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Agency

Office of
Radiation Programs
Washington, D.C. 20460

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Radiation

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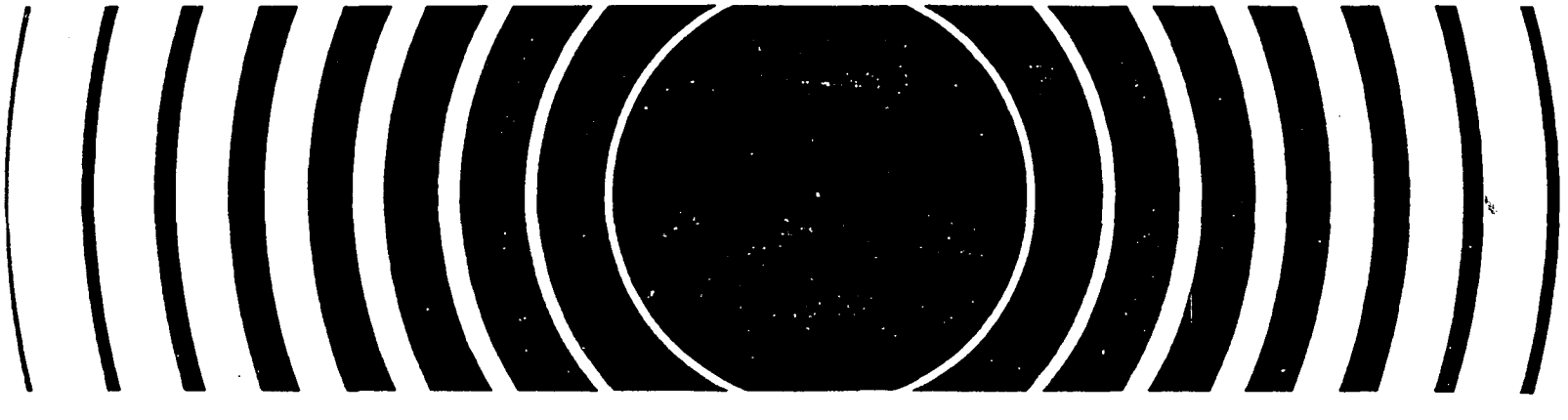
Federal Radiation Protection Guidance for Occupational Exposure

Response to Comments



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RESPONSE TO COMMENTS

FEDERAL RADIATION PROTECTION GUIDANCE

FOR OCCUPATIONAL EXPOSURE

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Office of Radiation Programs
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INTRODUCTION

The U.S. Environmental Protection Agency responds in this report to comments received on proposed Federal radiation protection guidance for occupational exposure (46 F.R. 7836, January 23, 1981). This guidance was proposed to replace those portions of existing Federal guidance (25 F.R. 4402, May 18, 1960) that apply to radiation protection of workers. EPA Background Report No. 520/4-81-003 of January 16, 1981, contains detailed information to supplement the text accompanying the EPA proposal published as a Federal Register notice.

The Agency appreciates the interest and effort of all those who submitted comments. They provided an essential part of the information and opinion that went into the formulation of the final guidance.

We have attempted to include all of the substantive comments received in writing and in public hearings. They have been grouped into three major sections and the topical categories and subcategories listed in the Contents. In preparing this report, we generally found it necessary to rephrase the language in order to combine similar comments into single statements. We gave care, however, to preserve the essential intent of each. A letter-number code (e.g., B.a-5) is used to identify the type and name of each commenter. The letters in the code indicate type of commenter: the first stands for one of six major categories (e.g., B for industry) and the second one for the subcategory (e.g., "a" for nuclear power) as shown on the Contents for Appendix A. The complete code can be used to find the individual commenter's name and address in that Appendix. The original documents are filed in EPA Docket No. A-79-46. The large size of this file precluded our including reproductions of these documents in this report.

The Agency's response follows each of the comments. We have made every effort to be as candid and as objective as possible in these responses, which reflect the information and judgments which resulted in the final Federal guidance.

CONTENTS

CONTENTS (Continued)

CONTENTS (Continued)

APPENDIX A

COMMENTER IDENTIFICATION

SECTION 1.0 — GENERAL COMMENTS

1.1 COMMENDATION, AGREEMENT, AND SUPPORT

1.1.1 The proposed guidance to reduce health risks from radiation is reasonable and supportable (A.a-18, A.a-36, A.b-22, A.b-25, A.C-7, A.d-15, B.c-3, D.1, E.a-7).

Response: We appreciate the comment and trust that the final guidance is also reasonable and supportable.

1.1.2 The intent of the guidance to reduce the health risk associated with exposure to ionizing radiation is a common goal (D-11, E.a-2, E.b-3).

Response: No response required.

1.2 TERMINOLOGY, CLARITY, AND ACCURACY

1.2.1 The proposed guidance contains incorrect or insufficient definitions, particularly those for "rem", "rad", "dose", "dose equivalent", "occupational exposure", "radiation worker", "collective dose", and "radioactivity concentration guide" (A.a-5, A.a-12, A.a-23, A.a-42, A.b-15, A.d-13, A.d-14, A.d-21, A.d-26, A.d-40).

Response: In the proposed guidance, terms were explained in a manner intended to be readily understood by the lay reader. The Agency was not recommending that definitions of established technical terms (such as the units of dose) be changed, and the final guidance continues that precedent.

1.2.2 The statement is made on page 7837 of the Federal Register (Vol. 46) that "cancer is fatal at least half the time." Does EPA mean that radiation induced cancer is fatal half the time, rather than all cancers (A.d-14, A.d-22, A.d-40, B.c-20).

Response: The statement refers to all cancers, and infers that the same is expected to be true of radiogenic cancers. See also the responses to comments 1.4.40 and 1.4.41.

1.2.3 Both SI units and conventional units should be used with conversion factors given for SI units (D.1, E.a-4).

Response: The Agency did not use SI units because they have not been officially adopted by the United States. However, this does not preclude any of the Federal agencies (or Agreement States) from using SI units in their regulations implementing new Federal guidance. The final recommendations are expressed in conventional units with corresponding values in SI units given in parenthesis.

1.2.4 Many items in this guidance are nebulous. For instance, should a worker be punished with job loss for a "higher-than-normal" exposure caused by the negligence of the licensee (A.a-5)?

Response: The preamble to the recommendations, the background document, and the responses to comments all contain clarifications of the intent of the guides. The example cited by the commenter is outside the scope of Federal guidance. However, when regulations that implement Federal guidance are not met, the appropriate action to be taken is the responsibility of the cognizant regulatory agencies.

1.2.5 The term "justify" in recommendations 1 and 4 is unacceptably vague (B.a-7, B.a-33, E.a-2, E.a-4, E.a-2).

Response: The Agency tried to avoid the use of vague terms in the final recommendations. This particular term, however, is discussed in some detail in the background report (EPA81), and has an accepted meaning in radiation protection, cf. ICRP-26 (Paragraphs 12, 68 and 69).

1.2.6 Disagreement with EPA by scientists will lead to a deterioration of EPA's "scientific credibility" if it implements the recommendations (A.d-25, A.d-35).

Response: There is ample evidence that scientists often disagree among themselves, particularly on matters concerning radiation protection. Adoption of ICRP-26 recommendations in the final recommendations is likely to eliminate existing disagreement with some scientists, while giving rise to new disagreement with others.

1.2.7 EPA should use the adopted units of becquerel (Bq) and sievert (Sv) (B.c-11).

Response: See the response to comment 1.2.3.

1.2.8 Literature citations in the background report often do not provide adequate support and justification for the guidance proposed (A.a-12, A.a-14, A.a-23, A.d-14, A.d-22, A.d-40).

Response: In general, literature references in the background report (EPA81) were used to identify the source of data and information cited in

that report. Such data and information were considered in making the value judgments resulting in the proposed guidance. However, these value judgments were not necessarily already made in the cited references.

1.2.9 The proposed guidance is too vague and difficult to follow (A.a-17, A.a-19, A.d-40).

Response: We disagree. We note that this proposed guidance is much more explicit than the guidance it would replace, and that for 25 years radiation protection authorities have generally succeeded in interpreting that guidance.

1.2.10 The background material for the proposed guidance omits several data points, including: the magnitude of worker total exposure (external plus internal) and its relationship to the 100 rem limit; magnitude of internal exposure; magnitude of forearm exposure; and the impacts of lowering external limits (E.b-6).

Response: The external exposure of workers is covered in detail by the report "Occupational Exposure to Ionizing Radiation in the United States: A Comprehensive Review for the Year 1980 and a Summary of Trends for the Years 1960-1985" (EPA-520/1-84-005) (Ku84). However, there is a paucity of national or international data on internal exposures. What data are available, however, indicate that the magnitude of those exposures in comparison to that of external exposures is small.

We have no data on external doses to the forearms, as such. We do have some data, however, on annual doses to "extremities," normally taken to be "hands and forearms." About half of those records showed no measurable exposure while less than 0.1% of them indicated exposures greater than 30 rems. Final recommendations specify an annual limit of 50 rems for extremities (i.e., hands and forearms, feet and ankles).

Impacts of the recommended limits are covered in responses to comments 1.9.1 through 1.9.18.

1.2.11 There is a clear need to monitor and regulate "non-nuclear" workers in the medical profession (A.c-8).

Response: We would agree that there are workers in the medical profession whose jobs may involve sufficient potential for exposure that they should be monitored even though they may not be directly involved in the administration of radiation to patients. Federal radiation protection guidance for occupational exposure applies to all workers exposed on the job. Regulatory agencies will incorporate the new Federal guidance, which includes a recommendation on monitoring, into their regulations. Thus, all workers who may be significantly exposed should be monitored and regulated in accordance with these recommendations.

1.2.12 EPA should stick to policy, not regulation (E.a-5).

Response: We agree. It is the responsibility of EPA to recommend the basic policies and standards for radiation protection related to occupational exposure; EPA does not regulate in this area.

1.3 ADEQUACY OF EXISTING GUIDELINES AND REGULATIONS - NEED FOR CHANGE

1.3.1 The current limits are adequate. EPA has not demonstrated a need for or benefits from any changes in the existing limits (A.a-6, A.a-11, A.a-14, A.a-15, A.a-17, A.a-20, A.a-21, A.a-23, A.a-24, A.a-25, A.a-26, A.a-27, A.a-28, A.a-29, A.a-30, A.a-31, A.a-32, A.a-33, A.a-34, A.a-35, A.a-41, A.a-46, A.a-52, A.a-53, A.a-54, A.b-4, A.b-10, A.b-12, A.b-15, A.b-16, A.b-19, A.d-1, A.d-5, A.d-6, A.d-7, A.d-10, A.d-13, A.d-14, A.d-16, A.d-18, A.d-19, A.d-21, A.d-22, A.d-25, A.d-26, A.d-28, A.d-29, A.d-31, A.d-33, A.d-35, A.d-39, A.d-40, B.a-2, B.a-3, B.a-4, B.a-6, B.a-9, B.a-11, B.a-12, B.a-13, B.a-14, B.a-15, B.a-17, B.a-18, B.a-21, B.a-25, B.a-27, B.a-28, B.a-29, B.a-31, B.a-32, B.a-34, B.a-36, B.a-37, B.a-38, B.a-39, B.a-44, B.a-47, B.a-48, B.a-54, B.b-6, B.b-7, B.b-22, B.c-9, B.c-10, B.c-12, B.c-13, B.c-14, B.c-16, B.c-18. B.c-20. B.c-22, B.c-23, C-2, D-6, E.a-2, E.a-3, E.a-5, E.b-3, E.b-4, E.b-8).

Response: We do not agree. The interagency review of occupational radiation protection confirmed that it was the unanimous opinion of Federal agencies that revision of existing Federal guidance, which was promulgated in 1960, was long overdue. Since that time knowledge of the effects of ionizing radiation on humans has increased substantially. We now have a greatly improved ability to estimate risk of harm to individual organs and tissues from radiation. As a result, some of the old numerical guides are now believed to be less, and some more, protective than formerly. Other risks, particularly those to the unborn, are now considered to be more significant, and were not addressed by the old guidance. These disparities and omissions are corrected by the new recommendations. The International Commission on Radiological Protection (ICRP) published, in 1977, new recommendations on radiation protection philosophy and limits for occupational exposure. These new recommendations are now in use, in whole or substantial part, in most other countries. We have considered these recommendations, among others, and believe that it is appropriate to adopt the general features of the ICRP approach in radiation protection guidance to Federal agencies for occupational exposure. In two cases, protection of the unborn and the management of long-term exposure to internally deposited radioactivity, we have found it advisable to make additions.

The relatively large number of commenters who advocate making no change perhaps reflect the adage that change is generally resisted. We believe that the new recommendations will result in improved radiation protection for occupationally exposed workers.

1.3.2 The guidelines and supporting data require further analysis (A.a-24, A.a-25, A.a-27, A.a-28, A.a-29, A.a-30, A.a-32, A.a-33, A.a-41, A.a-52, A.a-53, A.a-54, A.d-21, A.d-25, A.d-29, B.a-25, B.a-37, B.a-54, B.b-6, B.c-13, B.c-18).

Response: As promised, the Agency has carefully considered all oral and written comments in preparing its final recommendations. Additionally, the Agency requested and obtained the advice of representatives of the principal Federal and State agencies concerned, as well as of the National Council on Radiation Protection and Measurements and the Health Physics Society.

1.3.3 Since EPA's proposed guidance is more stringent than that of recognized national and international committees, the guidance should be substantiated by an impartial review board (A.b-20).

Response: There is neither a statutory requirement nor an existing institutional framework for such a review. The Agency itself serves the function of an impartial body, since it has neither a regulatory role for occupational exposure, nor is it a user of radiation. The proposed guidance was only marginally more stringent than the referenced international and national private advisory bodies. In any case, the issue is moot since the final recommendations are effectively the same as those of the ICRP, except for the recommendations addressing protection of the unborn, which incorporates the same overall limit as that advocated by the NCRP.

1.3.4 EPA should withdraw its proposed guidelines until input and approval has been obtained from all Federal agencies (A.d-31).

Response: EPA afforded opportunity for input from all affected Federal agencies during the formulation of the proposed guidance, during the public comment period, and during formulation of its final recommendations. There is no statutory requirement that EPA obtain "approval" from Federal agencies prior to submitting its recommendations to the President. Nevertheless, the Agency has requested and obtained concurrence of the Federal agencies on these final recommendations.

1.3.5 The proposed guidance is based on the criterion that no limit should be established at a value higher than experience shows is needed (B.a-8).

Response: No response required.

1.3.6 The existing guidelines are inadequate and should be revised (C-6).

Response: We agree, and have done so.

1.3.7 In some respects, the present RPGs appear to be too restrictive. Operational experience would not suggest unwarranted exposures to large numbers of workers (NUREG-0463, NUREG-0594, DOE/EV/007271) (E.b-4).

Response: We do not agree that present guides may be too restrictive just because few workers exceed the guides. The explicit intent of the guides is that no worker should exceed them.

1.3.8 EPA should immediately lower exposure limits by a factor of 10 to 50 (A.a-7).

Response: It is true that many occupational tasks can be carried out under lower exposure limits; however, some cannot. This is indicated by our studies of occupational exposure in 1975 (Cob80) and 1980 (Ku84) and by some comments (see the response to comment 2.1.9). For this reason the final guidance provides for such lower limits to be established as administrative control levels. See also the response to comment 2.1.9.

1.3.9 EPA's proposal does not go far enough; consideration should be given to engineering and personnel protection, rather than administrative controls (D-11).

Response: We agree that administrative controls alone are not sufficient, and that engineering safeguards and personnel-protective measures and devices are essential for properly protecting workers. They receive explicit mention in those parts of the guidance that concern keeping exposures ALARA. Their application, however, does not obviate the need for administrative controls.

1.3.10 The goal should be elimination of radiation exposure (A.a-5).

Response: We agree in the sense that a goal of automobile safety is the elimination of traffic deaths. However, the analogous goals of eliminating radiation exposure and traffic deaths are realized in a way that does not foreclose the benefits of using radiation and automobiles. In the same sense that the extremes of zero and unlimited speed limits are not acceptable, so also are we led to accept some range of risks in activities using radiation rather than forego desirable benefits. Thus, we seek the elimination of unjustified and unnecessary exposure while providing an upper limit on the maximum risk to individual workers through radiation protection standards.

1.3.11 The major thrust of new guidelines should be further education (A.d-19).

Response: We agree that adequate instruction of radiation workers and their managers is essential, and such a provision is included in the recommendations.

1.3.12 If exposure limits are changed, workers' confidence in their level of health protection would erode (A.d-39, B.a-21).

Response: We recognize the possibility of this occurring. However, the converse is also true. That is, if knowledge of risks changes and the limits do not reflect this, confidence would also erode. This is one reason for instructing workers and persons concerned with worker protection on the health basis for the recommendations.

1.3.13 EPA is dragging its feet in establishing new exposure guidelines (A.a-5).

Response: Admittedly, it has taken a long time for the Agency to recommend new guidance. However, from the very early stages (1974) of the review of existing guidance, it was apparent that there was no need for any drastic, or immediate changes to existing Federal radiation protection guidance for occupational exposure. This permitted the Agency to carry out studies and to consult with affected Agencies.

1.3.14 The existing limits are not being abused, yet there is sufficient latitudes to allow exposures up to 3 rems a quarter if the need arises. You have assumed that there is a significant amount of unjustified exposure, but the small percentage of workers with exposure over 5 rems per year does not support that premise (B.a-21).

Response: EPA did not assume or imply that there was a significant amount of unjustified exposure above 5 rems per year. In any case, any need to allow exposures up to 3 rems is not precluded by the new recommendation of 5 rems per year.

1.4 RISK

1.4.1 EPA risk estimates are based upon the linear dose-response model set forth in the 1972 BEIR (BEIR-I) report, and ignore the 1980 BEIR (BEIR-III) report which suggests that a linear-quadratic model is more appropriate, resulting in reduced risk estimates (A.a-18, A.a-19, A.a-31, A.a-38, A.a-40, A.b-1, A.b-3, A.b-17. A.d-9, A.d-14, A.d-16, A.d-21, A.d-25, A.d-31, B.a-1, B.a-12, B.a-18, B.a-21, B.a-29, B.a-30, B.a-44, B.a-24, B.c-12, B.c-20, B.c-22, E.a-7).

Response: The risk estimates for occupational exposure that were published in the background report (EPA81) were prepared before the 1980 BEIR-III report, "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation: 1980" of the National Academy of Sciences (NAS), was published (NAS80). The Agency has now updated these estimates. In doing so, we have used the age-dependent risk coefficients for a linear response given in the BEIR-III report. Our use of the BEIR-III report for risk

estimates is described in the document, "Radionuclides - Background Information Document for Final Rules - Volume I," EPA 520/1-84-022-1 (EPA84a), in which the Agency's choices between the various models proposed by the BEIR-III Committee are examined in more detail than outlined in this response to comments.

To allow for an assumed lesser response at low doses and dose rates, the 1980 NAS BEIR Committee based its "preferred risk estimates" on a hypothetical linear-quadratic dose response function. The Committee made this choice after examining, analytically, the cancer mortality data (and particularly the leukemia mortality data) for A-bomb survivors on the basis of three dose response functions: linear, linear-quadratic and quadratic. The Agency believes only the first two of these functions are compatible with data on human cancer. A quadratic response function has been shown to be inconsistent with the observed excess risk of solid cancers at Nagasaki, where the estimated T65 gamma-ray doses are not seriously confounded by an assumed neutron dose component. The chance that a quadratic response function underlies the excess observed in the Nagasaki incidence data for solid cancers is only one in ten thousand (Wab83).

Although a quadratic response function is not incompatible with the observed leukemia incidence at Nagasaki, Beebe and others (Be78, E177) have pointed out how unrepresentative the Nagasaki Life Span Study Sample on leukemia is, in comparison to the observed dose response for total leukemia experience in that city. Moreover, even for the total A-bomb Survivor Life Span Sample there is no evidence that a quadratic response function provides a better fit to the observed leukemia excess than a simple linear model (NAS80). The Agency does not believe a quadratic response can be used in a serious effort to estimate cancer risks due to ionizing radiation.

Although the majority of the members on the BEIR-III Committee "preferred" a linear-quadratic response in 1980, we believe the quantitative basis for this judgment is considerably weaker now because of the subsequent reassessment of the A-bomb dosimetry. The Committee's analysis of dose response functions assumes that most of the observed excess leukemia (and solid cancer) among A-bomb survivors was due to neutrons (NAS80). Current evidence, however, is conclusive that neutrons were a minor component of the dose in both Hiroshima and Nagasaki (Bob82, RERF83, RERF84). Therefore, it is likely that the linear response observed among the A-bomb survivors, which the BEIR Committee largely attributed to neutrons was, in fact, due to their gamma dose, not a dose of high LET radiation (EPA84a).

Although there is evidence for a nonlinear response to low-LET radiations in some, but not all, studies of animal radiocarcinogenesis, the Agency is not aware of any data on human cancers that is incompatible with a simple linear model. In such a case, we believe it is preferable to adopt the simplest hypothesis that adequately models the observed radiation effect. Occams' razor is still a viable scientific rule for separating necessary from ad hoc assumptions. Moreover, EPA believes that risk estimates for the purpose of assessing radiation impacts on public

health should be based on scientifically credible risk models that are not likely to understate the risk. Given the current bias in the doses assigned to A-bomb survivors, such an approach seems particularly reasonable, as well as prudent. Therefore, the estimates of the risks of radiogenic cancer presented below are based on an assumed linear response.

The Agency also does not assume that only doses above some unspecified threshold level can start the chain of molecular events that lead to cancer and hereditary defects. We note that neither the International Commission on Radiological Protection (ICRP) nor the National Council on Radiation Protection and Measurements (NCRP) have adopted a nonlinear dose response function or a threshold hypothesis as the basis for recommending limits to avoid stochastic damage due to occupationally-incurred exposures. While retaining a linear response function, both groups have, however, either explicitly or implicitly assumed that the carcinogenic effects of radiation are, like radiogenetic effects, reduced at low dose rates. In particular, NCRP Committee 40 has suggested that the carcinogenic effects of low-dose and low-dose-rate exposure to low-LET radiations may be a factor of 2 to 10 times less than that observed at high doses (NCRP80).

The low-dose, low-dose-rate effectiveness factors developed by NCRP Committee 40 are based on their analysis of a large body of plant and animal data that showed reduced effects at low doses for a number of end-points, including (to a lesser extent) radiogenic cancer in animals, chiefly rodents. However, no human data confirm these findings. A few human studies contradict them. Highly fractionated small doses to human breast tissue are apparently as carcinogenic as large acute doses (NAS80, Laa80). Furthermore, small acute doses (less then 10 rad) to the thyroid are as effective per rad as much larger doses in initiating thyroid cancer (UN77, NAS80). Moreover, the increased breast cancer due to chronic low dose occupational gamma ray exposures among British dial painters is comparable to, or larger than, that expected on the basis of acute high dose exposures (Ba81). While none of these examples are persuasive by themselves, collectively they indicate that it may not be cautious to estimate cancer risks due to low doses and low dose rates on the basis of an assumed reduced effectiveness of low doses compared to observations at large doses.

The Agency notes that the ICRP risk estimates for cancer assume a dose rate effectiveness factor of 2.5. Moreover, cancer risk estimates for occupational exposure based on the BEIR-III linear quadratic model are 2.4 times smaller than those based on their linear model. Except for breast cancer, it is possible that a linear model does overestimate the risk due to low-dose-rate low-LET exposures. If so, estimates based on the BEIR-III linear model would be conservative. However, the Agency has reservations concerning the adequacy of BEIR-III linear-quadratic risk estimates, due to the errors in the dose estimates the Committee used for the A-bomb survivors (EPA84a) and its assumptions regarding the transferability of animal data to humans. Selection of the Committee's linear response estimates minimizes these sources of bias in the BEIR-III Committee's risk estimates.

Risk estimates for fatal cancer based on the 1980 and 1972 BEIR reports are compared in Table 1. These estimates assume exposure at a dose rate of 5 rad per year of low-LET radiation from age 18 to 65 (U.S. Life Tables: 1969-71, NCHS75). They were obtained using a life table methodology to account for age dependence of risk, and to correct for the effect of competing causes of death (Bu81). A linear response is assumed in both sets of calculations. Following BEIR-III, the expression period for leukemia is assumed to be 25 years, after a minimum induction period (mip) of two years. After a ten year mip, a balance of lifetime expression period is assumed for solid cancers (NAS80). Risk estimates that assume that radiocarcinogenesis is reduced by a factor of 2.5 at low dose rates (or an equivalently model, such as the BEIR-III linear quadratic dose response function) would be 40% of those listed in Table 1.

Table 1. Estimated probability of fatal cancer due to continuous exposure to low-LET radiation at 5 rad per year from age 18 to 65

	Relative Risk[a] Projection		Absolute Risk Projection	
	Males	Females	Males	Females
NAS-80 (BEIR-III)	0.066	0.091	0.035	0.050
NAS-72 (BEIR-I)[b]	0.064		0.027	

[a] Absolute risk used for leukemia and bone cancer; all other cancers based on relative risk.
[b] Average for both sexes

For comparison, the balance-of-lifetime probability of cancer in U.S. males and females at age 20 was 0.17 and 0.16, respectively, in the year 1970. From Table 1, it is seen that risk estimates for male workers based on the NAS BEIR-III estimates are quite comparable to those provided (average for both sexes, only) in the 1972 NAS BEIR-I report; while for women, the newer risk estimates are somewhat larger.

Table 1 refers to cancer mortality, not cancer incidence. Although some have argued that cancer incidence is a better indicator of cancer risk than is fatal cancer (NAS80), the Agency has continued to use cancer fatality as its index of radiogenic risk for several reasons. The mortality data for radiogenic cancer is more extensive than that for incidence. (This may change fairly soon when the Hiroshima A-bomb survivor cancer incidence data is published.) A second reason is that comparisons of risk between industries should be made using a common end point. Mortality estimates meet this criterion. Comparisons between the number of industrial accidents and the total number of radiogenic cancers are not

meaningful. Comparisons based on days of employment lost may be better, but are still not a true measure of impact. It should be noted, however, that the estimated total number of cancers due to occupational exposure is considerably greater than the estimated number of fatal cancers. Incidence is estimated as being about 54% greater than mortality for males and 100% greater for females in NAS80. The difference between the sexes is largely due to the much higher incidence of radiogenic thyroid cancer (20% mortality) and breast cancer (39% mortality) in females (NAS80).

1.4.2 From the large variety of studies on radiation-induced cancer, the best current dose-response relationship for cancer risk is described by a shallow linear component at low levels and a curvilinear or quadratic component at intermediate and high levels (B.a-40).

Response: The linear-quadratic response risk coefficients in the NAS BEIR-III lead to risk estimates for occupational exposure that are smaller by a factor of about 2.5 than those shown in Table 1 (see comment 1.4.1.) It is possible that at low doses (and low dose rates) the induction of some forms of human cancer is reduced. However, the only human cancer for which there is enough data to test this hypothesis, breast cancer, indicates that any quadratic component in the dose response is negligible and in fact may be negative (Lac83). Examination of cancer incidence for all solid cancers at Nagasaki leads to a similar conclusion (Wab83).

The Agency does not know of any human data on radiogenic cancer at low doses that is appreciably more consistent with a linear-quadratic dose response function than with a simple linear response function. Some data sets, such as that for the radium dial painters, do show a quadratic component at extremely high doses. In contrast, other studies, such as the one on U.S. uranium miners, show a reduced effect per unit dose in the high dose range. However, these perturbations occur at doses too large to be of regulatory concern for occupational exposure. The Agency acknowledges that the precise shape of the dose response function for chronic exposure in the normal range of occupational exposure is unknown. In this range of exposure, both the linear and linear quadratic hypotheses assume no threshold and a proportional response between dose and effect. The difference between the calculated risks using these two models, about a factor of 2.5, is smaller than the uncertainty as to what the risk actually is. See also the responses to comments 1.4.1 and 1.4.25.

1.4.3 In the region from natural background radiation rates to the occupational annual limit of 5 rem/yr, the overall cancer mortality risk is in the range of 1×10^{-5} to 5×10^{-5} per rem (B.a-40).

Response: The above estimate of mortality risk appears to be derived on the basis of the 10^{-4} lifetime risk estimate for occupational exposure described in ICRP Publication 26 and the Dose Rate Effectiveness Factor (DREF) discussed in NCRP Report No. 64. This NCRP Committee said "The effectiveness per unit dose of high vs. low dose-rate exposure ranges from

a factor of about 2 to about 10. However, it is incorrect to apply the NCRP DREF to the ICRP Publication 26 risk estimate, since this risk estimate already includes a dose rate reduction factor of 2.5, based on the limited analysis of leukemia mortality among A-bomb survivors presented in UN77. See also the response to comment 1.4.1 and the document referenced as EPA84a.

1.4.4 Use of the BEIR-III dose-response relationship, rather than the EPA risk model, results in a risk from occupational exposure to radiation which is a factor of 1.5 to 2.2 times lower than the EPA estimates, and is a more appropriate risk model than that used by EPA (A.b-17. B.a-30).

Response: The actual difference between the BEIR-III linear and linear-quadratic models is a factor of 2.5. See the responses to comments 1.4.1 and 1.4.2.

1.4.5 The linear hypothesis probably overstates the risk by a factor of two to ten for low doses and low dose rates (B.a-13, B.a-30).

Response: This comment apparently refers, by implication at least, to conclusions reached in NCRP Report No. 64. This report is considered in the response to comment 1.4.1.

1.4.6 The linear, nonthreshold dose-response hypothesis is merely a theory, and should not be used as the basis for setting lower occupational exposure limits (A.a-12, A.d-40).

Response: The ICRP, the NCRP, and the United Nations Scientific Committee on the Effects of Atomic Radiation, as well as EPA, estimate radiation risks based on this hypothesis. Moreover, we know of no human data that seriously conflicts with the linear, nonthreshold hypothesis. It is a prudent hypothesis for evaluating radiation risks.

The Agency does not believe use of a linear, nonthreshold response function to evaluate radiation risks is unduly conservative. The late Dr. Walter Snyder, a respected senior radiation protection scientist at the Oak Ridge National Laboratory, summarized the case for linearity many years ago in testimony before the Joint Committee on Atomic Energy: "Those who prefer to base radiation protection on a threshold hypothesis, which is just as unproven and just as uncertain and unsupported by data as is the linear hypothesis, often charge the linear hypothesis is too conservative. There is no evidence...that it is conservative at all. However, one may wonder why it is considered so undesirable to use a conservative criterion where human life is in question. Surely if the linear hypothesis is conservative and is not in conflict with the data that are available, this is a point in its favor. When human life is in the balance, it would seem that conservatism in safeguarding these lives has much to commend it." (Sn67).

1.4.7 EPA's estimate of an increased risk of 3 to 6 in 100 of dying from occupational exposure to radiation at the maximum hypothetical lifetime limit of 235 rems is based on conservative assumptions and is likely to be an overestimate (E.a-5).

Response: We have tried to be reasonably conservative in our choice of a dose response function. (See responses to comments 1.4.1, 1.4.2, and 1.4.6, above.) However, given the current uncertainties in risk estimation, the likelihood that risks due to radiation have been either overestimated or, less likely, underestimated cannot be established. Current data supports the use of a relative risk model, indicating the maximum occupational risks may be nearer the higher estimate than the lower one (Ka82, Jaa83).

1.4.8 Risk estimates based on linear extrapolation from high doses do not provide realistic estimates of actual risks from low-level, low-LET radiations (A.a-13, A.d-13, E.a-5).

Response: See the responses to comments 1.4.1, 1.4.2 and 1.4.7.

1.4.9 The 1980 BEIR report, as well as other published studies, were not able to demonstrate effects at the level of current limits (A.d-31).

Response: Current limits were set with the expectation that any increase in detrimental health effects due to allowed exposures would be so small as to be hidden by normal biological variations (ICRP64, NCRP71). We agree that, in this regard, current guidance and the use of the ALARA principal have been successful. Nevertheless, excess breast cancer has been observed among occupationally exposed workers (Ba81). Although the Agency hopes the result of this study is not confirmed by studies of other exposed groups, we do not believe it is in the public interest to be sanguine on this point.

1.4.10 There are no demonstrated somatic or genetic effects at low levels of radiation (A.a-17, C-2).

Response: If by low levels of radiation one means dose rates comparable to background radiation, 0.1 rad per year, this statement is true. Dose-response models are used to interpolate between the lowest exposures at which excess cancer has been observed and exposure levels due to background. This is reasonable, since there is no reason, a priori, to conclude that risk is zero even when it cannot be demonstrated statistically. It is unlikely that a study of a large enough group of animals or persons can be mounted to irrevocably answer this question. However, the data on excess cancer due to in utero exposure indicate that single doses as low as a few hundred mrem may cause cancer (St73, Ha75)

and occupational exposures of a few rems per year are likely to be the cause of increased breast cancer (see the response to comment 1.4.9). The Agency believes it is likely that some radiation risk does accrue from even very low levels of exposure.

1.4.11 There is no evidence to indicate that biological risk factors are any higher than they were considered to be when current guidelines were promulgated (A.d-31).

Response: The comment does not reflect what was known about risk factors when the current guidelines were promulgated in 1960. This was well before any numerical risk estimates for radiogenic cancer became available. The first comprehensive and quantitative discussion of radiation risks, those of the NAS-BEIR Committee, was published in 1972. The first explicit risk estimates by the Federal Radiation Council were made in their 1962 report on health implications from fallout.

1.4.12 In its risk estimates, EPA should correct surface doses to mean whole-body dose, which would result in lower risk estimates by at least a factor of two (A.b-17, A.d-22).

Response: Like the NAS BEIR-III Committee, the Agency uses organ doses, not surface doses, as the basis for its risk estimates. It is true that occupational exposures are often regulated in terms of the dose measured at or near the body surface. Depending on how penetrating the radiation is, the dose to body organs may be quite comparable or in some situations, such as for diagnostic radiation and deep organs, substantially less. This is a problem related to implementing the Federal Guidance, not risk estimation. We see no merit in specifying a "mean whole-body dose". A weighting system that considers the difference in the radiosensitivity of various organs as proposed in ICRP 26 and adopted in this guidance is preferable.

1.4.13 EPA's risk-estimating methodology is flawed because one-half of the calculated cancers occur past the average life expectancy; also, the dose received later in life is less likely to have a genetic effect (A.a-12).

Response: The comment is not correct; the Agency's risk-estimating methodology does not contain such flaws. In 1978, the Agency developed a life-table methodology for cancer risk estimation to avoid the problem cited in this comment (Coa78, Bu81). It has subsequently been adopted by other Federal agencies and was used by the BEIR committee to prepare their 1980 report. The EPA lifetable analysis accounts for exposure, minimum induction period, and the period of expression across a full life span, as well as for all of the competing risks leading to other causes of death (Bu81).

Our genetic risk estimates are based on accumulated dose to age 30, which is the midpoint of reproductive activity. The total genetic risk, including that due to doses received past age 30, is then estimated from the mean accumulated dose at age 30 to the gonads of persons having children.

1.4.14 There is no scientific support for the assumption that all radiation exposure is harmful (B.a-54). Indirect evidence suggests that there is a threshold value of radiation below which it is harmless (A.c-6).

Response: Most radiation scientists, including all of those on the NAS/BEIR-III Committee, support the use of a nonthreshold hypothesis for estimating the likelihood of radiation-induced cancer and hereditary effects. The Agency follows the criterion for the use of risk estimates outlined in 1972 BEIR report (p. 96); "If the intent of authorities is to minimize the loss of life that radiation exposure may entail, they must, indeed, be guided by such estimates, and will not rely on notions of a threshold." While the lack of a threshold is unprovable experimentally, we know of no indirect evidence for a threshold for radiogenic cancer or hereditary effects. See also the responses to comments 1.4.6, 1.4.9, and 1.4.10.

1.4.15 EPA does not consider the mounting evidence that at low levels, radiation may even be beneficial (A.a-31, A.a-46, A.d-35, B.c-22).

Response: The Agency is familiar with reports of the beneficial effects of radiation, often referred to as radiation hormesis. The hormetic action of radiation, and a number of other nonspecific hormetic stimuli, is usually seen in an animal population reared under sub-optimal conditions i.e., a high intercurrent infectious disease level. However, there is no demonstrated hormetic affect on tumor induction or the aging process. Hence, the risk of premature death due to radiation induced cancer presented in the Background Report would be unchanged by consideration of hormesis. This conclusion is largely based on the discussion of radiation-induced hormesis presented in "Handbook of the Biology of Aging" (Saa77).

1.4.16 There are no nonstochastic effects at an exposure level of 15 rem/yr, and the stochastic effects are independent of dose rate (A.a-41).

Response: The purpose of nonstochastic limits is to prevent the occurrence of impairment due to a large amount of cellular damage by limiting the rate at which radiation injury occurs. It is presumed that at low dose rates cellular repair prevents any manifestation of nonstochastic effects.

Not all stochastic effects are dose rate independent. For example, genetic injury is believed to be dose rate dependent at exposure rates greater than 0.8 R/min [NAS80, p.107]. As noted in the response to

comment 1.4.1, the Agency agrees that it is prudent to assume that the probability of inducing fatal cancer is likely to be independent of dose rate.

1.4.17 The linearity assumption for genetic effects is erroneous, because dose rate exerts a significant influence on the hereditary effects of a given radiation dose (B.a-42).

Response: The variation in genetic response with dose rate does not confound the linear dose response relationship at low dose rates (BEIR-III p.113). The Agency agrees that for low-LET radiations, genetic risks are somewhat less for chronic than for acute exposures. This has been taken into account in the Agency's estimates of genetic damage (EPA81, EPA84a). However, there is a limit to how much genetic risks are reduced at low dose rates. Dose rate effects for genetic risk estimations have not been noted at exposure rates less than 0.8 R/min [NAS80, p.107]. Few occupational exposures are expected to occur at higher dose rates.

It should be noted that the genetic risk estimates published in the background report (EPA81) may be underestimates. The genetic risk estimates were based on the 1972 BEIR report which assumed the sensitivity of the oocyte was near zero. The BEIR-III committee assumed the female (oocyte) was about 40% as sensitive as the male (NAS80). More recent studies have reported that the male and female are equal in sensitivity (Doa83, Dob84). See the documents referenced as EPA84a for a more complete discussion of current EPA genetic risk estimates. See also the response to comment 3.8.51.

1.4.18 It is a prudent and conservative approach, for regulatory purposes, to assume a linear, nonthreshold dose-response model (B.a-38, B.a-40, B.a-41).

Response: The Agency agrees.

1.4.19 EPA does not call attention to the weaknesses of the 1980 BEIR report, and in particular, its failure to note the biases in the supporting data (A.b-25). BEIR-III's numbers are not firm and they don't really allow you to set firm guidelines for safety (A.d-25, A.b-4).

Response: Strengths and limitations of the 1980 BEIR-III report are described in EPA84a and in the response to comment 1.4.1 above. The Agency believes it is the best available source of information, but that it must be interpreted carefully in terms of more recent information (see the response to comment 1.4.1 and reference EPA84a).

1.4.20 Based on the work of Bross, Mancuso, Morgan, and Rotblat, the risk factors are higher than those derived from the Japanese studies; therefore, the linear hypothesis is nonconservative (A.a-4, A.c-6, C-6).

Response: While a "supra-linear" dose response for low-LET radiations at low dose and dose rates has been postulated by some, almost no quantitative data have been presented. The hypotheses proposed by Bross, Mancuso, Morgan, and Rotblat have not been corroborated by other investigators. The cited studies are often based on preliminary data, unknown or incomplete exposure data, confounding with chemical and industrial carcinogen exposure, short follow-up, etc. The Agency is familiar with these works as well as those which contradict them. The linear, nonthreshold hypothesis still appears to be the prudent approach to use in assessing the maximum risks permitted by radiation protection standards.

1.4.21 Exposure at EPA's proposed limits for bronchial and female breast tissues would at least triple the lifetime risk of lung cancer for nonsmokers, and almost double the lifetime risk of breast cancer (A.a-38). The doses of low level radiation currently permitted by NRC standards cause at least a doubling of the risks of leukemia, lung cancer and other fatal and nonfatal diseases (A.a-4).

Response: The Agency believes consideration of the estimated fatality due to all radiogenic cancers, as shown in Table 1 at comment 1.4.1, is a better indicator of occupational risks than the potential increase of any particular cancer. If a radiogenic cancer is of a type common in the U.S. population, the percentage increase due to radiation is smaller than for a relatively rare cancer; yet the numerical impact is larger. For example, the Agency has calculated breast cancer mortality for a dose of 5 rems per year for age 18 to age 65. (An annual dose to the breast that exceeds the whole-body dose limit is unrealistic.) The results of a life-table analysis using the data in tables A-4 and V-15 of NAS80 are shown in Table 2 below. These indicate that the estimated increase of fatal breast cancer due to the unrealistically high assumption of a lifetime exposure at 5 rads per year is 50 to 80%.

The comment concerning the probability of lung cancer due to occupational exposure appears to assume the Agency's risk estimates for the entire population may be applied directly to smokers and nonsmokers considered separately. As there is yet insufficient data on radiogenic lung cancer to calculate separate risk coefficients for smokers and nonsmokers, the risk coefficients used in NAS80 and those used by EPA are average values for smokers and nonsmokers combined. Moreover, they are based on mortality data for males. Table 2 compares the ambient risk of lung cancer among U.S. males with the increased risk due to 5 rems per year from age 18 to 65 (U.S. Life Tables: 1969-71, NCHS75). At this dose rate, the risk of radiogenic lung cancer is appreciably smaller than the normal risk for the U.S. male population as a whole. For leukemia, the increased probability of induction by the maximum allowed occupational exposure compared to normal incidence is much greater than for radiogenic breast or lung cancer, see Table 2. Because of these differences between cancer types, the Agency believes the estimated total of all fatal cancers (See Table 1 in the response to comment 1.4.1.) is the best index of increased cancer mortality.

Table 2. Lifetime probability of fatal cancer due to continuous exposure giving 5 rems per year from age 18 to age 65

Cancer	Increase in Lifetime Probability (5 rems per year)		Normal Lifetime Probability at age 20 (no occupational dose)
Breast (female)	0.024[a]	0.016[b]	0.03
Lung Cancer (male)	-----	0.014[b]	0.052
Leukemia (male)	-----	0.011[b]	0.0066
Leukemia (female)	-----	0.0085[b]	0.0060
All Cancer[c] (male)	0.066[a]	0.035[b]	0.17
All Cancer[c] (female)	0.091[a]	0.050[b]	0.16

[a]Based on a relative risk projection and a linear dose response model.
[b]Based on an absolute risk projection and a linear dose response model.
[c]Including leukemia.

1.4.22 Because of new evidence concerning dosimetry to be applied to dose-response results for the Hiroshima A-bomb survivors, EPA's risk estimates must be recognized as too low (A.a-38). New guidelines should be delayed until the questions regarding the Hiroshima-Nagasaki dosimetry are resolved (A.a-19, A.b-16, A.d-14, A.d-22, A.d-27, A.d-33, E.a-4).

Response: In view of the current uncertainty concerning the doses to individual A-bomb survivors, we believe it is premature to categorize our risk estimates as either too low or too high. While the neutron doses (in air) from the Hiroshima weapon were probably much smaller than assumed in the 1980 BEIR report and other contemporary analyses, new estimates of organ doses due to gamma radiation are somewhat larger for unshielded survivors (RERF 83, 84). Final resolution of this question will depend on the doses to individual survivors, most of whom were not in the open, but shielded. We do not expect, however, that large changes will occur in risk estimates. In any event, EPA risk estimates will be re-evaluated as new data becomes available and are conservative to the extent that they are based on an assumed linear nonthreshold response, rather then the linear quadratic dose response proposed in the 1980 BEIR report.

1.4.23 The potential impact of the revised Hiroshima dose estimates does not justify any delay in the development of new radiation guidance or regulations (E.a-6). The reexamination of the Hiroshima data is not expected to significantly alter current dose-effect estimates (A.d-13).

Response: The Agency concurs to the extent outlined in the response to comment 1.4.22.

1.4.24 The existing data base relating to risk is adequate for judgments relating to radiation guidelines (B.a-40).

Response: The Agency agrees to the extent outlined in the response to comment 1.4.22.

1.4.25 Direct observations of human populations under 20 rad are not going to improve the risk estimates (B.a-41).

Response: Whether this is true or not depends on the size of the population under observation and how frequently cancers of a particular type are observed in an unexposed population (see Laa80, Lab80). Nevertheless, compatibility of observations at less than 20 rads with those at higher levels are of interest even if they have low statistical significance. This is because they still can provide information on the shape of the dose response curve. For example, breast cancer incidence among the Atomic Bomb survivors at doses less than 20 rad (low-LET) is compatible with a linear projection of the incidence observed at much high doses. This sets a limit on how much the response at high dose might be increased by a dose squared response. It is anticipated that longer follow-up periods will clarify this result for other radiogenic cancers.

1.4.26 The time has come to answer the question of health effects at occupational levels of exposure based on observed scientific data, rather than on estimates, assumptions, and hypotheses (A.a-4, A.a-13). No one has been identifiably injured by ionizing radiation while working within the existing standards (B.a-1).

Response: The absence of observed excess cancer in most occupationally exposed groups is evidence that current regulations and health physics practices are sufficient to keep the detriment due to radiation below uncertainties due to normal variation in nonradiogenic cancer introduced by sampling variation and normal population variability. However, the experience of the early radium dial painters illustrates that estimating risk on the basis of observation at higher doses and modeling assumptions is a small price to pay compared to the ultimate cost inherent in basing radiation protection limits on a requirement that detriment be observed before establishing adequate protection. See also the response to comment 1.4.10.

1.4.27 Animal data from inbred strains, although not used for absolute values of risk, provide information vital to our understanding of radiation effects (A.d-22).

Response: Animal data can provide insights into possible carcinogenic processes. However, in view of the heterogeneity of all human populations, we believe considerable caution must be exercised when drawing conclusions from observations on irradiated animals - particularly inbred strains of laboratory animals. Results of animal studies must also be examined carefully to determine if comparable physiologic and metabolic systems occur so that results can be extrapolated to man in a rational way. It is often difficult to interpolate between different strains of even the same species for similar insults.

Extrapolation to other species requires very considerable caution and qualification, particularly when large differences in life span are involved. Those who perform animal studies are usually careful to indicate that the comparatively large risks per unit dose observed in some studies should not be applied to estimates of human risk. Yet they generally fail to present evidence that such increased sensitivity is unrelated to other physiological parameters that affect interspecies comparisons. For example, inbred species which are much more prone to radiogenic cancer than humans often show a quadratic response beginning at 100 rad or so (NCRP80). No evidence has been published indicating why a quadratic response in the less radiosensitive human species would a priori begin at a comparable dose level.

1.4.28 The Bross reanalyses of the Tri-State study adult leukemia data are flawed by an erroneous statistical analysis, a correct version of which leads to results which are so statistically indeterminate as to be meaningless (B.a-41).

Response: The Agency did not base estimates of occupational radiation risks on the study referred to above. See also the response to comment 1.4.20.

1.4.29 Since we have no way of preselecting the individuals most susceptible to radiation effects, limits set to protect these individuals will be set unrealistically low for the majority of workers (A.d-31). The thesis of significant variation in radiosensitivity used in EPA's background report is not supported by any quantifiable data, and in any case, hypersensitivity should not be used as a factor in risk estimation of large populations (A.b-17).

Response: The recommended level was not chosen based on estimates of risk to highly susceptible individuals. Nevertheless, it is useful to recall the heterogeneity of human populations when drawing conclusions from the shape of the dose response function observed in studies with animals (see the response to comment 1.4.22). The purpose of the discussion in the Background Report (pp. 43-44) was to highlight the uncertainty of using data from inbred animal strains. It also points to the possible lack of conservatism for estimating the risk to particular individuals using the linear dose response models. To the extent that a portion of an exposed

population is significantly more sensitive to radiation than the average, a linear response function does not provide an estimate of upper limit of the risk. However, observations on exposed human populations to date, which presumably are a cross section of the human condition, are compatible with a linear response function (Wab83).

1.4.30 We do not know that the range of sensitivity of individuals is as extreme as that quoted in EPA's background document (A.d-22).

Response: The discussion of the possible consequences of population heterogeneity in the background document is illustrative, not quantitative. (See also the response to comment 1.4.29).

1.4.31 It would seem prudent to avoid occupational exposure in the radiation sensitive subpopulation rather than lower the maximum permissible exposure (B.a-52).

Response: Adequate techniques to identify sensitive or unique subpopulations have not been developed. (See also the response to comment 1.4.30).

1.4.32 EPA should consider in its risk estimates the genetic as well as the somatic risk (A.a-3).

Response: EPA's assessment included consideration of genetic risk.

1.4.33 Genetic damage and mutations may well be the greatest risk of all; yet we have very little information in this area (C-8).

Response: While the Agency agrees that the amount of information on genetic risk is limited, based on BEIR III analyses (NAS80), it doubts that the hereditary risk exceeds that of radiation induced cancer. Extensive study of the offspring of Japanese A-bomb survivors fail to show any statistically significant increase in genetic effects (Sc81, Sab82), while excess cancer is clearly evident in the survivors themselves (Ka82, Wab83). See also the response to comment 3.8.51.

1.4.34 Limits for workers which deal with genetic risk should deal with all generations, rather than just the first two generations (C-8).

Response: EPA estimates of hereditary risks include two cases: the first generation, and the 1st generation plus all succeeding generations (EPA81, EPA84a). We have considered both immediate and long term hereditary damage, recognizing that estimates of future risks are based on indirect evidence on the prevalence of recessive mutations and how long they will be maintained.

1.4.35 Any radiation exposure limit which adequately protects the worker against the risk of cancer will automatically protect the population against hereditary effects, because risks of the latter are significantly smaller than risks of the former (B.a-42).

Response: While the Agency agrees that genetic risks are probably less than somatic risks, it does not believe they should be ignored. In the final recommendations, the risk of hereditary damage is included in the calculation of the effective dose equivalent limit.

1.4.36 There is no evidence to support EPA's contention that the oocytes in the female fetus are more sensitive to radiation-caused mutations than are those of adult women (B.a-42).

Response: Information in BEIR III (Note 9. Oocyte Sensitivity, p. 110) shows the relationship is more complex than originally thought (EPA81). There is now evidence of species-specific differences in oocyte killing and mutation sensitivity. However, BEIR III indicated there is still uncertainty as to which stage of mouse oocyte development is similar to the immature arrested human oocyte. While it may be conservative to consider fetal oocytes more sensitive than immature arrested adult oocytes, such prudence is not unreasonable in light of what is currently known. See also the response to comment 3.8.51.

1.4.37 The relative role of radiation risk is significantly distorted, given the very high risk of cancer from other causes (A.a-41, A.d-13, B.a-31, B.c-12).

Response: The relative probabilities of fatal cancer due to occupational exposure and due to other causes was not a basis for these recommendations.

1.4.38 Based on the 1980 BEIR report and a linear quadratic dose response function, the additional cancer deaths projected over a lifetime due to lifetime occupational exposure in nuclear power plants at the collective dose rate occurring in 1979 are 1.2 to 2.0 percent of the deaths from all forms of cancer, depending on the risk projection model used, absolute or relative risk. If the linear dose response model from the 1972 BEIR report is used, these values would rise by a factor of only 2 to 3 (A.a-42).

Response: The Agency agrees and notes that if the commenter had based his estimates on the linear dose response estimates in the 1980 BEIR report, his estimate of absolute risk would be about 1.5 times larger than absolute risk estimates based on the 1972 BEIR report. In contrast, relative risk estimates have remained about the same for exposure of adults. This is because additional cancers have continued to occur in exposed groups at about the same rate as in nonradiogenic cancer in these aging populations, in accordance with the basic assumption underlying the relative risk model.

1.4.39 EPA should consider in its risk estimates the incidence of nonfatal as well as fatal cancers (A.a-38, D-11).

Response: Data on the incidence of radiogenic cancer is very limited in comparison with mortality data for excess cancer due to radiation. Nevertheless, we estimated that incidence exceeded mortality by about a factor of two (NAS80, EPA81, EPA84a), and considered this ratio in proposing these recommendations. Information on excess cancer incidence among irradiated A-bomb survivors at Hiroshima is now being analyzed by the Radiation Effects Research Foundation. When these data are published, along with new estimates of the doses to individual survivors, it then may be possible to make more acute estimates of the increased risk of cancer incidence due to radiation. See also the response to comment 1.4.1.

1.4.40 The estimate that 50% of cancers are fatal is not supported by U.S. death statistics (A.d-22, B.a-26).

Response: Death statistics do not provide information on the incidence of nonfatal cancer. The background report discussed various ways of estimating the ratio of incidence to mortality; none are exact. Table V-15, page 200 in the 1980 BEIR report indicates a ratio of 2 for females and 1.54 for males. In our 1981 "Background Report", page 41, we estimated this ratio as between 2.0 and 1.5 (average for both sexes). Reconsidering this question in 1985, the Agency has concluded that incidence cannot be estimated with any more accuracy now, but it may be possible to do so in the foreseeable future. See also the response to comment 1.4.39.

1.4.41 EPA states that cancer is fatal "at least" half the time; this should have been stated "at most half of the time," since it is not expected to rise from its current value (A.b-1).

Response: Based on information available at this time, half or more of all cancers combined is fatal. We do not know whether this will increase or decrease in the future. See the response to comment 1.4.40.

1.4.42 The use of measures of life-reduction provides better perspective than the use of average early fatalities when comparing various types of risks (B.a-30).

Response: A number of perspectives are useful when comparing different kinds of risk. Along with the average years of life lost to affected individuals, we have also included lifetime risk and the average years of life lost in the population as whole. We think all of these measures should be available for judging the hazards associated with exposure to radiation.

1.4.43 The weight of evidence appears to favor the absolute over the relative risk model (A.d-13).

Response: We disagree. The appropriate model for projecting future risk varies with the specific cancer being considered. An absolute risk projection model appears to be appropriate only for leukemia, and, possibly, for bone cancer. For all solid cancers a relative risk model agrees much better with epidemiological observations (Ka82, Jaa83). The observational evidence is that absolute risks increase with the duration of follow-up, regardless of the age at exposure, while the relative risk remains fairly constant (Ka82, Wab83). We note that these results are unlikely to be very dependent on the results of the ongoing dose reassessment for A-bomb survivors.

1.4.44 A combination of a threshold system of setting exposure limits with a risk-based system is unappealing (A.d-22).

Response: Some types of radiation injury are nonstochastic, that is, both the likelihood and severity of response changes with dose, and may exhibit a threshold. Other injuries are stochastic, that is, the probability of their occurrence increases with increasing dose without exhibiting any threshold, and their severity is independent of dose. While it may be unappealing, each type of radiation injury must be considered and controlled on a basis that is appropriate to the characteristics of its relation to dose.

1.4.45 At occupational levels of exposure, the quantification of risks are so highly uncertain that the balancing of risks and benefits is not useful to pursue (A.a-13).

Response: We do not agree. Reasonable estimates can be made of the impact of various levels of radiation exposure on those occupationally exposed. It is more often the benefits of the radiation exposure which are difficult to quantify. However, we believe both estimates are necessary to informed decision making.

1.4.46 With the assumption of uniform whole-body exposure the difference of 1.6% in life expectancy is presumptive and impossible to detect (A.d-21).

Response: We agree that it is unlikely that a 1.6% difference in life expectancy could be accurately assessed in any practical follow-up study of the occupationally exposed. It is not clear, however, what relevance this observation has to the establishment of radiation protection limits.

1.4.47 Fanned by the media, the public's perception of radiation risks is grossly distorted from the actual facts (B.a-35, B.a-39).

Response: The purpose of the documents supporting this guidance is to attempt to provide factual material to assist the public in its evaluation of radiation risks.

1.4.48 The radiation worker should be allowed to decide whether or not to accept the risks associated with radiation (A.a-31, A.a-36, A.a-41, A.d-19, B.a-54).

Response: This observation can be made (and has been) for all industrial hazards. However, the Government has an overall duty to its citizens to limit the hazards of the workplace in a reasonable manner, since economic pressures could otherwise force unwise decisions by individuals.

1.4.49 The excess population dose due to living in Colorado (200,000 person-rem/yr) is about five times the collective occupational dose attributable to the nuclear power industry in 1979 (40,000 person-rem/yr), yet no one is recommending evacuation or restriction of growth in Colorado (B.a-39).

Response: The above-cited excess collective dose for Colorado residents (2,890,000 persons in 1980) is in error. The correct value is about 106,000 person-rem/yr above average U.S. background exposure. Residents of Colorado are not exposed annually to incremental background terrestrial and cosmic radiation anywhere near the current mean annual occupational exposure to nuclear power workers. The average dose equivalent from background cosmic and terrestrial radiation for the entire U.S. population is 53.4 mrem compared to a low of 40.4 mrem in Florida and a high of 90.1 mrem in Colorado (Boa81). Thus, the mean incremental risk to Colorado residents from such background radiation (an average increment of less than 40 mrem/yr above the U.S. average) is much lower than that for nuclear power workers (650 mrem/yr) (Ku84).

1.4.50 There is real concern that the reduction in occupational exposure limits for nuclear medicine workers will have the effect of increasing risks to patients (A.d-21).

Response: While this concern was expressed occasionally by medical practitioners at public hearings on the proposed recommendations, all agreed that risks at their own institutions would not be increased. Rather, the concern was for other institutions which had less sophisticated radiation protection programs. If this guidance encourages better radiation protection at such institutions, it will have fulfilled one of its purposes. We believe this can and will be done without any increase in patient risks.

1.4.51 The full range of risk given by the 1980 BEIR Report (BEIR-III) should be used in lieu of the risk quoted from BEIR-I (A.d-22).

Response: The delay in publication of the BEIR-III Report, coupled with ensuing uncertainties concerning this report, precluded its detailed treatment in the background report. The Agency, however, did determine that the risk information in BEIR-III was not inconsistent with the BEIR-I risk estimates. In formulating the final guidance we have included assessments of risk based on applicable results from BEIR-III. See also the responses to comments 1.4.1 and 1.4.2.

1.5 COMPARISON OF RADIATION RISKS WITH OTHER OCCUPATIONAL RISKS

1.5.1 Radiation risks to nuclear power workers are not higher than the risks experienced by workers in non-nuclear industries (A.d-21, B.a-31, B.a-34).

Response: We agree in general. The estimated average lifetime risk of premature death for nuclear power workers exposed to 650 mrem annual dose (i.e. 0.3-0.8%) is comparable to the average lifetime risk of accidental death for all industry workers (i.e. 0.5%) (NSC84), assuming a working lifetime of 47 years. However, see the response to comment 1.5.4 for further detail of accidental death risks to specific worker groups and for discussion of comparability of accidental and cancer deaths.

1.5.2 EPA should consider the value of radiation use in its judgment concerning acceptable occupational risk (A.d-14).

Response: This consideration is covered by the first recommendation.

1.5.3 The comparison of the risk of maximum radiation exposure with average accidental death rates in other industries is methodologically improper and overstates the comparative risks of radiation exposure (A.a-19, A.a-40, A.a-41, A.d-18, B.a-3, B.a-29, B.a-30, B.a-34, B.a-39, B.a-24, B.c-12, E.b-8).

Response: We agree, and stated in the Background Report (EPA81) that such comparison was not appropriate. Without knowledge of the distribution of risks that lead to the average value, it is not possible to ascertain and compare maximum risks.

1.5.4 The risk from occupational exposure to radiation is much smaller than other occupational risks (A.a-12, A.b-2, A.b-16, A.d-22, A.d-40, B.a-38, B.a-39, B.c-12).

Response: One must be careful in making comparisons of radiation risks with other occupational risks. For example, there are significant

differences in accidental death rates among different groups of workers. Similarly, there are significant differences of exposure to radiation among different groups of workers. Unfortunately, appropriate data are not generally available so that the distributions of these two different risks can be compared. However, using available data, we can make the following comparisons. There are large numbers of individuals who work in retail trades and service professions and who experience very small risks of accidental death compared to the average risk of accidental death for all U.S. workers. The estimated incremental risk of premature death (0.01-0.03%) for the average worker measurably exposed to radiation (230 mrem) in one year is less than the average annual risk of accidental death to workers in construction (0.04%), mining (0.05%), or agriculture (0.05%) and is higher than the average risk of accidental death for such workers as those in trades (0.005%), manufacturing (0.006%), or services (0.007%) in 1983 (NSC84). We finally note that a premature cancer death attributed to radiation is not equivalent to a premature accidental death. It is estimated that the average number of years of life lost is 12-18 years for a premature cancer death due to radiation, whereas it is approximately 35 years for premature accidental death (EPA81). See also the response to comment 1.5.3.

1.5.5 The risk at 5 rem/yr is significant, but not excessive compared to other industries (F-3).

Response: See the responses to comments 1.5.1, 1.5.3, and 1.5.4.

1.5.6 Using the 1980 BEIR results, and comparing the maximally exposed radiation workers with the maximally exposed workers in other industries, results in comparative risk estimates almost an order of magnitude lower than the EPA risk estimates (A.d-18).

Response: We disagree. Use of the BEIR-III estimates does not result in an order of magnitude change in these comparisons. See the responses to comments 1.5.1, 1.5.3, and 1.5.4.

1.5.7 Comparison with the risks of other occupations is not a justification for the acceptability of occupational risks from radiation (A.a-38, A.c-7).

Response: The comparison of risks of other occupations with those for exposed workers provides just one basis for judgment. We agree that this comparison alone cannot provide justification for acceptability of risks.

1.5.8 EPA should establish a consistent level of protection for all industries utilizing hazardous substances (A.a-11).

Response: Many different Federal agencies have diverse responsibilities for providing protection of workers. In addition, the practicality of risk avoidance may vary widely for different hazards.

1.5.9 EPA assumes that it must provide for a risk-free work environment, whereas the intent of Congress was that the hazards of atomic energy be controlled (B.c-20).

Response: EPA does not make such an assumption.

1.5.10 In all risk comparisons, EPA fails to combine radiation risks with non-radiation risks to the workers before comparing the risks to the workers with risks to other occupational groups (A.a-3).

Response: The EPA has estimated only the incremental risks of premature death due to radiation exposure because that is the only hazard addressed by these recommendations. In any case, although values of average risk of accidental death are published for some specific types of workers for whom statistics are collected and analyzed by the Bureau of Labor Statistics (BLS84) and by the National Safety Council (NSC84), these classified worker groups are not also further identified as to radiation exposure. To this end, it could be useful to have sub-code classifications for workers exposed to radiation and other carcinogens under the Standard Industrial Classification (SIC) code of the Bureau of Labor Statistics (BLS84). A comparison of radiation risk with risk of death from other carcinogenic agents in occupational environments would be relevant, but adequate data for such comparisons are not available. See also the response to comment 1.5.4.

1.5.11 EPA should compare the risk of cancer for radiation workers with that of other workers occupationally exposed to carcinogenic agents (A.d-13, A.d-22, E.a-4).

Response: See the response to comment 1.5.10.

1.6 CONSISTENCY WITH AND VALIDITY OF ICRP-26

1.6.1 The EPA guidance should be consistent with the ICRP-26 system of dose limitation; EPA has not sufficiently justified its deviations from the ICRP recommendations (A.a-1, A.a-17, A.a-20, A.a-22, A.a-40, A.a-46, A.b-16, A.b-22, A.b-23, A.d-13, A.d-22, B.a-6, B.a-12, B.a-13, B.a-17, B.a-20, B.a-23, B.a-24, B.a-29, B.a-33, B.a-34, B.a-38, B.a-39, B.a-46, B.a-48, B.a-53, B.c-12, B.c-20, D-6, E.a-5, E.a-6, E.a-16, E.b-1, E.b-2, F-2).

Response: The Agency adopts most of the basic recommendations of ICRP-26 in its final recommendations. See also response to comment 1.3.1.

1.6.2 EPA should use ICRP-26 consistently "in toto" or reject it completely (A.a-17, A.a-40, A.d-22, A.d-34, B.a-6, B.a-32, B.c-20, E.a-2).

Response: The Agency adopts in its final recommendations most of the basic recommendations of ICRP-26, but not the contents of ICRP-26 "in toto." This is consistent with the following statement of the ICRP in that publication: "Because of the differing conditions that apply in various countries, detailed guidance on the application of its recommendations, either in regulations or in codes of practice, should be elaborated by the various international and national bodies that are familiar with what is best for their needs." In addition, the premise of the comment (that different parts of ICRP-26 are interdependent) is not correct. Some recommendations, such as those for overexposure, stand alone.

1.6.3 EPA's proposed guidance adopts parts of the many principles and recommendations of ICRP-26, but there are so many deviations in major respects from the ICRP system that the intent and effectiveness of the dose limitation system is destroyed (B.a-29, B.c-20).

Response: We do not agree. The basic intent and effectiveness of ICRP-26 is retained in the proposal and in the final recommendations. See also the responses to comments 1.6.1 and 1.6.2.

1.6.4 There is no consistent basis for the proposed limits due to arbitrary adoption of only selected parts of ICRP. This leads to confusion and a loss of the basic premise of equivalent risk (A.a-11, A.b-22, A.d-13, A.d-14, B.a-17, B.a-23, B.a-32, B.a-33, E.a-4).

Response: We do not agree. In fact, the equivalency of risk was enhanced through the separation of genetic and cancer risk in the proposal. See also the responses to comments 1.6.1 and 1.6.2.

1.6.5 EPA's dose-equivalent limits are not based on specified acceptable levels of risk, as are those recommended in ICRP-26 (A.a-46, A.d-9, B.a-17, B.a-24, B.a-29, B.c-10, E.a-5, E.b-2).

Response: We disagree. The estimated risks corresponding to the proposed limits were specified in the Background Report (EPA81). In addition, since the proposed limits were only marginally different from corresponding limits in ICRP-26, they corresponded to the same risk levels that are "acceptable" to the ICRP. Also, see the response to comment 1.6.1.

1.6.6 EPA should withdraw its proposed recommendations; changes should be made only after full consideration of BEIR-III, NCRP, ICRP-26, and other pertinent studies (A.a-18, A.a-22, B.a-7, B.a-34, E.b-4).

Response: The Agency's proposed guidance did take into consideration the cited studies. See also the responses to comments 1.4.1, 1.4.2, 1.4.3, and 1.7.1.

1.6.7 For the sake of political expediency, EPA ignores the recommendations of the ICRP when they conflict with current standards and practices (A.d-9, F-3).

Response: "Political expediency," played no part in the formulation of the recommendations, either proposed or final.

1.6.8 The 100 rem lifetime limit is inconsistent with ICRP-26 (A.b-22, B.a-46).

Response: Consistency with ICRP was not a precondition for acceptability. The "100 rem lifetime dose" was not intended as a limit, but as guidance for limiting career exposure. In addition, it is not inconsistent with the ICRP acceptable risk concepts.

1.6.9 The ICRP-26 guidance is not appropriate for regulation. Some European nations that have adopted ICRP-26 have found it to be unworkable (A.a-35, B.a-12).

Response: We are aware that some practical problems in implementing ICRP-26 recommendations exist, but they can and are being resolved. The final guidance makes some additions to ICRP-26 formalism to assist in the solution of such problems with respect to committed dose. It is evident that some "retooling" efforts would be required to change from pre-existing radiation protection systems. It is also clear, however, that the ICRP system has now gained almost universal acceptance in the international community. See response to comment 1.6.2.

1.6.10 ICRP-26 concepts cannot be effectively applied for dose evaluation of long-lived emitters such as the actinides (E.b-7).

Response: We disagree, in general, although some difficulties do exist. Although the prospective control of such radionuclides is practicable, the sensitivity of available human assay techniques is only marginally adequate with regard to retrospective assessment of dose to individual workers. The final recommendations recognize this difficulty and provide for practical means of implementation.

1.6.11 EPA's adoption of ICRP methods results in a proposed system of guidance based on limiting the prospective dose and in which the retrospective dose is irrelevant. Since all dosimetry programs measure retrospective dose this leads to confusion in the proposed guidance (E.a-5).

Response: This is not the case. The final recommendations provide that future exposure of the worker be appropriately managed where assessment of actual intakes of radioactive materials shows conditions for limitation of intake (past) have not been met. In further response to this comment, we offer the following quotes from ICRP-26 (page 16): "In principle, the use of the dose-equivalent commitment concept does permit the dose equivalent received in a single year to exceed the annual limit (e.g., in the case of an intake in 1 year of a material of long effective half-life, followed by an intake in the next year equal to an ALI of a material of short effective half-life). In practice such situations will be rare and the dose equivalent during any year in excess of the annual limit will normally be small...." "The dose-equivalent limits should not be regarded as a dividing line between safety and danger; when limits have been exceeded by a small amount it is generally more significant that there has been a failure of control than that one or more individuals have slightly exceeded a certain agreed dose." See also the response to comment 2.1.11.

1.6.12 ICRP-26 reverses the trend for reducing radiation exposure to workers. It recommends changes that would increase exposures to sensitive organs where radionuclides are deposited in one organ alone (C-6).

Response: Although the statement may be true for some limited examples, the reverse is true for the majority of situations. The organ dose limits in the current (old) system were not set on the basis of equivalent risks. ICRP-26, however, limits the annual dose to a given organ on the basis of its weighted stochastic risk (genetic plus somatic), relative to that of whole-body, and additionally (when applicable) restricts it to a limiting dose of 50 rems (15 rems to lens of eye) to prevent non-stochastic effects. Consequently, some derived limits for radionuclides increase and others decrease. However, even in the case of a numerically higher derived limit workers would not necessarily be subject to higher doses. The ALARA principle is still a radiation protection requirement.

1.6.13 The ICRP-26 limit of 50 rems per year for single organ exposure cannot be shown to adequately protect worker health (C-6).

Response: This limit applies to non-stochastic risks only, and the commenter does not supply any evidence that such risks are significant at this dose. Also, see the response to comment 1.6.12.

1.6.14 Nearly all members of the ICRP have been employees of governmental atomic energy agencies or have worked in government-related laboratories and are unlikely to be inclined to reach conclusions that make nuclear energy more expensive or difficult (A.a-38).

Response: The Agency concluded that an overall limit of 5 rem/yr was appropriate independent of ICRP recommendations.

1.7 CONSISTENCY WITH NCRP

1.7.1 The proposed limits should be consistent with the recommendations of the NCRP (A.a-15, A.b-15, A.b-16, A.b-22, A.d-9, A.d-12, A.d-22, A.d-34, A.d-15, A.d-22, B.a-5, B.a-32, B.a-34, B.a-53, E.a-5, E.a-7, E.b-4).

Response: In formulating the proposed recommendations, the Agency took NCRP recommendations into consideration. We have also consulted with the NCRP in our consideration of final recommendations. However, the Agency's final recommendations are based on ICRP recommendation and cannot at the same time adhere strictly to all of the recommendations of NCRP. (There is no legal requirement for such consistency of Federal radiation protection guidance.) We do adopt, however, those elements of NCRP recommendations that are appropriate, such as their recommendations concerning exposure of the unborn, and these recommendations provide overall protection consistent with NCRP recommendations.

1.7.2 The proposed changes in the RPGs should be reviewed and approved by the NCRP before any significant changes are promulgated (A.a-40, A.b-15, A.d-9, A.d-22, B.a-34, E.a-5, E.b-4).

Response: See the response to comment 1.7.1.

1.7.3 Both the ICRP and NCRP are reviewing their radiation protection standards; adopting new RPGs before the positions of the scientific community are established is not needed and will not improve personnel safety (B.a-24, B.a-34).

Response: Both ICRP and NCRP have their current recommendations under continuing review. The existing Federal radiation protection guidance for occupational exposure has not been changed since its approval in 1960. EPA, in view of its responsibilities, considers it appropriate to review the guidance, and to update it in light of its findings and of significant advances since 1960. We have concluded that changes are needed and will improve radiation protection of workers.

1.7.4 The EPA method of calculating radiation exposure, based on the 1977 recommendations of the ICRP, has not been recommended for use by the NCRP (E.a-5).

Response: See the response to comments 1.7.1 and 1.7.2.

1.7.5 The NCRP, as well as other scientific advisory groups, have found after continuing review that there is no need for a downward revision of the RPGs (B.a-12, E.b-4).

Response: The comment is incorrect. The NCRP has recommended adoption of a 5 rem/yr limit. See also the response to comments 1.3.1, 1.6.12, and 1.7.1.

1.7.6 The proposed organ limits differ from the limits accepted by the NCRP (B.a-14).

Response: See the response to comment 1.6.12.

1.7.7 The 100 rem lifetime limit is inconsistent with NCRP recommendations (A.b-13, A.b-22, B.a-38).

Response: See the response to comment 1.6.8.

1.7.8 Scientists working in the NCRP have a number of potential biases due to their affiliations; these biases make them less appropriate arbitrators of the risks that other individuals should accept than scientists whose livelihoods are not so directly related to the day-to-day use of radiation (A.a-38).

Response: The recommendations were based on EPA's independent assessment.

1.8 COORDINATION WITH OTHER U.S. AGENCIES

1.8.1 There is a need to develop one set of guidelines applicable to all Federal agencies (A.b-20, A.d-8, A.d-27, B.a-3, B.a-8, E.a-2, E.a-3, E.a-4, E.b-1).

Response: These recommendations for Federal radiation protection guidance for occupational exposure are applicable to all Federal agencies.

1.8.2 EPA's proposed guidelines are inconsistent with NRC's recently promulgated regulations. The discrepancies should be resolved (A.d-14, A.d-29, A.d-40).

Response: The NRC has only recently, December 20,1985, proposed its draft revisions to 10 CFR Part 20 (NRC85); final promulgation is not likely to occur in less than several years. In any case, NRC will revise its regulations as necessary to conform with newly approved Federal guidance.

1.8.3 EPA's proposed guidance is too restrictive. Standards should be set by the federal agencies; generic guidelines for these standards should be written by EPA (D-10).

Response: The division of responsibility proposed by the commenter is that actually in effect. EPA's statutory responsibility in the area of radiation protection for occupational exposure consists of making recommendations to the President for the guidance of Federal agencies in their formulation of radiation standards. Regulatory Federal agencies translate this guidance into regulations.

1.8.4 The following sentence should be added for clarification: "These proposals have not had a formal review by these agencies and, therefore, they do not carry the endorsement of these agencies" (E.a-4).

Response: In the section titled "Previous Actions by EPA" of our proposed guidance (46 F.R. 7836), we stated: "These agencies, which have not formally endorsed these recommendations, will formally review final proposals when they are developed following public review."

1.8.5 EPA should clarify the role to be played by the Interagency Working Group during the remaining phases of this review (E.a-4).

Response: In the section titled "Previous Action by EPA" of our proposed guidance (46 F.R. 7836), we state that the role of the "Interagency work group" is an advisory one: "In developing these proposals, we have also consulted with the technical staffs of the Federal agencies that regulate or influence the regulation of occupational exposure, and will continue this consultation in developing final recommendations." The final recommendations represent the result of this consultation with affected Federal agencies.

1.8.6 All federal agencies concerned with radiation should have the technical capability for independent evaluation of scientific evidence upon which the standards to minimize exposures to radiation rest (A.a-38).

Response: We agree that this would be desirable, to the extent required to carry out their responsibilities.

1.9 ECONOMIC COSTS AND COST/BENEFIT

1.9.1 EPA's estimate of total cost to comply with regulations ($35 million) is simplistic, theoretical, and/or wholly unrealistic (A.a-3, A.a-13, A.a-31, A.d-9, B.a-5, B.a-9, B.a-28, B.a-33, B.a-46, B.c-22).

Response: EPA funded an independent study, "Analysis of Costs for Compliance with Federal Radiation Protection Guidance for Occupational Exposure; Volume I: Cost of Compliance with Proposed Radiation Protection Guidance for Workers, and Volume II: Case Study Analysis of the Impacts of Proposed Radiation Protection Guidance for Workers (November 1983)," to provide cost estimates for the proposed guidance (EPA83a). In addition, the NRC funded a similar study, "Cost of Compliance with Occupational Exposure Revisions to 10 CFR Part 20 (December 1982)," to provide estimates for implementation of Federal guidance (NRC82). These cost analyses by Jack Faucett Associates and S. Cohen Associates, Inc. (JFA/SCA) are based on case studies of representative establishments in conjunction with industry profiles and are extrapolated to the entire private industry sector. Several cost estimates were updated for the NRC as a result of changes to draft revisions of 10 CFR Part 20 (Coc83, Lad84). Some of the estimated costs are attributable to changes in guidance, while others are attributable to regulatory updates necessitated by changes in scientific information; these are discussed below.

The summary costs for implementation of new recommendations include NRC licensed operations in Federal agencies, but do not include activities of Federal agencies exempted under the Atomic Energy Act. To confirm that there are no unusual new requirements for Federal agencies that will require above normal program costs, EPA's case studies (EPA83a) included two Department of Energy facilities, Rocky Flats Plant and Idaho National Engineering Laboratory, where the normal operations include routine bioassay programs for surveillance of workers subject to internal exposure. These were selected to assess unusual costs where the greatest impacts would be expected in implementing the final recommendations. Because the workers are not currently exceeding the annual effective dose equivalent of the final recommendations from combined internal and external exposures and since the affected agencies routinely update their radiation safety programs, the associated costs would be part of normal operations.

Costs of implementing the 5-rem limit (0.3 $M initial plus 0.75 $M annually), ALARA (2.16 $M initial plus 1.48 $M annually), and the new limits for the unborn (0.06 $M annually) are shown in the first three entries in the table below. The JFA/SCA cost estimate for instruction on levels of risk (9.87 $M annually) is high, since much of this instruction is possible within existing programs and/or with appropriate written materials. In addition, only new workers would lead to recurring annual costs. We have assigned 60% of the JFA/SCA cost estimate to recurring annual costs.

There normally are some costs due to revision of manuals and procedures for carrying out new regulations. However, the JFA/SCA estimates of costs for manual/procedure revisions (10.74 $M initial only) are primarily for implementation of new dosimetric models and summation of internal and external doses. These costs are not attributable to changes in guidance; they would also be incurred under existing guidance. Therefore, costs for manual/procedure revisions (shown in parenthesis) are omitted from the total.

Table 3. ESTIMATED IMPLEMENTATION COSTS
(thousands of 1982 dollars)

One-time Initial	Annual	Provision	Change
$300	$750	5 rem limit	Reduction from 12 to 5 rem maximum dose.
---	$60	Unborn (0.5 rem limit)	New requirement.
$2160	$1480	ALARA program	Re-emphasized requirement.
$3950	$5920	Levels of risk instruction	New requirement.*
($10740**	---)	Manual/procedures revision	New dosimetric models (update under 1960 guidance)
$6410	$8210	Total	

* These values are high, since they are based on hiring experts to conduct instruction. Much of this instruction should be possible within existing programs and/or with appropriate written materials. Initial costs for all workers need not be repeated; only new workers generate recurring annual costs. Thus, only 60% of the JFA/SCA annual cost estimate ($9,870,000) has been assigned to recurring annual costs.

** Only a very small fraction of this cost is attributable to proposed changes in Federal guidance, since these costs are almost wholly generated by the need to update allowed values of radionuclide airborne concentrations (to conform to new scientific information) and to sum internal and external doses; these changes would also be required under existing guidance.

Some costs are attributable to new monitoring needs (due to changes in scientific data that reduce limiting values of radionuclide concentrations in air or water) or to summation of external and internal exposure. Since these are necessary under existing guidance, the JFA/SCA cost estimates for internal exposure monitoring (8.7 $M initial plus 4.1 $M annually), retraining (3.61 $M initial), recordkeeping (3.67 $M initial plus 0.14 $M annually), and reporting (0.18 $M annually) are not due to new provisions and, therefore, not included in Table 3.

The total estimated costs attributable to changes in guidance are therefore a first-year total cost of $14.62 million and subsequent annual costs of $8.21 million. Since the estimated costs of instruction on levels of risk are believed to be too high, realistic costs of about $10 million in the first year, and about $5 million annually, thereafter, appear more likely.

1.9.2 Administrative detail/recordkeeping will be a significant portion of the costs that would occur should the regulations be promulgated (A.a-10, A.b-15, B.a-32, B.a-37, B.a-48, B.b-1).

Response: We agree that there would have been additional administrative detail/recordkeeping costs associated with implementation of the proposed recommendations. However, the final recommendations do not lead to such additional costs. While it is true that the NRC proposed revision of 10 CFR 20 (NRC85) will lead to costs for manual/procedure revisions, these costs would occur under existing guidance and are not attributable to changes in Federal guidance. See the response to comment 1.9.1.

1.9.3 The additional cost to U.S. industry inhibits its ability to compete with foreign producers (B.c-22).

Response: We disagree. Workers around the world have experienced levels of exposure comparable to those of U.S. workers (UN77, UN82) and operate under regulations requiring levels of protection comparable to those recommended here for U.S. workers.

1.9.4 To remove flexibility, such as stated on p. 7838 (46 F.R. 7836) for the overall cumulative limit [5 (N-18) rems] will result in more unnecessary regulatory procedures at increased cost to the taxpayer and consumer (A.a-31).

Response: We disagree. We do not believe that repeated exposures at or near the 3 rem quarterly limit in a given year are justified in view of the estimated risks. Removal of the 5(N-18) rems and 3 rem quarterly dose limitations leads to small increased hiring/training of some additional workers. Although those workers eligible under the 5(N-18) cumulative dose limitation to receive 3 rems per quarter and up to 12 rems per year will no longer be allowed to exceed 5 rems per year, no single job currently requiring 3 rems will be affected by the new limitation.

1.9.5 Training of additional workers will be costly, and will actually lead to increased risks, as more workers will be exposed, raising the collective dose. Further, there is a shortage of workers able to qualify as inspectors (A.d-40, B.a-21, B.a-28, B.a-37, B.a-44, E.a-3, E.b-6, E.b-55).

Response: Where additional workers are necessary there will be incremental costs for workers and their training. The total costs estimated for meeting the 5 rem limit are $300 thousand (initial)and $750 thousand (annual) (NRC82). We do not believe that there will be increases in collective dose or risk as a result of final recommendations (see the response to comments 2.7.2 and 2.7.6). In addition, some period of time will elapse between Presidential approval and regulatory implementation of the guidance, so that the training of new workers can be anticipated and carried out over a reasonable period of time; the NRC regulatory implementation proposes a five year period (NRC85). See the responses to comments 2.3.5 and 2.7.4.

1.9.6 The present economic situation of the U.S. makes these recommendations particularly ill-timed and unjustifiable (A.a-3, A.d-21, A.d-25, A.d-31, B.a-26, B.a-54).

Response: The incremental costs of implementing the new recommendations are small fractions of existing costs of radiation protection or health and safety programs. Furthermore, such costs are inherent to an acceptably safe program for workers, regardless of economic situations.

1.9.7 The cost of the EPA recommendations is not justified as the resultant benefits are not recognizable, or are insufficient to justify the cost (A.a-31, A.a-34, A.a-41, A.a-46, A.b-10, A.d-21, A.d-27, A.d-40, B.a-21, B.a-28, B.a-54, B.b-3, B.c-9, B.c-12, D-2, E.a-2).

Response: These recommendations are the result of over ten years of extensive review and deliberation by Federal agencies and other interested parties. The recommendations are in accord with the internationally-accepted recommendations of ICRP-26. We expect that the implementation of this guidance will lead to appropriate protection of the unborn and to few workers approaching the annual limiting effective dose equivalent of 5 rems and that overall exposure to workers will decline. The latter benefits should be readily documentable after the new limits go into effect. See also the response to comment 1.11.19.

1.9.8 We suggest that the EPA perform a cost benefit analysis before releasing these recommendations (A.a-11, A.a-13, A.a-23, A.b-11, A.b-17, A.d-14, A.d-31, A.d-35, A.d-40, B.a-17, B.a-29, B.b-5, B.c-20, D-2, E.a-5, E.a-6, E.b-5, E.b-6, E.b-9).

Response: The EPA has conducted an assessment of the estimated costs of implementation and expected benefits. See the responses to comments 1.9.1, 1.9.2. 1.9.5, 1.9.7, 1.9.11, 1.9.13, 1.9.16, and 1.9.17.

1.9.9 Presidential Executive Order 12291 requires cost benefit assessment before the release of regulations that may have a major effect on the public. EPA did not supply this analysis. (A.b-4, A.d-25, A.d-27, B.a-14, B.a-32, B.a-38, B.a-48 B.c-2, B.c-22).

Response: Executive Order 12291 applies only to rules (regulations) that may have a major impact on the economy ($100 million or more per year); would result in major increases in prices and costs; or would have significant adverse effects on competition, employment, investment, productivity, or innovation. We have judged these recommendations would not qualify under any of these criteria.

1.9.10 Money could be more effectively spent on worker safety than by reducing one cancer death at a cost of $1 million (EPA estimates reducing cancer deaths by 35 at a cost of $35 million) (A.a-12, E.a-5).

Response: Agency guidelines suggest that the value of a statistical life be established in the range of $0.4 to 7.0 million in 1982 dollars (EPA83b). The value cited falls within this range.

1.9.11 The added cost of one person to the radiation safety programs of hospitals alone is estimated at $40 million. This assumes 2,000 new hospital hires (radiation protection personnel) @$20,000/hire = $40 million (A.d-14, A.d-40).

Response: The costs of implementing the supervisory requirements of the proposed Minimum Radiation Protection Requirements for Range C were quite large when based on a strict interpretation of the proposal. However, such costs will not occur due to elimination of these requirements. The estimated costs for implementation of the final recommendations by hospitals is $5.1 million for the first year and $3.1 million annually thereafter (EPA83a, NRC82). These costs include part-time consultants (these eliminate the need for hiring new full-time employees) for training/instruction on levels of risk. Other costs associated with monitoring of internal exposure, regulatory reporting, and manual/procedure revisions are not attributable to new recommendations; they would be incurred as a result of utilization of new dosimetric models and summation of internal and external doses under existing guidance. See also the response to comment 1.9.17.

1.9.12 If dose limits are to be decided by what a given industry can afford, then EPA should abandon all attempts at estimating risk from actual data, and leave it to the economy to set radiation levels (A.c-6).

Response: The basis for setting the dose limits was not what an industry can afford.

1.9.13 Increased labor cost for commercial light water reactors is estimated at a minimum of $152 million per year (B.a-3).

Response: Increased labor cost to meet the 5 rem limit is estimated to be $340 thousand per year for all 1982 nuclear power reactors (NRC82).

1.9.14 Additional costs for the Department of Defense due to a reduction of the RPG from 5 to 0.5 rem are estimated at $12 million initially, and $4 million annually thereafter (E.a-2).

Response: Since the dose limit adopted in final recommendations remains at 5 rems, these incremental costs will not occur.

1.9.15 Industry should estimate the cost due to the proposed recommendations (B.a-16).

Response: The EPA is aware of one such study. An assessment of the costs associated with the "Dosimetry and Recordkeeping Implications of the Proposed Revisions to 10 CFR 20" was sponsored by the Atomic Industrial Forum, Inc. (AIF80). This assessment only included consideration of nuclear power plants and fuel fabrication facilities.

1.9.16 Overall medical costs continue to rise, while technical radiologic workers continue to be underpaid. Understaffing in this area is severe: EPA's additional regulatory burden would only exacerbate a serious problem (A.d-39).

Response: The final recommendations do not result in significant needs for additional full-time radiation safety staff. Much of the training on the subject of worker risk (EPA83a) can be handled by part-time consultants. See the response to comment 1.9.11.

1.9.17 The cost to patients, hospitals, and insurers will increase significantly if the recommendations are instituted (A.d-27).

Response: We disagree. With over 36 million admissions (and over 200 million outpatient visits per year) to U.S. community hospitals in 1980, the incremental cost to admitted patients from implementation of the final recommendations would average less than $0.14 per patient for the initial year ($5.1 million first-year costs) and $0.08 per patient for each year thereafter ($3.1 million annual costs). These costs would be more than six times smaller if outpatients also shared these costs. In either case, the incremental costs are trivial compared to average expenses at community hospitals amounting to about $1,900 per admission and about $250 per inpatient day in 1980 (AHA81). See also the response to comment 1.9.11.

1.9.18 Utilities would need to evaluate internal procedures, retool recordkeeping, and re-educate its work force, all at significant cost (B.a-37).

Response: We agree that there will be some incremental costs associated with these activities. See the responses to comments 1.9.1 and 1.9.2 for proper assignment of such costs to new recommendations or existing guidance.

1.9.19 A study for AIF indicates that for nuclear power facilities one could expect an adverse negative impact exceeding the benefits to be derived from the proposed 100 rem lifetime limit (B.a-50).

Response: Although we do not agree with this conclusion, the comment is moot because this proposed lifetime dose figure does not appear in final recommendations.

1.9.20 The EPA should fully evaluate the impact of its recommendations on waste management and disposal facilities and spent fuel reprocessors (B.a-32).

Response: EPA requested comments on its proposed guidance from all interested persons, in all types of activities involving radiation exposure of workers. The comments received have been taken into consideration in formulating final recommendations. Additionally, a two-volume report was prepared for EPA regarding the impact of the proposed guidance and the cost of compliance with that guidance (EPA83a). The report was based on case studies which involved obtaining first-hand information from a number of activities representative of the spectrum of diverse types of facilities involving occupational exposure, in both the public and private sectors. Included in these studies are waste-management and fuel reprocessing. We analyzed the results of these contract studies and took them into consideration in formulating final recommendations. See the response to comment 1.9.1.

1.10 RECORDKEEPING

1.10.1 The recordkeeping requirements associated with the proposed guidelines would result in increased costs to those regulated, with little, if any corresponding benefit (A.a-11, A.a-26, A.b-10, A.d-14, A.d-39, B.a-d, B.a-1, B.a-12, B.a-13, B.a-36, B.a-38, B.a-54, E.a-5).

Response: Changes in recordkeeping requirements are best inferred from the final recommendations, which may entail some new recordkeeping costs. However, our assessment showed that final recommendations do not lead to additional recordkeeping costs over those that would occur under existing guidance. See the responses to comments 1.9.1 and 1.9.2 for more detailed discussions.

1.10.2 Eliminating recordkeeping by substituting the three-tiered grading system is not advised, as it may invite noncompliance due to its complex nature (A.a-5, C-6, E.a-5).

Response: It was not intended to eliminate recordkeeping practices through use of the "three-tiered" system.

1.10.3 All workers should be given access to their records and the records should be made available for epidemiological research (B.a-38, C-6).

Response: The recommendations contain explicit provision for informing workers of their exposures. There may be valid reasons why an employer

should not make radiation exposure records available to anyone requesting them for epidemiological or other research. A worker's radiation exposure record is in some respects akin to his medical record and should therefore be handled accordingly. When these matters are handled in accordance with law, we agree that there may be value in using worker exposure records for epidemiological studies, particularly if the technical dosimetric data on which those records are based are also made available to and used by the investigator. However, legal aspects of access to radiation exposure records are not within the scope of these recommendations.

1.10.4 Additional lifetime recordkeeping requirements can be instituted at minimal cost as the requirements differ little from current practice (A.a-38, A.a-39).

Response: We believe this is true for most existing recordkeeping systems.

1.10.5 The impact on the practice of medicine will be almost exclusively to increase administrative recordkeeping (A.b-4).

Response: See the response to comment 1.10.1 above.

1.10.6 The elimination of Form NRC-4 is not compatible with other changes in notification and reporting requirements (B.a-38).

Response: Such a decision by the NRC is outside the scope of Federal radiation protection guidance.

1.10.7 Records should be kept on diseases and defects of worker's children (A.c-6).

Response: This comment is outside the scope of consideration for these recommendations.

1.10.8 A central data bank of radiation exposure histories for permanent and temporary workers is needed (A.c-6).

Response: Such a data bank could serve a number of useful functions. However, this matter is outside the scope of consideration for these recommendations.

1.11 MISCELLANEOUS

1.11.1 EPA's Federal Register Notice is inadequate in that it does not address the issues raised by NRDC, et al. (A.a-5, A.c-3).

Response: We disagree. The issues listed in the proposal (46 FR 7836), and discussed more completely and extensively in the background report (EPA 520/4-81-003), encompass the issues raised by NRDC. Additionally, and as stated in the Public Hearings sections of the Federal Register notice containing the proposed recommendations, "The issues to be covered by these hearings are those listed above under the heading 'Issues Addressed.' They include those listed in our advance notice of September 17, 1979 (44 FR 53785) and additional issues suggested since then. As indicated in that notice, both EPA and NRC have been petitioned by the Natural Resources Defense Council, Inc., to revise occupational guidance and standards. The subject matter of these hearings encompasses the issues raised in those petitions (See 40 FR 50327 of October 29, 1979)." The Agency considered the NRDC petitions in formulating both its proposed and final recommendations. Explicit issues are addressed in the detailed subheadings of this response to comments.

1.11.2 By relaxing certain organ dose limits, EPA is inviting public criticism (A.a-3).

Response: We invited the public to comment on our proposal, and received a large number of both written and oral comments. We did not anticipate all comments to be positive, and they were not. However, as promised, we have carefully considered all of them in preparing final recommendations.

1.11.3 Cost-benefit analysis is irresponsible until all premature deaths are eliminated (A.c-8).

Response: Cost benefit analysis after elimination of all premature deaths would be meaningless. In the context of the models used to estimate the risk of premature death from occupational exposure to radiation, elimination of all such premature deaths would require completely eliminating all such exposure. This, if it were feasible, would require elimination of all activities and radiation sources giving rise to any exposure. Also, see the response to comment 1.3.10.

1.11.4 We encourage EPA to take to heart the comments of the Health Physics Society (A.a-41, A.d-1, D-10).

Response: The Society's comments have been taken into consideration. See the response to comment 1.3.2.

1.11.5 New York City and Boston should have been public hearing sites (D-5).

Response: We regret that due to limited resources available, we were unable to hold public hearings in New York City and Boston (as well as in other cities). We conducted a carefully researched selection process for the hearing sites so as to afford an opportunity for attendance by as many and as diverse types of workers and interested parties as possible.

1.11.6 Submitted comments are not adequately considered (B.a-31).

Response: We have made every effort to do so.

1.11.7 EPA should incorporate notes into the recommendations (B.c-22).

Response: The "notes" are designated as such because they are of an explanatory nature, not basic requirements. However, since they serve to clarify the intent or application of the recommendations, they should be considered to be effectively part of them.

1.11.8 "Guidance" will become "regulation" (B.a-10, E.b-8).

Response: We hope so. Radiation protection guidance is for the use of Federal agencies in the conduct of their radiation protection activities, which includes the development and enforcement of standards. Guidance, however, is intended to be used with a degree of flexibility.

1.11.9 Include the background report as a part of the guidance when completed (A.b-5).

Response: The President approves only the recommendations themselves as Federal guidance. However, the background report may be used to clarify the intent of the guidance.

1.11.10 Effective radiation safety is not related to legalistic endeavors of pressure groups, government bureaucracy, or political expediency (A.a-26).

Response: The comment is not necessarily correct. Endeavors of "pressure groups" (environmental, industrial, worker, women's rights, etc.) often serve to call attention to the need for a change or to whether a change is desirable. They are a legitimate part of the existing institutional framework of democracy in this country. Radiation protection of workers is a legitimate concern of many of these groups.

Further, an effective national radiation protection program that excludes the active participation of government is difficult to envision. However, we certainly agree that "political expediency" does not serve a useful role in the formulation of radiation protection guidance, or, for that matter, in radiation protection in general. See also the response to comment 1.6.7.

1.11.11 Independent researchers must be granted access to the atomic bomb casualty data (A.a-7).

Response: These data are not within EPA's jurisdiction.

1.11.12 The recommendations are unfeasible (A.d-40).

Response: We disagree. See, for example, the responses to comments 1.6.9 and 1.6.10 regarding specific provisions.

1.11.13 Why did EPA request comments from the public before requesting them from other federal agencies (A.a-18)?

Response: Representatives of the principal Federal agencies played an active role in the formulation of both the proposed and final recommendations. Also, see the response to comment 1.3.4.

1.11.14 The nuclear power industry will need an approximately 2 years implementation period (B.a-20).

Response: We recognize that certain types of regulated activities will require more time than others to implement the regulatory changes resulting as a consequence of new guidance. We have explicitly recognized that regulatory agencies should allow an appropriate amount of time for compliance with regulatory changes. See the response to comment 1.9.5.

1.11.15 The requirement to "provide an estimate" if finally determined personnel monitoring results are not available at the time of termination does not address the issue of who is responsible if the estimates prove incorrect (B.a-38).

Response: No response required. This comment is apparently meant for an NRC proposed rule. The EPA proposal did not cover record requirements for termination of employment.

1.11.16 The guidelines mean nothing if there is no enforcement mechanism (A.c-7, C-5, D-1).

Response: The regulatory Federal agencies (and those of Agreement States) translate Federal guidance into regulations which they then enforce.

1.11.17 EPA perpetuates itself by establishing guidelines that will be enforced by EPA (B.a-26).

Response: EPA has a statutory responsibility to recommend Federal radiation protection guidance. Upon approval by the President, Federal agencies develop regulations which they themselves prepare and enforce. In occupational radiation protection matters, EPA is not one of these regulatory agencies, and hence it is not an enforcer.

1.11.18 A number of the proposed provisions could be disastrous to the medical radiation field (A.d-5).

Response: We disagree. Large costs of implementation were suggested by some commenters who made erroneous interpretations of the proposed recommendations. See the responses to comments 1.9.11, 1.9.16, and 1.9.17.

1.11.19 The statement on page 7841, "If this new guidance is adopted, workers should be harmed less in the future," is unsupported by any evidence presented (A.d-5).

Response: The proper interpretation of this sentence is that the Agency believes that proposed guidance should lead to lower average annual doses to workers. The text also acknowledged that it was not possible to quantify this belief because EPA cannot predict how effectively these recommendations will be implemented.

1.11.20 EPA should place emphasis on overall assessments of radiation exposure as they appear in the perspective of a national radiation budget (B.a-35).

Response: There is no "national radiation budget" nor, in our view, should there be one. All exposures should be justified on their own merits. This principle is basic to all radiation protection, and has been for many decades.

1.11.21 EPA should propose an agency-wide federal ALARA program designed to reduce population exposure to ionizing radiation. This should be organized along cost-benefit evaluations so as to achieve maximum reduction in person-rem per dollar spent (B.a-35).

Response: We thank the commenter for this suggestion, but feel that it is not appropriate for EPA to propose a detailed ALARA program for occupational exposure. (These recommendations do not address exposure of the general public.) The requirement for ALARA programs, however, is contained in the recommendations and such programs are the responsibility of the implementing agencies.

1.11.22 EPA should coordinate with other agencies of Government a 10-year program targeting a national annual dose reduction of 5 million person-rems by 1990 (B.a-35).

Response: The comment provided a table giving a U.S. population dose of 45 million person-rems of which 22.5 million person-rems and 22.0 million person-rems were for natural radiation and patient medical radiation exposure, respectively. Since national occupational exposure was only 0.15 million person-rems in 1980, such a program is not relevant to occupational exposure, which is the subject of this rulemaking.

1.11.23 EPA should provide the American people with a timely annual report on radiation exposure, similar to the NRPB document, Radiation Exposure of the UK Population" (B.a-35).

Response: EPA prepares reports on occupational exposure in the USA at five-year intervals. The first report [EPA 520/4-80-001] was for 1975; the second report [EPA 520/1-84-005], covers 1980. We have found that the preparation of these reports is time-consuming and costly and that some data are difficult to obtain. However, since radiation exposures change relatively slowly over time, an annual report is not necessary.

1.11.24 The EPA should establish an Industrial Advisory Committee with representatives from industry and professional societies to advise on occupational issues relating to ionizing radiation (B.a-35).

Response: EPA provides for input from such groups on the same basis as other special interests and members of the general public; that is, through the mechanism of public hearings and comment.

1.11.25 EPA should form an Ad Hoc group to visit operating commercial power facilities, so as to gain first-hand knowledge of radiation protection practice (B.a-35).

Response: EPA staff and that of other Federal agencies that participated in the formulation of these recommendations include personnel with such first hand knowledge.

1.11.26 EPA should recognize that its guidance on radiation protection does not have the force of law in the courts. It should coordinate an effort by federal agencies to develop information on radiation risk that would be useful to the courts and to the Congress (B.a-35).

Response: We do recognize that it is not guidance, but regulations (based on guidance) that "have the force of law in the courts." We have sponsored all of the definitive reviews of radiation risk carried out by the National Academy of Sciences since 1970, and will continue to do so.

1.11.27 The purpose of the guidance is to deal with risk to the worker, not measure societal cost (A.a-38).

Response: An important component of societal cost is the total detriment to workers. The recommendations seek to minimize this detriment (i.e. collective dose), while also assuring an appropriate level of protection to individual workers.

1.11.28 The draft proposals would not in the aggregate be beneficial for among other reasons, there are no directly identifiable health effects for

exposure levels imposed by current RPGs and EPA declines to recognize any obligation to justify the costs of its actions to the users of ionizing radiation (A.d-40).

Response: There is clear societal recognition and acceptance of the need to set radiation protection standards at levels lower than those at which health effects are observed. Although there should be no directly observed health effects, we have estimated the range of health effects anticipated at occupational levels of exposure. See also the responses to comments 1.3.1, 1.4.6, 1.4.7, 1.4.9, 1.4.10, 1.4.26, and 1.9.1.

1.11.29 The proposed guidelines remove any of the flexibility to administer a total program of radiation safety (E.b-9).

Response: We disagree. No evidence has been advanced to support this comment. We believe, along with participating Federal agencies, that the recommendations provide for appropriate flexibility throughout.

1.11.30 Are federal agencies required to implement the guidance (A.a-5)?

Response: Upon the President's approval of EPA's recommendations, they become a Presidential directive to the Federal agencies.

1.11.31 The proposed guidance will be binding upon radiation workers but not federal regulatory agencies (A.d-14).

Response: Federal guidance is not directly binding on workers, regulations derived from guidance are binding on their employers. The recommendations are for the guidance of Federal agencies in the conduct of their radiation protection activities, including the development of their regulations. Also, see the response to comment 1.11.30.

1.11.32 EPA's proposal will be beneficial to individual workers at the expense of society because of increased collective dose. (A.b-4).

Response: We do not agree that there is any need for increased collective dose under these recommendations, which replace the former (3 rems) quarterly limit with a higher (5 rems) annual limit. See also the response to comment 2.1.5.

1.11.33 Death certificates should tell how long a person had a given disease (A.c-6).

Response: None required. Such requirements are outside the scope of Federal guidance.

1.11.34 Existing guidance purports to be 5 rems per year; this is more myth than reality (A.c-6).

Response: In existing Federal guidance (25 FR 4402) for radiation workers, the limits for whole-body exposure are: a dose of 3 rems per 13 weeks; and an accumulated dose (in rem) of 5 times the number of years beyond age 18 [i.e. accumulated dose of 5 (N-18) rems]. Thus, some workers could be permitted to receive a dose of 3 rems for 4 consecutive quarters, that is, 12 rems in a given year. The notion of "5 rem per year" in connection with the existing guidance therefore refers to the average annual limit over a working lifetime and not necessarily to the limit in any one year.

1.11.35 X rays do not prevent anything; the semantics on this point should be cleaned up in the guidelines (A.b-4).

Response: The final recommendations have been carefully edited to prevent unintended implications.

1.11.36 The guidelines should be based on a more carefully critiqued background document (A.b-4).

Response: Comments received on our proposed recommendations and background report were taken into consideration in preparing final recommendations and this response to comments.

1.11.37 What is the legal meaning and definition of the proposed Guidance in regards to other government agencies and the private work place (A.a-5).

Response: See the responses to comments 1.11.8, 1.11.16 and 1.11.17. Federal radiation protection guidance affects the private work place via the regulations of cognizant Federal agencies (and Agreement States).

1.11.38 We question the authority of EPA to prescribe regulatory approaches for all other Federal agencies (B.a-38).

Response: In our proposal (46 FR 7836) we cited EPA's statutory authority in the following statement:

> "Statutory Authority: The Administrator of the Environmental Protection Agency (EPA) is charged under Executive Order 10831, Reorganization Plan No. 3 of 1970, and Public Law 86-373 to '... advise the President with respect to radiation matters, directly or indirectly affecting health, including guidance for all Federal agencies in the formulation of radiation standards and in the establishment and execution of programs of cooperation with States.' This guidance has historically included both qualitative and quantitative formulations. The recommendations

we propose here would replace those portions of existing Federal guidance that apply to radiation protection of workers, which were adopted in 1960 (25 FR 4402)."

EPA prepares and submits to the President recommendations for new Federal radiation protection guidance. Upon his approval, these recommendations become guidance to Federal agencies in the conduct of their radiation protection activities. Thus, it is not EPA, but the President who prescribes new guidance to Federal agencies. This is the procedure followed during and subsequent to the existence of the former Federal Radiation Council (FRC), whose functions were transferred to EPA by the Executive Order cited above, under which the FRC was abolished. A significant new feature added by EPA to this procedure is that of providing the opportunity for public participation in the formulation of recommendations to the President.

1.11.39 The establishment of a value of person-rem would be the most important contribution the EPA could make to the development of a system of dose limitations (A.a-40).

Response: EPA has given some consideration to the appropriate value for the unit of collection dose, person-rem, in a number of its rulemaking activities. We recognize that the choice of an acceptable value could, in some respects, simplify the regulatory process. However, in real applications, different values may be appropriate, and other considerations are invariably also relevant to the choice of an appropriate level of control. We have concluded that a fixed value for this parameter is not achievable at the time.

SECTION 2.0 -- SPECIFIC ISSUES

2.1 LOWER RPGs

2.1.1 The costs of lowering the RPG below 5 rems are not justified by any substantial benefit (A.b-20, A.d-19, B.a-4, B.a-8, B.a-22, B.a-32, B.c-22, E.a-6).

Response: In the final recommendations, the limit for the effective dose equivalent is 5 rems, as in the proposed recommendations.

2.1.2 There is no scientific reason to set the annual limit below 5 rems (A.a-41, A.d-12, B.a-8).

Response: We disagree, since we assume a linear dose-effect relationship, not a threshold relationship. However, the choice of an annual limit can not be made solely on scientific grounds. See also the responses to comments 1.4.6, 1.4.9, 1.4.10, 1.4.14, and 1.4.26.

2.1.3 The annual limits should not be set below 5 rems (B.a-6, B.a-17, B.a-22, B.a-26, B.b-7, B.c-23, D-4, E.a-5).

Response: See the response to comment 2.1.1.

2.1.4 Setting the RPG below 5 rems is impractical, since some jobs require exposures near 5 rems (A.b-18, B.a-8, B.a-32).

Response: See the responses to comments 2.1.2 and 2.1.9.

2.1.5 A reduction in the annual limit below 5 rems would increase collective dose and health effects (A.a-42, B.a-1, B.a-6, B.a-22, B.a-32, B.a-33, B.a-48, E.a-6).

Response: We believe that this could occur only if the annual limit were established below 3 rems, the current quarterly limit. The magnitude of such counter-productive results would depend on how much lower than 3 rems the annual limit were set.

2.1.6 A reduction of the RPG to 3 rems would result in costs for equipment modifications, etc. A RPG less than 3 rems would impact the operational capabilities of DOD (E.a-2).

Response: See the responses to comments 1.9.14, 2.1.1, 2.1.5, and 2.1.9.

2.1.7 A reduction of the RPG to 0.5 rem/yr, 1 rem/yr, or 3 rem/yr would result in an increase in the number of workers at a nuclear plant and the associated costs would increase dramatically (B.a-48).

Response: See the responses to comments 2.1.1, 2.1.5, and 2.1.9

2.1.8 Limiting lifetime accumulated dose is a "more viable" approach than reducing annual dose limits (A.a-49, A.a-50, A.a-51, A.b-18).

Response: In part, we agree. However, because a large majority of commenters and Federal agencies opposed a lifetime dose limit, the final recommendations do not specify a limiting lifetime accumulated dose. See also the response to comment 1.6.8. However, the final recommendations do address the recording and minimization of cumulative lifetime individual dose.

2.1.9 Since 97% of all workers surveyed received less than 1 rem/yr, the limit of 5 rem/yr is unrealistically high (D-1).

Response: A number of commenters cited a need for a 5 rem/yr dose limit rather than a lower limit. In the nuclear power industry commenters testified that a 5 rem annual limit is needed for a small number of highly skilled workers doing such specialized work as steam generator repairs and steam generator eddy current inspections (B.a-1, B.a-8, B.a-28, B.a-37). Westinghouse testified their experience suggests a further need for exposures above 5 rem/yr for a small number of skilled workers involved in nuclear power plant service (B.a-46). They wrote: "Hiring or training qualified replacement workers is difficult or impossible for many of the complex skills and tasks involved ... that limits such as these would severely restrict specialty workers to the point of making certain tasks difficult or even impossible to perform (B.a-48)." The result of not utilizing experienced workers is increased worker exposure and/or costs or increased length of power outages (B.a-34, B.a-44, B.a-46, B.a-47, B.a-49). In the medical profession, commenters said the limited number of certain professionals, such as cardiologists, to conduct critical procedures could lead to restrictions on the numbers of such procedures, and that the current national manpower pool does not contain adequate duplication of workers for certain skills (A.d-14). In addition to the difficulty of obtaining qualified personnel, we estimated associated annual costs to be on the order of several hundred million dollars for hospitals for a limit of 1-2 rem/yr (EPA83a). A similar impact was estimated for increased manpower, facility, and health physics costs in some government research and development programs (DOE80).

EPA assessed the impact for an annual limit of 1.5 rems. Although risks to the highest exposed individuals would decrease, there is general agreement that the overall risk or collective dose would increase, as would costs for equipment and additional manpower. We estimated a total increase of approximately 6000 person-rems and almost 30,000 workers would

be required, at a first year cost of over $100 million and recurring annual costs of $400-700 million (EPA83a, DOE80).

For the above reasons we concluded that there is a limited number of situations in which it may be justified for workers to receive annual doses up to five rems. Consideration of the low level of worker exposure under current limits, and the large costs and difficulty of worker duplication in these areas led us to conclude that there is sufficient reason to retain a 5 rem annual limit at this time.

2.1.10 The RPG should be set at 0.5 rem/yr (A.a-38, A.a-44, A.c-6, A.c-8, C-6).

Response: See response to comments 2.1.5 and 2.1.9.

2.1.11 The annual dose limit should be 0.5 rem/yr, as 5 rem/yr does not provide an acceptable level of risk (A.c-7).

Response: The level of risk to the average worker under a limit of 5 rem/yr is expected to be less than the risk of accidental death in industries considered "safe" (ICRP77). The estimated average incremental risk of premature death (approximately 2 to 5 in 100,000) for measurably exposed (0.2 rem) U.S. Workers in 1980 (Ku84) is comparable to the safest industry group, trades (averaged about 5 per 100,000 from 1980 to 1984), and less than the incremental risk of accidental death (11 per 100,000) for all-industry workers in 1984 (NSC84). The maximum annual risk at 5 rem/yr is approximately 1 per 1,000 for premature death from radiogenic cancer. The guidance further specifies that this annual risk should not be incurred for a substantial portion of a working lifetime.

2.1.12 The dose limit to women should be 0.25 rem/yr (A.c-6).

Response: We disagree. There is insufficient difference between the radiogenic risks to men and women to justify a lower limit for women, except when pregnant and then for the protection of the unborn. For this case, our recommendations provide for protection of the unborn child without economic penalty or loss of job opportunity and security to women. See also the responses to comments 1.4.1, 1.4.2, 1.4.9, 1.4.21, 1.4.22, 1.4.26 and 2.13.6.

2.1.13 The RPG should be 2.5 rem/yr, with a quarterly exposure limit at 25% of the annual RPG (C-5, C-7, C-8).

Response: See the responses to comments 2.1.2, 2.1.5 and 2.1.9.

2.1.14 The weighted sum of annual dose equivalents and committed dose equivalents should be less than 1 rem (A.c-1, C-4).

Response: See the responses to comments 2.1.2, 2.1.5 and 2.1.9

2.1.15 The annual whole-body dose limit should be 1 rem, with limits to the gonads of 1 rem, to the eye lens of 1 rem, to the hands of 30 rems, and to any other organ of 15 rems (A.a-1, C-4).

Response: See the responses to comments 2.1.2, 2.1.5 and 2.1.9.

2.1.16 The annual whole-body limit should be 1 rem, with limits to the gonads of 1 rem, to the eye lens of 1 rem, to the hands of 10 rems, and to any other organ of 6 rems (D-5).

Response: See the responses to comments 2.1.2, 2.1.5 and 2.1.9.

2.1.17 Given the proven hazard of radiation at all levels, there is no justification for exposure beyond background levels (A.c-7, C-6).

Response: The possibility of risks from exposure at levels within the dose limits is not, by itself, justification for shutting down all beneficial activities that involve exposure to radiation. Most employment carries some attendant risks, and in most cases the observed risks of accidental death are comparable to or greater than those estimated for average occupational exposure to radiation. Also, see the response to comment 1.3.10.

2.1.18 The maximum permissible exposure to gonads and red marrow should be reduced to 5 rem/yr (A.c-6).

Response: The final recommendations adopt the limits specified in ICRP-26. These values were chosen so that all types of exposure are limited to approximately the same level of risk. Also, see the responses to comments 1.3.1 and 1.6.12.

2.1.19 Whole body occupational exposure limits should be 0.5 rem per year and the population environmental exposure should be limited to 25 millirem per year (A.c-6).

Response: See the response to comment 2.1.9. The subject recommendations are confined to occupational exposure. Other EPA standards (40 CFR 190 and 40 CFR 61) limit dose to members of the public to 25 millirem per year.

2.2 VALUES OF RPGs AND RIFs ONLY ALLOWED TO DECREASE

2.2.1 There is no sound technical basis for accepting only those ICRP recommendations that produce more restrictive limits and selectively

rejecting those that produce less restrictive limits (A.a-41, A.b-16, A.b-18, A.d-9, A.d-12, A.d-15, B.a-6, B.a-7, B.a-9, B.a-17, B.a-23, B.a-34, B.c-22, E.a-5, E.a-6, E.b-2, E.b-3, E.b-9, F-2).

Response: We agree, in general, and have deleted this provision. However, the proposed recommendation was based on the assumption that conformance to existing limits demonstrated that such levels were achievable and "ALARA;" therefore, no justification existed for use of higher values. In situations identical or similar to those in effect in the past this observation would continue to be true and higher values should not be used, since the final recommendations continue to require that ALARA be practiced.

2.2.2 Part b of Recommendation No. 5 has no justifiable basis other than the Agency's reluctance to change to less restrictive values, and should be deleted (A.a-41, A.d-19, A.d-21, A.d-40, B.a-13, B.a-27, B.a-32, B.a-34, B.a-46, B.a-48, B.c-12, B.c-21).

Response: See the response to comment 2.2.1.

2.2.3 In order to properly allocate radiation protection resources based on risk, limits should be raised and lowered as the evidence suggests (A.b-15, A.b-20, A.d-23, B.a-8, B.a-17, B.c-10, E.a-6, E.b-8).

Response: We agree. See, however, the responses to comments 2.2.1 and 2.2.8

2.2.4 The policy that limits be no higher than currently in use will result in confusion among radiation protection professionals (A.a-6, E.a-5, E.b-8).

Response: The final recommendations do not contain such a provision.

2.2.5 The refusal to increase an RIF despite the indication to do so tends to discourage research, since results that lead to an increased RIF would be ignored (E.b-2).

Response: We do not agree. However, see the responses to comments 2.2.1 and 2.2.8.

2.2.6 Reducing guides to levels that have been shown to be possible will reduce the incentives to maintain exposures ALARA (B.a-29, E.b-8).

Response: We disagree. However, see the response to comment 2.2.1.

2.2.7 The ALARA criterion and not the arbitrary lowering of limits if they can be achieved, should be used to reduce risk (E.a-6, E.b-5, E.b-10).

Response: We agree. See the response to comment 2.2.1.

2.2.8 To raise the MPCs merely because it can be done without surpassing the whole body annual dose equivalent is contrary to the basic objective of radiation protection; keeping all exposures ALARA (C-1).

Response: The MPCs and the ALARA principle serve two different functions. The MPCs correspond, for normal circumstances, to the limit on maximum committed dose. The ALARA principle requires that doses be maintained as far below that limit as reasonably achievable. The importance of maintaining exposures ALARA is emphasized in the recommendations. Under the ALARA principle, the calculational increase of a regulatory MPC value, per se, is not sufficient justification for then allowing the increase of an individual's exposure. See also the response to comment 2.2.1.

2.2.9 Recommendation 5b suggests that errors in the past should be promulgated into the future (A.a-40, A.a-49, A.a-50, A.a-51, A.b-18).

Response: This is incorrect. The proposal was based on the assumption that past practice demonstrated that the previous levels were reasonably achievable. However, see the response to comment 2.2.1.

2.2.10 Recommendation 5b applies ALARA separately to each radionuclide, virtually guaranteeing a misallocation of resources (E.b-2).

Response: See the response to comment 2.2.3.

2.2.11 The real harm of constantly "ratcheting" limits is the misimpression given to the general public; namely, "If there isn't any harm in radiation exposure, why are the limits constantly being lowered" (A.a-41)?

Response: Although it is a basic assumption that some harm is associated with any radiation exposure, we did not use the "ratcheting" approach. Under the system of dose limitation adopted in our final recommendations, some of the new derived limits are higher and others lower than in existing guidance. These recommendations, as well as those of ICRP, NCRP, etc., are based on the belief that there <u>are</u> risks involved in exposures at any level, even at the levels within recommended limits. The limits are not to be considered a division between "safe" and "unsafe" levels. See also the responses to comments 1.6.11 and 2.2.1.

2.2.12 If EPA feels unable to increase limits, the lower values should be listed as an advisory list that EPA believes can be met in the cause of ALARA (A.b-16).

Response: See the responses to comments 2.2.1 and 2.2.8.

2.2.13 We agree with EPA that the ICRP recommendation should only be adopted in situations where current exposures are maintained or reduced (C-2, C-6, E.a-6).

Response: We assume the comment is directed to proposed recommendation 5b. The final recommendations adopt the ICRP approach that the maximum annual risk should be limited to that associated with an effective dose equivalent of 5 rems and that ALARA requires that doses be maintained as far below that limit as reasonably achievable. See also the response to comment 2.2.8.

2.2.14 No standard should be adopted that will result in increased exposures from any sources (A.c-4).

Response: See the response to comment 2.2.13.

2.2.15 Selective changes should not be made when the new RPGs are higher than existing values (B.a-46).

Response: See the responses to comments 2.2.1 and 2.2.8.

2.3 TRANSIENT WORKER ISSUES AND ADEQUACY OF OCCUPATIONAL EXPOSURE DATA BASE

2.3.1 Transient workers are receiving the greatest burden of occupational dose, and utilities are using such workers and "burning them out" so that they can preserve their skilled labor pool and claim their regular workers are receiving less than the legal dose (A.a-5, A.c-6).

Response: The issue raised by the commenter is a difficult one. The guidance is applicable to all workers, and it is not easy to differentiate between permanent and transient workers. Utilities control exposures to employees and transient workers within their plants (including contractor workers) subject to the same limits. A characterization of the temporary radiation work force at U.S. nuclear power plants for the years 1980-1982 showed comparable exposures to contractor and utility workers (AIF84). Under the final recommendations, exposure (whole-body) of <u>any</u> individual worker would be limited to 5 rems in a year; whereas previous guidance permitted up to 3 rems per quarter and 12 rems per year under the accumulated dose condition of 5(N-18). The new dose limits would therefore reduce the exposure of all workers now receiving doses between 5 and 12 rems in a year; however, it would permit short term workers to receive 5 instead of 3 rems. It is the intent of the provision for

recording lifetime doses to establish recordkeeping requirements that will help to minimize abuse of temporary workers.

2.3.2 Transient workers require special protection since they do not admit their exposure at previous plants, are not well educated, have small regard for the risks, and frequently are in such a financial position that if and when they develop radiation-related cancer their children become a financial burden to society (A.a-5).

Response: Workers who are able to circumvent the rules and regulations designed to implement dose limits present a difficult problem. The new requirements for instruction on risks (including information on the specific risks of their jobs) and for recording of lifetime dose may lead to rules that will reduce such occurrences. It would be ideal to provide protection for even those who, for whatever reason, wish to ignore or circumvent regulatory dose limitations. See also the response to comment 2.3.1.

2.3.3 A partial solution to the abuse of transient workers is to redesign reactors and improve shielding to minimize high dose maintenance jobs (A.c-6).

Response: Substantial efforts have been and are being made to keep exposures of both transient and regular workers ALARA; these include engineering efforts. See also the response to comment 2.3.1.

2.3.4 EPA & NRC underestimate the number of transient workers and the doses they are receiving, and these workers may not be fully informed of the hazards of radiation (A.b-21).

Response: The EPA reports on occupational exposure in 1975 and 1980 do not contain separate statistics on "transient workers" (Cob80, Ku84). Such workers at nuclear power plants are included in the statistics for all workers in the Nuclear Fuel Cycle category in these reports. The NRC has regulations designed to provide the same protection to all these workers and to provide instruction on the risks of exposure to radiation. Under NRC regulations, the dose record of any worker at a nuclear power station is submitted to NRC each time he terminates employment at a given station. These records are maintained by NRC. See also the response to comments 2.3.1 and 2.3.2.

2.3.5 EPA has not assessed the impact of its guidance on the highly skilled, but limited pool of transient workers. The guidance would limit the use of these workers, thus increasing total radiation exposure of the workforce (B.a-46).

Response: Although we have not carried out an independent study on this matter, we have analyzed the reports of others, including those of the

Atomic Industrial Forum (AIF80, AIF84). We conclude that the change of the basic limit from 3 rems per quarter to 5 rems per year, will have no significant adverse effect (if any) on either the highly skilled transient workers or on collective dose. If any new workers must be trained to avoid exposures greater than 5 rem per year, the guidance recognizes the need for an appropriate period of time for implementation. See also the responses to comments 1.9.5, 1.11.14 and 2.1.5.

2.3.6 A dose limit should be established beyond which documentation of a transient worker's year-to-date exposure record must be obtained (A.a-19, A.b-21).

Response: Appropriate monitoring, maintenance of a cumulative record, and availability of the workers exposure record on an annual basis are addressed in the final recommendations. However, detailed implementation must be based on procedures specified in regulations by the cognizant Federal agency.

2.3.7 The current regulations are sufficient to protect transient workers (E.a-5).

Response: Without commenting on the validity of this comment, it should be noted that we believe the new recommendations will lead to improved protection to all workers, including transient workers.

2.3.8 NRC, not EPA, should develop strict regulations to cover non-nuclear utility station employees assigned to temporary nuclear duties (A.c-6).

Response: We agree that NRC is the agency responsible for detailed regulations concerning all workers, permanent and temporary, at nuclear power plants. EPA is charged to advise the President on appropriate recommendations to Federal agencies applicable to the protection of all workers; it does not directly regulate worker exposures to ionizing radiation.

2.3.9 The occupational exposure data base used by EPA is questionable, since personnel monitor readings misrepresent whole body doses (A.b-15, A.d-22, A.d-28).

Response: The significance and possible shortcomings of the data used by EPA to derive exposure statistics are discussed in our occupational exposure reports [EPA 520/4-80-001 (Cob80) and EPA 520/1-84-005 (Ku84)]. For example, "A monitoring device only records the dose it receives...the recorded dose may or may not approximate...whole-body dose" (Cob80). We believe, however, that these possible shortcomings do not affect the recommendations.

2.3.10 By using the arithmetic mean to indicate the average worker's exposure, EPA has overestimated occupationally-related radiation risk (A.b-1).

Response: We disagree. EPA Reports No. 520/4-81-003 (EPA81) and No. 520/4-80-001 (Cob80) contain all essential data, including dose distributions, and explain in detail the methods used in the computations. For estimating radiation risks, the statistic of "average" (arithmetic mean) dose is the relevant quantity for estimating the detriment in a group of known size.

The problem may be one of semantics. We have defined the term "mean" annual dose to be the collective dose of all potentially exposed workers divided by that number of workers. This may not be equivalent to the "average worker" referred to by the commenter.

2.3.11 In some risk comparisons, EPA averages in unexposed workers to make the mean worker exposure appear lower (A.a-3).

Response: We believe we presented a clear, objective, and meaningful analysis of worker risks. These risks were given both for "all potentially exposed" workers and for just those workers "measurably exposed." See also the response to comment 2.3.10.

2.3.12 The occupational exposure data base is inadequate, as monitoring in many occupations is nonexistent while in others it is not universal; until badging is universal EPA should err on the side of safety (A.a-5).

Response: There are, indeed, many difficulties in making comprehensive radiation exposure analyses of occupational exposures in the United States. These are discussed for the period from 1960 to 1980 in our reports EPA 520/4-80-001 (Cob80) and EPA 520/1-84-005 (Ku84). Although we expect to make continued improvements in future analyses, we believe a careful reading of these reports will show that the exposure of workers is adequately assessed for the purposes of risk assessment.

2.3.13 EPA should update its information base before decisions on this guidance are made final, since it does not reflect 6 years of ALARA reductions and occupational exposures since 1975 (B.a-1, B.a-29).

Response: We have done so. Recently we completed a comprehensive reanalysis of occupational exposure for the period 1960 to 1980 and made projections for the year 1985 (EPA 520/1-84-005). The results of these analyses do not differ significantly enough from the earlier analysis (EPA 520/4-80-001) to warrant changes in the proposed guidance.

2.3.14 EPA overstates the number of radiation workers in medicine (A.b-4).

Response: In our report covering 1980 exposure, we use improved methods for estimating the number of workers in medicine (Ku84). These estimates indicate there are 584,000 potentially exposed workers in medicine, which comprise approximately 44 percent of the potential exposed work force in this country; corresponding figures in the report for 1975 exposures were 546,300 persons and 49 percent (Cob80). Revised estimates for 1975 are 485,000 persons and 44 percent (Ku84), which indicate our original estimates (Cob80) were only slightly high.

2.3.15 Since the data base on dose to medical radiation workers is deficient, it is difficult to analyze the effectiveness of the proposed minimum radiation protection requirements (A.d-8).

Response: The proposed minimum radiation protection requirements do not appear as such in final recommendations. In the final guidance, general recommendations are used to carry out the objectives of those proposals.

2.3.16 All nuclear licensees should obtain and take account of cumulative radiation doses of temporary workers before exposing them to more radioactivity (A.c-6).

Response: The final recommendations encourage maintenance of a cumulative record of lifetime occupational dose. However, such procedures are specified in regulations and regulatory guides of the Federal agencies, such as NRC.

2.4 OMISSION OF MEDICAL AND OTHER NON-OCCUPATIONAL EXPOSURES

2.4.1 EPA should include guidance on medical exposures (A.a-12, A.c-8, A.d-8, B.a-35).

Response: Radiation exposure of all workers, including medical workers, is covered by this radiation protection guidance for occupational exposure. But "occupational exposure" does not include exposure received as a patient. Medical exposure of patients to diagnostic x rays is the subject of separate EPA recommendations for Federal radiation protection guidance (43 FR 4377), approved by the President on February 1, 1978.

2.4.2 EPA's omission of guidance for medical exposures can only be the result of political expediency (A.b-8).

Response: See the response to comment 2.4.1 above.

2.4.3 If EPA's concern for somatic and genetic effects in radiation workers is real, diagnostic medical exposures must be controlled.

Physicians cannot make risk-benefit judgments, as they have no idea what occupational exposures their patients receive (B.c-21).

Response: EPA is concerned about all unnecessary exposure to radiation. However, occupational exposure usually has no bearing on whether or not a medical exposure is justified. The decision for each medical exposure should be based on its own individual merits, without regard to occupational exposures. (A possible exception may occur when the non-stochastic limits are exceeded.)

2.4.4 EPA should require medical practitioners to provide patients with doses for each medical exposure. Such information is essential for intelligent career planning (A.a-8).

Response: EPA does not have the authority to require medical practitioners to provide patients with a statement of the dose received in each medical exposure. See also the response to comment 2.4.3.

2.4.5 EPA should require informed consent prior to radiologic or nuclear medicine procedures. This would eliminate unnecessary procedures and reduce exposure to patient and worker populations. (A.c-8, A.d-8).

Response: This comment is outside the scope of this rulemaking on occupational exposure to ionizing radiation.

2.4.6 Epidemiological studies require records showing both occupational and medical exposures (A.a-8, C-5).

Response: We agree that this would provide the most meaningful results, all other applicable requirements for such studies also being met.

2.4.7 The EPA should outlaw dangerous practices in health institutions, such as holding of patients during x rays, that cause radiation exposures of workers (A.c-8).

Response: To the extent that such practice represents unnecessary exposure of workers, it should be avoided. The ALARA provision of Federal radiation protection guidance directs that such unnecessary exposure should not occur. However, it is the responsibility of regulatory agencies, not EPA, to assure that ALARA practices are followed.

2.4.8 The Federal Radiation Guides should require the identification of radioactive patients and require standard care plans to protect medical personnel caring for such patients (A.c-8).

Response: Such requirements would be useful for the achievement of ALARA exposures. However, the suggested requirements are most appropriately

promulgated by Federal and State regulatory authorities in their regulations and guides, since these requirements are of a detailed nature not normally addressed by Federal guidance.

2.4.9 Adequate shielding of patients and medical workers should be mandatory (A.c-8).

Response: See the responses to comments 2.4.1, 2.4.7 and 2.4.8.

2.4.10 EPA should provide guidance for x-ray exposures that would keep doses as low as reasonable achievable, and forbid diagnostic x rays unless other diagnostic procedures indicate such x rays will be useful (A.a-5, A.c-6).

Response: See the responses to comments 2.4.1 and 2.4.11.

2.4.11 The EPA should recommend against routine pre-employment and annual x rays for employment screening purposes (A.c-6, A.c-8).

Response: EPA has done so in its Federal radiation protection guidance for diagnostic x rays (43 FR 4377; February 1, 1978).

2.4.12 Medical exposures should be treated separately (A.b-10, A.b-17, A.b-26, A.d-13, A.d-22, B.a-20, B.c-23).

Response: They are. See the responses to comments 2.4.1 and 2.4.3.

2.4.13 The guidance proposed by EPA should include consideration of variations in natural radiation levels and the many activities that can technically enhance the natural radiation background (A.a-10).

Response: Under the caption, "Other Considerations," in the preamble to our proposed recommendations (46 FR 7836) we state:

> "These recommendations apply to workers exposed to other than normal background radiation on the job. It is sometimes hard to identify such workers, because everyone is exposed to natural sources of radiation and many occupational exposures are small. Regulatory agencies will have to use care in selecting classes of workers whose exposure does not need to be regulated. In selecting such classes we recommend that the agency consider both the collective dose which is likely to be avoided through regulation and the maximum individual doses possible."

We recognize that there are wide variations in normal background radiation. See the response to comment 1.4.49. Doses received by workers

from such radiation are not considered "occupational," under Federal guidance. However, a variety of working environments can involve "technically enhanced natural radiation" levels. Although the radiation involved is "naturally occurring," workers may have the potential for receiving significantly more than normal background exposure as a result of their occupation and therefore it is considered "occupational exposure." For certain activities, such as uranium mining and milling, this is recognized as such and worker exposure is controlled accordingly. In other activities, such as air transportation, some exposure of workers occurs but it may or may not warrant regulatory control.

2.4.14 The EPA should release the research information and data pertinent to occupational exposures caused by radon decay products in new energy efficient buildings so that all significant exposure sources of occupational exposure can be examined in evaluating the proposed guidance (B.c-1).

Response: This involves an issue (radon decay products) that is not addressed by the proposed guidance. However, EPA continues to gather information, sponsor studies, and publish reports related to such exposure as suggested by the comment. Although such exposure can be characterized as technologically enhanced, it is more properly considered as a generic issue involving the entire U.S. population when indoors, regardless of the location of a workplace or home. See also the response to comment 2.4.13.

2.4.15 EPA should withdraw the proposed guidance and concentrate on the much larger and more dangerous problem of indoor radon exposures (A.a-9).

Response: The Agency has proceeded with the formulation of final recommendations for new Federal radiation protection guidance for occupational exposure because we believe it is needed and will benefit workers. However, we agree that indoor radon exposure is a major public health issue, and EPA is conducting, in concert with other Federal agencies, a careful study of this problem and its solutions.

2.4.16 Rather than set extremely rigorous standards for indoor radon exposures, EPA should relax the recommended guidance to reflect the growing consensus that exposures to low-LET ionizing radiation at low dose rates are less hazardous than previously assumed (A.a-9).

Response: Standards for indoor radon exposures are not a part of the new recommendations for occupational exposure (See the response to comment 2.1.14). As indicated in its background report, EPA makes use of the best available scientific information on the biological effects of ionizing radiation. This information includes consideration of low-LET ionizing radiation at low dose rates (See the response to comment 1.4.1).

2.4.17 Persons incidentally exposed, i.e., the general public, should also be protected by guidelines (A.d-13).

Response: They are. As stated in the preamble to the proposed recommendations (46 FR 7836), the new recommendations "would replace those portions of existing Federal guidance that apply to radiation protection of workers, which were adopted in 1960 (25 FR 4402)." Thus existing guidance for the protection of the general public would continue in force.

2.5 OMISSION OF UNDERGROUND MINERS AND OTHER OCCUPATIONAL CATEGORIES

2.5.1 EPA should reconcile its recommendations with the Mine Safety and Health Administration (E.a-3).

Response: A close liaison is maintained between EPA and the Mine Safety and Health Administration (MSHA). MSHA is a member of the interagency working group formed by EPA to develop this Federal radiation protection guidance for occupational exposure, and has concurred in the final recommendations.

2.5.2 EPA should take note, particularly of highly damaging alpha radiation released in uranium mines, that doses to uranium miners are calculated from air concentrations measured at regular intervals in mines but which do not account for high individual doses (A.c-6).

Response: It is the responsibility of regulatory agencies to require types and frequency of measurements appropriate to assuring that individual workers do not exceed the limit specified by Federal guidance. We note, however, that existing Federal guidance for radon decay products is not changed by the subject guidance. See also the response to comment 2.5.3.

2.5.3 EPA should establish a RIF for uranium miners (in terms of rems) consistent with the RIF's for other categories of nuclear workers (C-5).

Response: The existing guide (36 FR 12921) for limiting exposure of underground miners to radon decay products is not changed by the final recommendations for Federal radiation protection guidance for occupational exposure. We intend, however, to review that guidance in the near future. In the meantime exposure of miners to radiation other than from intake of radon decay products is governed by the new recommendations.

2.5.4 EPA should review the guide for exposure of uranium mine workers as there may be serious adverse health effects at levels formerly considered relatively safe (A.b-9).

Response: As stated in the preamble of our proposed guidance (46 FR 7836), "We expect to review the guide (36 FR 12921) on exposure of miners to decay products of radon in the future."

2.5.5 What radiation protection guide applies to non-uranium miners exposure to radon decay products and how does it compare to the uranium miners' guide (A.a-10)?

Response: Although the Federal guide (36 FR 12921) for radon decay products (4 WLM/yr) addressees "underground uranium miners," it is applied by regulatory agencies (e.g., MSHA, NRC) to other classes of miners, and workers in other employment activities, for which that guide is appropriate.

2.5.6 EPA should consider the doses received by non-radiation workers in industries such as phosphates, fertilizers and the airlines (A.b-4).

Response: EPA was cognizant of exposures received by such groups of workers (Co80, Ku84) in the phosphate (EPA76), fertilizer (EPA76) and the airline (EPA74) industries, as part of the background information used in developing new recommendations for Federal guidance on occupational exposure. See the response to comment 2.4.13.

2.5.7 EPA should not allow transportation workers to receive radiation exposures higher than the general public (A.c-6).

Response: Many transportation workers are already protected to the same level as members of the public. There are, however, transportation workers engaged wholly or significantly in the transportation of radioactive materials who may receive higher doses. EPA is not the appropriate agency to decide that a lower dose limit should apply rather than the maximum permitted other workers. However, Federal radiation protection guidance provides the basis for such regulations by the regulatory agencies (DOT, NRC, etc.) when they are appropriate for the protection of such workers.

2.6 OMISSION OF EMERGENCY EXPOSURES

2.6.1 Setting guidelines for accidental or emergency exposures serves no purpose as such exposures are, by definition, uncontrolled (B.c-23).

Response: While it is true that accidental exposures are uncontrolled, the same is not true for "emergency exposures." Emergency exposures are controlled exposures involving doses above the established limits received by workers in assignments of an emergency nature, such as a lifesaving operation.

2.6.2 Emergency exposures should be addressed in the recommendations (A.a-18, A.a-19, A.d-9, A.d-22, B.a-20, B.a-32, C-22, E.a-5).

Response: Recommendation 10, which addresses emergency exposures, does not include specific limits. This matter is left to the Federal agencies, to be determined on the basis of the general guidance provided, because they are most knowledgeable about the specific situations under their jurisdiction in which emergencies may occur.

2.6.3 Emergency guidance should include the recommendations of the NCRP and the application of ALARA (A.a-8).

Response: Recommendation 2 (which addresses ALARA) applies to all types of controlled exposures, including emergency exposures. See also the response to comment 2.6.2.

2.6.4 The only way to eliminate "Higher Than Normal" doses is to eliminate accident and incident prone situations. Exposures can be minimized through employee education (A.a-5).

Response: While we agree in general, it should be noted that higher-than-normal doses are not confined to accidents and emergency situations. There are unusual circumstances (e.g., astronaut missions) for which it may be necessary to permit doses higher than the limits. These situations are covered by Recommendation 10. Also, see the response to comment 2.6.3.

2.7 IMPACT OF RPGs ON COLLECTIVE DOSE

2.7.1 A reduction in the individual dose limit will result in an increase in collective dose (A.a-19, A.a-42, A.d-31, B.a-1, B.a-2, B.a-3, B.a-17, B.a-21, B.a-38, B.a-39, B.a-46, B.a-54, C-2, D-6, D-11, E.a-5, E.b-6, E.b-8, E.b-10).

Response: There is a possibility for this to occur, depending on the extent to which the dose limit is reduced. We gave this matter serious consideration and concluded that the dose limits chosen in the final recommendations would not lead to an increase in the collective dose to the work force. See the response to comment 2.1.5.

2.7.2 Guidance should be provided on how to weigh the benefits of decreased individual exposure against the costs of increased population exposure (A.a-42, B.a-1, B.b-5, D-6, E.b-10).

Response: We know of no single method for determining trade-offs between the reductions in dose to an individual and in collective dose that would be applicable to all cases. Rational decisions on trade-offs between individual and collective doses can only be made on a case-by-case basis, and may, in rare cases, have to be arbitrary.

2.7.3 EPA should clarify its position on ALARA individual vs. ALARA collective doses and revise the guidance accordingly (A.d-40, B.a-54).

Response: See the response to comment 2.7.2.

2.7.4 Since only trained persons are used, collective dose will not increase when rotation of workers is used to reduce individual doses (C-8).

Response: We agree that this is generally true, and employers should ensure that only properly trained workers are used. However, the extent of unavoidable unproductive exposure (such as that during entry to and exit from high radiation areas) can be relevant in high dose rate situations. While there is the possibility of an increase in the collective dose in such operations, we do not believe that the final recommendations will lead to increasing the collective dose in the work force due to increase in such exposure, because the limit applicable to any single job has not been decreased. (In fact, it has been increased: the effective previous limit applicable to such situations was 3 rems; the new effective limit is 5 rems.) See also the responses to comments 1.9.5 and 2.3.5.

2.7.5 Collective dose is less significant than individual dose; the primary risk is to the worker and his family (C-8).

Response: This depends upon the point of view that is relevant to the judgment. However, EPA believes that both types of doses have significance and therefore are addressed by the final recommendations. From a national point of view the total detriment, which is related to the collective dose, is most significant. From the point of view of sufficiently limiting the risk to each worker, the maximum individual dose is most significant.

2.7.6 The consequent increase in collective dose resulting from the guidelines will lead to an increase in potential health effects (A.a-42, A.b-4, A.d-5, A.d-14, B.a-17, B.a-18, B.a-46).

Response: We do not believe these recommendations will result in any increase in collective dose to the work force. See the responses to comments 2.7.1 and 2.7.4.

2.7.7 Lowering the individual RPG implies that engineering controls must be improved to keep collective doses from rising (C-5).

Response: We disagree. See also the responses to comments 2.7.4, 2.11.1, 2.11.3 and 2.11.4.

2.8 CONSIDERATION OF WORKER AGE

2.8.1 Age is also an important factor in determining risk. EPA's guidance should consider age in justifying the proposed lifetime limit (B.a-46).

Response: We agree that age is an important factor in estimating risk. However, because of overwhelming opposition in public comments, the admonishment or objective to manage workers so that their lifetime accumulated dose is less than 100 rems does not appear in the final recommendations.

2.8.2 Setting reduced exposure limits for young workers creates two inconsistencies: first, the majority of the high exposure jobs are physically strenuous and require younger workers, and second, older workers are typically given more frequent physical exams to detect physical limitations (E.b-8).

Response: The recommendations do not differentiate younger from older workers, except in the case of minors. The lower dose limit for minors (workers younger than 18) is consistent with previous guidance and longstanding custom that underage persons should be given greater protection against occupational hazards than adult workers.

2.8.3 EPA should include the age factor in its guidance (A.a-38, A.a-46).

Response: We recognize that the risk from exposure generally appears to decrease with age. However, age-dependent limits discriminate against younger workers. They would also be difficult to administer. We have concluded that it is not practical to limit doses to workers on the basis of an assumed age-dependence of risk, given the present state of knowledge. See also the response to comment 2.8.5.

2.8.4 Consideration of worker age will only result in additional work and lack of acceptance by both labor and management (A.d-22).

Response: We have no comment on this opinion.

2.8.5 EPA should not include a higher limit for older workers since specific health problems may put them at higher risk (A.b-26).

Response: We are not aware of any scientific support for the thesis that such workers are at higher radiation risk. However, the dose limits in both our proposed and final recommendations are age-independent.

2.8.6 The possibility of increased cancer risk from radiation in both younger and older workers compared to middle-aged workers should be explored (A.c-6).

Response: EPA considered the available data on age dependence of risk. This information is further updated and discussed in the responses to comments given in subsection 1.4.

2.8.7 The genetic risks do not justify setting age-dependent dose limits (B.a-42).

Response: The limits recommended are intended to protect against both somatic and genetic risks. However, the recommendation of an age-independent limit does not imply that we consider genetic risks to be negligible.

2.8.8 Since older workers are more experienced and generally can do difficult jobs which might involve higher exposures more efficiently than less experienced younger workers, a scheme allowing older workers higher dose increments in any time period would probably result in a lower total workforce exposure (A.a-38).

Response: The recommendations permit this type of strategy to be followed, provided the overall annual limiting doses are adhered to and continued exposure of a worker at or near annual limiting doses for substantial portions of a working lifetime is avoided.

2.9 NEGLECT OF PROCEDURES FOR OVEREXPOSURES

2.9.1 ICRP recommendations for handling overexposures should be included in the guidance to allow needed flexibility (A.d-13, B.a-46, B.a-48).

Response: The recommendations do not address overexposures with respect to the limiting values for annual dose, since we believe this is a matter properly addressed by regulatory authorities. (However, for the case of failure to satisfy the recommendations for control of committed dose due to intake of radioactivity, there is follow-up management of a worker's future exposure. That is, when conditions for control of intake of radioactive materials have not been met, the recommendations provide that annual dose equivalents from such intakes should be assessed for as long as they are significant for ensuring conformance with the limiting values for effective dose equivalent in any year.)

2.9.2 Situations requiring larger doses should have been part of the guidance (A.d-22, A.d-24, B.a-46, B.a-48).

Response: Recommendation 10 provides for such unusual circumstances.

2.9.3 EPA should clarify the consequences to both the worker and the employer when an RPG is exceeded (A.b-15, A.d-21).

Response: These matters, by law, are determined by the cognizant regulatory agencies, not EPA.

2.9.4 EPA must provide guidance for reporting and evaluating overexposure incidents and prescribe and enforce penalties that will induce industry to limit worker exposures to within the proposed limits (C-6).

Response: See the response to comment 2.9.3.

2.9.5 Failure to provide for overexposures may result in serious distortions of the significance of minor overexposures (in the range of 6-10 rems) and lead to emotional trauma for the worker and other undesirable over-reactions (A.b-13).

Response: We disagree that such overexposures should be considered minor. In any case, the risks from such exposure can be evaluated. This evaluation should be made available to the worker to avoid inappropriate reactions.

2.10 ADEQUACY/ACCURACY OF DOSE MEASUREMENT TECHNOLOGY

2.10.1 Internal dosimetry techniques are not, in general, sufficiently sensitive or sophisticated to provide the data required by ICRP's concept of weighting factors for organ doses from internal emitters. The 50-year annual committed dose equivalent concept only compounds the difficulty, effectively reducing the RIF for long-lived biologically persistent isotopes by a factor of 50 (A.d-12, A.d-15, B.a-24, E.a-5, E.b-3, E.b-6).

Response: The comment is based upon an apparent misconception of the use of weighting factors. It is not necessary that dose to each of the organs of a worker be measured for internal emitters. Instead, the total intake is measured (or inferred from workplace conditions) and models specified by ICRP-30 (or their equivalent) are used to calculate the effective (i.e. weighted) dose. Detailed tables already exist (ICRP80) for this purpose. Thus, the estimation of dose is, in effect, identical in procedure to that now employed for determination of conformance to the existing limits based on the Maximum Permissible Concentrations (MPCs). The assertion that the RIF is effectively reduced by a factor of 50 over the MPCs for long-lived radioisotopes is incorrect. Current MPCs are based on a similar concept

involving the assumption of 50 years of intake, and yield identical values for equivalent metabolic and internal distribution models.

2.10.2 In Vivo counting, in some cases, cannot establish that EPA's required RIF's are not being exceeded (E.b-5, E.b-6).

Response: See the response to comment 2.10.1.

2.10.3 Neither personnel dosimeters nor air monitors are sensitive enough to detect exposures at the levels provided for in the guides (A.c-6, B.a-24, E.a-5, E.a-7).

Response: We disagree. See the responses to comments 2.10.1, 2.10.4, and 2.10.5.

2.10.4 The 50-year dose commitment requirement will require greatly improved surveillance methods and greatly increased bioassay frequencies (E.a-5, E.a-7, E.b-6).

Response: This is not the case. The existing regulatory requirements are based on models that are mathematically identical or equivalent to the 50-year dose commitment. That is, the old MPC and the new DAC values are based on the same 50-year dose commitment requirement. Thus, the new guidance imposes no new burden. The sometimes large changes in these values are primarily the result of improved dosimetric and metabolic models (EPA84b), not changes in the limits. See the responses to comments 1.6.12 and 2.10.1.

2.10.5 Low-level chronic uptake of internal emitters makes it virtually impossible to determine what fraction of the material in the body organs is attributable to the current year's intake (E.6-3).

Response: Such difficulties are not new to these recommendations. However, health physicists have been able to deal with them in the past, and we expect that they will continue to be able to do so. See also the responses to comments 2.10.1 and 2.10.4.

2.10.6 Personnel dosimetry is not accurate for extremity exposures. If limits to extremities are unnecessarily reduced, more frequent and accurate measurements will be needed and applied health physicists will be faced with the task of interpreting the actual dose from a multiplicity of conflicting data (E.b-8).

Response: Final recommendations adopt the dose limitations in ICRP-26, in which the annual limiting dose to the extremities (hands and forearms,

feet and ankles) is 50 rems. This limiting annual dose of 50 rems is only marginally lower than the 75 rem limit in previous guidance (25 F.R. 4402). We believe there will be no difficulty arising from this modest reduction.

2.10.7 EPA should delay implementing its proposed guidance until a detailed analysis of dosimetry and internal measurement methods are shown to be practical (E.a-7).

Response: We do not believe this is required. See the responses to comments 2.10.1, 2.10.4, 2.10.5, and 2.10.6.

2.10.8 The ICRP scheme of weighted whole body equivalents for organ doses ignores the lack of data on factors such as chemical species, physical form, and route or intake that affect the movement and fate of radionuclides taken into the body. Thus, the amount in a given organ cannot be easily deduced (E.b-3).

Response: Values of the ALIs (and DACs) are available in ICRP-30 for different chemical species, physical forms, and route of intake. Additional values may be computed for special cases using the models provided or by developing, in rare cases, new models, as has been the practice in the past. See also the responses to comments 2.10.1 and 2.10.4.

2.10.9 Accurate dosimetry monitoring is essential if recordkeeping and remedial actions based on recordkeeping are to have credibility. Current dosimeter processing techniques are so variable that performance standards are necessary (C-5).

Response: We agree to the desirability of performance standards for dosimetry processing. Actions are already underway, by the Federal agencies, for assuring the reliable processing of personnel dosimeters for external radiation (NRC84).

2.10.10 In the physical conditions at a nuclear station, the current badge system in conjunction with area surveys is as good as can and need be achieved (A.a-46, A.b.4).

Response: We concur, in general, although improved measurements may be required in a few situations where intake of radioactive materials is possible.

2.10.11 Film badges are not an accurate measure of actual exposure, but interpretation can make the readings meaningful (C-8).

Response: We agree that appropriate interpretation of film badge readings is needed to determine the meaning of the actual exposure measured. Obviously the type and energy of the radiation are important considerations for determining deep dose and shallow dose, as defined by the ICRU (ICRU76). In some cases the exposure of worker to beam vs isotropic radiation situations is important to proper estimates of dose. See the response to comment 2.3.9.

2.10.12 Film badge readings do not reflect actual exposure, but are useful as moving environmental monitors for design purposes (A.a-46, A.b-4).

Response: We disagree. However, film badge readings do require proper interpretation. See response to comment 2.10.11.

2.10.13 EPA's choice of committed dose equivalent as a primary control will not afford any greater worker protection. The effort required to implement the required air monitoring system could be better spent on other protection activities (E.b-6).

Response: We do not believe it is appropriate to relax the currently used system for controlling internal exposure, which is equivalent to the new recommendation based on committed dose equivalent. See the response to comment 2.10.1.

2.10.14 EPA's guidance (proposed Recommendation 5) calls for establishing committed dose equivalent on the basis of intake data. This method gives a less accurate indication of internal dose than the current practices of whole body counting and urinalysis (A.d-13).

Response: The recommendations do not specify whether compliance should be assessed based on exposure or intake. The use of derived limits such as the DAC is a generally accepted practical means for control of anticipated dose. However, we agree that, when significant doses are involved, accurate establishment of committed dose equivalent requires assessment of actual uptakes via whole-body counting or urine/fecal analysis methodologies. See the responses to comments 2.10.1 and 2.10.8.

2.10.15 Personnel dosimeters do not measure whole or partial body radiation doses or organ doses. They are merely assumed to do so, despite the overestimation, for administrative purposes. To use data derived from these inaccurate devices as a basis for assessing noncompliance penalties or as a basis of legal action is untenable (A.d-13, A.d-21).

Response: Use of personnel-dosimeter data as a basis for imposing penalties or for taking legal actions, involve issues which are outside the scope of Federal radiation protection guidance. Such matters are determined by regulatory authorities.

2.10.16 The gross inaccuracy of personal monitoring devices leads to underestimating doses and a false sense of security for workers (A.c-8).

Response: Proper use and processing of personnel dosimeters can provide acceptably accurate exposure data. We do not agree, in general, that data from such dosimeters are "grossly inaccurate." See also the responses to comments 2.3.9 and 2.10.11.

2.10.17 Occupations involving unsealed sources, dust problems, or high yield source material will require complex monitoring systems to comply with the proposed guidance (E.a-3).

Response: Monitoring systems to comply with these recommendations need, in general, be no more complex than has been required heretofore. Increased complexity might occur for some operations where changes in metabolic models lead to greatly reduced derived limits and the margin of safety is correspondingly reduced. However, this would have occurred whether or not Federal radiation protection guidance was revised (EPA84b).

2.10.18 The proposed guidance will reduce the effectiveness of lapel air samplers as a tool for providing timely exposure evaluations (B.a-16).

Response: On the contrary, such samplers could provide the means for readily evaluating the significance of suspected radionuclide intakes.

2.10.19 A guide on an acceptable means of measuring whole body dose is needed (A.a-41).

Response: Note 3 of the recommendations provides references for such means.

2.10.20 There are so many difficulties in monitoring a total body exposure that attempting to regulate a partial body exposure is unreasonable (A.a-38, A.b-10).

Response: Such difficulties do not preclude the need to control partial-body exposure. Usually this can be accomplished by the simple conservative measure of monitoring the most exposed part of the body and treating this exposure, for control purposes, as whole body exposure.

2.10.21 Improved dosimetry will be needed to monitor doses at the lower limits on feet, ankles, and forearms (E.a-5).

Response: We disagree. The limit for the extremities is 50 rems. This is 10 times the limiting dose equivalent for whole-body exposures.

2.10.22 Indirect measurements, such as air concentration or exposure duration and/or body burden measurements, should be considered to be acceptable methods for the demonstration of compliance with the proposed guidance (B.a-33, B.a-46, B.b-2, E.a-2, E.a-2).

Response: We agree, in general, although at higher doses approaching the limits indirect measurements may not always be sufficient.

2.10.23 The limits that would be imposed by the EPA recommendations are so restrictive for plutonium that the existing state-of-the-art does not permit the detection of the proposed limits (E.b-7).

Response: The premise of the comment is incorrect. Plutonium is one of the radionuclides for which the derived air concentration (DAC) is significantly reduced due to revised metabolic models. This change is not imposed by the recommendations; rather, it is the result of improved knowledge of how much dose is delivered by a given intake of plutonium. Regarding existing state-of-the-art, detection capability for exposure at derived limits (DACs) is adequate, but the adequacy of detection of intake (ALIs) corresponding to committed dose depends on timing of urine and/or fecal sampling (See the response to comment 2.10.14). See also the responses to comments 2.10.1 and 2.10.4.

2.11 ENGINEERING CONTROLS/DESIGN LIMITS

2.11.1 EPA's proposed guidance totally ignores engineering controls which are the preferred method of reducing exposure (A.c-6, D-11).

Response: We do consider engineering controls to be important. However, Federal guidance specifies what is required, while the regulatory agencies and management determine how those requirements are to be met.

2.11.2 Exposure levels should be based on technical feasibility (A.c-7).

Response: We agree, to the extent that technically feasible levels are ALARA. However, we do not agree that exposure should be reduced to the lowest levels that are technically feasible, without regard to costs and other relevant factors. The recommendations require exposure to be kept ALARA by taking all relevant factors (including technical feasibility) into consideration, on a case by case basis. This will assure the most efficient use of resources to provide radiation protection.

2.11.3 The low average doses received by workers are the result of extremely conservative engineering design (A.d-38).

Response: No response required.

2.11.4 Rather than set exposure limits for workers, EPA should replace the ALARA principle with a design limit for facilities of 500 mrem/yr. This design limit should not be construed as a regulatory limit (A.a-38).

Response: Design limits for facilities are not within the scope of Federal radiation protection guidance. Such limits, however, could be specified by regulatory agencies, on either a generic or case-by-case basis. However, imposition of a single design limit, e.g., 500 mrem/yr, to be applied to all facilities without regard to site-specific factors, could lead, in some cases, to serious misallocations of resources and to unwarranted costs, and, in others, to unnecessarily high exposures.

2.12 QUALITY AND OTHER MODIFYING FACTORS

2.12.1 EPA should specify quality factors so that all the various effects of ionizing radiation can be added to determine the magnitude of the total injury (C-8).

Response: Footnote 3 of the recommendations provides, in part, that:

> "The values specified by the International Commission on Radiological Protection for quality factors and dosimetric conventions for the various types of radiation...may be used..."

We will recommend other factors when and if they are more appropriate.

2.12.2 Quality and other modifying factors should be dealt with by the regulatory agencies (A.d-13).

Response: See the response to comment 2.12.1.

2.12.3 Reevaluation of the Nagasaki and Hiroshima data suggests a quality factor of about 10 for fission neutrons at dose rates below 25 rads, not the quality factor of 50-100 suggested by BEIR-III (A.b-1).

Response: There appears to be an error in interpretation of BEIR-III. Neutron RBEs are 27.8 in the LQ-L model and 11.3 in the L-L model in BEIR-III [Table V-8, p. 184]. The RBE of 27.8 was used in the "preferred model" in BEIR-III, the LQ-L model [equation V-10, p. 187].

As regards what will happen when the reevaluation of Hiroshima and Nagasaki data is complete, it is premature to make an estimate. Both gamma and neutron air kerma estimates and the proper shielding factors for

individuals are still in a state of flux. It may be possible to reestimate RBEs when the dose reassessment in Japan is complete, hopefully late in 1986.

2.12.4 How can limits be set in terms of dose equivalent without an agreement upon uniform parameters that should be used in the determination of quality (A.d-22).

Response: Use of quality factors, dosimetric conventions, and metabolic models are specified in Note 3. See also the response to comment 2.12.1.

2.12.5 It is undesirable to leave the specification of quality factors and metabolic models to the discretion of the user or regulatory agency, as suggested by EPA in Note 3 (B.a-8, B.a-34, E.a-4).

Response: The intent of the recommendations is that ICRP quality factors and models be used, to the extent feasible. The use of the phrase "may be used," provides for unforeseen developments or situations that make it desirable to use alternative quality factors and models.

2.13 DIFFERENT GUIDES FOR DIFFERENT CATEGORIES OF WORKERS

2.13.1 All workers should be equally protected by law. It is unreasonable to support one set of limits and one level of risk for some workers and a different set of limits and levels of risks for other workers (A.a-5, A.c-6, A.c-7, A.c-8, A.d-13, A.d-22, B.a-34, B.a-37, B.c-23, C-5, C-8)

Response: The recommended guidance specifies only one set of limits for adult workers. However, competent authorities may, on the basis of ALARA considerations, specify varying lower limits for specific categories of workers or work situations. We do not believe this represents unequal protection under law, since the ALARA provision applies equally to all. (The dose ranges identifying the proposed Ranges A, B, and C were not limits. Those ranges simply served as a structure for specifying proposed minimum radiation protection requirements. No such range system appears in the final recommendations.)

2.13.2 The provision for certain categories or levels of exposure limit based on type of work is a good idea (A.d-8, A.d-18, A.d-30, D-1).

Response: We concur. Recommendation 9 provides for such situations.

2.13.3 The practice of informed consent is the only practical solution to the women worker exposure question, as labor agreements make no mention of

distributing overtime on the basis of sex or exposure to ionizing radiation (C-2).

Response: We disagree. Informed consent amounts to offering a pregnant woman the choice of subjecting her fetus to up to 5 rems, finding other employment, or not working while pregnant.

2.13.4 Potential legal conflicts should be resolved prior to implementing any changes which would discriminate between men and women (B.a-13).

Response: We believe the final recommendations are clear on the question of discrimination. The recommendation for protection of the unborn specifies that conformance to the limiting value should be achieved "...without economic penalty or loss of job opportunity and security...." See also the response to comment 3.8.22.

2.13.5 The rationale for establishing different guides for different categories of workers is not clear (A.d-22).

Response: See the response to comment 2.13.1.

2.13.6 Lower exposure levels should be used for women, as they are the most sensitive segment of the population (A.a-38).

Response: The risk differences between men and women are believed to be relatively small, and in any case are not known with sufficient confidence to justify establishing two different sets of limits. See the responses to comments 1.4.1, 1.4.2, 1.4.9, 1.4.21, 1.4.22 and 1.4.26.

2.13.7 Current radiation protection guides are adequate for medical radiation workers, although current facility design requirements do not measurably affect occupational exposure (A.b-10).

Response: None required.

2.13.8 Guides should be developed for temporary workers (A.a-5).

Response: The recommendations apply to all workers, regardless of their status as regular, transient, or temporary. We are aware that there are problems associated with temporary workers, such as recordkeeping and the use of such workers for short periods near the dose limits. Provisions (e.g. regulations and regulatory guides) to assure compliance with the recommendations are the responsibility of the regulatory agencies. EPA will monitor the implementation of these recommendations, and, if warranted, propose supplementary recommendations or issue clarifications of this guidance. See also the responses to comments 2.3.2 and 2.3.7.

2.13.9 Guides should be based on health risk, not the type of work (A.c-6, A.d-13, A.d-22, B.a-34, B.c-23).

Response: We agree, and this is reflected in the recommendations for limiting values. However, the type of work does affect the dose levels that are ALARA, as in the past.

2.13.10 Different guides for different classes of workers must not be used as a disguise for discrimination. Exposure limits should be set at a level that protects the most vulnerable worker (A.a-38, A.c-7, B.a-13, C-5, C-6, C-8).

Response: See the responses to comments 2.13.1 and 2.13.4. The recommended limits provide for the protection of such broad classes as adult workers, minors, and the unborn. We know of no means for predetermining which individual adult workers are "most vulnerable," nor the applicable risk factors. See also the response to comment 2.1.12.

2.13.11 Exposure limits for the general public should apply to nonnuclear workers exposed to radiation in the workplace (A.d-22).

Response: See the response to comment 2.13.9. The commenter does not provide a basis for such differential treatment. However, the guidance provides for establishing lower limits for groups or classes of workers when this is justified on the basis of ALARA. See the responses to comments 3.6.1, 3.6.6 and 3.6.14.

2.14 OTHER ISSUES/CONTROVERSY

2.14.1 EPA should take a position on how to monitor the radiation exposure of persons wearing lead aprons during fluoroscopy. Dose to the "whole body" is best assessed by a dosimeter beneath the lead apron, while dose to the "lens of the eye" is best assessed by a dosimeter outside of the lead apron at collar (neck) level. Which measurement should be used to determine "lifetime dose"? (A.b-5).

Response: Actual "how-to" provisions are not within the scope of Federal guidance, but are the responsibility of the regulatory Federal agencies (and Agreement States). However, in this case, both measurements may be needed, since there are limits applicable both to whole-body (effective) dose and the lens of the eye. The final recommendations substitute recordkeeping of cumulative dose and the admonition to avoid continued exposure at or near the limiting values for substantial portions of a working lifetime in place of the proposed admonition to maintain lifetime dose below 100 rems.

2.14.2 To reduce overexposure to radiation from medical and dental x-ray equipment, the operator of the radiographic equipment should be competent in radiation safety and technique (A.d-30).

Response: Recommendation 7 provides for this.

2.14.3 There should be two main types of numerical exposure limits: first, a strict design limit for purposes of guiding personnel in designing facilities and procedures, and second, a worker protection limit expressed in terms of long-term exposure limits with an upper limit over short periods of time (A.a-38).

Response: Design limits for new facilities and procedures are not within the scope of Federal guidance. See the response to comment 2.11.4. With respect to limits for longer and shorter periods of time, since there is no biological basis for imposing restrictions for different periods, these recommendations do not do so. This, however, does not obviate the imposition of limits for shorter term periods, for management purposes, by regulatory agencies or by management at the user level, or by both.

2.14.4 EPA guidance on internal exposure should address accidental internal exposure, as internal exposure is seldom planned or deliberate (E.a-5).

Response: We agree. Recommendation 4 provides guidance for such situations.

2.14.5 Society must decide whether or not society's gene pool should be damaged, not the individual radiation worker (A.c-6).

Response: The potential risk to society's gene pool from occupational radiation exposure is limited by the limiting values for dose for individual workers. This recommendation, when approved, would represent a societal decision that includes consideration of the risk of genetic effects.

2.14.6 EPA should maintain one year as the averaging period over which dose rates apply (B.a-34).

Response: Except for protection of the unborn, limiting values for dose and dose commitment in the recommendations are for one year. See the response to comment 2.14.3 for further discussion.

2.14.7 There is a problem in communication and public education when the ideals of the BEIR committee, recognized for purposes of scientific conservatism, are written as regulations (A.d-36).

Response: The findings of the BEIR committee were intended for use in establishing guidance and regulations. That was the basis of the charge to the BEIR committee by EPA.

2.14.8 The proposed guidance is based partially on the philosophy that all the workers are already down in the proposed exposure ranges. However, that philosophy could repeat itself in the future, resulting in changing regulations without a cutoff (A.d-38).

Response: The comment is, in part, true. However, the burden involved in maintaining a given level of protection is also considered before lowering limits.

2.14.9 Radiation exposure guides should not be provided for periods shorter than one year (A.d-22).

Response: Guides for periods shorter than one year are not included in either proposed or final recommendations, with the exception of those for protection of the unborn. However, also see the response to comment 2.14.3.

2.14.10 Physical exams and medical tests for workers in high risk jobs should be paid for by the employer and the frequency of such exams should be set forth in the guidelines (A.d-8).

Response: These are regulatory matters not within the scope of Federal radiation protection guidance.

2.14.11 Employee protection and monitoring should be a requirement for all licensing of equipment and reimbursement for treatment and diagnostic procedures which involve radiation exposure in hospitals, clinics, and private practices (A.d-8).

Response: These are regulatory matters outside the scope of Federal radiation protection guidance.

2.14.12 Employees transferred out of high radiation areas after having received limiting radiation doses should retain full job security, seniority, and pay (C-5).

Response: We agree. The guidance specifically covers this situation with respect to exposure of pregnant women. See the response to comment 2.13.4. However, the handling of such cases is the responsibility of the employer and the Federal agency having regulatory or administrative jurisdiction.

2.14.13 The proposed guidance would require approximately 20,000 additional special procedures and radiation therapy technologists (A.d-14).

Response: This could be possible only under unreasonable interpretation of the requirements of the minimum radiation protection requirements of proposed recommendation 4. The final recommendations do not contain this provision.

2.14.14 The proposed guidance, by limiting the availability of trained workers, would have a negative impact on safety (B.a-38).

Response: We disagree. It is the responsibility of users of radiation to ensure that sufficiently trained workers are used to assure physical safety as well as ALARA exposure. See also the responses to comments 1.9.5, 1.9.16 and 2.3.5.

2.14.15 To assure objectivity the DOE should be relieved of its responsibility for radiation health-effects research (A.c-6).

Response: This question is outside the scope of Federal radiation protection guidance for occupational exposure.

SECTION 3.0 -- PROPOSED RECOMMENDATIONS

3.1 JUSTIFICATION

3.1.1 Implementation of justification on a detailed individual work situation basis will result in severe administrative costs (A.a-12, A.d-9, A.d-29, A.d-42, B.a-5, B.a-8, B.a-12, B.a-14, B.a-28, B.a-32, B.a-48, B.a-53, B.c-22, E.a-5, E.b-3).

Response: This comment was sometimes made in reaction to proposed Recommendation 1 and sometimes in reaction to proposed Recommendation 4. Recommendation 1 in existing Federal radiation protection guidance (25 F.R. 4402; May 18, 1960) states:

> "There should not be any man-made radiation exposure without the expectation of benefit resulting from such exposure. Activities resulting in man-made radiation exposure should be authorized for useful applications provided [the] recommendations set forth herein are followed."

We are not aware of any adverse impact in terms of "severe administrative costs" in the over 25 years of experience with this requirement.

Commenters did not present data supporting any such impact, but, instead anticipated future impact. Proposed Recommendation 1 was intended to continue the same requirement as that in existing Recommendation 1. Since it was commonly misinterpreted, it has been reworded in the final recommendation as follows:

> "There should not be any occupational exposure of workers to ionizing radiation without the expectation of an overall benefit from the activity causing the exposure. Such activities may be allowed, provided exposure of workers is limited in accordance with these recommendations."

We do not foresee any unwarranted costs arising from this recommendation. Also, see the response to comment 3.1.2. Regarding the implications of Recommendation 4, see the responses to comments in Section 3.4.

3.1.2 Justifying all exposures on a cost/benefit basis is unnecessary, considering nonexposure alternatives (A.a-39, A.b-23, A.d-18, A.d-29, A.d-40, B.a-8, D-2, E.a-3).

Response: Recommendation 1 concerns assuring an overall benefit from an operation or practice that involves radiation exposure of workers. Such a determination necessarily includes considering alternatives (if any) that

do not require radiation exposure. Determining whether a specific instance of worker exposure to radiation from an already justified operation or practice is necessary or not, may or may not involve a judgment about whether the exposure is justified, depending upon the specific circumstances. This is a matter for management of programs for radiation protection to decide. Maintaining justified worker exposure ALARA and within the limiting dose for individual workers are governed by recommendations 2-10.

3.1.3 Exposures from routine operations and maintenance are considered at the time a plant is designed. ALARA provides guidelines for any other exposures. This is sufficient; additional justification is unnecessary (A.d-42, B.a-8, B.a-10, B.a-12, B.a-14, B.a-27, B.a-36, E.a-2, E.b-1).

Response: Although this may often be true, it is not always the case. New practices may be considered for institution at an existing plant, and it may be appropriate to consider their justification under recommendation 1 before instituting them. See also the response to comment 3.1.2.

3.1.4 Justification of occupational exposures on the basis of net benefit cannot be done until a dollar/person-rem figure is established (A.a-40, A.d-13, B.c-10).

Response: The term "net benefit" does not require that precise quantification be carried out. In any case, the term "net" does not appear in the final recommendation.

3.1.5 As written, Recommendation 1 is not adequately directed to limiting occupational exposure. Better guidance, primarily on assessing net benefit, is needed by both implementing agencies and practicing health physicists (A.d-23).

Response: Recommendation 1 is aimed at preventing "unnecessary" worker exposure to radiation. Limiting doses from "necessary" exposures and keeping "necessary" exposures ALARA are covered in separate recommendations. See the response to comment 3.1.4.

3.1.6 The efforts required by Recommendation 1 would divert key technical and management efforts from protection activities (A.d-18, A.d-42, B.a-5, B.a-28).

Response: See the responses to comments 3.1.1 and 3.1.2.

3.1.7 Justification of exposures must be on a generic basis (A.d-42, B.a-2, B.a-5, B.a-8, B.a-9, B.a-11, B.a-32, B.a-33, B.a-48, B.a-53).

Response: We agree that this will often be the case. However, it may also be appropriate for individual practices or operations.

3.1.8 Recommendation 1 is impossible to implement (A.a-10, A.b-6, A.d-11, B.c-23, E.a-3, E.a-5, E.b-3).

Response: This is clearly not the case, since it has been implemented for 25 years. See the responses to comments 3.1.1 and 3.1.2.

3.1.9. Justification could be very beneficial, if carried out conscientiously (A.a-38, A.d-6, B.a-29, E.a-6).

Response: We agree.

3.1.10 To whom is the justification to be addressed? (A.a-7, A.b-23, B.c-20, B.c-21, B.c-22, B.c-23, E.a-2, E.a-5)

Response: Justification is reviewed through a variety of means. One example is the preparation of Environmental Impact Statements. Another example is the agreements reached in collective bargaining. Regulatory agencies may make such judgments. In other cases there may be no immediate review. However, such determinations are open to challenge and revised by society on a continuing basis through the various processes of government and other institutions.

3.1.11 What are the criteria for justification? (A.a-10, A.a-40, A.b-23, A.d-11, A.d-23, A.d-29, B.a-5, B.a-7, B.c-20, B.c-22, E.a-5, E.b-4)

Response: Criteria for justification are that the benefits of an activity are judged to exceed its costs, and that this overall benefit is greater than that achievable through alternative means not requiring radiation exposure.

3.1.12 Will justification be required for each occupational category of exposure, or for every individual exposure? (A.b-23, B.a-5, B.a-7, B.c-20, B.c-22).

Response: See the responses to comments 3.1.1, 3.1.2, and 3.1.3.

3.1.13 EPA should delete Recommendation 1 and adopt the ALARA statement in ICRP-26 (B.a-7, B.c-20, B.c-22).

Response: Recommendation 1 is not a substitute for ALARA. Recommendation 1 corresponds to the first of the three main features of the ICRP-26 system of dose limitation: "no practice shall be adopted unless its

introduction produces a positive net benefit." The recommendations also include ALARA provisions that are effectively the same as those in ICRP-26.

3.1.14 The need to consider alternatives not involving exposure to radiation could lead to regulatory interference and abuses, particularly in determining appropriate medical procedures (A.b-5).

Response: Regulatory "interference and abuses" should be identified and eliminated on specific merit; the mere possibility of abuse should not prevent making a recommendation to avoid nonbeneficial practices.

3.1.15 Exposure limits should reflect acceptable levels of risk that are comparable to other safe industries. Industry should then be free to operate within those limits without the added burden of justifying each exposure (A.a-38, A.d-13, B.a-26, B.b-3, B.c-12).

Response: See responses to comments 3.1.1 and 3.1.2. We note that operation simply within exposure limits alone is, in any case, not sufficient. Two other features are inherent elements of an adequate system of dose limitation, namely, (1) elimination of "unnecessary" exposure, and (2) maintaining "necessary" exposures ALARA. Implementation of these two features is a continuing function of the operational radiation protection organization of each activity. See also the responses to comments 1.6.11, 2.1.11 and 2.7.11.

3.1.16 The justification for allowing any exposure is the trading of human life for profit. An individual can only make such a choice if he is completely informed of the dangers. And a society can only permit such a choice if it is willing to pay for the cancers and genetically damaged children that result (A.a-5).

Response: The first premise might more accurately have replaced the word "profit" by "beneficial human activity." Since all jobs (radiation or nonradiation) entail risks, this same premise applies to all jobs. Recommendation 7 addresses education of workers on risks from radiation. Societal responsibilities for health care are not addressed by this guidance.

3.1.17 EPA has confused the concepts of justification and optimization. The atomic energy act justifies the peaceful uses of nuclear energy and ALARA optimizes exposures (B.a-24, E.b-1).

Response: The Atomic Energy Act does not "justify" any and all peaceful uses. Its purpose is to further the development of justified peaceful uses, and judgments on justification must be made independently.

3.1.18 Justification of exposures should not be adopted as a regulatory obligation (A.a-13, A.a-39, A.d-9, A.d-14, A.d-18, A.d-40, E.a-2, E.b-1, E.b-3).

Response: See the responses to comments 3.1.1, 3.1.2 and 3.1.17.

3.1.19 The extent and nature of justification should be left to the regulatory agencies implementing the guidance (A.d-13, B.a-33, E.a-2).

Response: In general, this is true. However, see also the response to comment 3.1.11.

3.1.20 The word "justified" in Recommendation 1 should be changed to "justifiable" (A.d-29).

Response: The word "justified" does not appear in final guidance. See the response to comment 3.1.1.

3.1.21 EPA is "waving the flag of carcinogenesis" instead of presenting scientific justification for the guidelines (B.a-26).

Response: We believe that our review of published studies on radiation risk (see for example the response to comments 1.4.1, 1.4.2, and 1.4.3.) and effects of exposure of the unborn (see for example response to comments 3.8.15, 3.8.17, 3.8.52, and 3.8.57) accurately reflects the substantial scientific basis for estimation of carcinogenic risks from exposure to radiation.

3.2 AS LOW AS REASONABLY ACHIEVABLE (ALARA)

3.2.1 The intent of Recommendation 2 is good (A.a-10, A.a-39, A.a-49, A.a-50, A.a-51, A.b-18, A.b-26, A.d-6, A.d-11, B.a-5, B.a-8, B.a-9, B.a-24, B.a-33, B.a-46, B.a-48, B.a-53, B.c-20, D-2, D-5, E.a-2, E.a-6, E.b-3).

Response: No response required.

3.2.2 Existing ALARA programs have been very effective (A.a-19, A.b-26, B.a-3, B.a-6, B.a-9, B.a-11, B.a-14, B.a-26, B.a-27, B.a-28, B.a-32, B.a-33, B.a-34, B.a-36, B.a-38, B.a-44, B.a-48, B.a-50, B.a-53, B.c-21, B.c-22, E.a-5, E.b-8).

Response: We agree.

3.2.3 EPA's recommendation is unnecessary given existing ALARA programs and regulations (A.a-19, A.a-41, A.d-18, B.a-26, B.a-27, B.a-28, B.a-33, B.a-34, B.a-36, B.a-44, B.c-23).

Response: We disagree. The ALARA provision in Federal guidance provides a basis for existing ALARA programs. Such provision should continue to provide the basis for future such programs.

3.2.4 ALARA should be applied only as an operating philosophy and not a standard until it is defined in quantitative terms such as dollars/person-rem (B.c-10, B.c-21).

Response: The recommendations in Federal guidance are not regulatory standards. They constitute guidance for the Federal agencies in the conduct of their radiation protection activities. While a fixed, dollar value per person-rem may facilitate some ALARA analyses, it is not necessary for such a value to be established under Federal guidance. Different values may be appropriate for different situations, and for different periods of time. Many ALARA determinations can be made without such a value. We have concluded that it is not possible or even desirable to recommend a value for a person-rem in Federal guidance at this time. See the response to comment 3.1.4.

3.2.5 EPA should define a de minimis dose so that jobs resulting in exposure below such a dose would be excluded from ALARA considerations (A.b-7, B.a-14). There must be some limits below which further reductions are unjustified (B.a-1).

Response: We recognize that for workers engaged in certain types of activities, maximum feasible exposures may be so small as to warrant their not needing or requiring regulatory controls. This concern was expressed under "other considerations" in the preamble to our proposed guidance by the following statement:

> "Regulatory agencies will have to use care in selecting classes of workers whose exposure does not need to be regulated. In selecting such classes we recommend that the agency consider both the collective dose which is likely to be avoided through regulation and the maximum individual doses possible."

As this statement reflects, application of the ALARA principle in an activity of a given type requires optimizing both collective and individual doses. Since this is generally a complex function involving many factors, which can vary from one activity to another, the optimal solution, in terms of individual doses, is not necessarily the same for all situations. We conclude that a single de minimis dose that applies to an individual for all situations is neither feasible nor appropriate.

3.2.6 ALARA must be implemented on the basis of expert judgments. To try to regulate the implementation of ALARA could be counter-productive (A.d-40, A.b-10, B.a-38, B.a-46, D-10).

Response: We agree that judgments are required in applying the ALARA principle, but this does not eliminate the need for Federal guidance and corresponding regulations to require that this principle be implemented. We agree, however, that regulations on ALARA should be formulated with care to avoid causing possible counter-productive consequences.

3.2.7 Implementation of ALARA should be left to the regulatory agencies (A.a-21, B.a-24).

Response: It is.

3.2.8 Regulators, not industry, should bear the burden of proof that exposures below 5 rem/yr are not ALARA (B.c-12).

Response: It is the responsibility of regulators to assure that industry applies ALARA. "Burden of proof" responsibility, therefore, exists at two levels: first, industry should be able to demonstrate to regulators that ALARA is being applied, and second, regulators should be able to demonstrate that they are requiring industry to do so.

3.2.9 ALARA should be applied to individual rather than collective dose so that individuals are not sacrificed to save the group (C-4).

Response: Reducing the dose to one individual at the expense of increasing collective dose of the group by a significantly larger amount would amount, on the other hand, to sacrificing the group to benefit the individual. It is true that repetitive assignments to one individual to perform a given task involving high level exposure simply because he becomes expert (and presumably receives a smaller dose per task than would other workers) is also not in keeping with the ALARA principle for individual dose. Equity considerations would suggest a rotation of assignments, even if the collective dose should increase somewhat at the start. Thus, a difficult balance is involved in the trade-offs between equity and reducing collective risk. Care must be exercised in assuring that equity considerations are not disregarded in efforts to keep the collective dose ALARA. However, keeping the collective dose ALARA is most generally achieved by methods (e.g., engineered safeguards) which also reduce the exposure of each worker in the group or task involved, so that such difficult decisions do not occur in the majority of occupational exposure situations.

3.2.10 Current practice of maintaining each task ALARA insures that collective doses are ALARA (B.a-14, B.a-26, B.a-32, B.a-38, B.a-48).

Response: No response required.

3.2.11 EPA's recommendation to hire additional workers to keep within the proposed limits is not compatible with ALARA (A.a-3, B.a-44, E.b-7).

Response: We disagree. See the response to comment 3.2.9.

3.2.12 Incorporating the ALARA concept in the guidelines may result in legal liabilities, as it could be interpreted as overriding the guides provided in Recommendation 3 (A.d-29).

Response: These are independent requirements that must both be satisfied.

3.2.13 EPA should adopt the ALARA language of the ICRP, which includes the need to consider social and economic factors (B.c-20, B.c-22, E.a-4).

Response: We agree and equivalent wording appears in the final recommendations.

3.2.14 Since rigorous, quantitative implementation procedures for ALARA have not been perfected, EPA should add a note that ALARA implementation should proceed on a structured qualitative basis (E.a-6).

Response: We agree. The preamble to the recommendations makes it clear that ALARA will require qualitative judgments.

3.2.15 EPA should emphasize that ALARA is the fundamental concept of radiation protection (A.b-10, A.d-23, B.a-19).

Response: We agree that ALARA is of fundamental importance. ALARA is one of the three principles that constitute the basic system of dose limitation in Federal radiation protection guidance for occupational exposure: (1) elimination of unnecessary exposures; (2) keeping necessary exposures ALARA; and (3) not exceeding the dose limits.

3.2.16 EPA should emphasize that meeting the RPG limits is not ALARA (A.a-38, A.c-1, A.d-23).

Response: We agree, and this point is made in the final guidance.

3.2.17 The phrase "sustained effort..." in Recommendation 1 should be clarified so that it does not imply more than continuing professional evaluation (E.b-2).

Response: The recommendations require more than "continuing professional evaluation." For example, workers should play a major role in keeping their exposures ALARA.

3.2.18 EPA should adopt the following wording for Recommendation 2: "for any justifiable activity a sustained effort should be made to assure that the collective dose of all individuals involved in this activity is as low as is reasonably achievable" (A.b-5, A.d-29).

Response: We believe Recommendations 1 and 2 clearly include that intent.

3.2.19 The theory of radiation hormesis may invalidate the concept of ALARA (A.d-35).

Response: To date, the theory has not received sufficient scientific support that it needs to be considered seriously. In any case, it is not clear that it would apply at occupational levels of exposure. See the response to comment 1.4.15.

3.2.20 The ALARA concept should be dropped since it has resulted in annual exposure limits being improperly adopted as engineering design criteria (A.a-38).

Response: We do not believe the premise is generally correct. Even if it were, the solution would be to enforce use of the ALARA concept in engineering design, not to drop it.

3.2.21 Inclusion of proposed Recommendation 2 makes proposed Recommendations 1 and 4 superfluous (A.a-12).

Response: We disagree. Recommendations 1, 2, and 4 deal with justification, optimization, and implementation of optimization, respectively. These are separate matters.

3.2.22 Adoption of the proposed guidelines codifying ALARA will make protection programs less flexible and effective (A.a-41, A.a-45, A.d-21, A.d-31, B.a-27, B.a-32, B.a-34, B.a-38, B.a-48, B.c-20, B.c-22, E.b-8).

Response: This was not the intent of the proposed recommendation on minimum radiation protection requirements, and we do not believe it would have been their effect. In any case, the issue is moot, since proposed Recommendation 4 does not appear in the final recommendations.

3.2.23 ALARA is too vague in a legal sense to serve as a basis for regulation (A.a-38).

Response: ALARA has been an explicit part of existing Federal guidance since 1960, and has been a successful and integral feature of the radiation protection programs of Federal agencies. Insofar as implementation of the ALARA principle results in regulatory requirements, such implementations are not vague and have a legal and enforceable meaning. See the response to comment 3.2.12.

3.3 RADIATION PROTECTION GUIDES (RPGs)

3.3.1 WHOLE BODY, INCLUDING 5(N-18)

3.3.1.1 EPA has not presented a convincing scientific argument that the risk associated with a 5 rem annual limit is substantially lower than that associated with a 3 rem quarterly limit coupled with the 5 (N-18) cumulative limit (A.a-8, A.a-15, A.a-41, A.d-9, A.d-14, A.d-19, B.a-9, B.a-18, B.a-20, B.a-27, B.a-32, B.a-48, B.c-14, B.c-20).

Response: The proposed limit permits a dose of 5 rems in a year to an adult worker, regardless of the worker's age. Existing guidance permits doses in excess of 5 rems up to a limit of 12 rems in a year, if the accumulated dose does not exceed 5(N-18) rems, where N is the worker's age in years. Thus, for example, under a 5 rem annual limit the maximum accumulated dose for a specific worker first employed at age 40 for only 5 years would be a maximum of 25 rems (i.e., 5x5). Under a 3 rem quarterly limit, the accumulated dose allowed would be 60 rems (i.e., 5x12).

It is true that the maximum lifetime risk possible under the new recommendations is the same as under the former guides for a worker receiving 5 rems every year from age 18 to age 65. However, the general pattern of dose accumulation by individuals during an occupational lifetime indicates that elimination of the 5(N-18) flexibility will reduce cumulative dose and, hence, risk.

3.3.1.2 The imposition of the proposed 5 rem limit would increase the work force by 75 percent (B.a-33).

Response: The comment is grossly in error. Independent studies indicate that less than a few percent increase would be needed, at most, even in those few industries that now deliver high doses to workers. We believe even these studies are overly pessimistic, since only 0.1% of workers now receive more than 5 rems per year (AIF80, Cob80, DOE80, Ku84).

3.3.1.3 A change in the limit to 5 rem/yr is not necessary in view of the relative level of safety in the radiation industries and the inherent margin of safety in radiation risk assessments (B.a-17).

Response: This view is not shared by EPA, the majority of commenters, nor by national or international communities of radiation protection. See the responses to comments 1.5.4 and 1.5.6.

3.3.1.4 The imposition of the 5 rem limit would not substantially reduce current exposures, while it would increase the administrative burden of radiation protection (A.a-10, A.d-18).

Response: The 5 rem limit should not impose any increase in administrative costs, since annual doses and cumulative doses are less difficult to record than quarterly doses and the 5(N-18) record. See also the responses to comments 3.3.1.1 and those regarding collective doses.

3.3.1.5 Because most exposures at nuclear power plants occur during the six to seven week outages, the five rems per year limit, or some straight-line interpolation thereof, would severely hamper activities during these outages (B.a-54).

Response: The contrary is true, since the recommended dose limit of 5 rems for one year actually provides more operational flexibility than a 3 rems per quarter limit.

3.3.1.6 A revision in the current 5(N-18) rems dose limitation to 5 rem/yr would present problems in performing major tasks at nuclear power plants (B.a-50).

Response: We disagree. See the responses to comments 1.9.13 and 3.3.1.5.

3.3.1.7 An inflexible dose limit of 5 rem/yr would require some work to be deferred until the next calendar year (B.a-38).

Response: The comment implicitly assumes that use will be made of the so-called 5(N-18) "budget." It is the intent of these recommendations to prevent this practice.

3.3.1.8 The 5 rem limit might do more harm than good, because a larger number of less skilled workers would have to be used to perform necessary maintenance and modification work (B.a-47).

Response: See the responses to comments 3.3.1.5 and 3.3.1.6.

3.3.1.9 A change in the dose limits at this time will be misperceived by the public and/or workers as indicating that radiation is more hazardous than thought in the past (A.d-14, B.a-38).

Response: If so, the public perception would be correct. The risk assumed associated, in 1960, with the previous limits was smaller than is now estimated for the same dose.

3.3.1.10 The 5(N-18) cumulative dose limit should be retained; however, the 3 rems per quarter restriction, which is arbitrary, should be abandoned (A.a-41).

Response: We disagree. This proposal would allow very large annual doses in some cases. For example, a newly-employed 26 year-old worker with no previous accumulation of radiation dose could receive a dose of up to 60 rems the next five years. The opportunity for abuse of such a system is obvious.

3.3.1.11 A quarterly limit of 3 rems should still be maintained, even if an annual 5 rem limit is adopted (B.a-32, B.a-33, B.a-36, B.b-7, B.c-10).

Response: Since there is no biological basis for specifying limits for periods of less than one year, except for the unborn, we have not specified such shorter term limits. Regulatory agencies, may, however, adopt limits for shorter periods for operational reasons. Such limits should take into account the need for operational flexibility required to maintain doses ALARA. This might very well lead to a decision to retain a 3 rem quarterly limit. See the response to comment 3.3.1.5.

3.3.1.12 A quarterly limit should be retained to distribute the exposure evenly (A.a-18, C-8).

Response: See the response to comment 3.3.1.11.

3.3.1.13 The replacement of the quarterly limit with an annual limit removes a radiation protection tool which assures management that the worker's exposure is accurate within three months (B.a-11).

Response: The absence of dose limits in Federal guidance for periods of less than one year does not preclude regulatory agencies or management from specifying administrative control levels or reference levels for periods of less than one year.

3.3.1.14 If the regulatory agency were to impose a quarterly limit at one-quarter of the 5 rem annual limit, or 1.25 rems per quarter, many tasks at nuclear power plants could not be performed (B.a-48).

Response: There is no requirement that regulatory agencies do so. See the response to comment 3.3.1.11.

3.3.1.15 Any quarterly limit more restrictive than 3 rems would cause unwarranted hardship and unnecessary costs (B.a-20, B.a-33).

Response: See response to comments 3.3.1.11 and 3.3.1.14.

3.3.1.16 It is not beneficial for the worker to be exposed up to 5 rems in a quarter, since he would be unable to work for the remainder of the year (B.a-33).

Response: This same comment applies to using up any limit (including the previous value of 3 rems per quarter) early in the period to which the limit applies. We assume that the same forces of self-interest on the part of the worker (in the case of temporary employees) or the employer (in the case of permanent or tenured employees) will operate under the new limits as formerly.

3.3.1.17 The 5 rem annual limit is justified based on the recommendations of the ICRP and the NCRP (A.d-42, F-3).

Response: No response required.

3.3.1.18 Setting annual occupational exposure limits at a whole-body dose equivalent of 5 rems is quite reasonable (A.b-9, B.a-53, D-2, E.a-2, E.a-5, E.a-7).

Response: No response required.

3.3.1.19 The proposed 5 rem annual limit, coupled with a 100 rem lifetime limit, will allow flexibility and at the same time restrict the maximum dose (A.b-8, B.a-5).

Response: We agree. However, the "100 rem lifetime dose" was not presented in proposed recommendations as a dose limit. The recommendations now include an admonition to avoid exposures near the limit for a substantial portion of a working lifetime, as a substitute for this numerical objective. See also the response to comment 3.4.6.

3.3.1.20 EPA should establish quarterly limits equal to no more than one-half of the proposed 5 rem annual limit (A.c-7).

Response: Dose limits for periods of less than one year, except for protection of the unborn, are an operational matter left to the regulatory agencies. See the response to comment 3.3.1.11.

3.3.1.21 Workers should have the option of building a "bank" for potential exposures under the present 5(N-18) formula, with the worker assuming the

responsibility of increased risk in return for higher compensation (A.b-20).

Response: We believe that the existence of such a "bank," which was permitted under the old guidance, leads to the possibility of unacceptably high lifetime risk.

3.3.1.22 A worker should be permitted to receive a 7 rem/yr external whole body dose equivalent for routine plus planned special exposures and an additional contingency of 3 rem/yr should be available (B.a-38).

Response: We disagree. The risk associated with 10 rem/yr is unacceptably high.

3.3.1.23 The total of the exposure in excess of the 5 rem/yr should go into a dose bank which should not exceed 25 rems over a lifetime (B.a-34, B.a-38).

Response: There is no "dose bank" in final guidance. (See the response to comment 3.3.1.21.) However, regulatory agencies may establish provisions for unusual circumstances under Recommendation 10.

3.3.1.24 The proposed guidance should, following the lead of ICRP-26, allow an exposure as high as 10 rems for a single event (C-2).

Response: See the response to comment 3.3.1.23.

3.3.1.25 EPA claims that a 100 rem lifetime limit would be adequate to insure that radiation workers would be as safe as those in other industries; if this is true, it would not be necessary to impose any particular short-term or annual limits (B.a-38).

Response: We made no such broad claim for the objective of a 100 rem lifetime dose. See also the response to comment 3.3.1.21.

3.3.1.26 Whole-body limits should be the following: for any radiation worker - 5 rem/yr deep dose and 25 rem/yr shallow dose; for radiation workers with recorded radiation histories - 15 rem/yr deep dose [limited by 5(N-18) and 45 rem/yr shallow dose] (A.a-41).

Response: The recommendations provide a similar limit (50 rems) for skin (which is approximately equivalent "shallow" dose), based upon avoidance of nonstochastic effects. A whole-body limit of 5 rem/yr deep dose corresponds to the ICRP limit of 5 rem/yr effective dose equivalent. We see no basis for allowing a higher dose to workers with recorded radiation

histories. The substitution of a 5 rems per year limit for the 5(N-18) rule obviates the need for making assumptions of previous exposure history. See also the response to comment 2.10.11.

3.3.1.27 Whole-body limits should be the following: 15 rem/yr deep dose and 45 rem/yr shallow dose.

Response: See the response to comment 3.3.1.26.

3.3.2 GONADS

3.3.2.1 The separate limit for the gonads is the most "incoherent" part of the Guidelines, since the total stochastic risk is the sum of the somatic risk to all organs of the body plus the genetic risk (A.a-40).

Response: The commenter assumes that the only "coherent" way to approach risk limitation is to combine all effects designated as "stochastic" for the purpose of limiting dose. This is an incorrect assumption. Genetic and somatic effects are nor the same. The severity and significance of genetic effects varies from inconsequential to lethal. Somatic effects are usually lethal. Furthermore, genetic effects occur only in descendants of the individual receiving a dose, and somatic effects occur only in the individual. It is necessary to make a judgment of the relative severity of and the importance of avoiding these quite different types of effects in different groups of people (the workers who receive a direct benefit from work involving exposure, and descendants who, in general, may not, and who clearly do not make the decision to assume the risk). Only if this judgment is that the severity and importance of these different risks (on a unit risk basis) are both the same is it appropriate to combine them. In the proposed recommendation we did not elect to do so. Limiting the genetic and somatic risks separately, as we proposed, permits an independent judgment to be made (or changed) on genetic risk without affecting the judgment on somatic risk. Final recommendations combine these stochastic risks using the ICRP-26 weighting factors for genetic vs somatic risk only because the difference in protection is minimal, and it is in the interest of international uniformity.

3.3.2.2 The effect of placing the same nonstochastic limit (5 rem/yr) on the gonads as on the whole body has effectively raised the weighting factor for stochastic risk estimation for the gonads from 0.25 (ICRP) to 1.0 (EPA) (E.a-5).

Response: The comment is correct. In part, this compensates for the failure of the ICRP's weighting factor to account for any genetic effects beyond the 2nd generation. In practice, this limit would almost always be

satisfied through the 5 rem limit for somatic stochastic effects, so that the effective factor is 1.2, not 4. See the response to comment 3.3.2.1 for further discussion.

3.3.2.3 The proposed annual limit of 5 rems is sufficient to protect against genetic damage. No further action is necessary (A.a-31, A.a-36, A.a-46, B.a-52).

Response: This comment is in agreement with our proposed guidance for limiting genetic or mutational effects in progeny. It may be useful here to distinguish between the two types of radiation effects in progeny. Genetic (or "hereditary") effects refer to those affecting the progeny of the irradiated person, and the risks of those effects is limited by restricting the dose to the gonads of the irradiated person. Somatic effects (teratogenic and carcinogenic) are manifested in children from their exposure in utero. See Section 3.8 for further discussion of the risks of such effects, particularly the responses to comments 3.8.15 and 3.8.51.

3.3.3 LENS OF EYE

3.3.3.1 We agree that a dose limit to the eye lens should be maintained at less than 5 rem/yr (D-2).

Response: The current consensus for protracted irradiation of the lens with high or low-LET radiation is that a total dose equivalent of 1500 rems over an occupational lifetime would be below the threshold for the production of any lens opacification that would interfere with vision (ICRP 77). However, some opacities might be produced which, while not in themselves detrimental to vision, might develop without further exposure to the point of causing deterioration of vision. Therefore, the recommended dose-equivalent limit to prevent nonstochastic effects for the lens of the eye over a working lifetime was reduced from 30 rems in a year to 15 rems in a year (ICRP80).

3.3.3.2 The lens of the eye has a threshold for vision-impairing opacity at around 1000 rad (A.b-24).

Response: The dose value cited lies within the range of reported thresholds for observed lens opacities that are not vision impairing (ICRP80). See also the response to comment 3.3.3.1.

3.3.3.3 It takes exposures in excess of 200 rems to produce cataracts (B.b-4, E.a-5, E.b-1).

Response: See the response to comment 3.3.3.1.

3.3.3.4 The annual dose limit to the lens of the eye should be increased from 15 to 30 rems (A.b-14, B.b-1, E.b-1); to 50 rems (E.b-8).

Response: Final recommendations specify an annual dose limit of 15 rems for lens of eye in agreement with ICRP recommendations. See the response to comment 3.3.3.1.

3.3.3.5 A limit of 5 rem/yr to the eye lens would bring a number of radiation workers into Range C, which would require "professional radiation protection supervision before and while such jobs are undertaken"; which would impose considerable operational difficulties (A.b-17, A.d-5).

Response: Final guidance adopts an annual limit of 15 rems for lens of eye and the proposed ranges for the minimum Radiation Protection Requirement do not appear.

3.3.3.6 The proposed RPGs in Recommendation 3a. of the guidelines are not entirely understandable. For example, the dose equivalent of 5 rems from external sources cannot equal that of the lens alone (A.b-15, A.d-21).

Response: We do not agree. The limit for lens of the eye is independent of that for the whole body, as in the 1960 guides.

3.3.4 HANDS

3.3.4.1 EPA does not present adequate justification for reducing the annual limit on hand dose from 75 to 50 rems (A.d-23, B.a-8, B.c-21, E.a-2).

Response: Final recommendations adopt the ICRP-26 system of dose limitation, in which nonstochastic effects are believed prevented by applying a dose-equivalent limit of 50 rems in a year to all tissues except the lens of the eye, for which the limit is 15 rems in a year. This ICRP limit is based on preventing any one organ or tissue from receiving a total dose over a working lifetime that could lead to the induction of nonstochastic effects. Although irradiation of extremities does not include all skin of the body, there is no demonstrated need to exceed 50 rems, even in glove box operations.

3.3.4.2 A dose limit of 50 rem/yr to the hands is reasonable (D-2).

Response: No response required.

3.3.4.3 Feet, forearms, and ankles should be addressed in a category labeled "extremities" with the same limit as the hands (A.a-41, A.d-23, B.a-4, B.a-5, B.c-12, E.b-3, E.b-5).

Response: This has been done in the final recommendation.

3.3.4.4 Feet should be included with hands, whereas forearms and ankles should be included with "any other organ" (E.b-8).

Response: In the final recommendations, "hands" is replaced by "extremities" (i.e., "hands and forearms, feet and ankles") for which the annual limit is 50 rems. Forearms and ankles are therefore included in extremities and are not included in the "remainder" organs in the weighted summation for the effective dose equivalent. This is done because it is convenient to apply such a limit in practice, and there is no special biological significance to the ankles and forearms with respect to radiosensitivity. Final guidance provides an expanded but not exhaustive listing of tissues and organs to be considered in the "remainder" and from which five are selected for calculation of effective dose equivalent.

3.3.4.5 Separate dose limits for the forearms, feet, and ankles equal to those proposed by the ICRP should be included in the proposed guidance (A.d-9).

Response: See the response to comment 3.3.4.4.

3.3.4.6 Since there is generally not a large dose differential between the hands and forearms, the effective limiting factor under the EPA guidelines would be the whole-body limit of 5 rem/yr (B.a-46).

Response: Final guidance limits the dose to hands and forearms ("extremity") to 50 rem/yr. When the entire body is uniformly irradiated then the hands and forearms are effectively protected to a 5 rem/yr limit.

3.3.4.7 EPA does not justify the reduction in the foot limit from 75 to 30 rems (B.c-21).

Response: The limit in final guidance for extremities is 50 rems. This limit is also recommended by the ICRP. In addition, we know of no requirement for extremity doses greater than 50 rems. See the response to comment 3.3.4.1.

3.3.4.8 The whole-body limit may be controlling for the forearms and ankles under the proposed EPA guidance, which could result in serious time restrictions or major facility modifications (E.a-5, E.b-6).

Response: Final guidance specifies extremities to mean the forearms and hands, or the lower legs and feet. The limit of 5 rem/yr would be limiting for the extremities only in the case of essentially uniform irradiation of the whole body. See the responses to comments 3.3.4.1 and 3.3.4.6.

3.3.4.9 EPA's justification for reducing the limit for the forearm is that "such a high value is not needed"; this is neither adequate justification nor is it necessarily true (A.a-4, A.d-9, B.a-47, E.a-5, E.b-7).

Response: Final guidance limits the extremity dose to 50 rem/yr rather than the proposed 30 rem/yr. See the response to comment 3.3.4.1.

3.3.4.10 In applying the whole-body limit to the forearms, feet, and ankles, EPA has not considered future activities such as decommissioning and cleaning (B.a-47).

Response: The final recommendations provide a 50 rem/yr nonstochastic limit of protection for the extremities, which are defined to include the forearms and hands, or the lower legs and feet. The commenter does not provide a reason why such future activities would justify a limit higher than the assumed threshold for nonstochastic effects.

3.3.4.11 The low proposed limit to the forearms could result in high costs for the chemical processing of plutonium, since remote operations would likely be required; this expense is not justified in light of EPA's apparent reason for lowering the limit ("such a high value is not needed") (E.a-5).

Response: We do not believe that the modest reduction from 75 to 50 rems would result in such major changes being required.

3.3.4.12 There are some occupational tasks in which the whole-body/skin limits are not appropriate to the extremities; a case in point is work inside a steam generator or a recently drained reactor cavity (B.a-28).

Response: The whole-body dose limit does not apply to the extremities or the skin. The applicable limit for both is 50 rems. See the response to comment 3.3.4.1.

3.3.4.13 Extremity limits should be the following: For any radiation worker - 50 rem/yr deep plus shallow dose; For radiation workers with recorded radiation histories - 75 rem/yr (A.a-41).

Response: See the responses to comments 3.3.4.1 and 3.3.1.26.

3.3.5 ANY OTHER ORGAN

3.3.5.1 EPA has not adequately justified the selection of a 30 rem organ limit, rather than the internationally-adopted value of 50 rems (A.a-40, A.a-41, E.a-6). EPA should adopt the ICRP-26 organ limit of 50 rem/yr (A.a-46, B.a-32, B.c-10, E.a-5, E.a-6, E.b-5, E.b-10).

Response: The final recommendations adopt the ICRP-26 annual limit of 50 rems.

3.3.5.2 EPA should adopt a value of 15 rem/yr as the organ limit, rather than 30 rem/yr (A.c-1).

Response: This comment is apparently based on the precedent established by the previous guidance, in which the organ limits addressed both stochastic (e.g. cancer and genetic) risks and nonstochastic (e.g. opacification of the cornea, skin erythema) risks. In the present recommendations the so-called "organ" limit addresses only the latter type of risk. The former (stochastic risk) are addressed by the effective dose equivalent limit of 5 rems through use of the organ and tissue weighting factors.

3.3.5.3 A confusing precedent is set by EPA in including skin as a specified organ within the weighted sum of annual dose equivalents, since ICRP chose to exclude it (B.6-7).

Response: The ICRP, at its 1978 meeting at Stockholm, noted that a weighting factor equal to 0.01 (as proposed by EPA) was appropriate for cases in which the detriment from skin irradiation was to be accounted for.

3.3.5.4 Is the dose equivalent limit to a small area of the skin the same as that to the skin of the whole body? (A.d-22, B.6-7)

Response: Yes. However, the dose is to be over an appropriate area of the skin. As provided in note 3 of the proposed and final recommendations, dosimetric conventions specified by the ICRP for measurement of the various types of radiation may be used for determining conformance to these recommendations. Paragraphs 182 and 183 of ICRP Publication 26 specify the appropriate areas for averaging as 1 cm^2 for external radiation and 100 cm^2 for surface contamination of the skin.

3.3.5.5 EPA should define in the guidance what the organs are that are protected by the 30 rem organ limit (A.a-46).

Response: This has been clarified in the final recommendations.

3.3.5.6 It is not clear what constitutes an organ; are the head and neck governed by the whole-body limit of 5 rems or the organ limit of 30 rems if lead glasses are worn to protect the eye lens? Does "whole-body" literally mean the whole body and not a "major part thereof," such as the head and trunk (A.b-24).

Response: This has been clarified in the final recommendations. The application of the "whole body" limit is governed by the degree of exposure of individual organs (e.g. the thyroid and such "other" organs as thymus and brain).

3.3.5.7 Exposure to the four tissues which have a sensitivity to cancer incidence greater than for the whole body - thyroid, bone marrow, breast, and bronchial epithelium - should be equivalent to whole-body exposure (A.a-38).

Response: Even though some tissues have a sensitivity greater than that of average tissue, the total risk from whole body irradiation cannot exceed the sum of risks from all individual organs and tissues irradiated at the same dose level. The weighting factors represent the proportion of stochastic risk for each tissue when the whole body is irradiated uniformly. They thus provide a consistent system for calculating the effective dose equivalent, regardless of whether the whole body is irradiated uniformly or not.

3.3.5.8 EPA should consider addressing the problem of partial-organ doses (A.a-14).

Response: In general, this is accomplished by averaging the dose to an organ over the entire organ. See also the response to the comment 3.3.5.4.

3.3.6 WEIGHTING FACTORS

3.3.6.1 EPA has not sufficiently justified their departure from the ICRP-recommended weighting factors (A.a-18, A.b-17, A.d-18, B.a-5, B.a-14, B.a-34, C-5, E.a-5, E.a-6, E.b-5).

Response: The final recommendations adopt ICRP-26 weighting factors. This was done because the difference in protection between use of ICRP and the proposed EPA weighting factors is minimal and it is in the interest of international uniformity. See also the response to comment 3.3.2.1.

3.3.6.2 There is no scientific validity in the weighted sum of annual dose equivalents (A.d-19, B.a-9, E.a-5).

Response: We disagree. There is now sufficient knowledge to permit the summation of detriment according to the relative risks of irradiated tissues.

3.3.6.3 Deviation from the ICRP-26 values would cause much confusion in the scientific and radiation protection community (B.a-36, E.a-5).

Response: See the response to comment 3.3.6.1.

3.3.6.4 EPA should use the organ weighting factors recommended by ICRP-26 to relate organ risk to whole-body risk (A.a-6, A.a-38, A.a-46, A.b-23, B.a-6, B.a-14, B.a-17, B.a-46, B.c-11, B.c-21, B.c-22, D-10, E.a-5, E.b-1, F-2).

Response: We have done so. See the response to comment 3.3.6.1.

3.3.6.5 EPA's weighting factor for gonad dose should be the same as ICRP-26 (A.a-6, A.a-38, A.b-23, A.d-13, B.a-17, B.a-53, B.c-11, D-6, E.a-6, E.b-10).

Response: Final recommendations adopt the ICRP-26 weighting factor for gonads. See the responses to comments 3.3.2.1 and 3.3.2.2.

3.3.6.6 EPA should have set the gonad weighting factor at least as low as any of the other weighting factors, i.e., 0.2 or lower (E.a-5).

Response: See the response to comment 3.3.6.5.

3.3.6.7 EPA may depart from the ICRP weighting scheme as long as they are able to justify their departure on the basis of significant differences in risk evaluation (A.d-23).

Response: See the responses to comments 3.3.2.1 and 3.3.2.2.

3.3.6.8 Application of the ICRP-26 concept of weighted whole-body equivalent doses for organ doses is not practical and results in overestimation of individual exposures (E.b-3).

Response: We disagree. The system has been shown to be practical through its wide international application. We are not aware of any significant examples of this system leading to an overestimate of effective dose equivalent or risk.

3.3.6.9 EPA should consider the adoption of separate risk factors for organs dominant in one sex only (A.a-18).

Response: This was considered, but it was rejected as an unnecessary complication that was not justified by a large enough difference in risk, and that could encourage sex discrimination. See the response to comment 2.13.6.

3.3.6.10 The weighting factor of 0.20 for breast is inconsistent with the "other organ" limit of 30 rems for breast (B.a-9).

Response: The weighting factor and "other organ" limit address different types of risk, and therefore need not be the same.

3.3.6.11 The EPA weighting factors are unnormalized (i.e., sum to 0.68) (B.a-17).

Response: This is not true. The commenter evidently applied the weighting factor (0.08) to only one of the "other organs," instead of to five "other organs," as indicated in proposed guidance.

3.3.6.12 The stochastic formula would permit an intake of strontium - 90 of 17 times the uptake of this substance under the critical organ concept (C-5).

Response: As illustrated for various radionuclides in Table B1 of the Background Report (EPA 520/4-81-003) of our proposed guidance, computations based on the proposed dose limits and the new dosimetric/metabolic models result in intake limits that are higher for some radionuclides and lower for others. These new models result in an intake limit 7 times higher for the old critical organ limit for Sr-90. Only the additional factor of two is attributed to the conversion from critical to weighted organ limits.

We note that the fact that the proposed intake limit for a given radionuclide may be substantially higher is not a valid reason to permit otherwise unnecessary intakes or necessary intakes that are not ALARA. The dose (and intake) limits do not stand by themselves: unnecessary exposures should not occur; necessary exposures should be kept ALARA; and, finally the limits should not be exceeded.

3.3.6.13 In the EPA weighting scheme, the thyroid gland is given little emphasis despite the fact that this organ is as sensitive to induction of cancer by external radiation as any tissue in the body (A.a-38).

Response: While the thyroid is sensitive to the induction of cancer by radiation, only a small percentage (about 6% or less) of those cancers are lethal. On the other hand, mortality for lung cancer and for leukemia (red bone marrow) is nearly 100%. These differences are considered in the weighting factors.

3.3.7 50-YEAR DOSE COMMITMENT

3.3.7.1 The age of a worker should be taken into account when assigning dose commitment; for older workers, much of the 50-year dose commitment will occur after the individual has died (E.a-5).

Response: One purpose of the committed dose equivalent is to assure that for the limiting case of intake of radionuclides every year during a 50-year working lifetime, the annual dose received in the 50th year from accumulated body burdens will not exceed the annual dose limits. When workers experience intakes late in their careers it is true they may never actually receive an entire 50-year dose commitment. On the other hand, there will also be workers who receive more than the 50-year committed dose equivalent, because they live longer than 50 years after intake. It would be difficult to accurately adjust the committed dose equivalent for each worker, because longevity cannot be predicted. We have concluded that it is not practical to adjust committed doses according to age. (See also responses to comments 2.8.1, 2.8.2, 2.8.3, and 2.8.6.)

3.3.7.2 It is neither reasonable nor justified to assign all of the dose from long-lived radionuclides to their year of intake, since this is not the manner in which the dose would actually be delivered (A.b-23, A.d-13, A.d-22, B.a-24, E.a-5, E.a-7, E.b-5, E.b-6, E.b-7).

Response: We disagree. The primary purpose of the use of the committed dose concept is to assign accountability for the future dose that will accrue to the worker to the situation under which the intake occurs. In some cases, however, it is important to also manage committed doses on a year-to-year basis. For the case of large intakes where the committed dose equivalent significantly exceeds the limiting values for committed dose, the final recommendations provide that the doses received from that intake in subsequent years be considered so that the sum of annual doses from such intakes and additional exposures do not exceed the annual limiting values. See also the response to comment 3.3.7.1.

3.3.7.3 The use of annual committed dose equivalent operates to shorten the working life of a worker by approaching the lifetime dose limit faster (E.b-9).

Response: The commenter is apparently concerned that the summation of committed dose equivalents would cause, for long-lived radionuclides, a lifetime dose limit to be reached (or exceeded) at some time considerably before the doses were actually received. This would be particularly relevant if a worker received large intakes whose committed doses exceeded a lifetime limit early in his career. If this were the case it would indeed be necessary to avoid future intake or external exposure to avoid

an excessive lifetime dose (and hence risk). This specific issue is moot, however, since no lifetime dose value is given in the final recommendations. However, the recommendations also contain an applicable admonition to avoid continued exposure at or near the limits that has a similar objective.

3.3.7.4 Doses should be assigned in advance for each year from intake to age 65 or 70 (A.a-14).

Response: The suggestion that annual doses from actual uptakes be assigned in advance for each year through age 65 or 70 would entail burdensome and unnecessary recordkeeping. In addition, it is an arbitrary assumption that most workers will die (or risk should be neglected) at age 65 or 70. It is not clear why this would be preferable to the present 50-year assumption. See the response to comment 3.3.7.2.

3.3.8 COMBINED INTERNAL AND EXTERNAL DOSES

3.3.8.1 We are in agreement that nonuniform exposure should be treated using a weighted sum of doses to individual organs (A.a-18, A.a-46, A.a-49, A.a-50, A.a-51, A.b-9, A.b-18, A.c-6, A.d-13, A.d-23, A.d-42, B.a-3, B.a-5, B.a-33, B.a-34, B.a-46, B.a-53, C-5, C-6, D-4,).

Response: No response needed.

3.3.8.2 The additional cost of combining internal and external dose equivalents is not justified by the decrease in risk or by its technical validity (A.a-8, A.a-19, A.a-41, A.d-18, A.d-40, B.a-11, B.a-31, B.a-36, B.a-37, B.a-39, B.a-48).

Response: We disagree. The commenters do not provide a basis for their assertion that risks for internal and external exposure are not additive. Current information on occupational exposure of workers indicates that relatively few workers receive significant doses from both external and internal exposure to radiation. Thus, the additional cost associated with informing and protecting the worker on the basis of total radiation risks is expected to be small.

3.3.8.3 The combination of external and internal dose equivalents using weighting factors will be difficult and costly to implement (A.b-6, B.a-14, B.a-32, B.a-33, B.a-48, B.b-7).

Response: The weighting factors are automatically incorporated into ALIs and DACs, just as they were into the formerly-used MPCs. Thus, it is

difficult to justify any need for large additional costs. The draft revisions to 10 CFR 20 regulations of the NRC show that a reasonable scheme can be devised to combine external and internal dose equivalents. See also the response to comment 1.9.2.

3.3.8.4 The guidance regarding internal exposures is difficult to interpret and will require the use of a consultant (A.d-6).

Response: Instructions on acceptable practical means for compliance are expected to be formulated by the regulatory Federal agencies. There should not be a general need for consultants to interpret new regulations. See also the response to comment 3.3.8.3.

3.3.8.5 Separate standards on internal and external exposure should be maintained (B.c-8).

Response: Separate standards would permit doubling the allowable annual increment of risk. The intent of new recommendations is to control the total risk from the sum of both types of exposure.

3.3.8.6 The critical organ methodology has been an effective means of control (E.a-5).

Response: We agree, in general. However, the new recommendations take much more accurate account of the total risk attributable to all irradiated tissues.

3.3.8.7 A "de minimis" value of internal exposure should be defined, below which it should not be necessary to combine internal and external exposures or report the dose (A.a-41, A.d-13, A.d-40, B.a-4, B.a-8, B.a-14, B.a-15, B.a-27, B.a-48, B.a-53, B.c-20).

Response: To the extent that such practical cutoffs are advisable, we expect the regulatory agencies to specify them.

3.3.8.8 As a practical matter, EPA should limit the combining of internal and external exposures to those situations in which an internal exposure has occurred which exceeds 1/10 of the applicable Radiation Protection Guide (A.d-42, B.a-5, B.a-6, B.a-9, B.a-10, B.a-32, B.a-33, B.a-46).

Response: See the response to comment 3.3.8.7.

3.3.8.9 Separate records should be maintained for external exposure and internal intake (A.a-41, A.d-40).

Response: The final recommendations provide that the committed effective dose equivalent and the quantity of each radionuclide in the body should be assessed and recorded for the intake of radioactive materials. In addition, a summary of annual, cumulative, and committed effective dose equivalent should be provided annually to workers. However, the actual details of recordkeeping requirements are left to the regulatory agencies.

3.3.8.10 The conservative assumptions which are necessary to comply with the internal exposure guidance will obviate the utility of any future epidemiological studies of radiation risk (A.a-10).

Response: It was not an objective of these recommendations to permit doses large enough to ensure the utility of such studies. In any case, such studies only require accurate dose information, whether it be from internal or external exposures, and do not depend upon the implementation scheme used to assure compliance with the standards.

3.3.8.11 Given the current state-of-the art, we are only able to develop an imprecise estimate of organ dose (B.a-31, E.b-7, E.b-9).

Response: We recognize there are limitations to the current state of the art, but believe it is adequate to assure proper protection of workers.

3.3.8.12 In implementing the internal exposure guidance, considerable care will have to be exercised to assure that the individual's exposure record reflects the true exposure and not some highly conservative estimate (B.a-33).

Response: We agree that an individual's exposure record should contain accurate data for internal as well as external exposures. Recommendation 8 specifies that the quantity of radionuclides in the body be assessed and recorded, to the extent practicable, in addition to the calculated committed dose equivalent. See the response to comment 3.3.8.9.

3.3.8.13 Guidance 3.c is not consistent with 3.a and 3.b; as it reads, it appears that two sets of records would be required - one for the sum of dose equivalents in the various organs and one for this sum plus the external dose equivalent (E.b-1).

Response: The comment apparently confuses partial exposures with whole body exposures. The final recommendations clarify this.

3.3.8.14 There exists no standard method for the calculation of dose to the breast or bone surface (B.a-9).

Response: Such methods were used to compute the limits for intakes listed in ICRP Publication 30 (ICRP80) and are described in Part 1 of that report.

3.3.8.15 Whether or not to require the summation of internal and external doses is a decision that should be left to implementing agencies (B.a-31).

Response: We agree that the specific situations which require summation of internal and external doses should be determined by the cognizant regulatory agency. See the response to comment 3.3.8.7.

3.3.8.16 The new MPCs for uranium Class Y material would result in the need to redesign major elements of fuel handling and processing equipment, yet it has not been adequately demonstrated that such lowering of limits is warranted by medical case histories (B.a-16).

Response: The changes in derived limits are the result of more accurate metabolic/dosimetric models, which show that a given intake of such material yields a larger dose than formerly assumed. It is not our intent to await medical case histories for each type of radionuclide before reflecting such improved knowledge in the MPCs.

3.3.8.17 The requirement to add dose-equivalent exposures of organs and tissues to whole-body doses is hopelessly complex and likely to be ignored (A.a-38).

Response: We disagree. Where such addition is required, the weighting system provides a straightforward methodology that is no more complex than current practice.

3.4 MINIMUM RADIATION PROTECTION REQUIREMENTS

3.4.1 OVERALL APPROACH

Comments:*

1. The proposed range requirements will increase paperwork (A.a-13, A.a-41, A.b-8, A.d-9, A.d-12, B.a-11, B.a-15, B.a-16, B.a-19, B.a-21, B.a-24, B.a-27, B.a-48, B.b-7, E.a-2, E.a-5, E.a-7, E.a-14, E.b-9).
2. The three-tier system is needlessly complicated and potentially expensive (A.a-16, A.a-39, A.d-11, A.d-14, A.d-21, A.d-22, B.a-3, B.a-21, B.a-31, B.a-37, B.a-44, B.c-12, E.a-6, E.a-7).
3. The range approach would introduce a degree of administrative and/or operational complexity not justified by any health benefit (A.b-10, A.c-13, A.d-9, A.d-38, B.a-6, B.a-11, B.a-15, B.a-17, B.a-24, B.c-12, E.a-12, E.a-5, E.a-6, E.a-7, E.b-2, E.b-8).
4. The varying dosimetry requirements for the proposed ranges will

*Note: Joint Response Immediately Following Comments 1-37.

result in less health physics protection than is currently provided (A.a-45. A.b-8, B.a-21, B.a-44, E.a-2, E.a-5, E.a-7, E.a-2, E.b-3).

5. The three-tier system may actually increase total occupational exposure by eliminating the flexibility in job planning and execution available under current standards (A.d-9, B.a-48, E.a-5).
6. The specification of minimum protection requirements limits the judgment and flexibility of qualified experts (A.a-24, A.a-25, A.a-27, A.a-28, A.a-29, A.a-30, A.a-32, A.a-33, A.a-41, A.a-52, A.a-53, A.d-23, A.d-40, B.a-25, B.a-27, B.b-6, B.c-16, B.c-18, E.b-3).
7. The proposed ranges are not needed (A.a-39, A.a-41, A.b-6, A.d-19, A.d-23, A.d-28, B.a-6, B.a-32, B.a-37, B.c-21, E.a-6, E.b-2, E.b-5, E.b-6, E.b-8, E.b-10, F-3).
8. Dose ranges are unnecessary if every exposure is justified and ALARA (A.a-16, A.d-28, B.a-11, E.a-5, E.a-7, E.a-6, E.b-9).
9. The range approach is unwarranted as workers will view it as a calibration of risk (A.d-28, B.a-35).
10. An expected level of dose for operations, based on optimization studies, would be preferable to the three-tier approach suggested (A.d-22).
11. The proposed scheme of anticipated exposure ranges is intended to place the ALARA concept into a cookbook formulation for use by nonprofessional, completely undermining the application of sound professional judgment (E.b-3).
12. Recommendation 4 contains requirements licensees cannot meet (A.a-19, B.c-21).
13. Implementation of Recommendation 4 will lead to program degradations (A.a-12, A.d-23).
14. Further detailed guidance on exposure of individuals is not needed (E.a-6).
15. The concept underlying the range approach is inherent in all existing ALARA programs (A.b-6, A.d-19, A.d-28, A.d-40, B.a-11, B.a-14, B.a-15, B.a-16, B.a-21, B.a-27, B.a-29, B.a-31, B.a-32, B.a-36, B.a-44, B.a-48, E.a-6).
16. The emphasis of regulatory requirements should be on ALARA, not the proposed ranges. This would allow organizations to develop radiation protection programs best suited to their specific needs and situation (A.a-45, A.d-9, A.d-18, B.a-24, B.a-36, E.a-6, E.b-1).
17. It should be made clear that any requirement or model procedures developed to implement ALARA, including Recommendation 4, are only for the guidance of federal agencies (B.a-34, E.a-4).
18. What are the criteria to justify the need for work situations that are expected to make a significant contribution to Range C exposures? Are cost/benefit analyses required as implied? If so must they be documented and will they be subject to regulatory review, inspection, and enforcement? (B.a-29)
19. Justification of Range C work situations must be generic. EPA should specifically state that it is not its intent to require case-by-case justifications of each exposure activity (B.a-3, B.a-6, B.a-17).

20. Justification of Range C work situations will result in unnecessary hardship and costs to the nuclear power industry. The need for such Range C activities has been historically demonstrated (B.a-6, B.a-20, B.a-46, E.a-2).
21. It is not clear to whom the justification of Range C exposures is to be addressed (A.d-18, B.a-4, B.a-6, B.a-36, E.b-3).
22. The concepts of "justification" and "ALARA" are used differently in Recommendation 4 than in Recommendations 1 and 2 (E.a-4).
23. Prior regulatory approval of Range C exposures is redundant and/or unwarranted (B.a-6, E.b-6, E.b-8).
24. In Range C, what constitutes a "significant contribution to exposure?" (B.a-4, B.a-6).
25. The requirements associated with Range C will result in increased collective exposures as more workers are used to perform a task (B.a-31, E.b-6).
26. A graded set of minimum radiation protection requirements based on expected dose in the work place, with specific dose ranges established by the implementing agencies, is a good approach (A.b-9, B.a-5, B.a-33, B.a-34, B.a-46).
27. The deterrent effects of increased justification, supervision, and monitoring are an administrative method of lowering the 5 rem/yr limit to 0.5 rem/yr (B.a-3).
28. Relaxing the personnel monitoring requirements (Range A) is morally and legally expensive (A.b-8).
29. The proposed Recommendation 4 should be deleted and replaced with the following guidance: "The appropriate authorities of each workplace should ensure that a competent health-physics program is in place" (A.a-12).
30. The varying dosimetry requirements for the proposed ranges will make it difficult to provide concise, realistic dose assessments to workers (A.b-8, A.a-18, A.b-18, B.b-7).
31. The ranges provided in Recommendation 4 are detailed administrative requirements for implementing the general guidance and RPGs. Such administrative requirements should be left to the cognizant regulatory agencies; they can fashion such requirements to their needs and practices (A.a-21, A.d-21, A.d-27, B.a-24, B.a-29, B.a-34, B.a-38, B.c-21, E.a-6, E.a-7).
32. A cost/benefit study should be made and considered before final inclusion of this recommendation (A.a-41, A.d-14, A.d-29, A.d-40, B.a-11, B.c-12, E.a-5, E.a-6).
33. Imposing minimum radiation protection requirements for different job categories could hinder new developments in these areas if a higher range designation is needed (A.d-22).
34. Field inspectors will abuse the three-tier concept (A.a-14).
35. The proposed ranges introduce many new requirements for occupations in which persons were not previously considered radiation workers (A.a-10).
36. The effect of the proposed ranges on dosimetry requirements will result in radiation workers being covered with dosimeters. It is clearly unworkable (B.c-21).
37. We do not support the proposal for a graded set of radiation levels within the RPGs (A.c-6).

Response: The proposed recommendation 4 for a graded set of minimum radiation protection requirements (MRPRs)does not appear in the final recommendations. Instead, three broad recommendations provide for (i) instruction on basic risk to health from ionizing radiation and radiation protection procedures for workers to avoid and minimize exposure; (ii) monitoring and recordkeeping of occupational doses, and (iii) supervision of workers and use of administrative control and reference levels for carrying out ALARA programs. Comments relative to these general topics that are not specific to the proposed use of a graded set of minimum requirements in these areas are addressed under separate headings.

Many of the comments explicitly or implicitly argued that the costs of MRPRs would not be justified by the health benefits. EPA considered the costs of such requirements (EPA83a) and found the cost/benefit ratio was, indeed, high. The estimated costs were $6-10 million for startup plus $500-700 million annually. If the MRPRs achieved an average dose reduction of 25%, this leads to roughly $40-170 million per death averted.

3.4.2 SUGGESTED NUMERICAL RANGES

1. ICRP's working levels A and B as reference levels would be preferable to EPA's ranges (A.b-15, A.d-21, B.a-7, B.a-19, B.c-20).
2. The two levels of control (above and below 25%) in the current regulations are adequate (A.a-10, A.a-14).
3. The current classification of radiation workers and the general public, with exposures to each minimized by application of ALARA by professional health physicists, is adequate (E.b-2).
4. The proposed ranges are too restrictive, preferable values would be: Range A: 0.02 RPG; Range B: 0.2-0.5 RPG; and Range C: 0.5-1.0 RPG (E.a-3).
5. Two ranges, below 0.5 RPG and above 0.5 RPG are all that is necessary (A.b-6).
6. The proposed ranges should be replaced with: 0-10%, no records; 10-100% keep lifetime records; above 100% report to the cognizant regulatory authority (B.a-26).
7. Range A should be eliminated; Ranges B and C are useless (A.a-46, A.b-16, B.a-7, B.c-20).
8. The ranges proposed are adequate as ALARA guides (E.b-1).
9. The range proposal would have merit if used to establish a de minimis category with minimal training and exposure control requirements (B.a-4).
10. The nuclear power industry is already meeting the requirements of Ranges A and B, and ALARA programs effectively accomplish "Justification" of the "Need for work situations which are expected to make a significant contribution to exposure in Range C." Therefore the recommended ranges are not justified (B.a-3).
11. EPA should explicitly state that exposures in Range C are not prima facia evidence of a poor radiation protection program, and should not be a basis of disciplinary action (A.b-5).

12. Additional requirements for Range C would effectively limit exposure to 1.5 rem/yr. The nuclear power industry cannot function with such a restrictive limit (B.a-3).
13. There does not appear to be any rational cost/benefit basis to restrict Range C exposures beyond the requirements of a 5-rem annual RPG (E.a-6).
14. In Range A, sub-part A, change "justified" activities to "licensed" activities (E.b-1).
15. In Range B, sub-part D, eliminate the word "justified" (E.b-1).
16. The minimum limit of concern should be half a rem a year; below that limit no regulations are necessary (A.a-46).

Response: Final guidance does not contain the proposed minimum radiation protection requirements with suggested numerical ranges. Instead of numerical ranges, final Recommendation 9 provides for establishment of administrative control and reference levels, usually below limiting values, for specific categories of workers or work situations, as dictated by the situations. See also the response to comment 3.4.1.

3.4.3 INSTRUCTION

3.4.3.1 Workers should be instructed on basic hazards of radiation and radiation protection principles, and on the specific risks and protection activities of their work situation (A.a-5, A.a-16, A.a-19, A.d-8, A.d-19, E.b-1).

Response: We fully agree and Recommendation 7 provides for this.

3.4.3.2 Workers do not know the risk; they assume the risks are minimal (C-9).

Response: Workers exposed to radiation and managers of activities involving radiation should be instructed on the basic risks to health from ionizing radiation. See the response to comment 3.4.3.1.

3.4.3.3 Whose version of radiation hazards should be used in instructing workers? (A.d-15)

Response: A current summary of EPA risk methodology and estimates is given in the response to comment 1.4.1. This discussion provides an update to the Background Report (EPA81), issued on January 23, 1981. Subsequent information should be disseminated by Federal agencies as appropriate. See also the responses to comments 1.4.10 for somatic or genetic effects at low levels of radiation, comment 3.8.15 for teratogenic effects to unborn irradiated in utero, and comment 3.8.51 for hereditary effects due to irradiation of the gonads of males and females.

3.4.3.4 EPA must specify the kind of information that workers are to receive to assure uniformity (A.c-1).

Response: See the responses to comments 3.4.3.1 and 3.4.3.3.

3.4.3.5 NRC licensees currently provide detailed instructions on health risks and protection methods to all individuals working in or frequenting "restricted areas" (B.a-29).

Response: No response required.

3.4.3.6 Although NRC licensees already have programs more extensive than required by EPA's recommendations, there is no justification for such unreasonable and burdensome requirements to be issued in a memorandum for the President (B.a-29).

Response: We do not agree that the recommendations for instruction of workers are unreasonable or burdensome. The fact that NRC requires this, and have not objected appears to demonstrate this.

3.4.3.7 Government-sponsored training in radiation safety is appropriate (A.a-8).

Response: It is up to Federal agencies in accordance with their statutory authorities to determine whether or not they sponsor training programs in radiation safety.

3.4.3.8 EPA should mandate standard training for health workers, to include personnel protection, identification, and hazards of radiation exposures. The requirements of Recommendation 4, being open to interpretations based on inadequate data, are of dubious benefit to workers (A.c-8).

Response: EPA has no authority to mandate training programs for health workers. This is the responsibility of cognizant Federal regulatory agencies. However, the final recommendations do specify that occupationally exposed workers be instructed on basic risks to health from ionizing radiation and on basic radiation protection principles.

3.4.3.9 No instruction requirements are needed for Range A exposures (B.a-29, B.c-8).

Response: We disagree. All workers with potential for exposure to ionizing radiation require some instruction on basic risks to health and on basic radiation protection principles.

3.4.3.10 Instruction must not leave the impression that doses below a certain limit are "safe" or "negligible" (A.d-8).

Response: We agree, and believe that this is clearly stated in the preamble to the recommendations. See also the responses to comments 1.6.11, 2.1.11, 2.2.11 and 3.1.15.

3.4.3.11 EPA should address the issue of the information flow between plant management and workers (A.a-5).

Response: Final recommendations provide the basic objectives for instruction, monitoring, recordkeeping, and supervision related to this matter. Federal agencies will stipulate the necessary regulatory detail for implementation of these recommendations.

3.4.3.12 The need for financial support for education and training programs in radiation protection should be considered (A.b-11).

Response: The substance of this comment is outside the scope of Federal guidance. The Federal regulatory agencies implementing the guidance may examine the need for financial support of education and training programs in accordance with their statutory responsibilities.

3.4.4 MONITORING AND RECORDKEEPING

3.4.4.1 Workers should be monitored and detailed records of all doses be maintained (A.a-16, A.a-38, A.c-4, A.c-8, C-4, C-6, C-7, E.a-3, E.a-5).

Response: Recommendation 8 specifies that there be monitoring of workers and exposure recordkeeping appropriate to insuring conformance to the recommendations. This includes the maintenance of a cumulative record of lifetime dose equivalents for each worker. However, individual monitoring and recordkeeping for all potentially exposed workers, without exception, could lead to substantial expenditures in many work situations without the possibility of increasing worker protection or benefits. Federal regulatory agencies will specify criteria for determining when monitoring and recordkeeping are required for individual workers. Such criteria, however, do not prohibit employers from providing such services to workers even though not required by regulation.

3.4.4.2 Maintenance of lifetime dose records implies a central records repository; EPA should clarify its intent (B.a-22, B.c-20).

Response: Establishment of a national central repository for occupational radiation exposure records is not within the scope of the subject guidance. See the response to comment 1.10.8.

It appears useful to clarify here the concept of lifetime dose as it is a focal point of many comments. "Lifetime dose" means accumulated dose from all occupational exposures. Current regulatory interpretation of the 1960 guidance requires maintenance of a lifetime dose record if a worker is to be permitted to receive, in a calendar quarter, a whole body dose in excess of 1.25 rems (up to the 3.0 rem limit) as proof that such a dose would not lead to exceeding the accumulated dose condition of 5(N-18) rems, where N is the worker's age in years. These recommendations, however, specify a simple annual limit of 5 rems, and there is no explicit lifetime dose limit. However, we do not intend that this be interpreted to mean that "lifetime dose" is now considered irrelevant. Such records are important in limiting accumulated lifetime risks. Thus, we encourage the maintenance of lifetime occupational dose records.

3.4.4.3 Expanded monitoring in the two higher ranges does not appear to be justified (E.a-5).

Response: The proposed recommendation 4 and its monitoring/recordkeeping requirements for dose ranges do not appear in the final recommendations. See also the response to comment 3.4.4.1.

3.4.4.4 Eliminate the additional monitoring and recordkeeping requirements in Ranges B and C (E.b-1).

Response: See the response to comment 3.4.4.3.

3.4.4.5 Any worker in exposure Range A should be entitled to 12 months of employer-paid monitoring to satisfy himself that he is not being exposed beyond the limits (A.a-36).

Response: The Federal regulatory agencies will specify minimum monitoring requirements. If an employee believes additional monitoring is warranted, that request should be made to the employer, the cognizant Federal regulatory agency, or the employee's union or professional organization, as appropriate. See also the response to comment 3.4.4.1.

3.4.4.6 Requiring lifetime monitoring and recordkeeping once a worker has been exposed in Range C places an unfair burden on future employers (A.d-12).

Response: The burden of maintaining an exposure record is very small. In any case, except for intake of radionuclides that exceed the limiting values and require future exposure management of the worker, the final guidance should not place new monitoring or recordkeeping burdens on future employers beyond those already in place. See also the response to comment 3.4.4.1.

3.4.4.7 Guidelines for monitoring should be evaluated on the basis of task-by-task risk assessments (A.d-8).

Response: The details of such guidelines, if justified, would be established by the Federal regulatory agencies.

3.4.4.8 The monitoring program required for Range B exposures will cover too many workers and be too expensive (B.c-14).

Response: See the responses to comments 3.4.4.1 and 3.4.4.3.

3.4.4.9 The minimal monitoring requirements for Range A exposures could fail to detect some potentially hazardous levels of radiation from unexpected contamination problems (A.a-36).

Response: See the response to comment 3.4.4.1. It is the responsibility of Federal regulatory agencies to specify criteria for monitoring sufficient to detect actual and potentially hazardous levels of radiation for all sources or activities that are included within their statutory authority.

3.4.4.10 A significant effort would be required to upgrade records programs to comply with the three-tier system (B.a-6, E.a-5, E.a-7).

Response: See the responses to comments 3.4.4.1 and 3.4.4.3.

3.4.4.11 Lax recordkeeping requirements will defeat all attempts to conduct low-dose epidemiology studies (A.b-23, A.c-4, C-4, C-6, E.a-5, E.b-1).

Response: We do not agree that the proposed (or final) recordkeeping recommendations encourage laxity. If the comment is suggesting additional recordkeeping beyond that required for administration of radiation protection programs for the purpose of low-dose epidemiology studies, that is beyond the scope of the subject guidance.

3.4.4.12 EPA's proposal will result in escalated monitoring and recordkeeping requirements without any justification being shown for such actions (A.d-40, B.a-29, B.a-50, E.a-5).

Response: We do not agree. The cognizant Federal regulatory agencies have sufficient experience in these matters to assure justified requirements. In addition, the public and affected parties will have an opportunity to assess and comment on proposed monitoring and recordkeeping regulations. See also the response to comment 3.4.4.1.

3.4.4.13 The burden of maintaining the required records would be lessened if the major dosimetry services would establish and share exposure data bases (A.b-5).

Response: This matter is not within the scope of the subject guidance.

3.4.4.14 The varying recordkeeping requirements are totally unworkable in the case of the transient worker (B.a-9).

Response: We are confident that the final recommendations are now flexible enough to permit the Federal regulatory agencies to provide "workable" recordkeeping requirements for all significantly exposed workers (transient and otherwise). See the responses to comments 2.3.1 and 2.13.8.

3.4.4.15 Records of annual exposure levels should be sufficient (B.a-10).

Response: Recordkeeping is required to demonstrate compliance with the limiting values of dose as well as other parts of the recommendations. Records of annual exposure levels may or may not accomplish this, and thus each Federal regulatory agency must make this determination. See the responses to comments 3.4.1 and 3.4.4.1.

3.4.4.16 How long must Range B exposure records be maintained (B.a-22)?

Response: At least long enough to compile lifetime dose records.

3.4.4.17 EPA's guidance should include a requirement to maintain (lifetime) records of consumer's medical and dental exposures (A.c-8, C-5, C-7, C-8, D-5, E.a-3).

Response: Medical and dental exposures are not within the scope of the subject guidance.

3.4.4.18 Workers should have access to all their dose records (A.d-8, A.c-1, A.c-4, A.c-8, C.2).

Response: Recommendation 8 provides that workers receive a summary of annual, cumulative, and committed effective dose equivalents on no less than an annual basis and further information upon their request. See also the responses to comments 1.10.3 and 3.4.4.1.

3.4.4.19 All workers subject to recordkeeping should be furnished quarterly dose and cumulative lifetime dose records on a quarterly basis (C-5).

Response: In addition to specifying recordkeeping requirements, the regulatory Federal agencies will also specify requirements for keeping workers informed of their radiation exposure status on at least an annual basis, consistent with these recommendations. More frequent informing of workers could be specified by the regulatory agency. See also the response to comment 3.4.4.1.

3.4.4.20 All workers in the nuclear industry should receive a current copy of their annual and lifetime accumulated whole body radiation exposure records from their employers on an annual basis (C-8).

Response: See the responses to comments 3.4.4.1 and 3.4.4.19.

3.4.4.21 Some workers have trouble getting their dose records (C-5, C-8).

Response: We are not aware of circumstances where occupational exposure information can properly be withheld from the worker. Any such current problems should be eliminated when these recommendations are implemented. See also the responses to comments 1.10.3, 3.4.4.1, 3.4.4.18, and 3.4.4.19.

3.4.4.22 Individual monitoring, as defined in 10 CFR 20, 2(b)(1), is inappropriate for assessing internal exposures in Ranges B and C (A.a-12).

Response: Regulations of the Federal agencies (for example, the cited Section of 10 CFR 20 of the NRC) will have to be revised to conform with final Federal radiation protection guidance. See the responses to comments 3.4.4.1 and 3.4.4.3.

3.4.4.23 Internal and external exposure records should be maintained separately (A.a-41).

Response: Although the final recommendations provide numerical limits that apply to the sum of the dose from both external and internal exposures, they also call for separate recording of internal and external exposures. The appropriate means of keeping records to demonstrate compliance will be detailed by the regulatory agencies. See the responses to comments 3.4.4.1 and 3.4.4.22.

3.4.4.24 Monitoring should be done by qualified personnel (A.a-16).

Response: No response required.

3.4.4.25 EPA should include in its guidance criteria for notification of workers exposure levels (E.a-6).

Response: Recommendation 8 specifies that workers should be so advised.

3.4.4.26 Lifetime dose records should be maintained for all radiation workers (A.a-38, A.a-45).

Response: We believe final recommendations are in agreement with this comment. Final recommendation 8 requires "Appropriate monitoring of workers and the work place should be performed and records kept to ensure conformance with these recommendations...Maintenance of a cumulative record of lifetime occupational doses for each worker is encouraged." Such records would be useful to both employer and employee if questions of a worker's occupational dose are raised at some later date.

3.4.4.27 A 100 rem lifetime limit will require employers to maintain a complete exposure record for each employee (A.a-19).

Response: We agree that this would be the case if and when a lifetime limit is adopted. However, it would not be unreasonable for employers to maintain complete exposure records even without a lifetime limit. See also the response to comment 3.4.4.26.

3.4.4.28 Lifetime dose records within the current limits are meaningless (A.b-10).

Response: We disagree. Such dose records establish that workers do not exceed standards and also the levels of dose actually received. These dose levels are important to any subsequent calculations of probability of causation for cancers that may occur for individual workers.

3.4.4.29 Recommendation 4.h appears to require the maintenance of a lifetime record even after an employee terminates employment. This places an unreasonable burden on the employer; this requirement should be reconsidered (A.a-19, B.a-6).

Response: We believe that lifetime dose records should be maintained by someone for some time after an employee terminates employment and that such a requirement can be formulated by the cognizant regulatory agency without an unnecessary or unreasonable burden on employers. Without such record maintenance it would seem impossible for either the employee or employer to accurately establish radiation exposures for any given period of employment. The actual location for maintenance of such records would be determined by the cognizant regulatory agency. This determination should include consideration of benefits and costs. Recent cases of litigation would appear to confirm the desirability of maintaining all exposure records, as there are potentially large benefits from being able to document what doses a worker did or did not receive. See the responses to comments 3.4.4.26 and 3.4.4.28.

3.4.4.30 What is the rationale for strongly encouraging lifetime records for workers exposed in Range B (A.b-5)?

Response: There is good reason for keeping lifetime records of monitored workers at all levels of exposure. Even where workers receive no measurable exposure lifetime records provide corresponding documentation to reassure the worker and to verify the level of protection provided by the employer's radiation protection program. See also the responses to comments 3.4.4.26, 3.4.4.28 and 3.4.4.29.

3.4.4.31 The 100 rem lifetime limit would require obtaining a worker's exposure history before Range B exposures would be allowed (A.a-19, B.a-29).

Response: We would agree that if and when a lifetime limit is established, it would require that a worker's exposure history be obtained to properly manage future exposure. However, the implementation of such a lifetime limit by regulatory agencies would have to include provisions for some appropriate and timely transfer of worker exposure histories.

3.4.5 SUPERVISION

3.4.5.1 Increased on-the-job supervision does not appear to be justified (B.a-4, B.a-29, B.b-7, E.a-2, E.a-5).

Response: This matter is left to the discretion of regulatory agencies.

3.4.5.2 The radiation protection supervision requirement should be clarified so that it is not interpreted to require the physical presence of the supervisor during the job (B.a-33, B.a-37, B.a-46, E.a-2).

Response: The intent of the proposal was not that radiation protection supervision involve exposure, unless that was essential to achieve adequate control of radiation protection.

3.4.5.3 A requirement that professional radiation protection personnel be available and empowered to do the necessary job would be preferable to the proposed guidance calling for these professionals to be in the workplace (A.d-13).

Response: See the response to comment 3.4.5.2.

3.4.5.4 Having supervision present (under Range C) will result in increased exposures (A.a-19, A.a-21, B.a-17, B.a-37, B.c-12).

Response: See the response to comment 3.4.5.2.

3.4.5.5 Part d of Recommendation 4 should be clarified. As presently written it could be interpreted as requiring certified health physicists to be stationed in all areas where individuals may receive in excess of 0.5 rem/yr (B.a-5, B.c-23).

Response: See the response to comment 3.4.5.2.

3.4.5.6 Supervision before and during jobs in Range C will increase costs (A.a-21, B.b-7).

Response: Such supervision should already be in place at such high doses. If they are not, costs may indeed increase.

3.4.5.7 The term "professional radiation protection supervision" must be clearly defined before the guidance is issued (A.b-11, A.b-23, B.c-23).

Response: The final recommendations do not include the specific elements of proposed recommendation 4 on minimum radiation protection requirements for supervision in dose ranges. They do, however, contain a broad recommendation on radiation-protection supervision.

3.4.5.8 Recommendation 4.f should be rewritten to read:"... and provide management supervision and radiation protection personnel review before, and frequent surveillance while such jobs are undertaken, to assure that collective and individual exposures are ALARA" (A.d-42, B.a-10).

Response: See the response to comment 3.4.5.7.

3.4.5.9 Range A would require professional radiation protection supervision to assure exposures are justified and ALARA. This is unnecessary since doses in this range should be considered de minimis (B.c-4, B.c-20).

Response: Doses below 500 mrem/yr are clearly not "de minimis." Recommendations 1 and 2 are intended to apply as fully to such doses as to higher doses.

3.4.5.10 Range A would require professional radiation protection supervision to assure that all exposures are justified and ALARA (B.a-39).

Response: We agree. However, such supervision could be managed on a generic basis.

3.4.5.11 Guidelines for supervision should be evaluated on a task-by-task basis (A.d-8).

Response: In some cases, yes. In others, more generic treatment may be adequate and appropriate.

3.4.6 LIFETIME DOSE

3.4.6.1 The 100 rem lifetime limit is unnecessary (A.a-18, A.a-41, A.a-46, A.b-15, A.b-16, A.b-26, A.d-9, A.d-21, A.d-29, B.a-3, B.a-6, B.a-9, B.a-17, B.a-21, B.a-22, B.a-31, B.a-44, B.a-46, B.a-48, B.a-53, B.c-12, E.a-4, E.a-5, E.b-6, E.b-7, E.b-8, E.b-10).

Response: We agree. Since few workers have historically received more than a 100 rem lifetime dose up to the present time it is unlikely, according to present levels and trends of exposure, that workers currently entering the work force would exceed such a lifetime dose.

3.4.6.2 The need and benefits of the 100 rem lifetime limit are unclear (A.a-8, A.a-13, A.a-39, A.b-22, A.d-6, A.d-22, B.a-4, B.a-20, B.a-23, B.a-24, B.a-27, B.a-32, B.a-33, B.a-34, B.a-37, B.a-39, B.a-46, B.c-12, B.c-20, E.a-7, E.b-5, F-1).

Response: The benefit of a lifetime limit is to clearly limit the maximum risk to an individual worker. See the response to comment 3.4.6.1 for the question of need.

3.4.6.3 The 100 rem lifetime limit would result in legal problems by making a worker unemployable (A.a-8, A.a-13, A.a-39, A.b-22, A.d-6, A.d-22, B.a-5, B.a-6, B.a-8, B.a-14, B.a-17, B.a-20, B.a-22, B.a-23, B.a-24, B.a-27, B.a-29, B.a-30, B.a-32, B.a-33, B.a-34, B.a-36, B.a-39, B.a-46, B.a-48, B.a-50, B.c-21, C-1, C-2, E.a-5, E.a-6, E.b-2, E.b-5, E.b-6, E.b-7, E.b-10).

Response: The issue is moot as no lifetime limit is adopted in final recommendations. However, a recent EPA analysis of accumulated doses of terminated workers indicates that such a limit would not affect even the currently highest exposed workers, such as those found in the nuclear industry (Ku84).

3.4.6.4 The 100 rem lifetime limit would adversely impact the nuclear industry by unnecessarily restricting the availability of skilled workers (A.d-18, B.a-1, B.a-3, B.a-20, B.a-21, B.a-27, B.a-32, B.a-33, B.a-36, B.a-37, B.a-44, B.a-46, E.b-2).

Response: See the response to comment 3.4.6.3.

3.4.6.5 Some formula to adjust the previous exposure of workers is necessary to protect the livelihood of veteran workers when a lifetime dose is established (A.d-5, A.d-12, B.a-7, B.c-20, C-8, E.a-3, E.b-3).

Response: We agree. However, see also the response to comment 3.4.6.3.

3.4.6.6 If the annual RPG is appropriately derived, there is no need for a lifetime limit (A.d-13, B.a-33, B.a-35, B.a-46, B.a-53, E.a-4).

Response: This is not the case. The justified need for allowing a maximum annual dose to a worker in any given year does not justify allowing that maximum annual dose in other years without considering the equity of utilizing other workers and other alternatives. Because the maximum annual dose allowed workers would result in an unacceptable level of risk if received every year of a working lifetime, a lifetime limit could become necessary if such patterns of worker exposure should develop.

3.4.6.7 The 100 rem lifetime limit is chosen to assure that the risk of a maximum exposed radiation worker is comparable to the average risk in other industries. This is not a valid method for making the comparison (A.b-1, A.d-18, B.a-6, B.a-22, B.a-31, B.a-33, B.a-37, E.a-6).

Response: This is not true. According to the relative risk model, the lifetime risk of death for workers receiving 100 rems uniformly spread over the age range 18 to 65 would be more than three times larger than the average accidental death risk for all U.S. workers.

3.4.6.8 The proposed 100 rem lifetime limit is appropriate (C-5, C-8, E.b-3).

Response: No response required.

3.4.6.9 The lifetime limit should be less than 100 rems (A.a-3, A.a-38, C-8).

Response: The comment is moot since the final recommendations do not include a numerical lifetime dose objective. However, the final recommendations encourage the maintenance of lifetime (accumulated) dose records for workers and stipulate that "continued exposure at or near [the] limiting values for substantial portions of a working lifetime should be avoided."

3.4.6.10 The lifetime limit should be restricted to 10 rems (A.c-6).

Response: See the response to comment 3.4.6.9.

3.4.6.11 The proposed 100 rem lifetime limit would increase the risk of genetic damage (A.a-19, A.b-16, A.b-20, A.d-18, B.a-7, B.a-21, B.a-29, B.a-30, B.a-31, B.a-32, B.a-44, B.a-48, B.b-1, E.a-5, E.a-6).

Response: We disagree. A lifetime limit would neither encourage the increase nor cause the increase of genetic or somatic damage. See also the response to comment 3.4.6.9.

3.4.6.12 The proposed 100 rem lifetime limit fails to consider the decreasing risk of radiation exposure with increasing age. As a result, total risk might be increased if workers receive most of their lifetime risk early in their careers (A.a-8, A.b-20, A.d-18, B.a-17, B.a-30, B.a-33, B.a-37).

Response: We agree. However, see the response to comment 3.4.6.9.

3.4.6.13 Exposure beyond 100 rems should be on the basis of the worker's informed consent (A.b-5, E.a-6).

Response: See the response to comment 3.4.6.9.

3.4.6.14 Workers approaching 100 rems accumulated exposure should be informed and restrictions of future doses decided on a case-by-case basis (C-1, E.b-2).

Response: See the response to comment 3.4.6.9.

3.4.6.15 Eliminate the 100 rem lifetime limit and replace it with the following guidance: "Maintain lifetime doses ALARA. The accumulated dose of individual workers should be managed so that it is less than a specified, reasonably achievable ALARA goal. Where workers have already accumulated more than 50% of this lifetime limit due to work under previous regulations, they should be allowed to accumulate additional exposures up to 100% of this lifetime limit" (E.b-1).

Response: See the response to comment 3.4.6.9.

3.4.6.16 Does the 100 rem lifetime limit include emergency exposures? (B.a-32, B.a-38, E.a-5).

Response: See the response to comment 3.4.6.9.

3.4.6.17 Employers might use lifetime dose histories to discriminate against workers with significant exposure histories (B.a-8).

Response: See the response to comment 3.4.6.9.

3.4.6.18 The 100 rem limit could lead to dose falsification by workers in high exposure industries (A.d-6).

Response: See the response to comment 3.4.6.9.

3.4.6.19 Lifetime dose records for all radiation workers must be available to all radiation workers (C-2).

Response: See the response to comment 3.4.6.9.

3.4.6.20 This recommendation could give rise to claims of apparent past negligence by the government for those workers who have exceeded the proposed lifetime limit (E.a-5).

Response: See the response to comment 3.4.6.9.

3.5 RADIOACTIVITY INTAKE FACTORS

3.5.1 EPA does not present sufficient justification for a change from the current MPCs to the proposed RIFs (B.a-3, B.a-4, B.a-27, B.c-21, E.a-2).

Response: Final recommendations adopt the internationally-accepted approach of ICRP Publication 26 (ICRP77), where the same basis (i.e. committed dose) used for deriving MPCs and the proposed RIFs or final ALIs is continued. In the ICRP-26 weighting system, the ALI (Annual Limit on Intake) replaces the RIF.

Some discussion of old and new acronyms and their relationships appears useful here. The DAC (derived air concentration) for a radionuclide under final recommendations is the counterpart of the old MPC. Thus, for inhalation of radionuclides, the DAC or MPC (microcuries/cc of air) of a specific radionuclide multiplied by the volume of air inhaled during a working year (2.4×10^9 cc of air/working year), by "Reference Man" (ICRP75) gives the ALI (microcuries/working year) of that radionuclide.

3.5.2 There is no need for the RIF approach, nor are there any benefits to be derived from it (A.a-39).

Response: We disagree. Although final recommendations adopt the ALIs rather than RIFs, as a result of adopting ICRP-26 weighting factors, both the ALI and RIF are based on the same committed dose concept used for the former MPCs. See also the response to comment 3.5.1. As a practical means of compliance (with the basic dose limits), presented in Note 2 of

our proposed guidance, use of the RIF greatly facilitates the control of workplace exposures to assure that the dose limits are not exceeded. The same is true of the ALI.

3.5.3 Exposure should not be regulated through use of RIFs (E.b-2).

Response: Secondary limits, such as RIFs or ALIs, provide a practical way to implement the basic limits. See also the responses to comments 3.5.1 and 3.5.2. Although the basic limits are expressed in units of dose equivalent or committed dose equivalent, secondary limits (ALI or RIF) are derived for practical radiation protection in terms of quantities that can be measured. These secondary limits reflect the use of models which relate a radionuclide quantity with the corresponding dose equivalent to an adult Reference Man. From secondary limits, a derived limit, such as the DAC, can be calculated which expresses the basic limit in terms of a limiting environmental condition for Reference Man.

3.5.4 The proposed use of Radioactivity Intake Factors will involve more operational problems in implementation then the continued use of Radioactivity Concentration Guides (RCGs) (A.b-11).

Response: We disagree. Both secondary limits (RIFs and ALIs) and derived limits (RCGs or DACs) have their necessary and practical use in operational radiation protection. See the responses to comments 3.5.1, 3.5.2, and 3.5.3.

3.5.5 It is more practical to regulate and monitor concentrations and contamination rather than intake (A.b-23).

Response: See the response to comment 3.5.4.

3.5.6 The added workload required by Recommendation 5 is not justified by the potential radiation exposure reductions (B.a-11).

Response: We disagree. Implementation of either the proposed RIF or the ALI of ICRP 26 adopted in final guidance would still involve the practical use of DACs analogous to the current use of MPCs. Recommendation 5b is not retained in final guidance, since the application of ALARA covers this consideration. See also the response to comment 2.2.8.

3.5.7 The RIF concept should be eliminated because there are not sufficient technical data on humans to establish the RIFs (B.a-26).

Response: We disagree. This concept has been accepted practice for several decades through use of the MPCs. See the response to comment 3.5.1.

3.5.8 Recommendation 5 should be covered as a part of Recommendation 3 (A.a-41) or as a part of Recommendation 4 (B.c-20).

Response: Proposed recommendation 5a appears in final recommendations as a note. See the response to comment 3.5.6.

3.5.9 The use of Radioactivity Intake Factors is an improvement over the current practice of basing internal exposure limits on airborne concentrations (B.a-5, B.a-33, B.a-46, B.a-53, D-2).

Response: We agree, for purposes of meeting the primary limits of dose, that the determination of actual radionuclide intakes is a better measure of compliance than the measurement of airborne concentration to which the worker was exposed.

3.5.10 Part b of Recommendation No. 5 is not consistent with ICRP Publication 30 and adds an additional element of confusion to radiation protection (A.d-18, B.a-33, B.a-36, B.c-22, E.b-1).

Response: Part b of proposed recommendation 5 has been deleted. See the response to comment 3.5.6.

3.5.11 Recommendation 5.b contradicts Recommendation 5 and is ambiguous (A.a-19).

Response: See the responses to comments 3.5.6 and 3.5.10.

3.5.12 We vigorously support Recommendation 5b, in part because of the large uncertainties in the organ weighting factors, w_i (C-5).

Response: When changes in metabolic and dosimetric models lead to higher ALI or DAC values, the application of ALARA should determine whether actual levels of exposure need to increase. Therefore, this recommendation has not been retained in final recommendations. See the response to comment 2.2.8.

3.5.13 Is it the intent of EPA to make the derivation of the RIFs the responsibility of each user? (A.b-5, A.d-11, A.d-14, A.d-29, A.d-40, B.a-33).

Response: We did not intend that users derive their own RIF values. It was our intent to furnish that set of values. Since we have adopted the ICRP Publication 26 basic system of dose limitation for final guidance, the ALIs (annual limit on intake) replace our proposed RIFs, and currently acceptable values of the ALIs are available in ICRP Publication 30.

3.5.14 Will EPA provide individual RIFs for each situation, each employer, and each job classification? (A.d-11, A.d-14, A.d-29, A.d-40).

Response: No. EPA will provide or reference ALI (RIF) values based on Reference Man. It is permissible to use more specific metabolic and dosimetric models in those situations where the necessary data are available. See the response to comment 3.5.13.

3.5.15 EPA should either derive and publish RIFs or use ICRP's ALIs (B.c-11, E.a-4).

Response: See the response to comment 3.5.13.

3.5.16 EPA should make the RIFs numerically equal to ICRP's ALIs in ICRP Publication 30 (A.a-1, A.a-49, A.a-50, A.a-51, A.d-13, A.d-18, B.a-29).

Response: See the response to comment 3.5.14.

3.5.17 EPA should permit the use of site-specific RIFs where actual data are available (B.a-33, B.a-46).

Response: This is EPA's intent. However, Federal regulatory agencies will determine the specific criteria for such use of site-specific ALIs. Modifications to the ALIs in ICRP-30 could be made for specific individuals where there is adequate metabolic/dosimetric data available to modify the model data assumed for Reference Man (see ICRP Publication 23). See the response to comment 3.5.14.

3.5.18 A consistent methodology, representing equal risks, should be used in deriving RIF values (B.a-22).

Response: This has been done by adopting the ICRP-26 basic system of dose limitation for final recommendations.

3.5.19 EPA uses complex mathematical models which may not be understood by the average Radiation Safety Officer (A.d-6).

Response: The mathematical formulations recommended are not complex.

3.5.20 Is a "Radioactivity Concentration Guide" the same as a "Radioactivity Intake Factor" divided by the amount of air or water an individual ingests in a year (A.a-12).

Response: Yes. See responses to comments 3.5.1, 3.5.2, and 3.5.3 for further discussion of the terms used in final recommendations.

3.5.21 The RIFs appear to be unnecessarily restrictive; there is no valid reason to arbitrarily reduce the airborne uranium concentration limit by a factor of 10 below its current value (B.a-14).

Response: The values for secondary limits (ALIs or RIFs) and for derived limits (DACs or MPCs) are not arbitrarily lowered or raised. They have changed due to improved knowledge of metabolism and dosimetry. The ALIs and DACs are the result of computations based on the models and parametric values described in ICRP-30. See also the responses to comments 2.2.8, 3.5.6, and 3.5.12.

3.5.22 EPA's substitution of the terminology "Radioactivity Intake Factor" for ICRP's "Annual Limit of Intake" is unnecessary and confusing (A.a-1, A.b-6, A.d-13, A.d-18, B.a-29, B.a-36, B.c-22, E.a-6).

Response: The proposed Radioactivity Intake Factors (RIF) were based on a system similar, but not identical, to that of ICRP's "Annual Limit on Intake" (ALI), because they depend on a somewhat different set of organ weighting factors. Hence, the RIF is not the same as an ALI. To use the same term would lead to confusion. As the basic system and numerical limiting doses in ICRP-26 have been adopted in final recommendations, the secondary limit will now be called the ALI.

3.6 LIMITS BELOW THE GUIDES

3.6.1 If the recommendations of ICRP, NCRP, and EPA's guidance are valid, there is no need for Recommendation 6 (A.a-14, A.b-5, A.d-12, A.d-40, B.a-14, B.a-15, B.a-27, B.c-12, B.c-14).

Response: We do not agree. Such additional limitations are part of the current framework of radiation protection programs, including the recommendations of the ICRP. Thus, the final recommendations provide for establishing administrative control levels below the specified limits by agencies or management. Such control levels are called "authorized limits" by the ICRP (See paragraph 148 of ICRP Publication 26) and may be established through an optimization or ALARA process.

3.6.2 Recommendation 6 defeats the purpose of having a lead agency set standards (A.a-41, A.d-14, A.d-24, A.d-40).

Response: We do not agree. The intent of this recommendation is to further facilitate the elimination of unnecessary exposure and the achievement of ALARA. See the response to comment 3.6.1.

3.6.3 Allowing federal agencies to set lower limits will lead to confusion and undermine the confidence of workers and the public in the

safety provided at the proposed limits (A.a-10, B.a-11, B.a-21, B.a-44, B.b-7, B.c-20).

Response: We disagree. On the basis of the linear nonthreshold hypothesis, risks are proportional to dose, and there is no completely risk-free level of radiation exposure. The recommendations therefore encourage administrative control levels below the limiting values to be established by agencies or management, on the basis of generic ALARA findings. Setting of such administrative levels has been a common practice in many user activities. This practice has not led to confusion or to undermining the confidence of workers and the public. See also response to comment 3.6.1.

3.6.4 We are opposed to Recommendation 6, as it would give regulatory agencies authority to establish arbitrary and discriminatory guides (A.b-15, A.d-11, A.d-14, A.d-18, A.-21, A.d-40, B.a-7, B.a-19, B.a-27, B.a-36, B.b-7, B.c-20, D-2).

Response: We do not believe that agencies would establish capricious or discriminatory regulations. If this were the case, administrative remedies are available.

3.6.5 We are opposed to Recommendation 6, as it gives regulatory agencies license to legislate ALARA (B.a-7, E.a-2).

Response: That is the intent, when it is justified. The intended use of administrative control levels is to further ensure that the objectives of that guidance, including ALARA, are met. See the responses to comments 3.6.1 and 3.6.4.

3.6.6 Establishing limits lower than the proposed guides should be an administrative option of the licensees, not a regulatory option of federal agencies (A.a-14, B.a-5, B.a-33, F-2).

Response: Radiation control measures should be determined and used by both management and regulatory authorities, as appropriate. See the responses to comments 3.6.1, 3.6.3, and 3.6.5.

3.6.7 Allowing federal agencies to set lower limits will lessen the willingness of licensees to employ ALARA principles (B.b-7, B.c-20, B.c-22).

Response: If this were so, then it would imply that the system of dose limitation, which depends on both the existence of limiting values and application of ALARA, is not feasible. This would imply the need for low enough limiting values so that ALARA is not needed. We hope this is not the case.

3.6.8 The effect of agencies setting lower limits will be to penalize licensee's with good radiation protection programs (B.a-33, B.a-46, B.c-20, B.c-22).

Response: If a licensee's radiation protection program is indeed a "good" one, it would not be adversely affected by such limits. See also the responses to comments 3.6.1 and 3.6.7.

3.6.9 Lower limits, set by regulatory agencies that do not fully understand the operational requirements of an activity, could cripple operations by denying needed flexibility (A.a-41, A.d-12, A.d-15, A.d-40, E.b-9).

Response: Regulatory agencies should be fully cognizant of the operational requirements of the activities they regulate. See the responses to comments 3.6.1, 3.6.3, and 3.6.8.

3.6.10 Many federal agencies do not have the expertise to set limits based on different categories of workers or work situations. If this recommendation is retained, it must specify that a certified health physicist make the determinations upon which the limits are based (E.a-3).

Response: The establishment of administrative control levels should be carried out by competent authorities, whether Federal regulatory agencies or management. See the responses to comments 3.6.1, 3.6.8, and 3.6.9.

3.6.11 Conscientious application of ALARA makes Recommendation 6 unnecessary (A.a-10, A.a-39, A.b-16, A.d-6, B.c-20, B.c-22).

Response: We agree with this comment insofar as ALARA is conscientiously applied. However, it is not possible to insure that a largely voluntary process will be universally or uniformly applied. To the extent that generic ALARA findings are possible, the establishment of administrative control levels would correct this deficiency. See the responses to comments 3.6.1, 3.6.8, and 3.6.9.

3.6.12 Recommendation 6 is unnecessary (A.a-41, B.a-8, B.a-14, B.a-26, B.b-7, E.a-2).

Response: We disagree. We believe the substance of this recommendation, as also recommended in ICRP-26, provides an important means for eliminating unnecessary levels of exposure that are within the maximum dose limits. See also the response to comment 3.6.11.

3.6.13 Recommendation 6 is unnecessary as Federal agencies already have the authority to set lower limits (E.a-6).

Response: It is true that Federal agencies already have such power. However, guidance promulgated by executive order provides clear direction from the President to Federal agencies to use this means to eliminate unnecessary exposure.

3.6.14 Recommendation 6 would vitiate any attempt at rational development of standards (A.a-13, A.d-21).

Response: This comment is not correct. The establishment of authorized limits or administrative control levels is a well-established component of radiation protection standards (see ICRP Publication 26).

3.6.15 Recommendation 6 is consistent with current policy (A.d-23, B.a-9, E.a-5).

Response: We agree.

3.6.16 If Recommendation 6 is retained it should be revised to encourage interagency cooperation and consistency in setting standards (A.b-6, E.a-4, E.a-6, E.b-2).

Response: Interagency cooperation and consistency are only particularly necessary for those facilities regulated by more than one Agency. Such cooperation already exists with few, if any, complications of recordkeeping, reporting, and administrative procedures.

3.6.17 If Recommendation 6 is retained, EPA should provide guidance for uniform implementation (A.b-5, A.b-15, A.d-23, B.a-21, B.a-44).

Response: The details of regulatory implementation are outside the scope of Federal guidance. However, EPA will keep informed of Federal agency actions to implement the guidance so as to promote a coordinated and effective Federal program of work protection. See the response to comment 3.6.17.

3.6.18 Recommendation 6 would unnecessarily complicate recordkeeping, reporting, and administrative procedures (B.c-33).

Response: We disagree. See the responses to comments 3.6.16 and 3.6.17.

3.6.19 Replace "federal agencies should establish..." with "Federal agencies may establish..." (E.a-4, E.a-6).

Response: The final recommendations make this change.

3.6.20 Recommendation 6 should be included in Section 4, and should refer to ALARA goals rather than limits (E.b-1).

Response: We believe the establishment of radiation exposure control measures is important enough to warrant a separate recommendation. Therefore, the use of administrative control levels is recommended in final guidance to achieve a key objective of the guidance, ALARA exposures. See also the responses to comments 3.6.1 and 3.6.7.

3.6.21 Setting administrative levels should be the function of industry, not federal regulations (A.a-45, A.a-8, A.d-18, A.d-42, B.a-2, B.a-32, B.a-46, B.c-12, E.b-8).

Response: We disagree. Administrative control levels can be used by either regulatory or industrial authorities. See also the response to comment 3.6.3.

3.7 OCCUPATIONAL EXPOSURE OF MINORS

3.7.1 The recommendation that occupational exposures to individuals younger than eighteen should be limited to one-tenth of the Radiation Protection Guides for adult workers is acceptable (A.a-10, A.a-39, A.a-41, A.b-5, A.b-6, A.d-11, A.d-14, A.d-29, A.d-40, B.a-5, B.a-8, B.a-11, B.a-14, B.a-26, B.a-32, B.a-33, B.a-46, B.a-48, B.a-53, B.c-12, D-2, E.a-2, E.a-3, E.a-5, E.a-6, E.b-2, E.b-9).

Response: No response required.

3.7.2 Adoption of this recommendation should have little or no effect on radiation exposure in the health care and nuclear industries (A.d-18, B.a-7, B.a-36, B.c-20).

Response: No response required.

3.7.3 Recommendation 7 is made without justification (A.d-23, B.a-7, B.c-20).

Response: This recommendation is implicit in previous guidance (25 FR 4402), complies with existing Federal laws on employment of minors, and is consistent with accepted international practice (IAEA82). Therefore, we proposed no change and it appears in final recommendations.

3.7.4 Recommendation 7, which restricts occupational dose to those under 18 to 0.1 RPG, would result in an annual permissible dose of 50 millirem if Recommendation 8.d is adopted (A.a-14).

Response: Proposed alternative 8d represented an extreme solution, out of four alternative recommendations for protection of the unborn, that was not adopted in final recommendations.

3.7.5 Recommendation 7 should be clarified to read "...in addition to any other Federal restrictions, the occupational exposure of individuals younger than eighteen years should be limited to 5.0 mSv per year." (A.b-8).

Response: The additional phrase "in addition to any other Federal regulations" was not included in final recommendations because it is implicit to all the recommendations. Numerical limitations in SI units are specified in parenthesis.

3.7.6 Is it the intent of Recommendation 7 that an individual under age 18 be limited to one-tenth of the 5 rem/yr whole body RPG or one-tenth of each range limit? (E.b-3).

Response: The Proposed recommendation 7 for minors explicitly refers only to one tenth of the numerical limits (RPGs), and not the suggested ranges for proposed recommendation 4.

3.7.7 Recommendation 7 requires clarification in view of the Range Guides (A.b-11).

Response: See the response to comment 3.7.6.

3.7.8 Individuals less than 18 years of age should not be allowed to work in a radiation area under any condition. (A.d-6, B.a-53).

Response: The guidance for minors serves for controlling exposures they might receive as a student apprentice or trainee, either in formal educational institutions or during on-the-job training (whether or not it entails their receiving wages). We believe that most (if not all) "employment" of minors in tasks involving radiation exposure is of this nature. This recommendation requires that any individual who is under age eighteen and is in an occupational type of environment be protected as though they were a member of the general population. See also the response to comment 3.7.3.

3.8 EXPOSURE OF THE UNBORN

3.8.1 Alternative A, which recommends that women voluntarily limit exposure to less than 0.5 rem during any known or suspected pregnancy, should be adopted by EPA (A.a-6, A.a-8, A.a-10, A.a-13, A.a-34, A.a-39,

A.a-40, A.a-41, A.b-17, A.b-20, A.b-23, A.d-11, A.d-14, A.d-19, A.d-23, A.d-29, A.d-34, A.d-40, B.a-3, B.a-6, B.a-13, B.a-17, B.a-22, B.a-26, B.b-1, B.c-11, B.c-12, B.c-14, B.c-20, B.c-21, D-2, E.b-1, E.b-2, E.b-3, E.b-5, E.b-9, F-3).

Response: This alternative was not adopted because it places the entire burden of protecting the unborn on women, i.e. could incur economic penalty or loss of job security. The final recommendations specify that the dose equivalent to an unborn child of a woman voluntarily declaring her pregnancy should be maintained ALARA and should not exceed 0.5 rem during the entire gestation period. In addition, efforts should be made to avoid variation above the uniform monthly exposure rate that would satisfy this limiting value. We believe this formulation reflects both the numerical level of protection and the acceptable voluntary elements of proposed Alternative A.

3.8.2 Alternative B, which recommends that women able to bear children voluntarily avoid job situations involving whole-body dose rates greater than 0.2 rem per month and to keep total dose to the unborn to less than 0.5 rem during a known pregnancy, should be adopted by EPA (A.a-13, A.a-36, A.b-5, A.b-20, A.b-22, A.b-26, A.d-6, A.d-9, A.d-11, A.d-14, A.d-19, A.d-29, A.d-40, B.a-3, B.a-6, B.b-7, B.a-12, B.a-20, B.a-22, B.a-26, E.b-1, E.b-5).

Response: This alternative was not adopted because it places the burden of protecting the unborn entirely on women, who could incur economic penalty or loss of job opportunity and security. See also the responses to comments 2.1.12, 2.13.4 and 3.8.1.

3.8.3 Alternative C, limiting women able to bear children to job situations involving whole-body dose rates less than 0.2 rem per month and limiting exposure of the unborn to less than 0.5 rem during any known pregnancy, should be adopted by EPA (A.a-2, B.a-19, B.a-31, B.a-42, E.a-3).

Response: Proposed alternative C was not adopted in final guidance because it would unnecessarily equal employment opportunities to women able to bear children; and the desired level of protection for the unborn could be achieved by less restrictive means. See also the responses to comments 2.1.12, 2.13.4 and 3.8.2.

3.8.4 Alternative D, restricting whole-body doses of both men and women to less than 0.5 rem per six-month period, should be adopted by EPA, as it would afford all workers equal protection from radiation exposure as well as protect the most sensitive individual (unborn) (A.c-1, A.c-2, A.d-20, C-4, D-11).

Response: Proposed alternative D was not adopted because of its unacceptable impact on necessary activities in defense, medical, and

energy applications and because the unborn can be provided the desired level of protection by other more acceptable means.

3.8.5 Alternative A is not acceptable (A.a-12, A.a-46, A.c-1, A.c-2, A.c-10, A.d-12, A.d-20, A.d-42, B.a-8, B.a-27, B.a-33, B.c-5, B.c-11, C-4, C-5, C-6, E.a-2, E.a-3, E.a-6).

Response: The final recommendation provides an assured level of protection to the unborn without relying on voluntary action by the mother, other than declaring her pregnancy. See also the responses to comments 2.1.12, 2.13.4 and 3.8.1.

3.8.6 Alternative B is not acceptable (A.a-6, A.a-12, A.a-16, A.a-41, A.b-17, A.c-1, A.c-2, A.d-10, A.d-20, A.d-34, B.a-8, B.a-12, B.a-27, B.c-5, C-6, C-8, C-4, E.a-3).

Response: The final recommendation achieves the desired level of protection of the unborn without denying equal opportunity rights to or placing the burden of protection on women. See also the response to comment 3.8.2.

3.8.7 Alternative C is not acceptable (A.a-13, A.a-16, A.a-36, A.a-40, A.a-41, A.a-46, A.b-16, A.b-17, A.b-23, A.c-1, A.c-2, A.c-10, A.d-11, A.d-12, A.d-14, A.d-20, A.d-22, A.d-23, A.d-29, A.d-34, A.d-40, B.a-3, B.a-8, B.a-17, B.a-20, B.a-22, B.a-26, B.a-27, B.a-33, B.b-2, B.c-12, B.c-20, C-4, C-5, C-6, C-8, E.a-2, E.a-6, E.a-7, E.b-1, E.b-3, E.b-6).

Response: See the response to comment 3.8.3.

3.8.8 Alternative D is not acceptable (A.a-13, A.a-34, A.a-40, A.a-41, A.a-46, A.b-16, A.b-17, A.b-23, A.d-9, A.d-11, A.d-12, A.d-14, A.d-22, A.d-23, A.d-24, A.d-29, A.d-34, A.d-40, A.d-42, B.a-3, B.a-6, B.a-7, B.a-8, B.a-17, B.a-20, B.a-22, B.a-26, B.a-27, B.a-33, B.a-42, B.b-2, B.c-5, B.c-12, B.c-20, B.c-21, C-5, C-8, E.a-2, E.a-6, E.a-7, E.b-1, E.b-3, E.b-6, E.b-8,).

Response: See the response to comment 3.8.4.

3.8.9 Alternative D would degrade the social benefits of radiation, and/or increase total doses and costs (A.d-9, A.d-23, B.a-22, B.b-2, E.a-7, E.b-8).

Response: We agree that Alternative D would lead to unacceptable impacts that are not necessary to assuring appropriate protection for the unborn child. See also the response to comment 3.8.4.

3.8.10 Alternative B would be acceptable for protection of the unborn if it were rewritten to include only pregnant women instead of all women of child-bearing age (A.b-17).

Response: This change would not completely satisfy the problems discussed in the response to comment 3.8.2.

3.8.11 Alternatives A and B are unacceptable since they assume that the women are sufficiently knowledgeable to make valid judgments regarding the welfare of themselves and any unborn child (E.a-3).

Response: The final recommendations provide that workers and their employers be informed of current knowledge of risks to the unborn from radiation and of the responsibility of both employers and workers to minimize exposure of the unborn and that protection of the unborn be achieved without economic penalty or loss of job opportunity and security to workers. However, the recommended limit for dose to the unborn is still only invoked when a woman voluntarily declares her pregnancy.

3.8.12 Alternative D is a "sleeper" that establishes the annual exposure limit at 1.0 rem. It is totally unacceptable (A.a-41, A.d-40, B.a-3, B.a-26).

Response: See the response to comment 3.8.4.

3.8.13 Alternative D would be acceptable if the reference to male workers were dropped (E.a-3).

Response: If the reference to male workers were dropped, Alternative D would still be subject to the objections to Alternative C.

3.8.14 The proposed guidance on Protection of the Unborn should be withdrawn since EPA has failed to construct a valid scientific, legal, or policy case for choosing amongst the alternatives (B.a-24).

Response: In proposing four alternatives we afforded the public the opportunity to raise the scientific, legal, and policy issues they feel are germane to protection of the unborn. The many comments received have been useful in that regard.

3.8.15 EPA's background report exaggerates the effects on children exposed in utero. There is insufficient evidence to make statistically valid conclusions on teratogenic effects of in utero exposure; including the mental retardation studies based on in utero exposures at Hiroshima and Nagasaki (A.c-1, A.c-2, A.b-17, A.d-20, B.c-11).

Response: The background report summarized the most current information on the effects of radiation on children exposed in utero. It was not our intent to exaggerate, and new evidence clearly substantiates our earlier conclusion that the risk of teratogenic damage is substantial and much greater than hereditary risks due to exposure of workers prior to conception. In our background report, we placed considerable emphasis on evidence of structural anomalies among the A-bomb survivors exposed to radiation in utero. For example, the risk of microcephaly was estimated, assuming a linear response, as between 5×10^{-3} and 20×10^{-3} per rem. New studies of doses at Hiroshima (RERF83,84) now indicate neutron doses were overestimated, so that the risk of microcephaly was very probably closer to the higher of these two values. These studies of structural anomalies were cited as indicative of the probable sensitivity of the fetus to more serious effects, such as severe mental retardation. It has now become clear that this concern was well founded. The recently published investigation by Otake and Schull of severe mental retardation among the A-bomb survivors irradiated in utero, 8 to 15 weeks after conception, indicates that the dose-response function seems to be linear and without a threshold. These authors estimate this risk to be about 4×10^{-3} cases per rad to the fetus (Ot84). This is not the total impact. Less severe mental retardation also occurred and its excess is the topic of a paper now being drafted (W.J. Schull, personal communication). We note that this work has been followed for a number of years by the International Commission on Radiological Protection and provides the basis for their current recommendations for increased protection of the fetus.

The question of the sufficiency of the evidence of teratogenic effects in Hiroshima A-bomb survivors is a question that can not be answered here. We have reviewed the results available in published studies and any rebuttal or disagreement should likewise be published so the scientific community can evaluate all the evidence. We note, however, that there are some animal studies that support the in utero studies on mental retardation of children of survivors in Hiroshima. Radiation exposure has been reported to interfere with normal neuronal development in rats (No79) and even relatively low levels of exposure can have detrimental effects on locomotor- and maze-learning in rats (We61, We62). The observations are also consistent with the types of teratogenesis seen in laboratory animals (Ru71) and with effects seen in animals at exposure as low as 1 rad (Mi78).

3.8.16 Since current managerial policy is generally to limit exposures to 60% of the RPGs, it is questionable if additional restrictions on fertile women are necessary or desirable. Such policies would limit (on the average) the potential exposure of a conceptus to 0.5 rem during the first two months of pregnancy without placing additional or discriminatory restrictions on the employment of fertile women in the radiation industry (A.b-1).

Response: We disagree. Such a general policy assures neither the protection of all unborn nor achievement of the desired level of dose

limitation. An explicit recommendation is required to assure protection of the unborn as well as rights of women to nondiscriminatory treatment in employment.

3.8.17 NCRP Report #53 gives adequate guidance on exposure to the unborn (B.a-14, B.a-21, B.a-44, B.a-48, E.b-2, E.b-3).

Response: These recommendations of the NCRP were taken into consideration and, in large part, adopted. See also the response to comment 3.8.37.

3.8.18 Current guidance such as NCRP 39 and Reg. Guide 8.13 appear to provide sufficient incentive for voluntarily limiting doses during pregnancy (A.a-16, A.a-46, B.a-4, B.a-6, B.a-32, E.a-5).

Response: The existence of NCRP recommendations and NRC Regulatory Guides do not obviate the need to include explicit provisions for protection of the unborn in Federal guidance.

3.8.19 Recommendations 8 (a)-(c) are unacceptable for women workers as they would violate federally secured rights to equal employment opportunities while hindering the exercize of the fundamental right of procreation and placing the burden of a healthy and safe environment on the worker. EPA must assure that regulatory agencies adopt a consistent policy in this matter (A.c-1, A.c-2, A.d-18, B.a-36, B.c-10).

Response: We agree, and the final recommendations encompass the goals expressed in this comment.

3.8.20 The legal constraints preventing issuing of guidance calling for mandatory protection of unborn children must be resolved and the federal government should take the lead (A.d-42, B.a-10, B.a-24).

Response: We believe the final recommendations achieve this objective.

3.8.21 EPA should postpone guidance on this issue until the Federal regulatory agencies can agree on the regulation (A.a-19, B.c-23).

Response: Federal agencies do agree on the final recommendation.

3.8.22 Congress should resolve the equal employment opportunity issues raised in connection with the protection of the unborn (B.a-12, B.a-38).

Response: The Congress has addressed these issues. The final recommendations are consistent with civil rights and equal employment opportunity laws and guidelines.

3.8.23 Alternative C is unlawful under Title VII; if the hazard affects the fetus through women only, the exclusion must be pregnant women only and not all women of child-bearing age (A.a-36, A.a-40, A.b-16, A.c-1, A.c-2, A.c-10, A.d-34, B.a-7, B.a-22, B.a-26, B.b-2, B.c-11, B.c-20, E.a-7, E.b-3, E.b-6).

Response: We agree. See the response to comment 3.8.24.

3.8.24 The reference to "women able to bear children" is over inclusive and discriminatory. It contains the assumption that such women are always potentially pregnant and that women cannot control when they become pregnant (A.c-1, A.c-2, A.c-10, A.d-20).

Response: We agree. Final recommendations provide an appropriate level of protection to the unborn child only for a woman declaring pregnancy.

3.8.25 Requiring all employers to make provisions for not exposing female workers to more than 0.2 rem per month could restrict employment opportunities for women (A.a-6, A.a-16).

Response: We agree. The appropriate protection of the unborn child does not require that occupational exposure of all women be restricted, just those who are pregnant. See the response to comment 3.8.24.

3.8.26 These guidelines will adversely affect labor agreements, particularly pregnant worker agreements (C-2).

Response: We disagree. The final recommendation for protection of the unborn is written so as to protect the rights of workers and should be supportive of labor agreements. Since 1975, the State of Michigan has required 0.5 rem protection of women who have submitted written notice of their pregnant condition to a licensee or registrant (MDPH75). There are no known cases where women have incurred discrimination, economic penalties, or loss of job opportunity and security as a result of this regulation.

3.8.27 Even excluding a worker from any exposure once a pregnancy is known may not be an adequate precaution against litigation (B.a-35).

Response: The subject of litigation is outside the scope of Federal guidance; protection of the unborn and not prevention of litigation is the objective of guidance. However, litigation could take into account all the relevant factors involved, including Federal guidance.

3.8.28 EPA should have adopted the legal opinion obtained by DOE and NRC that this problem should be treated through informed consent (E.a-5, E.a-6, E.a-7).

Response: These and other Federal agencies of our Interagency Working Group concurred with the formulation of the final recommendation.

3.8.29 Protection of future generations must be given precedence over equal job opportunity (A.a-2, A.b-20, B.a-42, D-3).

Response: Final guidance assures achievement of both objectives.

3.8.30 The mother should have the informed responsibility for protecting her unborn child from the risk of radiation exposure (A.a-6, A.a-14, A.a-46, A.b-1, A.d-5, A.d-23, B.a-3, E.a-7).

Response: We agree. Final guidance requires that workers (both male and female) be informed of current knowledge of risks to the unborn from radiation and of their responsibility to minimize exposure of the unborn. The final recommendation recognizes the responsibility of women to declare their pregnancies.

3.8.31 EPA should adopt the standard necessary to protect the future children of workers of either sex. It should express the same level of concern for the health and employment rights of both men and women (A.c-1, A.c-2, A.c-8, A.c-10, B.a-53, C-4, D-5).

Response: We believe the recommendations satisfy this objective. See the responses to comments 3.8.15 and 3.8.51.

3.8.32 Both male and female workers should receive instruction on the potential for genetic and somatic damage from radiation. Both males and females wishing to parent children should be allowed to remove themselves from exposure situations prior to conception and during pregnancy with provisions to retain seniority, payrate, and other benefits (A.c-1, A.c-2, A.c-6, A.c-10, A.d-20, C-4).

Response: Final guidance includes provisions for instruction for <u>all</u> workers. The proposal that both male and female workers wishing to parent children have the option to remove themselves prior to conception was not adopted because the risks are very significantly smaller than those to the unborn after conception. Protection of the unborn during a declared pregnancy is provided for. See the response to comment 3.8.31.

3.8.33 Exposure to the fetus should be restricted by ALARA procedures during any verified pregnancy with a limiting value of 0.5 rem during the entire pregnancy (A.a-16, B.a-7, B.a-34, B.a-48, C-8, E.a-2).

Response: The final recommendations contain these provisions.

3.8.34 EPA should establish a mandatory exposure limit to the fetus (A.b-13, A.d-37, B.a-33, B.a-46).

Response: The final recommendations provide for a limiting dose of 0.5 rem to the unborn.

3.8.35 An alternative approach would be to include the fetus, with appropriate weighting, in the list of critical organs (A.a-37, B.a-17, E.a-6).

Response: This approach would require establishing a weight greater than one (approximately 10) to achieve equivalent protection. This would be inconsistent with the logic under which weighting factors are developed, currently.

3.8.36 EPA should establish a mandatory exposure limit for females (B.a-27, B.a-38).

Response: This is neither needed nor desirable for either protection of the unborn or differential protection between males and females. While there are some differences in radiosensitivity between males and females, for radiation protection purposes the relevant differences do not warrant establishing separate sets of dose limits at this time. See also the responses to comments 2.13.6 and 3.3.6.9.

3.8.37 EPA should adopt the ICRP's recommendation of a dose limit of 1.5 rems during any known pregnancy (A.a-37, B.a-53, E:a-6).

Response: The comment does not accurately reflect the ICRP recommendation which assumes that, under normal practice, the use of working condition B will result in achievement of the recommended dose limit of 0.5 rem. The ICRP also recommends measures to assure a uniform rate of exposure.

3.8.38 There should be a mandatory limit of 0.5 rem during pregnancy, and a mandatory requirement for the employer to arrange the work situation so there is no penalty to the employee for carrying out the protection of the fetus (A.a-16, A.d-24, A.d-38, B.a-5, Ba.-11, B.a-42, E.b-8).

Response: These features are explicit in the final recommendation for protection of the unborn.

3.8.39 Any woman suspected or determined to be pregnant should be immediately removed from all radiation exposure for the balance of her pregnancy without loss of job security or economic penalty (A.a-43, A.c-4, A.c-6, C-5, C-6, C-8).

Response: We disagree in part with this comment. A woman who suspects or believes she is pregnant should have to voluntarily so declare to trigger appropriate protection of the unborn to less than 0.5 rem. Otherwise, abuse of women's employment security could occur on the basis of false concern for liability by an employer. Removal of the woman from all further radiation exposure may or may not be appropriate, depending on the level of exposure, and the availability of alternative work assignments. In any case, the exposure should be ALARA and assure the limit for the unborn.

3.8.40 EPA should adopt the State of Michigan's approach to the protection of the unborn (B.c-5).

Response: Although designed to achieve equivalent levels of protection, the final recommendations differ from the State of Michigan formulation (MDPH75). Final recommendations limit the unborn of a woman declaring pregnancy to a maximum dose of 0.5 rem whereas the State of Michigan approach limits the mother to a maximum dose of 0.5 rem after the mother has given written notice of her pregnant condition. In addition, Federal guidance requires efforts be made to avoid substantial variations above the uniform monthly exposure rate that would satisfy the limiting value. This is an important feature for avoiding the entire 0.5 rem being received in the relatively short period of greatest sensitivity.

3.8.41 Protection of the unborn would be achieved if all workers under age 35 are restricted to 0.4 rem per month, and if employers are required to badge all such workers and report doses before they could reasonably be expected to accumulate another 0.2 rem (A.a-46).

Response: In our opinion the adoption of such a recommendation would be unduly and unnecessarily restrictive when applied to all workers.

3.8.42 A female worker should not receive more than 0.5 rem in a six month period, and once her pregnancy is known, she should be treated as a burned-out worker until the baby is born (C-7).

Response: Such extreme measures may not be necessary if the desired level of protection can be provided by other means.

3.8.43 The RPG for fertile women should be 0.625 rem per three month period (C-8).

Response: We disagree. There is no scientific or other need to so restrict fertile women in order to protect the unborn child, if adequate measures are taken to restrict doses once conception occurs. In addition, this recommendation does not provide an adequate level of protection following conception. See also the responses to comments 3.8.19 and 3.8.42.

3.8.44 Since changing from a high-exposure to a low-exposure job is often unfeasible for workers in hospitals and clinics, standards applying to both male and female workers of child-bearing age should be set (A.d-8).

Response: We believe that the final recommendations are practical, and provide the desired level of protection for the unborn without unnecessary dose limitations on all workers of parenting age.

3.8.45 The guidance should simply be: "Pregnant females are limited to 0.5 rem for the year of the pregnancy." (A.a-41).

Response: The recommendations achieve this level of protection, while also requiring that discrimination in employment be avoided.

3.8.46 If doses are limited to 0.3 rem per month for all workers, no additional reductions on exposure of fertile women are necessary, and the only additional requirement would be to educate such employees to report possible pregnancies to their supervisors (A.b-1).

Response: In our opinion such a limiting dose applied to all workers would be unnecessarily restrictive, and appropriate protection is afforded to the unborn by the final recommendation.

3.8.47 Exposure to the unborn should be limited to one-tenth of the RPGs for adult workers, with special consideration of ALARA practices for women (A.b-8).

Response: We believe that final guidance accomplishes the intent of this comment.

3.8.48 The use of sterile workers in high-dose jobs would reduce genetic exposures (A.a-5).

Response: Yes, but we believe that such a requirement is both discriminatory and unnecessary.

3.8.49 Women of child-bearing age should be excluded from high exposure jobs (B.a-31).

Response: We disagree. Such exclusion is discriminatory and unnecessary. Not all women of child-bearing age are pregnant all of the time. Instruction on radiation risks to the unborn to all workers and their employers, limitation of the unborn to 0.5 rem when their mother declares pregnancy, and application of ALARA will provide adequate protection of the unborn.

3.8.50 The proposed NRC amendments to 10 CFR Parts 19 and 20 dealing with the unborn should be adopted in place of EPA's proposed guidance (B.c-12).

Response: The draft NRC amendments which were based on informed consent, would not provide assurance of protection of the unborn, and would subject women to potential economic penalty.

3.8.51 EPA has considered risks of teratogenic effects to liveborn, but has underestimated, particularly from exposure of males, the risks of genetic effects, including those that do not result in liveborn. This leads to inadequate protection of the unborn and to sex discrimination (A.a-5, A.c-1, A.c-2, A.c-10, A.d-20).

Response: Doses to the unborn give rise to teratogenic effects and occur as a consequence of exposure of the expectant mother, while doses to the gonads of male or female workers give rise to genetic (hereditary) risks, which affect the children of such workers.

Two issues need to be examined: first, the relative risks from irradiation of male vs. female prospective parents; and second, the size of these hereditary risks compared to the risks from direct irradiation of the fetus.

The 1980 National Academy of Sciences BEIR-III report (NAS80, pages 85 and 127) indicates that the risk to a child is between 4×10^{-6} and 61×10^{-6} per rad to the male gamete and because of lower sensitivity of the oocyte between 1×10^{-6} and 14×10^{-6} per rad to the female gamete [these values are somewhat smaller than those cited in our Background Report (EPA81), which was based on the earlier BEIR-I report (NAS72)]. Recently, our Science Advisory Board's Subcommittee on Radionuclides informed us that they believe recent studies by Dobson, et. al. (Doa83, Dob84), indicate that the BEIR-III Committee's assumption that oocytes are about 5 times less prone to genetic damage than spermatogonium may not be valid. The Subcommittee advised the Agency to use hereditary risk estimates that assume equal male and female sensitivity, i.e., hereditary risks per child of between 4×10^{-6} and 61×10^{-6} per rad to the gamete of either parent (EPA84c). Our staff believes that the Subcommittee may be correct, but, since the question is as yet unsettled, consideration of both ranges for females is appropriate in estimating hereditary risk.

It should be noted that these estimates of hereditary risks are based on animal studies. Excess genetic effects have not been substantiated in studies of the children of A-bomb survivors or in other studies of human populations; at most, the data are suggestive. And, although peer-reviewed quantitative estimates of the risk of severe mental retardation are, as yet, based on a single study (Ot84), the observed excess of this effect in humans as a result of fetal exposure is clear-cut. The

risk of severe mental retardation is 4×10^{-3} per rad or 2-3 orders of magnitude greater than genetic risk on a unit dose basis.

In comparing the risks from *in utero* exposure to hereditary risks, it should be noted that the relative importance of each depends on the duration and pattern of exposure. Most of the *in utero* risk seems to result from exposure during a very short period, from 8 to 15 weeks after conception. Risk of genetic damage, on the other hand, accumulates throughout the period of exposure. Therefore, the relative importance of each depends on to what extent male or female workers have been exposed before their children are conceived. Nevertheless, the *in utero* risks are very high, and since the estimated hereditary risks cited above are two to three orders of magnitude less per rad of exposure, even an exceptionally long term or high level of exposure prior to conception should not elevate hereditary risks to a comparable level.

Commenters have cited the following publications, among others, in support of increased sensitivity of males to contribute to adverse outcomes of pregnancy and to pass genetic effects on to future generations: L.K. Wagner and L.A. Hayman (Waa82), J.A. Bonnell and G. Harte (Boc78), J.F. Crow (Cr55), S.H. Macht and P.S. Lawrence (Ma55), and J. Boue, A. Boue and P. Lazar (Bod76). The Bonnell/Harte paper and the Wagner/Hayman paper discuss points of radiation protection philosophy and do not present data or discuss the question of maternal versus paternal contributions to genetic effects.

The paper by Crow addresses only the absence of a difference in fetal and infant death rates in progeny of male radiologists vis-a-vis male pathologists. However, the number of subjects was small, no exposure data is available and there is no comparison group of female radiologists. The Macht/Lawrence paper also addresses only small numbers of male radiologists with unknown exposures and concludes there is increased probability of congenital defects associated with radiation exposure. These papers shed no light on the question of differences of such effects in maternal versus paternal exposure to radiation.

The Boue *et al.*, paper concludes that in a comparison of cases of maternal and paternal exposure [of unknown magnitude] there is a significant increase in chromosome anomalies in cells obtained from spontaneous abortion tissues when the father was exposed to radiation in the occupational setting. However, the increase is all in the incidence of triploidy and tetraploidy. It has been estimated that 21% of cases of triploidy are due to maternal nondisjunction, 49% are due to dispermy and 30% due to dispermy or paternal nondisjunction with dispermy being more probable; while tetraploidy is due to failure of a cleavage division in the zygote (Jab80). Only nondisjunction is reported to be radiation related. Dispermy (fertilization of an egg by two sperm) is not considered a genetic effect but a problem of fertilization. Cleavage failure in the zygote is also not a genetic effect related to radiation exposure of the parental gametes. Therefore, the differences observed by Boue *et al.* appear unlikely to be related to differences in maternal versus paternal exposure.

Consequently, we conclude that for reproductive effects, for comparable exposures, the risk from irradiation of the unborn is substantially greater than the risk from irradiation of either parent or both prior to conception. Thus, control of dose to the unborn is the primary consideration for minimizing such effects, not control of dose to parents. We believe that the recommendations for worker exposure, designed primarily to protect against cancer in workers, are also sufficiently protective of genetic risks. It is perhaps worthy of note that although the risk of cancer fatalities is somewhat larger for female than for male workers because of the greater radiation sensitivity of breast tissue, the recommendations call for the same limit for protection of male and female workers. In part, this is due to our desire to avoid discrimination in employment. See also the responses to comment 2.13.6 and 3.3.6.9.

3.8.52 EPA has underestimated the effect of radiation on the unborn (A.c-4, A.c-6, D-3).

Response: We do not believe that we have underestimated these effects, on the basis of the most current available scientific information. See the responses to comments 3.8.15. and 3.8.51.

3.8.53 EPA should place the risk of radiation exposure to the unborn in perspective by comparing it with other risks taken during pregnancy. Limiting exposure of the mother once the pregnancy is known is the most reasonable approach (B.a-16).

Response: We do not agree that other types of risks during pregnancy are relevant to limitation of risks due to radiation. However, we agree that limitation of dose to the unborn only after pregnancy is known is the most reasonable approach.

3.8.54 EPA has not presented adequate information on the number of women of child-bearing age in the work-force, the possibility of their becoming pregnant, and the doses they now receive. Thus, the size of the problem is unknown (A.d-22).

Response: Contrary to the comment, EPA cited in the proposed guidance, as part of previous actions noted, its analyses of the estimated mean annual dose equivalent and collective dose equivalent to workers in the United States in 1975 by occupation, age and sex (Cob80). These same analyses were updated recently for 1980 (Ku84). The latter study shows collective dose equivalents of 29,438 and 29,913 person-rems to 436,231 and 568,121 women from age 18 to 49 corresponding to average mean dose equivalents of 67 and 53 mrem in 1975 and 1980, respectively.

3.8.55 EPA has ignored the fact that 0.5 rem refers to fetal, not maternal dose equivalent. Thus none of the alternatives are reasonable (A.d-12, A.d-15).

Response: The proposed alternatives were explicit regarding the distinction between dose to the whole body of the woman and dose to the unborn. The limiting dose of 0.5 rem in final recommendations refers to unborn.

3.8.56 EPA should resolve the scientific uncertainty regarding the risk of radiation exposure to the unborn. If restrictions are scientifically warranted, they must be made mandatory (B.a-24).

Response: There is admittedly scientific uncertainty in this matter. However, EPA cannot resolve scientific uncertainty in the absence of new information. Current knowledge and recommendations of radiation protection organizations, however, lead us to conclude that it is necessary to include radiation protection provisions for the unborn. Those provisions are under continuing review by EPA. Should new information warrant making future changes, we will do so promptly.

3.8.57 EPA should make it abundantly clear to the public that intrauterine exposures within the 0.5 rem per pregnancy limit are safe (B.a-42).

Response: Although the risks are believed to be acceptably small for doses to the unborn within a 0.5 rem limit, no one can state that such exposures are "safe" (i.e., zero) for that limiting dose, or for any of the limiting doses in Federal guidance. We assume that there is no completely risk-free level of radiation exposure. See also the responses to comments 1.6.11, 2.1.11, 2.2.11, 3.1.15, and 3.4.3.10.

3.8.58 None of the four alternative recommendations should be included in the guidance; such implementing choices should be left to the regulatory agencies (E.a-4).

Response: We disagree. The alternatives involve basic differences in radiation protection policy that it is the function of Federal guidance to resolve. However, specific implementation is left to the regulatory agencies, within the numerical limitation and objectives specified.

3.8.59 The proposed recommendations do not adequately provide for employee education so that workers can make informed decisions about their employment and radiation exposure. In particular, female workers should be fully informed of the risks to the unborn from radiation exposure (A.a-14, A.a-16, A.b-8, A.b-15, A,c-1, A.d-20, A.d-21, B.a-5, C-7, C-8, E.a-2)

Response: We disagree. Proposed and final recommendations make it clear that workers should be informed of the levels of risk from radiation in relation to protection of the unborn.

3.8.60 EPA should be aware that informing workers of the risks associated with radiation exposure of the unborn increases their apprehensions (A.d-36).

Response: To the contrary, we believe that proper instruction on the risks and on these recommendations for protecton of the unborn will dispel unwarranted apprehensions.

3.8.61 If workers quit their jobs because of the risk of continuing exposure, do worker's compensation and unemployment benefits apply (A.d-8)?

Response: These matters are not within the scope of Federal radiation protection guidance for occupational exposure.

3.8.62 Worker's compensation benefits should cover genetic damage of offspring, miscarriages, and early retirement due to chronic illness for any worker receiving more than 0.5 rem/yr (A.c-6).

Response: The applicability of worker's compensation benefits to these situations are outside the scope of Federal guidance.

3.8.63 Radiation workers should be monitored by independent researchers for miscarriage, genetic defects, and heart disease, and the observed effects assigned a probability of being job related (A.c-6).

Response: Such studies have been made and are ongoing. The results of such studies have been considered in this rulemaking and will be considered in future rulemakings. However, such monitoring is outside the scope of the subject Federal guidance.

3.9 EXCEEDING THE RPGs

3.9.1 We have no objection to Recommendation 9 (A.a-10, A.a-39, A.b-5, A.b-6, B.a-5, B.a-9, B.a-26).

Response: No comment necessary. [Note: Recommendation 10 in the final recommendations corresponds to proposed Recommendation 9.]

3.9.2 Since the proposed RPGs set limits substantially below the level of observable effects, Recommendation 9 is a good one (A.d-11, A.d-14, A.d-29, A.d-40).

Response: No response required.

3.9.3 EPA should adopt ICRP's guidance (ICRP-26, Paragraph 113) for exposures exceeding the limits of the RPGs (A.a-13, A.d-18, B.a-6, B.a-10, B.a-14, B.a-20, B.a-24, B.a-27, B.a-29, B.a-31, B.a-32, B.a-33, B.a-36, B.a-38, B.a-46, B.a-48, B.a-53).

Response: Final guidance does not adopt the dose limits in ICRP-26 (Paragraph 113) for "planned special exposures." This matter is left up to the Federal agencies because they have the detailed information required to make judgments on these matters, and we do not believe that generic provisions for such situations are appropriate.

3.9.4 Recommendation 9 should be deleted. Allowing "planned special exposures" will only allow the guidelines for worker protection to be ignored (A.a-5, A.c-4, A.d-8, C-1, C-6, E.b-3).

Response: We disagree. Proposed recommendation 9 is effectively the same as recommendation 7 of current guidance (25 F.R. 4402) which states: "The Guides may be exceeded only after the Federal agency having jurisdiction has carefully considered the reason for doing so in light of the recommendations in this paper." To our knowledge, that recommendation has not been abused. To date, we know of no use of this provision by the Federal agencies, other than the special guides established by NASA for the protection of astronauts from cosmic radiation exposures received on flight missions (NAS70). The basic guides are applicable to normal operations. It is appropriate to recognize that unusual circumstances can and do arise.

3.9.5 The restrictive wording of Recommendation 9 would deny management the flexibility needed to deal with unforeseeable circumstances (A.d-18, B.a-3, B.a-29, B.c-20).

Response: We disagree. Recommendation 9 may have been mistakenly thought applicable to emergency exposures, contrary to Note 5. This provision is clarified in the final recommendations (Recommendation 10) and we believe its scope and intent is amply clear to the regulatory Federal agencies to which the guidance is directed. Management at the user level will be guided by corresponding regulations and regulatory guides of the Federal agencies.

3.9.6 Allowing each regulatory authority to decide if, and by how much, the 5 rem/yr limit may be exceeded will lead to confusion and inconsistency (D-6).

Response: We very much doubt that such will occur because it has not occurred in the past under similar Federal guidance. See the responses to comments 3.9.3, 3.9.4, and 3.9.5.

3.9.7 The requirement for prior regulatory approval could result in administrative burdens and costly delays (B.a-3, B.a-6, B.a-32, B.a-37, B.a-48).

Response: The only previous approval for exceeding numerical limitations was given by NASA (NAS70) and administrative burdens and costly delays were not an issue. See also the response to comment 3.9.4.

3.9.8 The requirement for prior regulatory approval could jeopardize safety (A.d-18, B.a-6, B.a-29, B.a-36, B.c-20, E.a-6).

Response: We disagree. Short of emergencies that are excepted by this recommendation, there is no reason for prior approval to jeopardize safety.

3.9.9 EPA should provide criteria and standards for justifying planned special exposures (B.a-33, B.a-38).

Response: The regulatory Federal agencies have the best understanding of actual needs in activities under their jurisdiction. Hence, for unusual circumstances, they are better able to establish appropriate regulatory requirements for radiation protection.

3.9.10 Unless the intent is to gut the RPG limits, exceptional circumstances and maximum acceptable upper limits must be better defined (E.b-3).

Response: Past radiation practice provides no evidence for such an apprehension. See the responses to comments 3.9.4 and 3.9.9.

3.9.11 The requirement for mandated Federal review should be dropped (A.d-23, B.a-8, B.a-12, B.a-14, B.a-27, B.a-31, B.c-12, B.c-22, D-2).

Response: We believe that review and authorization by Federal agencies to exceed numerical limitations, except during emergencies, is a responsible requirement that assures due consideration of unusual circumstances. See the responses to comments 3.9.4, 3.9.7, 3.9.8, and 3.9.9.

3.9.12 The rationale for public disclosure is unclear. It will not help protect workers. It should be deleted (A.a-41, A.d-40, B.a-8, B.a-16, B.a-22, E.a-5).

Response: Public disclosure will provide public notice that an authorized use of final recommendation 10 was carefully considered to assure that workers are responsibly protected.

3.9.13 The burden for public disclosure must rest with the employer, not the licensing agent (A.d-6).

Response: An employer may also provide public disclosure, but Federal agencies acting on behalf of the public should make such authorizations a matter of public record. See the responses to comments 3.9.4 and 3.9.12.

3.9.14 EPA should state that Recommendation 9 does not apply in emergency/lifesaving situations (E.a-5).

Response: This was the intent of Note 4 of the proposed recommendations. However, Recommendation 10 (replaces proposed Recommendation 9) of the final recommendations explicitly exempts "emergencies," which would include lifesaving situations.

3.9.15 Recommendation 9 should be rewritten to include emergency situations (B.a-48, B.a-27, B.c-22).

Response: We disagree. Emergency situations are unpredictable and cannot by their nature be regulated. However, the handling of emergency exposures should involve the general principles of this guidance. See the response to comment 3.9.14.

3.9.16 The workers receiving the higher dose must be fully informed and voluntarily accept the risk prior to the exposure (A.d-29, B.a-33, C-1, E.a-4, E.a-6).

Response: Final recommendations require that occupationally exposed individuals be instructed on the basic risks to health from ionizing radiation. The degree and type of instruction that is appropriate will depend on the potential radiation exposures involved for their work situations, including those of an emergency nature where the worker knowingly and voluntarily accepts the risk.

3.9.17 The guidance to licensees should include: (1) Demonstration that exceeding the indivfdual limits results in the lowest practicable level of total person-rems for the activity; (2) the affected workers have had the potential risks explained, and that they are understood; and (3) the workers voluntarily accept the risk (B.a-33).

Response: The details of instructions to licensees are the responsibility of regulatory agencies which implement the Federal guidance. However, the response to comment 3.9.16 applies to the last two points of this comment. We cannot comment on how the regulatory agencies might implement the first point. In emergency situations, it would appear generally true that the fewer the number of emergency-workers the lower the collective dose to achieve the specified goal. This would be the case where there is high "unproductive" dose received during the periods of entry, tooling-up, and exit. However, very large individual doses would not necessarily be acceptable just to reduce collective dose. See also the response to comment 2.7.4.

3.9.18 If the old guidelines (3 rems per quarter, 12 rems per year) were retained, there would be no need for higher exposures (B.a-11).

Response: We disagree that retention of the previous guides would obviate the need for proposed recommendation 9, which is effectively the same as recommendation 7 of current guidance (25 F.R. 4402). Radiation exposure in other-than-normal situations (including emergencies) would likely take place during periods of less than one-quarter year. Thus, it is not clear how either the current guide of 3 rems per quarter or, for that matter, the final guide of 5 rems per year eliminate the need to provide for unusual circumstances.

3.9.19 If the prior approval requirement is retained, it must allow approval on a generic basis (E.a-6).

Response: Final recommendations require Federal agencies to make public any generic procedures that specify conditions under which such exposures may occur.

3.9.20 The need for exposures exceeding the limits should be judged by the practicing health physicist, not the EPA (A.a-41).

Response: EPA is not a regulatory agency of occupational radiation exposure. Regulatory Federal agencies provide the generic criteria and procedures governing these situations.

3.9.21 Proposed recommendation 9 should only be allowed if no individual is subjected to lifetime doses in excess of the cumulative RPG established in the guidance (E.a-4).

Response: The lifetime accumulated dose of 100 rems in proposed recommendation 4 does not appear in final recommendations. However, lifetime accumulated dose should be one factor, among others, in considering workers for tasks requiring established limits to be exceeded. See also the response to comment 3.9.16.

3.9.22 It may be necessary to justify a higher limit for an entire class of workers (D-2).

Response: We are aware of only one class of workers (astronauts) for which such justification was previously established. However, such justification by the regulatory agency having jurisdiction is provided for in the previous, proposed and final recommendations.

3.9.23 Add the following to the section on "other considerations": "For astronaut exposures in space, NASA will be the controlling Federal agency" (E.a-1).

Response: We believe it is obvious that NASA is the Federal agency having that responsibility. In addition, we know of no group of occupationally exposed workers for which there is not a controlling regulatory authority.

3.9.24 EPA should emphasize that ALARA is expected to be applied in emergency situations, and that regulatory agencies will consider to what extent ALARA was applied in assessing what actions to take if the RPGs are exceeded (A.a-8).

Response: We agree that ALARA should be applied in all situations, including emergencies. However, emergencies are exempted from proposed recommendation 9 and final recommendation 10. Regarding unusual circumstances, the wording of final recommendation 10 explicitly requires careful consideration of the reasons for exceeding the numerical limits by the Federal agency having jurisdiction.

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