estimates of hereditary damage, the number studied is too small to be conclusive. For types of genetic damage causing death before age 17, a lower limit on the doubling dose for males based on the fact that no exposure-related mortality was observed is 46 rem; for females, it is 125 rem. Both of these estimates are at a 95% confidence level and pertain to high dose-rate exposures. When allowance is made for the effects of dose rate, these lower limit estimates of doubling dose are, for low doses of low-LET radiation, increased to about 140 rem for exposed males and to more than 1000 rem for exposed females, yielding an average doubling dose for both sexes of about 250 rem (Ne74). This lower limit is about the same as the highest value estimated by the 1972 BEIR Committee (200 rem).

In estimating the number of mutations, we assume a linear, nonthreshold dose-response relationship. The risk of inherited mutational effects in children depends on a number of factors, including the sex of the exposed parent, whether or not both parents are exposed, and the gonadal dose before conception. Even for a constant rate of annual exposure the effect of the gonadal dose is a function of the age of the worker, because younger workers are more likely to have additional children than older workers.

The sex of the worker is also an important factor. Animal experiments generally show that at doses permitted by current guides, low-LET radiations have a much smaller mutational effect on oocytes

than on spermatagonia.* The 1972 BEIR Committee estimated the difference between male and female sensitivity as a factor of five for low dose, low-LET radiations. Because of this difference, we calculate the hereditary risk estimates in Section C separately for each sex.

In summary, there are three estimates of hereditary risk - all based on animal data but showing reasonable agreement. The 1977 United Nation's UNSCEAR Committee estimates of dominant mutations agree with the more indirect estimates made by the 1972 BEIR Committee. The upper and lower bound estimates in the 1972 BEIR Report differ by a factor of about 20, a degree of uncertainty which is consistent with what is known now about hereditary risks due to radiation. In Section C, we have used the estimates of the 1972 BEIR Committee to estimate the potential hereditary harm from occupational exposures.

3. The Risk Due to In Utero Exposure

An exposed unborn child** is subject to more risk from a given dose of radiation than is either of its parents. The biggest risks are of inducing malformations and functional impairments during the early stages of its development. A child is also more likely to get cancer if it receives radiation in utero. Moreover, the oocytes in the femal fetus are much more sensitive to radiation-caused mutations than are those of adult women (NA72).

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* Both rodent and human oocytes are formed prior to birth and are not a product of continuous cell division in adults, as are sperm. In their "resting stage" before being released from the ovary, oocytes appear to have little sensitivity to mutations from radiation.

** For simplicity we will designate all the stages from conception to birth as an "unborn child." These stages are discussed below.

It is likely that the major detrimental effect from radiation received *in utero* is the induction of malformations and functional impairments in the developing unborn child. The particular effect and its severity depend on the stage of development when exposure occurs. The development of a baby is usually divided into three stages: ovum, embryo, and fetus. A fertilized human ovum becomes an embryo after about seven days. The formation of body organs (organogenesis) is nearing completion at about eight weeks, after which the embryo becomes a fetus. The fetal period is mainly a period of growth, although development of the central nervous system and some other organs continues to some extent. Laboratory animals pass more quickly through similar stages of development. Therefore the effects of experimental *in utero* radiation on animal development, described below, are probably qualitatively related to effects in humans.

Relatively few cells are present in the fertilized ovum and animal studies show that the most common radiation effect at this stage is chromosomal injury leading to cell death. If enough cells are killed, this usually results in an intrauterine "death." Less frequently, malformations or neonatal death is observed. The dose response shows no evidence of a threshhold and usually a greater effect per rem at low doses (5 rem, low LET) than at higher doses (Un77). In the mouse, the most studied species, a one percent lethality rate per rem is reported (Un77), but there is considerable variation in sensitivity among the species studied.

After the formation of organs begins (the embryonic stage), intrauterine death is less likely for doses below 100 rem and

malformations are the most common effect. The cellular organization of the embryo is changing very rapidly during this stage. Cells become specialized and start processes leading to the development of specific tissues in a fixed sequence. Consequently the effect of radiation varies from day to day, causing different kinds and degrees of malformations depending on exactly when the exposure occurs.

An unborn child is more sensitive to radiation during the embryonic stage than in earlier or later stages of development. Although the dose response observed in animal studies is usually less than linear at low doses, in some cases the dose response is consistent with linearity (Un77). There is no good evidence for a threshold down to doses as low as 5 rem (low LET). The types of malformations in different laboratory animal species correlate with the developmental stage of the embryo. There is no evidence that the human embryo is an exception to this general pattern.

Defects in development caused by radiation in mice and rats include skeletal malformations, brain and spinal cord malformations, alterations of nerve cells and cortical architecture of the brain, heart and urinary tract malformations, and eye defects (Un77). Both the frequency and severity of these effects increase with dose. The UNSCEAR Committee has estimated for animals an increased frequency of 5×10^{-3} malformations per rem (low LET), but emphasizes that this estimate is tentative and not applicable to humans because of large interspecies differences.

During the fetal period, malformations are less common and less severe. The major effect is reduced growth, which may persist throughout life.

The effects of radiation on human development are not as well known as for animals. Most observed human exposures have occurred randomly throughout pregnancy and intrauterine doses are not known with much precision. The observations that are available indicate that human response is similar to that for animals. When an ovum is killed by radiation the death is usually not noticed. The major observed effects are malformations, which can occur in all stages of development, most frequently in the embryonic and early fetal stages. The most common radiation-induced malformations in humans are impaired development of the brain, skeleton, and eyes (Up69).

The central nervous system has a long period of development in an unborn child and the brain is particularly sensitive to radiation injury in utero. This is reflected by the frequent occurrance of microcephaly (small head size) among persons exposed in utero. Microcephaly is commonly defined as a head size two or more standard deviations smaller than the average (for any specific age). Its clinical importance is that it is often associated with microencephaly (small brain), but is much more easily measured. Mental retardation is strongly associated with microcephaly, particularly when the microcephaly is severe. Microcephaly and other malformations have been observed in clinical practice after high pelvic doses (250 rem of low LET radiation) from radiation therapy. The most frequently observed radiation-induced human malformations are small size at birth, stunted postnatal growth, microcephaly, microphthamia (small eyes), pigmentary degeneration of the retina and other eye defects, genital and skeletal malformations, and cataracts (Un77).

Microcephaly occurred frequently among the children of Japanese survivors exposed in utero, particularly among the Hiroshima survivors where there is a linear trend of increasing incidence of microcephaly with the dose from mixed gamma and neutron irradiation. Figure 5 shows the dose response for these survivors during the time span when the unborn child was at greatest risk, 6 to 11 weeks after conception. Estimates of the in utero dose are based on Ke78 and Be78 (about 8% of the in utero dose at Hiroshima was due to neutrons (Ke78)). Even in the lowest dose range (average in utero dose, 1.3 rad), the frequency of microcephaly is 11%, nearly 3 times that for the relatively unexposed controls, which was 4% (Mi76). Although this difference could conceivably be due to sampling error (only two cases were observed in the lowest dose range), the risk observed in this range is linearly proportional to the risk observed at higher dose levels where the frequency of microcephaly is so high that it is almost certainly not due to chance.

As an upper limit on microcephaly, the 1977 UNSCEAR Report lists a probability of one in a thousand per rem. This estimate may not be conservative since it is based on the dose to the mother's skin, not the much smaller in utero dose. Our calculations, based on the data shown in Figure 5 and a linear non-threshold model, give between 20 and 5 chances per thousand of inducing microcephaly for an in utero dose of one rem during the most sensitive period (6-11 weeks post conception) if neutrons are assumed to be between 5 and 50 times more effective per rad than gamma rays in causing microcephaly. This chance of injury is much larger than we estimate for genetic and cancer risks (see below) for the same dose. However we do not know if a minimum dose is required to cause microcephaly or how dependent the damage is on the type of radiation.

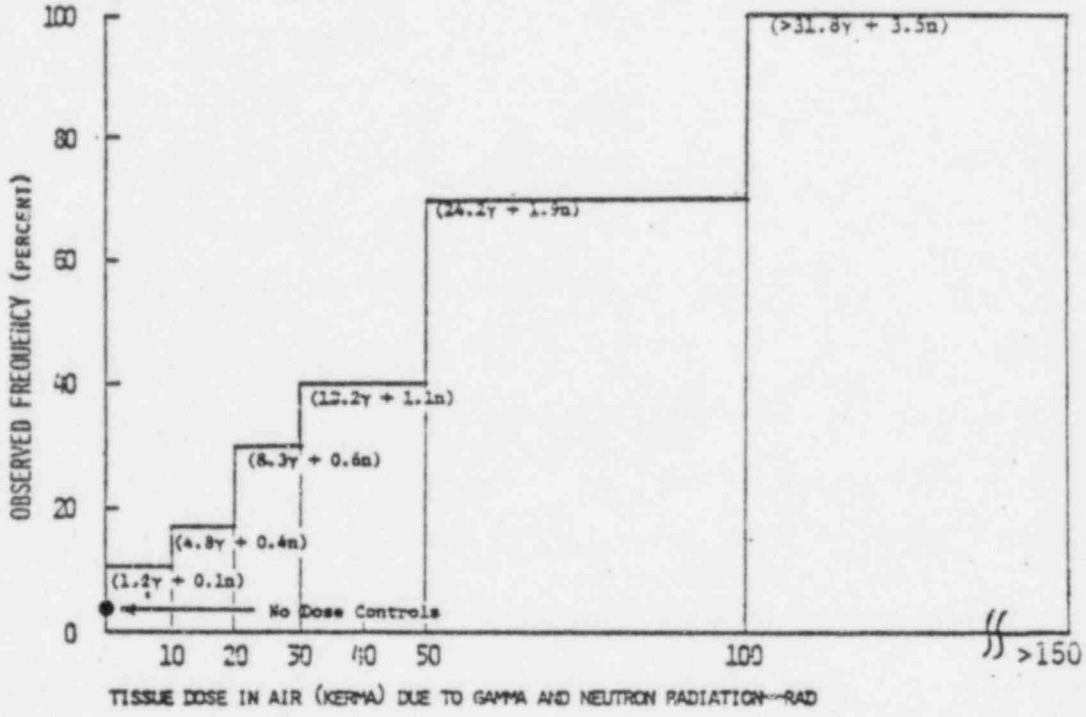

Figure 5. Frequency of microcephaly as observed at Hiroshima for different dose categories (Mi76). Average in utero gamma-ray (γ) and neutron (n) doses in rad are shown in parentheses for each dose range. There are 84 children in this group, 27 of whom were affected. The sample size at each dose level is small (2-7 cases) and thereby subject to considerable statistical variation.

Data on the frequency of microcephaly at Nagasaki would be useful for estimating the dose response from low-LET radiation alone, but the number of cases occurring in Nagasaki (15 total, and only 5 during the most sensitive period) is too small to allow this. There is essentially no difference in the reported incidence of microcephaly among all persons exposed in utero in the two cities: 17% in Hiroshima, and 15% in Nagasaki. Similarly, during the most sensitive period (6 to 11 weeks after conception) overall incidence was 32% at Hiroshima and 23% at Nagasaki. A difference this large would occur by chance about 30% of the time and is not statistically significant.* In both cities the incidence was 100% for doses larger than 60 rad during the most sensitive period. For in utero doses less than 60 rad during the most sensitive period, a 17% incidence was observed at Hiroshima and only 5.5% at Nagasaki. There is a 4% probability that a difference this large would occur by chance. This may indicate that in the lower range of in utero doses causes other than radiation were involved, or possibly that the neutron component at Hiroshima was particularly effective. However, at doses higher than 60 rad microcephaly was more frequent at Nagasaki than at Hiroshima, so that for all exposures occurring before 18 weeks of pregnancy the incidence in the two cities was nearly the same. In any case the samples are too small to provide a firm basis for any conclusions on the cause of differences between the two cities, particularly since sources of in utero and maternal trauma other than radiation were not the same within the two cities (Mi72).

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* All tests are for the null hypothesis, no difference between cities, hypergeometric distribution for sampling from a finite population without replacment (Wa60).

Severe mental retardation was also observed in Japanese survivors exposed to *in utero* radiation. This was often, but not always, accompanied by microcephaly (Wo67). At Hiroshima an increased frequency of severe mental retardation occurred at all exposure levels, but was not statistically significant (at the 0.01 level) for *in utero* doses below 20 rad (B173). Although at Nagasaki there was no increase in severe mental retardation related to *in utero* doses less than 120 rad, the Nagasaki sample is so small there would be a 25% chance of obtaining this result even if there were no difference between the two cities (Wa60). Among all persons exposed *in utero* there is no difference between the two cities.

Microcephaly and mental retardation are not the only dose-related effects observed. The height and weight of *in utero* Japanese survivors during childhood and as adults is less than for those not exposed (Un77). Long term studies of the mortality experience of the *in utero* survivors indicate higher than expected death rates occurred in the first year of life and after ten years of age (Ka71). Among those receiving high *in utero* doses, fetal and neonatal deaths were common (Un77).

Because of the sensitivity of the unborn to radiation, a number of epidemiological studies have been performed to see if developmental effects occur due to low-doses of diagnostic radiation (Di73,Ha69,Ki68, Op75). In contrast to the Japanese experience, such studies have shown negative or equivocal results (Un77). Because these studies were comparable in size to that of the Japanese survivors, this may indicate the importance of dose rate in initiating these effects. Studies of laboratory animals indicate fewer effects per rem at low dose rates for some, but not all, *in utero* effects (Un77).

The genetic and cancer risks per unit dose from in utero exposure also exceed those for adult workers. Unlike those in adults, oocytes in the female fetus are not in a resting stage, and may be nearly as sensitive as male spermatogonia. According to the 1972 BEIR Committee Report, this increases the risk of hereditary damage being transmitted by the female line by about a factor of five (NA72). The most sensitive period for genetic damage in both sexes is probably the last two trimesters.

The 1972 BEIR Committee estimated the leukemia risk from in utero exposure as ten times greater than that for adults who get the same dose. The follow-up period for excess solid tumors, which have a longer latency period than leukemia, has probably not been long enough to allow a good estimate of the total risk for other cancers due to in utero exposures. The absolute risk of getting fatal cancer, other than leukemia, in the first ten years of life due to in utero exposure, however, has been estimated as five times the risk that an adult has of getting cancer within ten years of receiving the same exposure (NA72).

4. Other Effects of Occupational Levels of Exposure

Nonstochastic effects following large radiation exposures are due to extensive cell killing coupled with imperfect repair. Laboratory animals show little or none of these effects at small doses and severe impairment at high doses. Loss of fertility by males is an example. Doses of several hundred rem to the testes can lead to a permanent loss of fertility; smaller doses cause only a temporary reduction in the number of sperm cells (He67,Ro74). Fertility is not impaired at doses permitted by the current guides limiting occupational exposure.

The blood-forming organs show nonstochastic effects at relatively low doses. A single dose of 20 rad can cause a measureable drop in the number of lymphocytes, but such changes are transitory (Wh71). Chromosomal aberrations in circulating lymphocytes have often been observed after low doses of radiation (Un77,Ev79). Some of these aberrations are permanent, but they have not been identified as a cause of any clinical condition. For other organs, acute doses of about 1000 rad are needed to cause a demonstrable non-stochastic impairment (NC71).

A threshold for skin erythema (reddening) occurs at doses of a few hundred rad for medium energy x-rays. Low dose rates or fractionation increase the threshold enormously; skin doses of several thousand rads occur in radiotherapy without permanent damage. Occupational radiation protection limits for the skin are designed to limit the incidence of skin cancer. Skin erythema does not occur at these dose levels.

Perhaps the most important nonstochastic radiation effect is cataract induction. The lens of the eye differs from other organs in that dead and injured cells are not removed. The size, location, and growth with aging determines how much a cataract interfers with vision. Single doses of a few hundred rem have induced opacities which interfere with vision within a year. When the dose is fractionated over a period of a few years, larger doses are required and the cataract appears several years after the last exposure (Me62,Me72). Judgments on the adequacy of exposure limits for the lens are based on extrapolating these findings to exposure periods well beyond the range of clinical observation (Ch79). For this reason, such extrapolation should include a large degree of safety.

Another major problem in selecting a safe occupational dose limit for the lens is that animal studies indicate that minor opacities are produced

at dose levels as low as 30 rads of x-rays or 0.5 rads of neutrons (Ba71). How much these minor opacities may increase in size with age is not known, particularly in long-lived species such as man.

C. Risk Estimates Used in This Review

As used here, "risk" is the probability of harm from radiation exposure. The term "risk coefficient" means the risk per unit of dose equivalent (rem). Three kinds of risk are considered: radiogenic cancer, hereditary effects, and effects from in utero exposures.

1. Radiation-Induced Cancers

The risk coefficients and other parameters shown in Table 4 were used to estimate the risk of cancer death for whole body exposure over a working lifetime, based on the absolute risk and relative risk models. Except for leukemia, the expression period (risk period) following the latent period is assumed to be the balance of a lifetime. The 1969-71 life table for the U.S. population was used to represent the normal mortality of workers (Na75).

Estimated future risks are shown in Figure 6 for the case of an 18 year-old entering the work force and receiving one rem per year to age 65, unless death from any cause occurs earlier. The curve drops to zero at high ages because the chance of dying from some other cause before being killed by radiogenic cancer grows rapidly during old age. The total risk faced by such an 18-year-old is obtained by summing the annual risks shown in Figure 6 over all ages. Note that the age-dependent risk of future cancer increases nonlinearly and remains at an elevated level long after exposure is over. This is due to the effect of latency, variation

Table 4.

Coefficients and Projection Models Used to Estimate the Risk of Fatal Cancer due to Whole Body Exposure of Adult Workers (NA72)

Model (cancer)	Latent Period (years)	Expression Period (years at risk)	Risk Coefficient (per rem; average for both sexes)
Absolute Risk			(cases/person-year at risk)
Leukemia	2	25	1×10^{-6}
All Other Cancers	15	lifetime	5×10^{-6}
Relative Risk			(percent increase)
Leukemia	2	25	2%
All other cancers	15	lifetime	0.2%

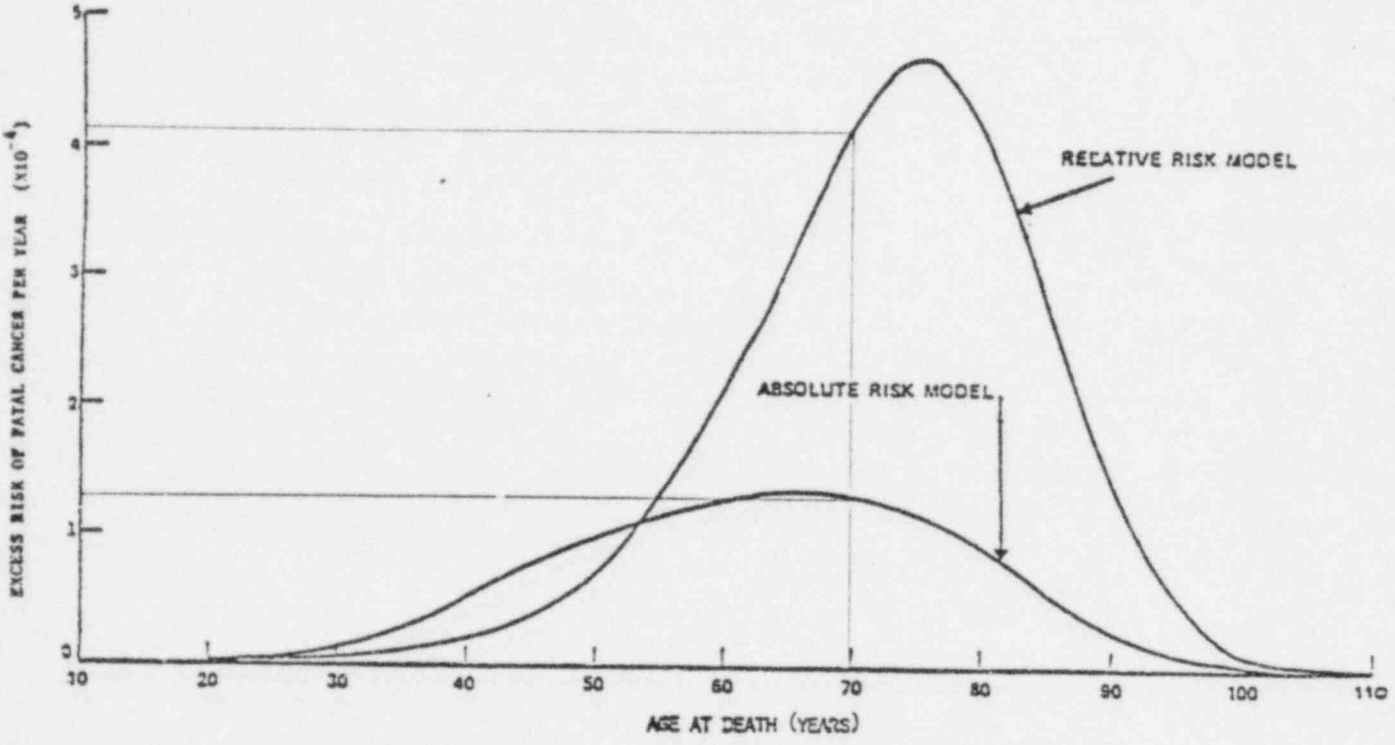

Figure 6 Excess annual future risk of cancer death by age for an average 18-year-old individual who will receive one rem per year from age 18 to age 65 or of death from any cause, depending upon which occurs first. With either risk model most excess cancer deaths are projected to occur beyond the age of retirement. The risks falls to zero at old age because of other causes of death.

with age of mortality rates, and, in the case of the relative risk model, the age-dependence of "natural" incidence of cancer. Although the estimated risk of death is greater for the relative risk model, death from radiation is predicted to occur earlier, on the average, by the absolute risk model. Different results would be obtained for initiating exposure at a later age, or for a worker who has already survived to any age beyond 18.

Figure 7 shows the annual risk at any attained age for a worker exposed to one rem per year from age 18. (For attained ages beyond 65 the exposure is assumed to cease at age 65.) The Figure includes the cumulative effect of all previous doses and competing risks of death, but does not drop to zero at old age because it assumes that the worker has survived to each age shown.

Because annual risks vary so much, they are not very useful for evaluating occupational exposure limits. Lifetime risk and the average number of years of life lost associated with a constant level of exposure throughout a working lifetime are more useful quantities for this purpose. Lifetime risk is defined here as the probability of incurring a specified radiation-induced effect due to receiving a specified dose annually over a working lifetime, that is, from age 18 to 65 unless death from any cause intervenes. When the dose received annually is the maximum permitted by a guide (e.g., 5 rem), this risk is called the maximum lifetime risk for that guide. Average lifetime risk is defined as the lifetime risk associated with the average annual dose actually experienced under the guide by the national work force or by any specified subgroup. Analogous quantities can be defined for years of life lost. A life table

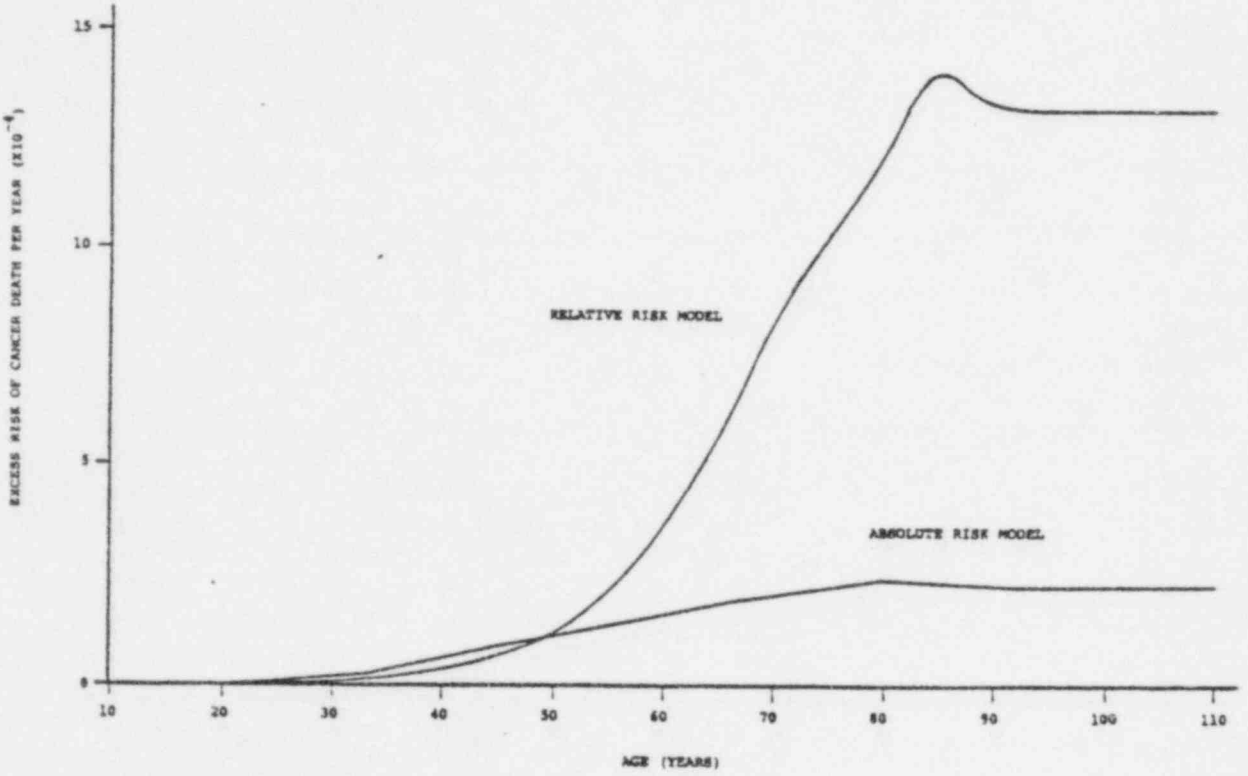

Figure 7 Excess annual risk of cancer death by attained age for an average individual exposed at one rem per year from age 18 to 65. The figure shows the risk for the year at each attained age; it does not show risks in either future or past years. The risk does not fall to zero because the risks shown are for those workers who survive all prior causes of death; it falls off slightly in old age because the expression period for leukemia from the last doses received has expired.

analysis (Bu70,Co78), which adjusts for the competing effect of normal causes of death, was used to estimate these lifetime risks of death and lost years of life.

Depending upon which risk model is used, the maximum lifetime risk for death from radiation-induced cancer is estimated to be from 3 to 6 in a hundred for an annual whole-body dose of five rems per year received throughout a working lifetime. Figure 8 shows lifetime risks faced by an 18-year-old entering the work force for annual doses ranging from zero to five rems, the range of exposure rates permissible under current guides. As illustrated, limiting the expression period of cancers, other than leukemia, to 30 years does not have a large effect on the lifetime risk.

Table 5 lists the average lifetime risks of death due to cancer for radiation workers in various occupational categories assuming they are exposed each year from age 18-65 at the average dose rates observed in 1975. These annual average doses are well below one rem per year; the average lifetime risks are therefore correspondingly smaller than the maximum lifetime risk.

A life table analysis provides two other indicators of the cancer risk due to occupational exposure: (a) the average reduction in life expectancy for the work force, and (b) the average number of years of life lost for each excess cancer death (Co78). Figure 9 shows the average reduction in life expectancy due to excess cancer for a group of 18 year-olds entering the work force as a function of lifetime exposure at annual doses ranging from zero to five rems. For those individuals who actually die of radiation-induced cancer the reduction in life expectancy is much greater than the average value for the work force shown in Figure 9. The average number of years of life lost for each cancer death

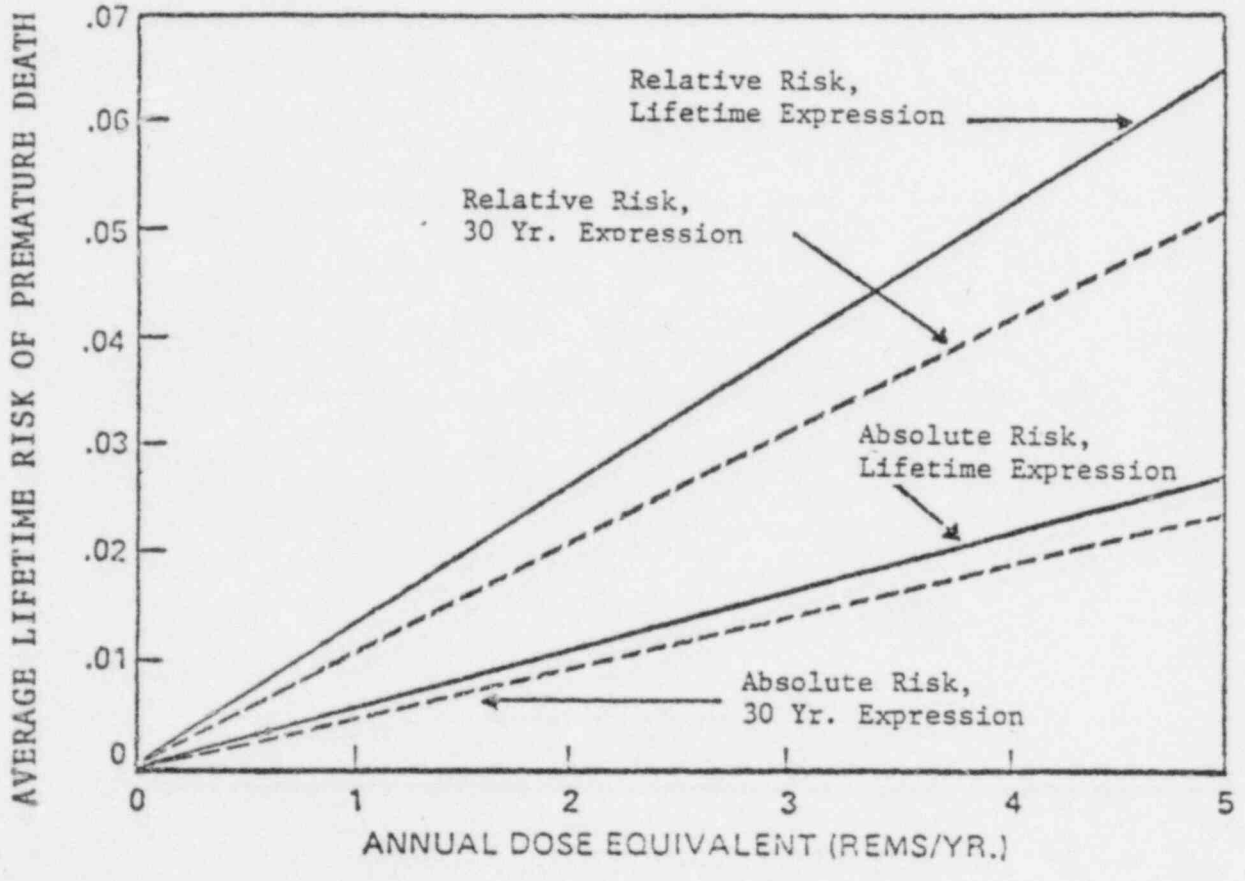

Figure 8. Average lifetime risk of death due to radiogenic cancer by annual dose level for four risk models. It is assumed that this dose level remains constant from age 18 to 65. Limiting the expression time for cancer to 30 years has relatively little effect on the lifetime risk.

Table 5

Estimated Lifetime Risk of Death Due to Radiogenic Cancer for Constant Annual Exposure in Various Occupational Categories*

Occupation	Annual Dose (rad)	Lifetime Risk: Relative Risk Model	Lifetime Risk: Absolute Risk Model
Education	0.20	1 in 370	1 in 910
Government	0.23	1 in 320	1 in 790
Medicine	0.32	1 in 230	1 in 570
Industry	0.52	1 in 140	1 in 350
Nuclear fuel cycle	0.63	1 in 120	1 in 290
Average for all	0.35	1 in 210	1 in 520
Allowed maximum	5.0	1 in 16	1 in 37
Chance without occupational radiation		1 in 6	

* Assumed exposure is from age 18 to 65 at the average dose rates observed in 1975 to workers measurably exposed.

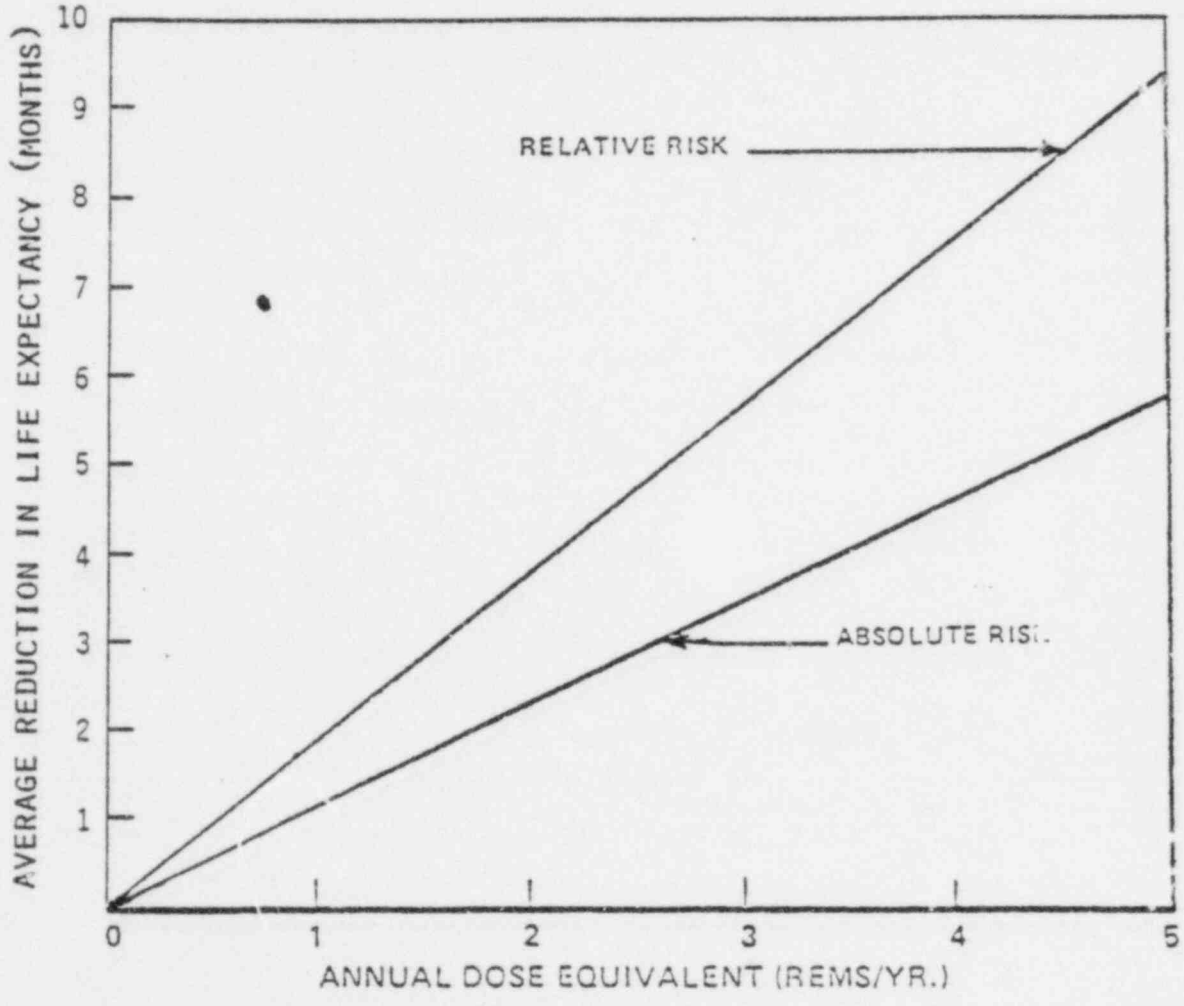

Figure 9. Average reduction in life expectancy due to radiogenic cancer by annual dose level for two risk models. It is assumed that the annual dose rate remains constant from age 18 to 65.

has a relatively constant value over the range of dose levels normally experienced in occupational situations - 12 years and 18 years for the relative and absolute risk projection models, respectively.

Table 6 lists the average loss of life expectancy projected due to death from radiogenic cancer for radiation workers in various occupational categories, assuming they are exposed each year at the average dose rates observed in 1975. These average lifetime losses of life expectancy are much smaller than the maximum lifetime loss of life expectancy for annual doses of 5 rem.

Risk estimates for individual types of cancer are considerably less reliable than for the total of all cancer fatalities, as previously noted in Section A of this Chapter. Of the various radiogenic cancers, leukemia, breast cancer, and lung cancer occur more frequently in exposed populations than fatal cancers of other types and are currently thought to account for about half the total risk of fatal radiogenic cancer.

The International Commission on Radiological Protection has developed weighting factors for the individual organs. These describe the proportion of the total risk (including both fatal cancer and mutational effects in the first two generations) from whole body exposure of adult workers which is assumed to arise from each of the various organs (IP77). The proportion of total cancer risk allocated to various organs by the ICRP is comparable to that identified by the 1972 NAS-BEIR Committee. These weighting factors were adopted by the ICRP to estimate the risk due to non-uniform exposure of workers, such as by inhalation or ingestion of radioactive materials. We have adopted the weighting factors used by ICRP for cancer death by excluding the ICRP weighting factor for the gonads (which applies only to

Table 6

Estimated Loss of Life Expectancy in Days Due to Radiogenic Cancer Death for Constant Annual Exposure in Various Occupational Categories*

Occupation	Annual Dose (rad)	Lost Life Expectancy (months) Relative Risk Model	Absolute Risk Model
Education	0.20	0.4	0.2
Government	0.23	0.5	[illegible]
Medicine	0.32	0.6	0.4
Industry	0.52	1.0	0.6
Nuclear fuel cycle	0.63	1.2	0.7
Average for all	0.35	0.7	0.4
Allowed maximum	5.0	9	6

* Assumed annual exposure is from age 18 to 65 at the average dose rates observed in 1975 to workers measurably exposed.

mutational effects) and renormalizing the sum of weighted risks to unity. These renormalized weights are listed in Table 7. Only six organs are identified by name. Organs usually considered under the heading "other" are ovaries, testes, muscle, four portions of the gastrointestinal tract, kidneys, liver, pancreas, spleen, uterus, adrenals, and bladder wall. These are organs in which inhaled or ingested radioactive materials may be concentrated. Each of the five "other" organs accumulating the highest doses from any such material are accorded equal weight (0.08) in the above scheme.

2. Hereditary Effects

Ranges of the estimated chance of mutational effects per live birth due to an accumulated gonadal dose of one rem before conception are listed separately for fathers and mothers in Table 8 (NA72). For perspective, the current incidence in a child of unexposed parents is about 10%. If both parents are exposed, the risks shown should be added. These estimates are for low-LET radiation. Dose equivalents from high-LET radiation, e.g., neutrons and internal alpha emitters, have a greater hereditary risk.

The risk coefficients shown are for mutational effects for two different cases: 1) first generation liveborn children, and 2) all generations of liveborn children. The former can be applied directly to the preconceptual gonadal dose to parents to determine the average risk to each liveborn first generation child. Both cases require assumptions on the expected number of children to parents in order to derive an estimate of total risk, either to first or to all generations of children, from exposure of a worker.

Table 7

Assumed Risks of Fatal Cancer for Exposure of Individual Organs Relative to Cancer Risk for Exposure of the Whole Body.

Organ	Relative Risk
Breast	0.20
Lung	0.16
Red Bone Marrow*	0.16
Thyroid	0.04
Bone Surfaces	0.03
Skin	0.01
Other Organs**	0.08

* Assumes leukemia only.

** Applies to each of the five other organs with highest dose.

Table 8

Range of Risk Coefficients for Mutational Effects (NA72)

	Effects per 100,000 live births per rem*	
	First Generation	All Generations
Fathers	1 - 16	5 - 120
Mothers	0.2 - 4	1 - 30

* These values are only applicable to doses of low-LET radiation.

The expected number of mutational effects in children of an exposed parent is a function of his or her accumulated gonadal dose. We have calculated these risks for first generation children for assumed constant exposure of parents starting at age 18, for normal parenting rates and ages at conception. The resulting values are shown in Figure 10. The number of mutational effects in all generations will be about six times greater than those estimated for the first generation alone. The expected number of first generation effects was calculated for the average number of children in 1975 as a function of parental age. This average, 2.1, includes childless married persons, but not unmarried parents. The expected number of children is probably lower now, but the average age of parents at conception (and therefore the average preconceptual gonadal dose) may be higher.

3. Effects of In Utero Radiation

Table 9, taken from the 1972 BEIR Report (NA72), lists risk coefficents for leukemia and solid tumors due to in utero exposures from low-LET radiations. These risks are more than a factor of 20 greater than those for adults for equal doses. However, the period over which the risk continues is appreciably shorter, cf Table 4. Unlike the case for adults, numerical estimates of the cancer risk for in utero exposure using the absolute risk model exceed estimates based on the relative risk model. This is because the normal rate of cancer in children is low. Hereditary risks due to in utero exposure are not well known, but we assume that the risk per rem for men shown in Table 8 applies to both sexes, since animal

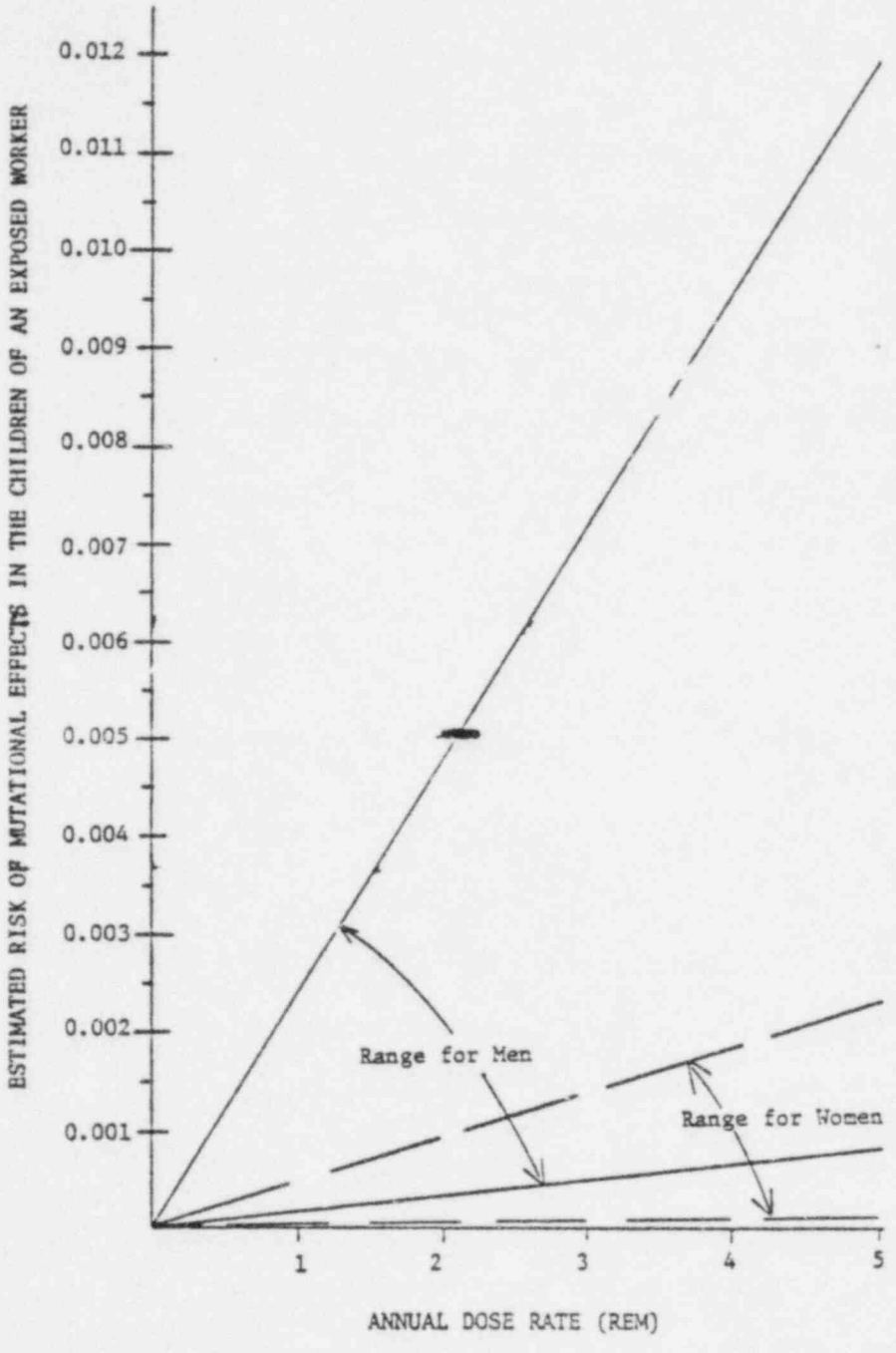

Figure 10. Risk that first generation children of men and women exposed beginning at age 18 will have a radiation-induced mutational effect as a function of the parent's annual dose rate. The risk to all generations combined is about six times greater.

Table 9.

Coefficients and Projection Models Used to Estimate the Risk of Fatal Cancer due to In Utero Exposure (NA72)

Model (cancer)	Latent Period (years)	Expression Period (years at risk)	Risk Coefficient (per rem; average for both sexes)
Absolute Risk			(cases/person-year at risk)
Leukemia	0	10	25×10^{-6}
All Other Cancers	0	10	25×10^{-6}
Relative Risk			(percent increase)
Leukemia	0	10	50%
All other cancers	0	10	50%

studies indicate that the radiosensitivity of the prenatal oocyte is comparable to that of spermatogonia (NA72).

The above cancer and hereditary risks from in utero exposures may be small compared to the risk of malformations and other developmental effects. For this to be so, there can be no threshold dose for developmental effects and the response would have to increase at least linearly with dose. As outlined in Section B of this Chapter, the data for Japanese children may indicate, for microcephaly, a risk coefficient as large as 5×10^{-3} to 5×10^{-2} per rem for an instantaneous dose of mixed neutron and gamma radiation delivered during the most sensitive period. This is much greater than the total risk for leukemias and solid cancers, which is 5×10^{-4} (see Table 9). Moreover, the occurrence of other kinds of malformations adds to these risks. However, for several reasons, we do not believe the data on Japanese children is sufficient by itself to be a basis for numerical risk estimates. Although the Japanese results are clearly related to dose, a number of other traumas could have contributed to the effects observed, including malnutrition and disease (Mi72), that would not contribute to the in utero risk from occupational exposures. Moreover, if the risks observed in Japan occurred proportionally in other populations at lower doses and dose rates, it is unlikely that the studies of in utero effects due to low doses of diagnostic and other sources of in utero exposure would be negative (Un77). These negative results do not indicate there is no danger to the unborn from low doses of occupational radiation, but they do indicate the Japanese results may not be applicable to all exposure situations. The presence of high LET radiation at Hiroshima and the instantaneous nature of the dose in both cities may be important confounding factors.

The developmental effects of radiation on an unborn child depend to a large extent on the time of exposure. In general, the most vulnerable period is the first several months after conception, when a woman is least likely to know whether or not she is pregnant. A major concern is that, without special precautions, it will be possible for an unborn child to receive a significant fraction of the 5 rem annual limit when the mother does not know that she is pregnant and when the unborn child is especially sensitive to radiation. Our inability to quantify this risk more completely does not lessen this concern.

IV. GENERAL PRINCIPLES FOR THE PROTECTION OF WORKERS

Three basic principles have governed radiation protection of workers in recent decades, both in the U.S. and in most other countries. Although the precise formulation of these principles has undergone evolution over the years, the basic intent has remained unchanged. The first requires that any activity producing occupational exposure be useful enough to society to warrant the exposure of workers; i.e., a process of "justification" must be carried out. The second requires that for justified activities exposure of the work force be the lowest that is reasonably achievable; this has most recently been characterized as "optimization" of radiation protection (IP73,IP77). Finally, in order to provide an upper limit on harm to individual workers, "limitation" of the maximum allowed individual dose is required. This limitation is required above and beyond the protection provided by the first two principles because their primary objective is to minimize the total harm from occupational exposure in the entire workforce, and they do not limit the way that harm is distributed among individual workers. These three principles are discussed in turn below.

A. Justification of Activities Leading to Worker Exposure

from the viewpoint of stochastic effects,

Since any exposure to ionizing radiation is assumed to be harmful, no exposure should be permitted unless it cannot reasonably be avoided and it will result in a benefit - both to the worker exposed and to society in

general. This requires two risk-benefit decisions. The first can be made by the worker, if he is properly informed of the risks, who can judge for himself whether the benefit of employment is sufficient compensation.

The judgment of benefit to society is less easily made. Only recently has the U.S. Government explicitly required that such general judgments be made for major Federal activities - through the National Environmental Policy Act of 1970 (NE70). There is no comparable general requirement for other activities. An obvious difficulty in drawing these judgments is the lack of common units of measurement (or in some cases the lack of any units of measurement) for a quantitative analysis of costs (including risks) and benefits. Given this situation, informed value judgments are necessary and are usually all that is possible.

The need to justify activities that result in occupational doses has traditionally been a part of guidance for radiation protection, even though it has seldom been possible to give it direct regulatory implementation. In the 1960 guidance the FRC said: "There should not be any man-made radiation exposure without the expectation of benefit resulting from that exposure" and "It is basic that exposure to radiation should result from a real determination of its necessity" (Fe60). Other advisory bodies have used language which has essentially the same meaning. In its most recent revision of international guidance (1977) the ICRP said "...no practice shall be adopted unless its introduction produces a positive net benefit," (IP77) and in slightly different form the NCRP, in a recent (1975) statement of position, said "...all exposures should be kept to a practical minimum;...this...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" (NC75).

This principle is adopted in these proposals as Recommendation 1 in a simple form: "All occupational exposure should be justified by the net benefit of the activity causing the exposure, including consideration of alternatives not requiring radiation exposure." We offer no specific advice on how costs, risks, and benefits, which are frequently incommensurate or unquantifiable, should be handled so as to show that this judgment has been properly reached for specific activities. It is perhaps useful to observe, however, that throughout history men and societies have formed risk-benefit judgments, with their usefulness usually depending upon the amount of accurate knowledge available. Since more is known about radiation now than in previous decades, the prospect is that these judgments can now be better made than before.

The preceding discussion has implicity focused on the need to justify entire activities, such as the construction and operation of a facility, or instituting a practice involving radiation exposure of workers. However, this principle is often most useful at a different level, that of detailed regulation of facilities and direct supervision of workers. Decisions about whether or not particular tasks involving exposure to otherwise justified sources should be carried out (such as inspecting control systems or acquiring specific experimental data) require justifications which may, in the aggregate, be as significant for reducing exposure as justification of the basic activities these tasks are intended to support.

B. Optimization of the Protection of Workers

When it has been determined that an activity requiring exposure of workers is justified, the next step traditionally required is to reduce the risks to levels that are "as low as is reasonably achievable" (this judgment is commonly designated by the acronym "ALARA"). This process is typically carried out in two different ways. First, it is applied to the engineering design of facilities so as to lower exposures of workers as far as is economically justified. Second, it is applied to actual operations; that is, work practices are designed and supervised so as to minimize exposure of workers. Both of these applications of ALARA are encompassed by Recommendations 2 and 3, which apply to collective and individual exposures, respectively. The Minimum Radiation Protection Requirements of Recommendation 4 give more specific guidance on means for insuring that ALARA is implemented for various levels of worker exposure. These minimum requirements, which encompass education of workers on health risks and on radiation protection measures, provision of radiation protection supervision, monitoring of exposures, and limitation of lifetime dose, are discussed in Chapter V.

The optimization of radiation protection of workers may sometimes involve the choice between minimizing collective dose to all of the workers involved in an activity on the one hand and minimizing dose to the most exposed individual on the other. In such cases, minimization of collective dose should generally take precedence, unless the limits permitted by maximum allowed annual doses to workers may be exceeded, or excessive lifetime doses to individuals would be incurred. Such a

procedure will minimize the total harm from radiation while preserving the protection afforded workers against excessive individual risk.

C. Limitation of Risk to Individual Workers and their Descendants

The above requirements are not sufficient by themselves. The harm from exposure to radiation is incurred by workers who, although they receive the direct benefits of employment, are usually not the principal beneficiaries of the activities involved. Limits are therefore required to assure that the maximum harm to every worker is acceptably low. These limits are provided by regulations which are bounded by numerical guides to Federal agencies for maximum allowed doses. These numerical guides are the Radiation Protection Guides (RPGs) provided in Recommendation 3. Recommendation 5 provides for more stringent limits to be established by regulatory authorities when this is appropriate. Specific values for the RPGs are developed in Chapter VI. We describe here the general considerations which governed their determination.

Two measures of risk are particularly significant to the individual worker. First, the typical risk to himself and his descendants in his specific job, and second, the maximum risk allowed, barring accidents. For most types of harm from radiation, the first of these is proportional to the average exposure for the job and the second to limits set by regulations bounded by this Federal radiation protection guidance. A third index of societal interest is the total somatic and genetic risk from occupational exposure and, thus, the total harm to society. This depends on the collective somatic and genetic dose to the entire workforce and on the collective dose to any exposed unborn.

In these recommendations we have tried to insure that the two measures of individual risk referred to above will be no greater than those from most other common occupational hazards and, to the extent feasible, that they will be lower. This approach is the same as that recommended by the ICRP (IP77). We know of no other criteria which provide a more rational approach to judging the acceptability of a guide than these, when they are coupled with the first two basic principles for radiation protection outlined above. We have also tried to design the guidance so that the total harm to the entire work force and its descendants will be as small as possible, while still limiting the maximum harm to individual workers and descendants. Finally, we have estimated the total harm to the population as a whole and found that it is small. Assuming experience for the year 1975 is typical for radiation exposures of workers, and using the risk estimates developed in Chapter IV, the total harm to the population from a constant annual collective dose equal to that in 1975 is projected to be an increase of about two to five thousandths of one percent in the annual cancer death rate, and a comparable rate of increase in the number of liveborn with mutational effects.

A striking feature of national statistics on occupational exposure is the large proportion of all potentially exposed workers who receive annual doses that are less than 500 millirem. This dose is one tenth of the 1960 guide of 5 rem average dose per year and only four percent of the maximum of 12 rem permitted in any single year. In 1975, the latest year for which extensive data are available, 95% of all occupationally exposed workers were in this group. Furthermore, all but six of 25 individual categories (see Table 2) have average annual doses of less than one half

of this value. These exceptions are nuclear waste workers, industrial radiographers, licensed and state registered source manufacturers, nuclear power reactor workers, and workers in fuel fabrication and reprocessing. Three major groups of workers - all those in medicine, government, and education - include no job category with an average annual dose greater than 250 millirem.

These statistics appear to testify to the success of radiation protection under the 1960 guidance. The typical risks in all occupations which involve radiation exposure appear to be small, both absolutely and in relation to other occupational risks (see Chapter VI). On the other hand, in many cases these doses are low because people in many jobs naturally have little exposure. And in all of these occupations the existing guides permit far higher doses than those commonly received. These statistics lead to two obvious questions: 1) Should the radiation protection guides be so much higher than the demonstrated need for exposure of the vast majority of workers? and 2) To what extent are the infrequent doses that are above a few hundred millirem really necessary?

Regarding the first question, we believe that the present guides, which permit doses from 5 to 12 rem in a single year, do not, by themselves, sufficiently protect most of the radiation work force. The 1960 guidance is, in effect, designed to control doses to the few percent of the work force whose work requires high exposures. The annual limits for most workers could be reduced to lower values if suitable provision is made for occasional higher exposures which are justified.

Detailed data on the extent of the need for annual doses above a few hundred millirem are not available for the entire work force, although

many individual cases of justified exposure in this range could be given. We believe that adequate justification for some such exposures exists, and that the guides should provide for this as long as a reasonably low upper limit on the maximum allowable risk is maintained.

Given the above conclusions, Federal radiation protection guides could take several forms. One alternative is to specify different guides for different occupations. However, special studies for each occupational exposure situation are required to do this well, and reliable information for determining what maximum exposures are justified in specific occupations is most appropriately obtained by the regulatory agencies.

Another alternative is to specify increasingly stringent protection requirements for a set of successively higher ranges of dose, within a basic upper limit which permits occasionally necessary higher than usual doses. Such a system should discourage higher doses except when they are well justified. Regulatory agencies should also then develop supplementary lower limits for specific types of workers, based on whatever detailed studies are required, whenever this is appropriate. We believe this is a more reasonable form for general Federal guidance than direct specification of different Federal guides for different occupations. It places the responsibility for detailed decisions for particular types of workers where it belongs, in the regulatory agencies who are directly involved in the specifics of working conditions. We have adopted this approach in formulating Recommendations 3, 4, and 5, since it simultaneously avoids the permissiveness of a single high limit that is only occasionally justified, and the arbitrariness of imposing the lower limits appropriate for most jobs on the few that are justified exceptions.

MINIMUM RADIATION PROTECTION REQUIREMENTS

In Chapter IV we concluded that the most appropriate guidance for occupational radiation protection consists of a set of successively higher dose ranges within a basic upper limit, each of which ranges may, if the need is properly justified, be available for any work situation. We have proposed Minimum Radiation Protection Requirements for three such ranges in Recommendation 4. These requirements include: 1) education of workers about the risks to health from radiation and on radiation protection requirements and practices; 2) supervision of radiation protection, including the justification and optimization of exposure; 3) monitoring and recording of worker exposure; and 4) limiting lifetime exposure. We discuss each of these in turn.

A. Education of Workers

Workers have been told more about the dangers of radiation than about many other occupational hazards. However, most of them do not know the most recent quantitative estimates of radiation risks, or what they are based on. They should be told. The discussion and numerical evaluations of risks in this report are examples of what is appropriate for this purpose. It is clearly not acceptable to inform a worker of the dose limits and leave the impression that doses below these limits are "safe" or "negligible." Workers must understand that most risks from radiation are assumed to be proportional to the dose and understand the size of

their risks. Since risks to the unborn are greatest from exposures in utero, female workers and those who supervise them should be specifically informed about risks to the unborn. Up-to-date knowledge of radiation risks should provide a significant incentive in any program for reducing doses to workers.

Education on radiation protection requirements and practices must be tailored to the needs of different kinds of work and workers - for example, dental technicians and welders in nuclear facilities have obviously different protection needs; and female workers and their supervisers in any kind of work should be well-informed regarding protection measures to reduce exposure of the unborn. As a starting point, all workers should be fully informed of the basic radiation protection principles and guides set forth in Federal guidance. Education of workers is basic to effective radiation protection and is therefore a minimum requirement for all three ranges of exposure.

B. Radiation Protection Supervision

Supervising radiation protection means assisting and guiding managers in deciding whether exposures of workers are justified and radiation protection is optimized (ALARA), as well as supervising day-to-day protection of workers. We have distinguished three levels of supervision, depending on the dose.

In Range A, which extends up to one tenth of the RPGs, the number of workers is large (95% of the work force) and doses to individuals are small. However, the collective dose is larger than for either of the other ranges - almost half that in the entire work force. Clearly, it

would be impractical and unreasonable to provide professional radiation protection supervisors for this large number of workers. However, because of the large collective dose, careful generic assessments of the justification of exposure and of the optimization of radiation protection measures and practices should be carried out. These include, for example, designing facilities, such as diagnostic x-ray installations; regulating the packaging of radioactive materials for handling by transportation workers; regulating the design of electronic products, such as diagnostic x-ray machines; and specifying minimum training or licensing requirements and work practices for the use of radiation equipment and radioactive materials.

In Range B, which encompasses intermediate doses above one tenth but below three tenths of the maximum allowable dose levels, professional supervision should be provided in the work place. At these dose levels, which involve less than 5% of all workers, the risks to individual workers are large enough so that on-the-job radiation protection supervision is justified. Furthermore, workers in this dose range are involved in a wide variety of specialized work situations that are not usually amenable to generic treatment for radiation protection.

We recognize that in some work places the numbers of workers may be so small that provision of professional radiation protection services could be burdensome, so that some flexibility will be needed in applying this requirement. Such supervision may, in a few cases, have to be provided on a part-time consulting basis, or a few workers may have to acquire advanced professional radiation protection training.

However, in the vast majority of hospital, industrial, and laboratory situations such professional protection services should be available on a

full-time basis. This is essential to provide the detailed attention to radiation protection - including justifying exposure and optimizing protection - that is required to insure that exposure of workers is minimized in this dose range. It is also essential that supervisors have the authority and access to management required to carry out these functions effectively.

The highest dose range, Range C, which extends upward from three tenths of to the full maximum allowed dose, involves less than two percent of all workers. However, it is these workers who are theoretically able to accumulate lifetime doses large enough to pose substantial risks to themselves and their descendants. These workers also tend to work in situations involving high dose rates and a high potential for accidental overexposures, so that vigilant care is needed. As in Range B these exposures should be properly justified and radiation protection optimized. Beyond this, for those tasks which may make a substantial contribution to doses in this range, supervision of radiation protection should be provided on a task by task basis - both before and during the work. This does not mean that radiation protection personnel should necessarily be located in high exposure areas during the work - that would not usually keep collective doses ALARA - but that they should ~~maintain~~ ASURE effective control over individual exposures of workers.

C. Monitoring and Record Keeping

An important element of control of occupational exposures is adequate monitoring and maintenance of records. In Range A monitoring of the work place, and, as appropriate, monitoring of individual workers should be

carried out to the extent necessary to assure that doses are ALARA and are within the range. In many cases monitoring of all workers in Range A work situations will not be necessary.

All workers who may receive doses exceeding one tenth of the RPGs (that is, doses in Ranges B and C) should be individually monitored and their doses recorded. Although we have not included a requirement for maintenance of lifetime records for all Range B exposures this practice is strongly encouraged when it is feasible. In Range C monitoring results should also be recorded for individual high dose tasks, as an aid to maintaining doses ALARA, and to provide a basis for review of these work situations.

D. Lifetime Dose

As discussed below in Chapter VI, in order to achieve the objective of limiting maximum lifetime risks to a value comparable to average risks from other occupational hazards, a two- to three-fold reduction of the maximum lifetime dose permitted by an RPG of five rems per year is required. This could be accomplished in at least the following ways: a) by lowering the RPGs, b) by limiting the total lifetime dose, c) by limiting the number of years the annual dose of a worker may exceed a specified value (which is significantly lower than the RPGs), or d) by limiting the lifetime sum of annual doses which exceed a specified value (which is significantly lower than the RPGs).

The first alternative has the advantage of simplicity. However, in order to achieve a significant lowering of potential lifetime risk a reduction of the present five to twelve rem limit in any single year to

significantly less than five rem would be required, and it appears likely that a significant increase in collective dose would result, or, at least, the incursion of clearly unreasonable costs (ref.) in certain subcategories of the work force (e.g., nuclear power facilities).

The second approach would require maintenance of lifetime dose records for the entire work force. An administrative requirement of this magnitude does not appear to be reasonable to protect the very small fraction of the work force that may receive large lifetime doses, if more reasonable approaches are available. Only a small fraction of the already very small fraction of the work force receiving annual doses of a few rem or more can be expected to continue at such dose rates for a working lifetime.

Alternatives c) and d) avoid the disadvantages of a) and b) for the small penalty of not counting annual doses that are less than some relatively small fraction of the maximum annual dose. In view of limitations on the accuracy of dosimetry, as well as uncertainties in risk estimates, we do not believe this penalty is significant. The differences between alternatives c) and d) include some possible administrative simplicity for the former and some increased accuracy (and possible usefulness for epidemiological studies) for the latter.

We have recommended that once a worker incurs a dose in Range C all subsequent yearly doses in both Ranges B and C be kept in a lifetime record and that every reasonable effort be made to avoid allowing this accumulated lifetime dose to exceed 100 rem. This would reduce maximum lifetime risk from radiation exposure to a level comparable with average risks due to other occupational hazards.

In the case of older workers somatic risks may be less than those for younger workers and genetic risks are usually no longer present. However, because of the highly individual nature of these considerations, and because we do not know age specific cancer risks well enough, we have made no age-specific recommendations.

As a general rule, workers who have already accumulated an occupational dose in excess of 100 rem should not incur Range C exposures. They should be assigned to duties for which the annual exposure is in Range A. This new guidance, however, should be introduced with discretion, taking into consideration the economic well-being and the preference of the individuals concerned. According to currently accepted radiation-risk models, the risk associated with the dose received in any year is in addition to and independent of the risk from previously received doses. The regulator, employer, and the worker should evaluate the potential incremental radiation risk in relation to available alternatives.

VI. RADIATION PROTECTION GUIDES FOR MAXIMUM ALLOWED DOSES

The 1960 radiation protection guides for limiting occupational whole-body and gonadal annual dose are 3 rem in 13 weeks and an accumulated dose of 5 rem times the number of years beyond age 18 (that is, 5(N-18) rem, where N is the worker's age in years). Two annual limits may be inferred from these guides: (1) a maximum dose of 12 rem in any one year; and (2) a maximum average annual dose of 5 rem over an entire lifetime, starting from age 18.

We estimate the harm associated with recent exposure experienced under these guides below, first for lethal and nonlethal cancers, next for effects on the unborn, and finally for a variety of less serious risks. Where possible, comparisons to comparable occupational hazards are made. This leads to our conclusions for the RPGs proposed in Recommendation 3.

A. Cancer Risks From Whole Body Exposure

1. Fatal Radiation-Induced Cancer

a. Lifetime Risks

Estimated lifetime risks of death from radiation-induced cancer were shown in Figure 8 (see Chapter III) for uniform annual doses of up to 5 rem per year over a working lifetime. Table 5 showed the average levels of risk estimated for the entire radiation work force and for its major components in 1975. The maximum lifetime risk of death from radiation-induced cancer allowed under the 1960 guide was estimated to fall between 3 and 6 in a hundred.

As an aid to placing these lifetime risks in perspective we have compared them to the risks of death from on-the-job accidents currently encountered in various industries in the United States. A comparison to risk of death from other carcinogenic agents in occupational environments would also be relevant, but adequate data for such a comparison are not available. In any case, comparison of radiation risks to risk of accidental death alone is conservative, since we assume other carcinogenic risks would increase the total risk of death from causes other than exposure to radiation. We have omitted radiation risks to workers from normal background radiation, from medical exposures, and from diagnostic x rays that are required as a condition of employment.

Table 10 lists average annual risk of death from on-the-job accidents in various broad groups of occupations (NS73-75). Within any of these groups of occupations individuals in different jobs obviously face different risks, varying from much less than the average value to values which are several times higher than the risk to the average worker. Numerical estimates are not available for the distribution of these risks by specific job assignment. Consequently, we could calculate only the average lifetime occupational risk. This is defined here as the average lifetime probability of death from an on-the-job accident faced by an 18-year-old about to enter employment in an occupation in which he or she will be exposed to its average risk annually until age 65, unless death occurs earlier.

In comparing these lifetime risks to those from radiation exposure, it should be born in mind that a premature cancer death attributed to radiation is not equivalent, in a number of respects, to a premature

Table 10. Annual Risk of Accidental Death in U.S. Industries (NS73-75)

	Deaths per 100,000 Workers						
Industry/Year	1971	1972	1973	1974	1975	1976	1977
Trade	7	7	7	6	6	6	6
Manufacturing	10	9	8	8	8	9	9
Service Industries	12	10	10	10	9	9	8
Government	13	13	13	13	12	11	11
Transportation and Public Utilities	36	36	35	34	33	31	33
Agriculture	66	61	61	54	58	54	53
Construction	71	70	71	63	61	57	60
Mining, Quarrying	100	117	117	71	63	63	63
All Industry Average	18	17	17	15	15	14	14

$63 \times 10^{-5} \times 50 = 3.150 \times 10^{-2}$

9×10^{-2} for [illegible]

accidental death. For example, the estimated average number of years of life lost is 12 to 18 years for a cancer death due to radiation, whereas it is approximately 35 years for accidental deaths, under the above assumptions (Bu80). A more-in-depth analysis would undoubtedly reveal additional differences, e.g., hospital costs, suffering, or impact on others, that could be greater or less than in the radiation case. Because we lack information on such other factors, the following comparisons were made on the basis of frequency of incidence (risk) and reduction in life expectancy only. In order to make these comparisons, annual accident rates were converted to lifetime risks and loss of life expectancy using a life table analysis (Co80).

Lifetime risks from radiation exposure are compared to lifetime risks of accidental death in major U.S. industries in Figure 11. As shown in the Figure, the risk associated with continuous exposure over a working lifetime to the average dose to the 1975 radiation workforce (0.12 rem) is lower than the average lifetime risk of death due to accidents in retail and wholesale trades, the safest occupational group. The range of lifetime fatal cancer risk to the radiation workers with the highest average annual dose (0.92 rem for nuclear waste disposal workers with measurable doses) brackets the average accident risk for all occupations.

Although data are not available for a comparison of maximum risk of cancer death from radiation with maximum risk of death from accidents, a comparison of maximum allowed radiation risks under the 1960 guide with average accident risk is possible and provides some insight. As shown in Figure 11, the maximum allowed lifetime risk of lethal cancer from radiation ranges from equal to about two and a half times the average risk

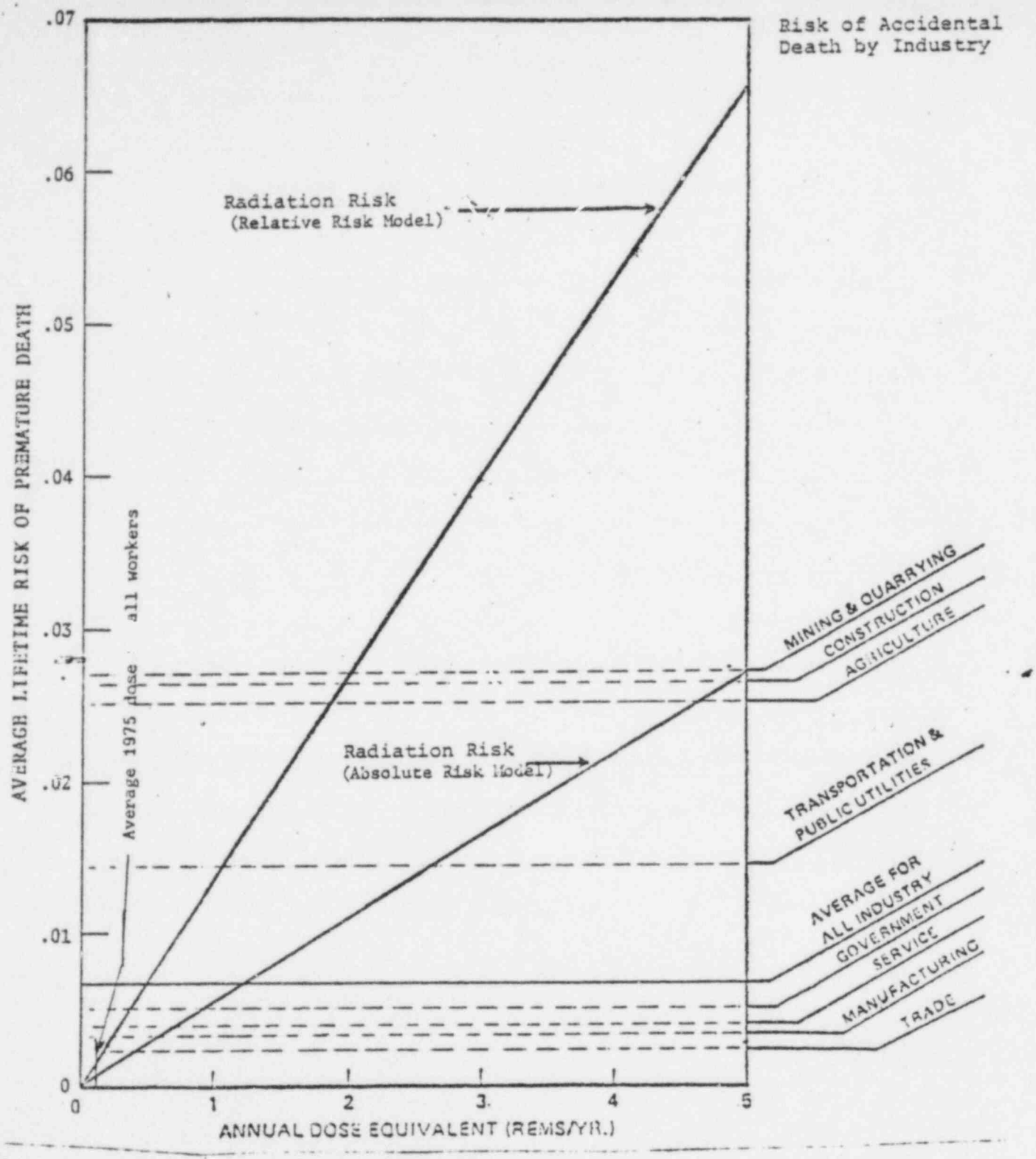

Figure 11. Lifetime risk of death due to radiogenic cancer by annual dose level for two risk models compared to average occupational risks of accidental death. It is assumed that the dose level to radiation workers and accidental death rates of workers in other industries remain constant from age 18 to 65.

of death due to accidents in mining and quarrying, construction, or agriculture, the three highest risk industries listed.

These comparisons are in terms of the number of premature deaths. Loss of life expectancy due to premature death may also be used for comparison. As noted above, the average number of years of life lost for a radiation-induced cancer death is only one half to one third that for a job-related accidental death. On the other hand, the effects on others that are associated with premature loss of life of a worker are not related in any unique or simple way to the number of years of life lost. We therefore do not make any judgment on the relative merit of comparisons based on chance of premature death versus those based on loss of life expectancy, but present both.

Estimated losses of life expectancy from exposure of radiation workers and from accidental deaths of workers in other industries are shown in Figure 12. Radiation workers in all job categories are estimated to experience a smaller average loss of life expectancy than that due to accidental death for the average U.S. worker. Moreover, even though an individual receiving a maximum allowable lifetime whole-body dose of 5 rem per year from age 18 to 65 is subject to a loss of life expectancy which exceeds the average due to accidental death for all workers, this maximum loss is still smaller than the average loss of life expectancy for workers in the three highest risk occupations listed (mining and quarrying, construction, and agriculture).

We draw two conclusions from the above observations. First, based on experience for the past 15 years, the risk of death from radiation-induced cancer for the average worker is low in comparison with risks of

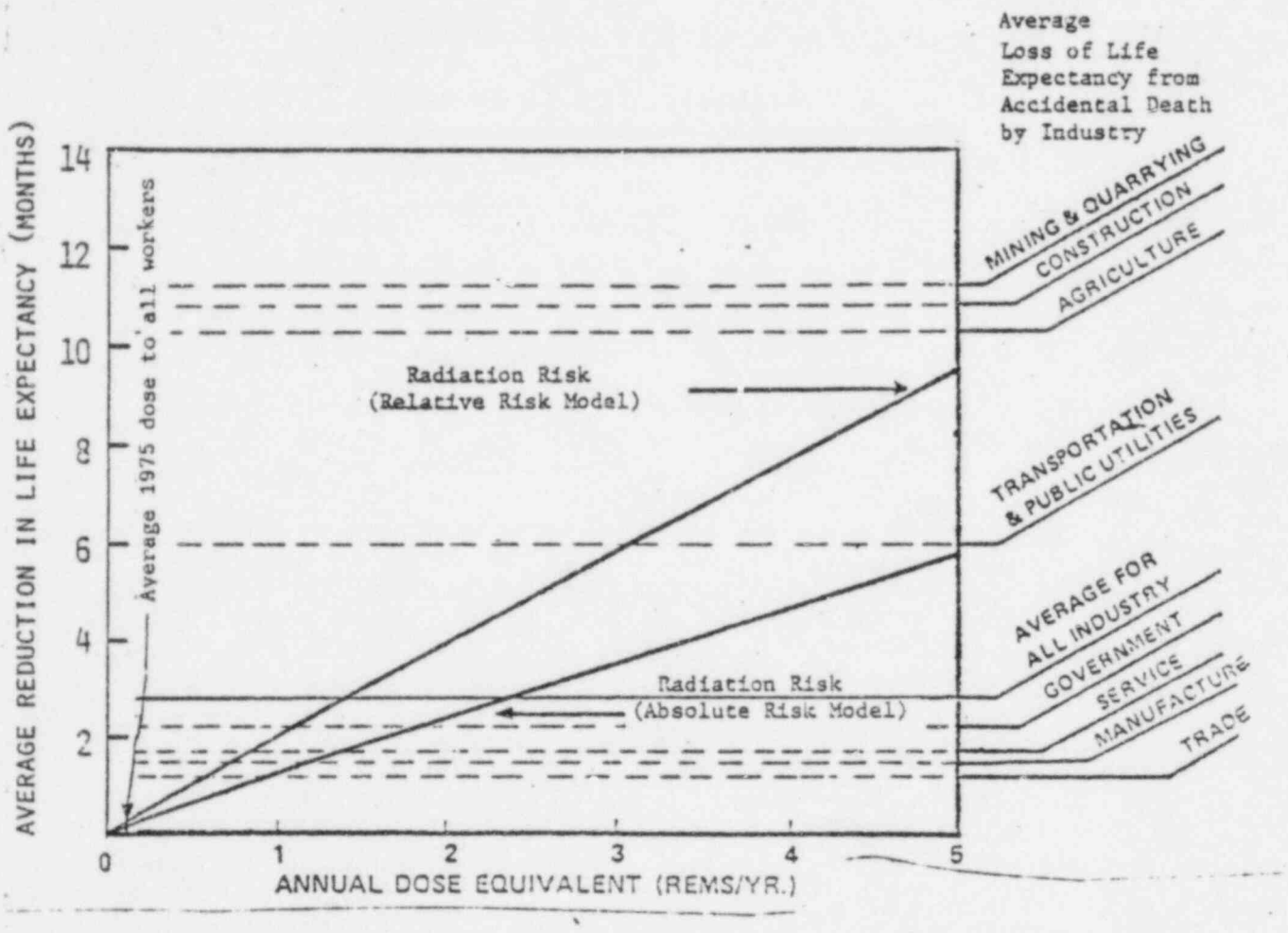

Figure 12. Average reduction in life expectancy due to radiogenic cancer by annual dose level for two models compared to average occupational reduction in life expectancy. It is assumed that the dose level to radiation workers and accident death rates to workers in other industries remain constant from age 18 to 65.

accidental death in other occupations. For this reason we do not find it necessary or justified to lower the whole body Radiation Protection Guide below 5 rem to provide greater protection from radiation-induced fatal cancer to the work force, taken as a whole. However, a worker who received the maximum allowed annual dose every year throughout his or her working lifetime could accumulate a lifetime risk higher than that of average workers in the three highest risk major occupational categories not normally exposed to radiation - mining and quarrying, construction, and agriculture. We believe that lifetime doses to radiation workers should normally be maintained at risks that are below the average for these three high risk occupations. This would be accomplished by maintaining lifetime doses at less than 100 rem, as proposed under Recommendation 4.

b. Age Dependence of Risk and the 3 Rem Quarterly Guide

The 1960 radiation protection guidance for the whole body is that the accumulated dose to a worker not exceed five times the number of years beyond age 18; that is, 5(N-18) rem, where N is the worker's age in years. Since the only limitation on the rate of dose accumulation is the guide specifying a maximum of 3 rem in 13 weeks, a worker may receive as much as 12 rem in any one year if he does not exceed the total specified by the 5(N-18) guide. The implications of lifetime accumulation of the maximum dose permitted under the 5(N-18) guide were discussed above.

The risk associated with the flexibility in the guides permitting maximum doses in any one year of 12 rem depends on the individual's age at exposure. The lifetime risk of cancer death is shown in Figure 13 for single doses of 12 rem given at different ages. These risks decline with

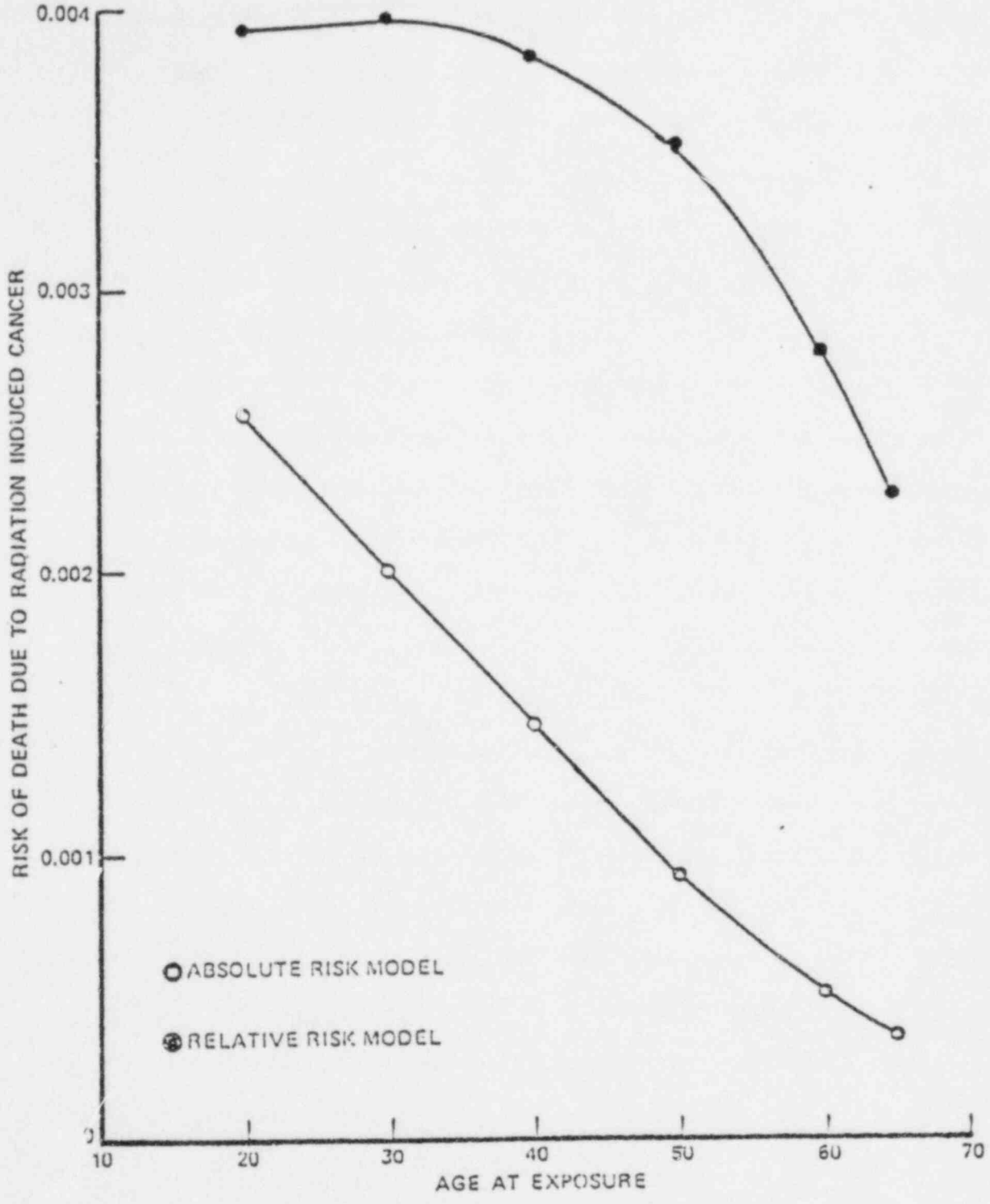

Figure 13. The risk of death from radiation-induced cancer due to a single dose of 12 rems, versus age at exposure. This graph assumes that the latency period is independent of age.

increasing age, but, especially in the case of the relative risk model, maintain high values throughout most of a normal working lifetime. In addition to the risks of cancer death shown in Figure 13, there are also substantial risks to the unborn (both genetic and to the unborn child) from doses to parents of 12 rem (see Chapter III).

The principal use of the flexibility permitting doses up to 12 rem in any year has been to permit multiple high exposures in any year of certain workers whose skills are in short supply, since the existing quarterly guide does not permit doses greater than 3 rem for any single task. Thus, there are no single work tasks now performed that use doses up to 12 rem. Annual exposures at this level can be avoided by training additional workers. We conclude that this flexibility should be discontinued, since the risks to individuals are not sufficiently warranted by demonstrated need.

2. Nonfatal Radiation-Induced Cancers

We assume that the risk of incurring nonfatal cancer is, at most, equal to that for fatal cancers (see p. 40). To put this type of harm into perspective, we made a comparison to job-related nonfatal injuries and illnesses in various industries and occupations in the United States. Nonfatal cancers are different from other types of injuries and illnesses and there is no completely satisfactory way to compare all types of nonfatal injury. Nevertheless, some useful insight may be gained from a simple comparison of time lost over a lifetime due to these causes. As before, statistics for the harm not involving radiation are only available for average workers, and comparisons with maximum allowable risk of harm from radiation must be made with care.

Table 11 displays reported statistics for annual incidence rates and our estimates of average lost time over a working lifetime for nonfatal occupational injuries and illnesses in the U.S. private sector in 1976. The private sector includes all but government workers. Nonfatal occupational injuries include all those requiring medical treatment other than first aid and occupational illnesses are defined as those associated with exposure to environmental factors in the workplace. Statistics for the latter include all identified acute and chronic illnesses possibly caused by contact, or inhalation, absorption, or ingestion of such factors (Bu78).

For an 18 year old, the average expected number of years of life to age 65 is 43.7 years, not 47 years, since some will die before reaching age 65. The annual incidence rates in Table 11 were converted to lifetime values by assuming that they remain constant over a working lifetime, using the above average expectation for length of a working lifetime, and by introducing a simple factor to convert working days lost to total days of lost lifetime. The resulting values are shown in the final column and compared to the impact of nonfatal radiogenic cancers below.

A recent study of U.S. experience for cancer morbidity indicates that the average lost time per diagnosed case is 1.8 months (ref.). Applying this value to the maximum lifetime risk of such cancers from radiation exposure developed in Chapter III, the average lost lifetime is estimated to be less than 0.01 years for the case of a worker exposed for his entire working lifetime to the maximum annual dose under the 1960 guide. This lost lifetime is an order of magnitude smaller than that estimated for the average of nonradiation causes in the private sector, as shown by Table 11.

Table 11. Nonfatal Injuries and Illness in U.S. Industries (Bu78)

Industry	Number of Workers (thousands)	Average Annual Rate/Worker			Working Lifetime Lost (Years)
		Total Cases	Lost Work-Day Cases	Lost Work Days	
Agriculture*, forestry and fishing	1,000	.110	.047	.833	.146
Mining	781	.109	.058	1.144	.200
Construction	3,564	.153	.055	1.050	.184
Manufacturing	18,883	.132	.048	.795	.139
Transportation and public utilities	4,528	.098	.050	.940	.164
Wholesale and retail trades	17,628	.075	.028	.432	.070
Finance, insurance, and real estate	4,149	.020	.007	.116	.020
Service Industries	14,158	.053	.020	.384	.067
Entire Private Sector	64,960	.092	.035	.605	.106

* Excludes farms with fewer than 11 employees.

On the basis of this low level of impact, coupled with the judgment that nonfatal cancer is ordinarily less severe in its impact than fatal cancer, we conclude that no additional protection beyond that provided for fatal cancers is warranted for nonfatal cancers.

B. Risks to the Unborn

1. Mutational Effects

The current guides for limiting dose to the gonads* are identical to those for the whole body. For a given annual dose, the risk of serious mutational effects in all of a male worker's descendants combined is believed to be numerically comparable to his lifetime risk of fatal cancer (cf Figures 8 and 10 in Chapter III, Section C). The medical severity of these hereditary defects is usually less than, and, at worst, comparable to death from cancer. Moreover, the largest risk to any single generation, that to first generation children, is about one sixth that to all generations combined. For these reasons we do not believe that a more restrictive guide is required for the male gonads than for the whole body. An argument could be made for increasing the guide for female gonads, since the sensitivity is much lower than that of male gonads. However, this would be meaningless, since the limit for whole body exposure will insure compliance with any such increased gonadal limit in all known situations. We have also not omitted females from the gonadal limit for the same reason, as well as to simplify administration of protection of workers.

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* Gonads include both testes and ovaries.

The proposed guide for gonadal dose is therefore identical to that proposed for the whole body, as was the previous guide. This guide is specified separately and not included in the scheme proposed below for partial body exposures because the risks involved are of a different nature: the affected individual is not the one exposed to radiation and the effects include different types of harm.

2. Risks Due to In Utero Exposure

Protection of those not yet born is an already well-established principle; the purpose of the guide for gonadal exposure discussed above is to limit mutational effects in children conceived after the exposure. However, those conceived but not yet born, the "unborn," are also at risk. Their risks are greater, for a given dose, than risks to those not yet conceived. Current guidance does not contain a lower dose limitation to protect the unborn from somatic effects, although such a limit has been recommended by NCRP for a number of years (NC75,NC77).

The risk of serious harm following in utero exposure demands careful attention because of the magnitude and diversity of the effects, because they occur so early in life, and because those who suffer the harm directly are involuntarily exposed. These risks are not as well quantified as those to adults, but available evidence indicates that at critical periods in the development of the unborn, for the same dose, they may be many times greater than those to adults.

There are several factors which mitigate this situation. First, the exposure of most workers under annual limits is relatively evenly

distributed over the year, so that only a quarter of a worker's annual dose is likely to be delivered to the unborn during any trimester. Second, the mother's body provides considerable shielding of the unborn for most types of exposure. For example, shielding factors for the degraded spectrum of x rays from 50 kev and 1000 kev photon sources are 0.12 and 0.55, respectively (ref.). Finally, the total period of potential exposure is small for the unborn compared to that for a worker - a period of months compared to a working lifetime.

It is difficult to provide for protection of the unborn without affecting the rights of women to equal job opportunities. This difficulty is compounded because the critical period for most harm to the unborn occurs soon after conception - during the second and third month after conception, when a woman may not know that she is pregnant. Based on our assessments of risks and the other factors noted above we believe that total dose to the unborn should be maintained a factor of ten below the maximum permitted adult workers in any year. In Recommendation 8 we propose four alternatives which would, with varying degrees of certainty, achieve this objective. Each involves a compromise of one kind or another:

a. Both workers and employers are encouraged to keep doses to any unborn less than 0.5 rem during any known or suspected pregnancy.

This alternative relies upon voluntary compliance. It assumes a woman knows she ~~is~~ may be pregnant within six weeks of conception, and will, along with her employer, take appropriate protective action. It therefore does not guarantee that doses to the unborn during the

critical early stages of pregnancy will be less than 0.5 rem. Equal job opportunities for women are not directly affected by this alternative.

b. Both workers and employers are encouraged to avoid job situations involving whole body dose rates to women able to bear children greater than 0.2 rem per month, and to keep doses to any unborn less than 0.5 rem during any known pregnancy.

This alternative adds a voluntary limit on dose rate to woman who can bear children so as to protect the unborn whose existence is not yet known. It permits women to hold any job, but encourages women able to bear children not to take those few jobs which potentially involve high dose rates. It would provide voluntary protection of the unborn, including during the critical early stages of pregnancy, in addition to voluntarily limiting the total dose to the unborn.

c. Women able to bear children should be limited to job situations for which the whole body dose rate is less than 0.2 rem per month. Doses to the unborn during any known period of pregnancy should be limited to 0.5 rem.

The third alternative assures protection of all unborn throughout gestation by making the voluntary requirements of the second mandatory. It would bar women from those few jobs which involve high dose rates.

d. The whole body dose to both male and female workers should not exceed 0.5 rem in any six month period.

The final alternative would restrict the exposure of all workers, male and female, to a level which would protect the unborn at almost

the level of alternative c. It would still subject the unborn to much greater risk of harm than a worker could incur in the same exposure period. This alternative preserves equal job opportunity for women at the cost of imposing increased risks on some portions of the work force. Studies of several high exposure activities show that decreasing the dose limits to this extent would significantly increase the collective dose to workers, and that some current activities would not be possible (ref.). Alternatively, society could avoid this increased risk by foregoing some high exposure activities, which can be expected to occur principally in the six job categories identified in Table 2 (Chapter II) that exceed 0.5 rems average dose per year.

None of these alternatives is completely satisfactory; they each involve either varying degrees of adequacy of protection of the unborn, some sacrifice of equal job opportunity for women, or increased risk to radiation workers and/or foregoing some of the benefits to society from activities using radiation. We invite public comment on the relative importance to be attached to each of these factors in formulating guidance, and on whether or not the guidance should address this matter now. We would also be happy to receive suggestions other than the four described above.

C. Health Risks from Partial Body Exposure

1. Cancer Risks to Organs and Tissues

The list of specific organs and tissues for which guides are required has evolved over the years as knowledge of radiation effects has

increased. We have reviewed previous choices in the light of current information, and the recommendations contain both additions and deletions.

We have added breast and lung to the list of specific organs considered in the 1960 guidance, since these are two of the principal contributors to the risk of cancer death from radiation. Forearms, feet, and ankles are now included under the category "other organs." Finally, the organs formerly designated as "blood-forming organs," "head and trunk," and "bone" are now covered as "red bone marrow," "whole body," and "bone surfaces," respectively, in keeping with current ICRP views on appropriate nomenclature (IP77).

Exposure of portions of the body can occur through localized irradiation of extremities (such as hands in glove boxes), or by breathing or swallowing radioactive materials which then migrate to different organs in the body. The current guidance limits such exposure through separate numerical guides for individual parts of the body. However, it does not consider the sum of the risks of cancer when more than one organ is irradiated. We propose to take the total risk of cancer death into account by assigning a weight to the dose to each organ equal to the risk from a dose to each organ divided by the risk from the same dose to the whole body and limiting the sum of these weighted doses. This scheme is similar to that recently adopted by the ICRP (IP77,IP78). These weights are listed in Table 6 (Chapter III).

We used three criteria to choose numerical guidance to limit exposure of organs or parts of the body: 1) the lifetime risk from exposure should not exceed that for the whole body, 2) any threshold for non-stochastic effects should not be exceeded in a working lifetime, and 3) no guide should be established at a value higher than experience shows is needed.

Proposed Recommendation 3, part b, provides that the sum of the weighted annual dose equivalents to all organs should not exceed 5 rem, the guide for exposure of the whole body. This provision, however, only limits the risk of cancer death and is not sufficient in itself to prevent large doses to a single organ in which other effects, such as non-lethal cancers and non-stochastic effects may cause harm. A supplementary annual limit of 30 rem to any single organ provides an ample margin of safety for these other effects and we propose it as an independent criterion.

We have chosen the limiting annual dose to any single organ to be 30 rem, rather than the internationally-adopted value of 50 rem, because we do not see a need for adopting a value higher than any now in use in this country. The risk associated with a 30 rem dose to any of the organs is equal or less than that of a 5 rem dose to the whole body. Additional differences from internationally-used values for gonads are discussed above under the heading "Risks to the Unborn; Mutational Effects," and for lens of eye and hands below under the heading "Other Risks."

It is usually impractical to directly monitor the dose received by a worker who breathes or swallows radioactive materials. In addition, it is useful to be able to predict doses that may be received from breathing contaminated atmospheres, such as at uranium mills. To make decisions about radiation protection of such workers possible it is necessary to calculate for different kinds of radioactive materials the amount which gives the maximum annual dose allowed by the RPGs. These calculations require complex models of metabolism and dosimetry. We propose in Recommendation 6 that these amounts of radioactivity be designated the "Radioactivity Intake Factors" (RIFs), and that they replace the currently used "Radioactivity Concentration Guides."

Note 3 to the recommendations specifies the appropriate models for use in calculating the RIFs. Recent advances in modeling of metabolism and for dosimetry have resulted in significant changes in the doses calculated for radioactive materials in the body (IP75,IP79). For most radioactive materials the changes in the calculated doses due to changes in the new models are considerably larger than the changes in the proposed new RPGs (ref.). These new models usually, but not always, reduce allowable intakes. A summary of the changes due to the new models and to the proposed new guides is provided for the more significant radionuclides in the Appendix.

2. Other Risks (Eyes and Skin)

The guidance recommends that, whenever reasonable, the lifetime dose to any worker be less than 100 rem, a total dose at which no harmful non-stochastic effects are expected to occur if the whole body dose in any one year is 5 rem or less. Threshold doses for non-stochastic effects are not well known at such low dose rates and it is likely that these values are well below the dose at which recognizable damage would occur. Nevertheless, all workers are unlikely to have the same sensitivity and we do not believe these limiting doses should be increased since no need for higher limits has been established.

The ICRP has very recently decreased its recommendation on the limiting annual dose to the [illegible] from 30 to 15 rem (IP80). While adequate protection against cataract of the lens of the eye might be provided by a higher maximum average annual dose than the 5 rem now allowed by U.S. guidance, no operational difficulty is reported with use of 5 rem as an annual limit (Ch79). That value is therefore retained in these proposals.

The threshold dose, protracted exposure, for [illegible] specification is now believed to be 400 rems. The lifetime dose allowed is 250 rems, considerably below the threshold. This is causing a problem. A limit of 5 rems/yr specifies that the average dose is maximum at about of 300 mg/cm^2, whereas the dose at 1000 mg/cm^2 is of greater interest.

The maximum annual dose for skin of the whole body is maintained at 30 rem, since a need for allowing higher doses has not been demonstrated. However, the current guide permits 75 rem annual doses to hands and forearms, or feet and ankles, because of the assumed lower risk when only these portions of the skin are involved. We agree that at low dose rates the risk of skin cancer depends on the amount of skin exposed, and that exposure of the hands is likely to be less dangerous than of other areas of the body. However, for forearms, feet, or ankles such a high value is not justified by need and we propose that the annual guide for doses to skin of the whole body (30 rem) include these extremities. For the hands alone a higher value appears to be justified by the need to work in glove boxes. We propose 50 rem, the limit recommended by the ICRP.

Measurement at 1000 mg/cm^2 would be allowed for photon energies > ___ KeV if the lens limit were raised to ___ rems/yr (___ rems in 30 yrs).

VII. SPECIAL EXPOSURE SITUATIONS

Previous chapters have addressed exposure of adults under normal conditions of exposure. We address some exceptions below. These include emergency and accidental exposures, exposure of workers from the activities of others, exposures for medical purposes (both those that are job-related and those that are not) and other non-occupational exposures, exposure of minors, and exposure of underground miners to radon decay products. There may be special circumstances other than emergencies for which exposures above the RPGs are justified. In addition, exposure limits may be required for periods other than one year, the period to which the RPGs apply, or for situations in which internal and external exposures are combined. We address each of these special exposure situations in turn.

Emergency situations are, almost by definition, unique. In Note 4 to the recommendations we choose not to provide numerical guides because of the great variability in the circumstances which may surround emergencies. Only the most general principles can be relied upon to provide useful guidance. These are provided by Recommendations 1 and 2. Additional guidance is also provided by Recommendations 7 and 8 that may be applicable to some emergency situations.

Accidental exposures may be high enough in some cases to require medical treatment. This guidance does not address such matters, which should be handled by medical personnel competent to deal with the acute effects of radiation exposure. We have not addressed the issue of whether

overdoses in one year should lead to additional restrictions on doses in future years. Such situations must be dealt with on the merits of each case and under the regulatory mandate of the responsible Federal agency (Note 5 to the Recommendations). We do not consider it either practical or reasonable to prejudge or prescribe general conditions for such situations beyond the general principles which apply to all radiation exposure contained in Recommendations 1 and 2.

In some situations workers are exposed to radiation from sources in locations not under the control of their employer, or due to contamination from previous use of the premises. In the former case these workers need not be considerd occupationally exposed, since existing laws require the owners of such sources to maintain doses in areas outside their control to levels acceptable for the general public. In the latter case workers are subject to regulations governing occupational exposure established under this guidance.

The question often arises whether or not private medical and other non-occupational exposures should be considered in radiation protection of workers. If there were a threshold for risk of health effects from radiation this could be an important consideration. However, since we assume that the risk at low doses is proportional to the dose, each exposure must be justified on its individual merits. For this reason in Note 1 to the recommendations we exclude medical and other non-occupational exposure from the assessment of occupational radiation exposure of workers.

In many jobs diagnostic x-ray examinations are a routine part of periodic or pre-employment physical examinations. Some of these examinations are a condition of employment and some are not. Federal

radiation protection guidance on use of diagnostic x rays was issued by the President on February 1, 1978 (En78). These recommendations provide that, in general, use of such x-ray examinations should be avoided unless a medical benefit will result to a worker, after consideration of the diagnostic yield, radiation risk, and economic factors. Although all of the recommendations in that guidance may be usefully applied to x-ray examinations of workers, Recommendations 1 through 4 are particularly pertinant. Because this matter has been addressed by separate Federal guidance, exposure from such diagnostic x-ray examinations is not included in this guidance for occupational exposure.

Current Federal guidance provides that occupational exposure of minors (those below the age of eighteen) be limited to doses one tenth those allowed older workers. Since no justification has been advanced or arises out of improved knowledge of health risks for either lowering or raising this guidance, in Recommendation 7 we propose no change.

No other general types of exposed workers are singled out for special protection by these recommendations. However, one special class of workers - underground uranium miners - is already subject to a separate Federal Guide (En71)(see Note 7 to the recommendations). This Guide limits their exposure to radioactive decay products of radon gas. The Mine Safety and Health Administration regulates exposure of all underground miners in accordance with this Guide. We expect to review the Guide for workers exposed to decay products of radon in the future.

Some situations may justify planned exposures exceeding the guides. The exposure of U.S. astronauts to doses exceeding the present quarterly limit is a recent example of such justified exposure (ref.). Recommendation 9 provides for such situations, but requires that

the responsible Federal agency fully consider the reasons for doing so on the public record, prior to any such exposures when possible.

The time period for which limits have been set has varied widely, from a daily basis for the first official limit recommended by the ICRP in 1934 (0.2 Roentgens per day) (ref.) to the current combination of a quarterly limit and the age-dependent annual limit of the 5(N-18) rule. In many cases the choice of time period can be considered largely a matter of administrative convenience, since only for potentially pregnant workers is there an adequate scientific basis on which to limit dose rate for the range of doses of interest here. In all but this case the proposed guides are expressed on an annual basis because this is the simplest choice available. Note 6 to the Recommendations provides that regulatory agencies may choose other periods for administrative reasons, if these are implemented in a manner consistent with the intent of the Guidance.

The proposed Guidance for internal exposure to radionuclides takes into account the additivity of risk when different organs of the body are non-uniformly exposed. These internal exposures may also take place in the presence of uniform combined external exposure of the whole body. In keeping with the principle of limiting the sum of all cancer risks (and consistent with current recommendations of the ICRP), the total risk should not exceed that allowed for external doses. When internal doses are due to intake of radioactive materials this limitation may be satisfied by following the condition on combined external whole body doses and intake of radioactive materials specified in Note 2 to the recommendations.

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APPENDIX A

Non-Linear Dose Responses in Human Populations

Leukemia data from the Life Span Study of Nagasaki survivors are often cited as an example of a nonlinear dose response in a heterogeneous human population, and these observations have been generalized to include most radiogenic cancers from low-LET radiation (Ro74, Ro78). We believe these data are insufficient to support any broad generalizations, since there are only five leukemia cases in the Nagasaki Life Span Study in the dose range between 5 and 100 rad (bone marrow dose) (Be78). As illustrated in Ge80 and other reports, such a small number of cases has such a large sampling variability that the observed response is consistent with a number of possible dose response models, including linear and quadratic.

In this regard, it is of interest to compare the leukemia experience among those Nagasaki survivors in the Life Span Study, which includes only 23 percent of those exposed at Nagasaki, with that of the larger Nagasaki Leukemia Registry. This registry contains 23 leukemia cases among those exposed to between 5 and 100 rad (bone marrow dose) (Be78). The Life Span Study contains only 5 cases in this dose interval. Since the neutron dose to bone marrow at Nagasaki was quite low in this dose range (less than 200 mrad), the dose response in both of these samples is mainly due to gamma (low-LET) radiation. Figure A1 (taken from Be78) shows the ratio of observed-to-expected leukemias in the Nagasaki Leukemia Registry and in

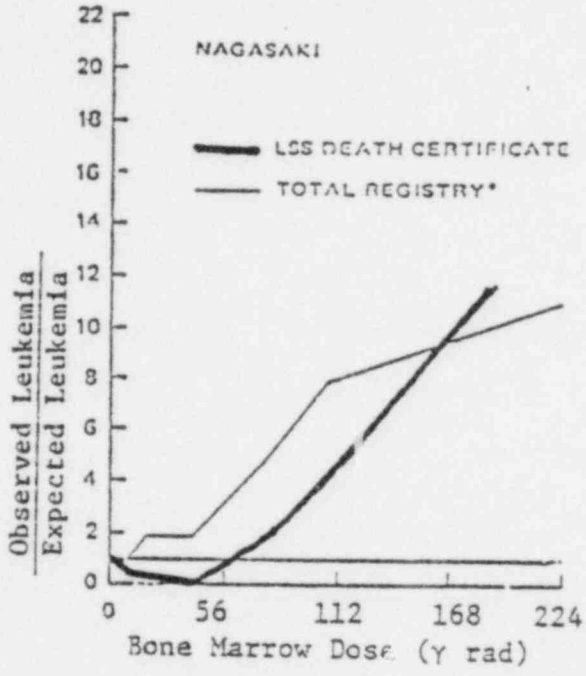

Figure A1. Dose response for leukemia in two samples of Nagasaki survivors. The Life Span Study results (mortality) contain 22 excess cases among persons exposed to more than 5 rads to the bone barrow. The Leukemia Registry (incidence) contains 86 excess cases among persons exposed to more than 5 rads to the bone marrow (Be78). In each sample, the expected (normal) number of leukemias is based on leukemia in low-dose survivors. The average bone marrow dose for those individuals is about 2 rads (Life Span Study) and 0.4 rads (Nagasaki Leukemia Registry)(Be78,Ke78).

the Life Span Study as a function of dose. The increased frequency of cancer as a function of dose for the larger tumor registry group looks quite different from the dose response in the Life Span Study. Both data sets are consistent with a linear response as well as a number of other possible relationships. In view of the variation between the larger and smaller samples, we are not sufficiently convinced by the available Life Span Study data to assume a reduced cancer response for low-LET radiation.

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APPENDIX B

The Radioactivity Intake Factors

Most occupational doses arise from external radiation and are to the whole body. However in some circumstances air or water containing radioactive materials can deliver doses to workers. Usually this occurs through breathing contaminated air. Occasionally it occurs through just standing in such air. Doses from contaminated water are extremely rare and almost invariably occur through accidental swallowing.

Doses from contaminated air or water are governed by where the radioactive materials go once they enter the body, and by how penetrating of human tissues their radiations are. Internal radiation usually does not affect the whole body equally and it is necessary to calculate where the radioactive materials go in the body and which organs and tissues their radiations penetrate. This depends, in part, on the metabolism and chemistry of the particular substance involved.

Over the past several decades our understanding of these processes has grown, and complex models have now been developed to determine the doses involved (IP79). These models have changed and have improved significantly since the current guidance was established in 1960 (IP59).

The results of calculations using these models are usually expressed in terms of the concentration of radioactivity in air or water that a "standard" man (IP75) would have to breath, stand in, or drink for a normal work week during an entire year to just meet the RPGs.

Table B1 shows the results of such calculations for radioactive substances in air for three different cases (Ec80). The table contains 48 examples encompassing the 26 most commonly encountered radionuclides. The first case is for the models used when the RPGs were established in 1960. The second shows the values obtained using the improved models now available, but retaining the 1960 RPGs. Of the 43 examples for which 1960 values exist, 23 are reduced, 5 do not change, and 15 are increased by the new models. The largest reduction is a factor of 17 (Uranium-234 and Uranium-235, Class Y), and the largest increase a factor of 7 (Strontium-90, Class D).

The last column shows the results for the proposed new guides, using the new models. Compared to the 1960 values, 21 are reduced, 6 do not change, and 16 are increased. The largest reduction is a factor of 14 (Thorium-232, Class Y) and the largest increase is a factor of 17 (Strontium-90, Class D).

It is clear from a more detailed examination of the results that the models play a far greater role in determing the values than the choice of which of these two sets of guides is used. We have chosen the "summation of risk" approach shown in the last column because it provides a more complete and consistent basis for risk limitation than the "critical organ" approach now in use.

Table B1. Maximum concentration of selected radionuclides in air (in millicuries/liter)[a]

Nuclide	Class[b]	Current Guides: 1960 Models[c]	Current Guides: New Models[d]	Proposed New Guides: New Models[d]
P-32	D	7(-8) bone	9(-8) red marrow	3(-7)
	W	8(-8) lungs	6(-8) lungs	1(-7)
Mn-54	D	4(-7) liver	4(-7) red marrow	4(-7)
	W	4(-8) lungs	3(-7) lungs	3(-7)
Mn-56	D	8(-7) LLI	4(-6) lungs	5(-6)
	W	5(-7) LLI	3(-6) lungs	5(-6)
Co-58	W	8(-7) LLI	2(-7) lungs	3(-7)
	Y	5(-8) lungs	1(-7) lungs	2(-7)
Co-60	W	3(-7) LLI	5(-8) lungs	5(-8)
	Y	9(-9) lungs	5(-9) lungs	8(-9)
Sr-89	D	3(-8) bone	1(-7) red marrow	3(-7)
	Y	4(-8) lungs	2(-8) lungs	4(-8)
Sr-90	D	3(-10) bone	2(-9) red marrow	5(-9) bone surface
	Y	5(-9) lungs	6(-10) lungs	1(-9) lungs
Zr-95	D	1(-7) whole body	3(-8) bone surface	3(-8) bone surface
	W		9(-8) lungs	1(-7)
	Y	3(-8) lungs	4(-8) lungs	7(-8)
Nb-95	W	5(-7) whole body	3(-7) lungs	4(-7)
	Y	1(-7) lungs	2(-7) lungs	4(-7)
Mo-99	D	7(-7) kidney	9(-7) liver	8(-7)
	Y	2(-7) LLI	3(-7) LLI	4(-7)
I-125	D		2(-8) thyroid	2(-8) thyroid
I-129	D	2(-9) thyroid	2(-9) thyroid	2(-9) thyroid
I-131	D	9(-9) thyroid	1(-8) thyroid	1(-8) thyroid
I-133	D	3(-8) thyroid	7(-8) thyroid	7(-8) thyroid
Cs-134	D	4(-8) whole body	4(-8) gonads	4(-8) gonads
Cs-137	D	6(-8) whole body	6(-8) gonads	6(-8) gonads
Ce-144	W	1(-8) liver	7(-9) liver	8(-9)
	Y	6(-9) lungs	2(-9) lungs	4(-9) lungs

Table B1. (Continued)

Nuclide/Class[b]		Current Guides: 1960 Models[c]	Current Guides: New Models[d]	Proposed New Guides: New Models[d]
Ra-226	W	3(-11) lungs	1(-10) .lungs	2(-10)
Th-228	W	9(-12).bone	2(-12) bone surface	2(-12) bone surface
	Y	6(-12) lungs	2(-12) lungs	5(-12)
Th-232	W	2(-12) bone	3(-13) bone surface	3(-13) bone surface
	Y	1(-11) lungs	7(-13) bone surface	7(-13) bone surface
U-234	D	6(-10) bone	3(-10) bone surface	3(-10) bone surface
	W		1(-10) lungs	2(-10)
	Y	1(-10) lungs	6(-12) lungs	1(-11) lungs
U-235	D	5(-10) kidney	3(-10) bone surface	3(-10) bone surface
	W		1(-10) lungs	2(-10)
	Y	1(-10) lungs	6(-12) lungs	1(-11) lungs
U-238	D	7(-11) kidney	4(-10) bone surface	4(-10) bone surface
	W		1(-10) lungs	2(-10)
	Y	1(-10) lungs	6(-12) lungs	1(-11) lungs
Pu-238	W	2(-12) bone	2(-12) bone surface	2(-12) bone surface
	Y	3(-11) lungs	4(-12) bone surface	4(-12) bone surface
Pu-239	W	2(-12) bone	1(-12) bone surface	1(-12) bone surface
	Y	4(-11) lungs	4(-12) bone surface	4(-12) bone surface
Am-241	W	6(-12) bone	1(-12) bone surface	1(-12) bone surface

a Exposure is assumed to continue for one year at the rate of 40 hours per week. When an organ is listed it is limiting and determines the value shown. If no organ is listed the value is determined by the sum of risk to all organs. Read 4(-7) as 4×10^{-7}. LLI means the large lower intestine.

b The letters D, W, and Y (days, weeks, and years) designating the class of the material in the first column of the table are rough measures of the amount of time the material remains in the lungs before elimination. This is mainly governed by the solubility of the chemical form of the radioactive material involved.

c ICRP-2 metabolic models, and intake and biological parameters for standard man (IP59).

d ICRP-30 metabolic models, and intake and biological parameters for standard man (IP75,IP79).

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