April 10, 1981

SECY-81-232

POLICY ISSUE
(Notation Vote)

For: The Commissioners

From: William J. Dircks, Executive Director for Operations

Subject: COMMENTS ON THE EPA PROPOSED FEDERAL RADIATION PROTECTION GUIDANCE FOR OCCUPATIONAL EXPOSURES

Category: This paper addresses a major policy matter.

Purpose:

1. To obtain Commission approval of comments to EPA concerning the proposed EPA guidance.

2. To inform the Commission regarding the views (majority and minority) of the staff concerning the proposed EPA radiation protection guidance for occupational exposure.

3. To provide the Commission with current staff recommendations on the Commission's interim position regarding limits for internal radiation exposure in the workplace.

Background:

1. By memorandum, S. J. Chilk to L. V. Gossick dated May 7, 1979, the Commission requested to be informed of the staff's input to the development of the EPA's proposed radiation protection guidance so that there would be adequate opportunity for the Commission to forward its views.

2. In SECY-79-[illegible], dated September 18, 1979, the Commission was informed of the development of the proposed EPA guidance on occupational radiation protection and of the position taken by participating staff members regarding dose limits for internal organs. Commission views were requested.

3. By memo from S. J. Chilk to L. V. Gossick dated October 30, 1979, the EDO was advised that the Commissioners concurred with the staff's recommendation, as an interim position, "to retain current NRC limits for internal radiation exposure in the work place."

Contact:
J. Guibert
443-5855

Discussion:

The proposed EPA guidance was published on January 23, 1981 (46 FR 7836) for public comment (Enclosure I). It reflects endorsement of the Commission's interim position noted above. A copy of the Background Document published by EPA in support of its proposed recommendations is provided as Enclosure VI.

Technical staff members from all major NRC offices have completed their reviews of the EPA proposal. Because the EPA guidance has a direct and substantial impact on NRC regulations, the ad-hoc technical staff group working on the comprehensive revision of 10 CFR Part 20 has also completed a review of the EPA proposal. Enclosure II is the proposed Commission response to EPA as requested by EPA in 46 FR 7836. EPA requested comments by April 24, 1981.

The comments to EPA (Enclosure II) identify areas of substantial disagreement between the proposed EPA guidance and the current staff views. The rationale and technical reasons for the disagreements are included in the comments. A more complete discussion is provided in Enclosure III which also addresses the current staff view regarding the Commission's interim position on limits for internal radiation exposure in the workplace. Among the features considered by the staff to require change are those tentatively endorsed by the Commission in its interim position concerning internal radiation exposures in the workplace (Item 3 of "Background".) In addition to comments provided to EPA staff by NRC staff who participated in the development of the EPA proposed guidance, the staff has recently advised EPA staff informally of its current views on the principal areas of disagreement on the proposed guidance, but has indicated that the Commission has not yet reviewed the staff's proposed positions and comments.

The EPA proposed guidance includes many of the concepts embodied in the ICRP recommendations published in 1977. However, the proposed guidance includes a number of departures from the ICRP system of dose limitation which, in the NRC staff's view, would significantly impair its usefulness. Since publication of the ICRP recommendations, additional information regarding the bases for these recommendations has become available. Open discussions of those bases have led to a more complete understanding of the ICRP system which, in turn, has resulted in a more complete endorsement of the ICRP system by the international radiation protection community and the NRC staff. As discussed in Enclosure III, the NRC staff believes that the ICRP system is based upon the best scientific information and methodology currently available and that the ICRP's general approach is consistent with the Commission's policies regarding (1) the appropriate application of risk-based methodology in regulatory decision making and standards setting and (2) the necessity of vigorously applying the ALARA concept in radiation protection activies.

The introduction of quantitative risk estimates into the system of dose limitation and the abandonment of the critical organ concept

in favor of the whole body dose equivalent concept are major steps toward a risk based system of radiation protection. Such a system will allow quantitative evaluation of risks incurred by workers under different conditions of exposure and will facilitate comparisons of risks encountered in various industries. Movement toward such a system is a necessary step in the implementation of the Commission's policy regarding the appropriate applications of risk assessment methodology.

NRC staff recommends adoption of the ICRP system of dose limitation as the principal basis for the revised 10 CFR Part 20. However, complying with the guidance proposed by EPA* would require NRC implementation of a system which differs substantially from the ICRP system.

In light of the NRC staff's current understanding of the ICRP system of dose limitation and the consideration of the pros and cons of alternatives and modifications to the system, including those proposed by EPA, staff proposes that the Commission reconsider the interim position adopted in October 1979 and endorse the position reflected in Enclosure II.

Staff endorsement of the "system of dose limitation" recommended by the ICRP recognizes that the system:

(1) is based on a contemporary radiation protection philosophy that would require (a) justifying why persons are to be exposed to radiation (b) ensuring that any exposures are as low as reasonably achievable, and (c) using appropriate dose limits,**

(2) is based on an "acceptable risk" rationale that is derived from the statistics of job-related risks to workers in the "safer" industries, excluding nuclear,

(3) provides a method (a) to combine doses to multiple organs, doses from multiple radionuclides, and doses from internal and external exposures and (b) to express these doses in terms of a whole-body effective dose equivalent on the basis of risk considerations, which may be compared to the dose limits,

(4) incorporates the state-of-the-art knowledge of biological, physical, and dosimetric information in deriving "annual limits of intake" (ALIs) and "derived air concentrations" (DACs), and,

*As a matter of policy and past practice, the NRC, like its predecessor agency, the AEC, has considered the guidance issued by the President as binding upon it although such guidance is not, in the opinion of OELD, binding on NRC as a matter of law.
**See Attachment A to Enclosure III.

(5) provides appropriate dose limits for normal working conditions which are generally more restrictive than previous limits, but provides flexibility for exceptional operational difficulties when it is in the public interest to exceed the primary limits.

Many of the quantities (such as ALIs and DACs) needed to implement a radiation protection program have been provided by the ICRP and the remainder are being calculated at the present time. The new calculational models are so complex that sophisticated computers are required for the calculations.

Owing to the complexities of the calculations and the interdependence of the features of the ICRP system of dose limitation, it is not possible to arbitrarily change some selected parts of the system without destroying the continuity and coherence of the whole which would be the effect of the proposed EPA guidance. If the proposed EPA guidance is promulgated in its present form, all of the calculations and tables provided by the ICRP must be replaced, and implementation by U.S. agencies would be made extremely difficult. In addition, communication with scientists of other countries, could be extremely difficult because the U.S. would have different definitions for the same concepts. The ICRP system has been adopted, or is in the process of being adopted, by the IAEA, the Commission of European Communities, the OECD Nuclear Energy Agency, and most countries with radiation programs. The selection of a specific system of dose limitation has a direct impact on international agreements, cooperative efforts, and guidelines related to radiation doses to workers and members of the public.

The proposed comments to EPA represent the consensus of the majority of the NRC staff. Minority views do exist, however. The minority views and their supporting arguments are presented in Enclosures IV and V.

The minority view expressed in Enclosure IV is that the EPA's proposal for a lifetime dose limit is too stringent and the staff's majority view based on worker informed consent is too lax. The view is expressed that an informed consent procedure should be used including mandatory notifications to workers when their lifetime theoretical risk reaches a pre-set value. It is further proposed that the interim position (Item 3 of "Background") be retained. The minority view expressed in Enclosure V is that the NRC should oppose implementation of either the EPA proposed guidance or the ICRP recommendations without a full evaluation of the potential costs and the potential benefits.

Attachment A to Enclosure III is a brief summary of some of the principal features of the ICRP system of dose limitation. This

attachment explains some of the complex issues that are discussed in Enclosure III. Attachment B to Enclosure III is an article from Nuclear Safety that discusses the recommendations of the ICRP as presented in ICRP Publication 26, including the system of dose limitation.

Recommendation: That the Commission:

(1) Approve and transmit the written comments on the proposed EPA guidance set out in Enclosure II;

(2) Support the implementation of the system of dose limitation recommended in ICRP Publication 26, and

(3) Note that the 10 CFR Part 20 Revision Drafting Group will use the proposed EPA guidance, as modified by the Commission's comments, as a principal input in drafting a proposed rule change to 10 CFR Part 20.

William J. Dircks
Executive Director for Operations

Enclosures:
"I" - Federal Register Notice on EPA Proposed Radiation Protection Guidance for Occupational Exposures (46 FR 7836)
"II" - Draft letter to EPA forwarding NRC Comments
"III"- Supplementary Information in Support of Proposed NRC Comments to EPA
"IV" - First Minority Opinion
"V" - Second Minority Opinion
* "VI" - Background Report--Proposed Federal Radiation Protection Guidance for Occupational Exposure" (EPA 520/4-81-003)

* (on file in Office of SECY - copies previously provided to the Commissioners)

Commissioners' comments should be provided directly to the Office of the Secretary by c.o.b. Monday, April 27, 1981.

Commission Staff Office comments, if any, should be submitted to the Commissioners NLT April 13, 1981, with an information copy to the Office of the Secretary. If the paper is of such a nature that it requires additional time for analytical review and comment, the Commissioners and the Secretariat should be apprised of when comments may be expected.

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ENCLOSURE I

Federal Register

Friday
January 23, 1981

Part XV

Environmental Protection Agency

Federal Radiation Protection Guidance for Occupational Exposures

[RH-FRL 1722-6]

Federal Radiation Protection Guidance for Occupational Exposures; Proposed Recommendations, Request for Written Comments, and Public Hearings

AGENCY: U.S. Environmental Protection Agency.

ACTION: Proposed recommendations for radiation protection of workers.

SUMMARY: We are proposing to make recommendations to the President for new guidance to Federal agencies for the protection of workers exposed to ionizing radiation. These proposals are based on a review of existing guidance in the light of scientific knowledge of radiation risks and of experience in the control of occupational exposure. The proposed recommendations include both qualitative guidance on radiation protection and numerical guides for maximum allowed dose equivalents (RPG's[1]). The most significant changes proposed are (a) that a graded set of minimum radiation protection requirements be introduced in three levels; (b) that the RPG for maximum whole-body dose equivalent be reduced from three rem [2] per quarter to five rem per year, and that regulatory agencies establish lower limits for specific types of work situations; (c) that limitation of internal doses [3] take into account the sum of the risks to all organs, rather than continue to be based only on the most significantly exposed organ; (d) that the RPGs for the whole body apply to the appropriately weighted sum of the doses from both internal and external exposures; and (e) that the dose to the embryo and the fetus be limited through one of several alternative recommendations.

We welcome written comments on these proposals and will hold public hearings as discussed below. We will carefully consider all oral and written comments in preparing our final recommendations to the President.

DATES: 1. All written comments in response to this notice must be received by us by April 24, 1981, in order to be used.

2. Public hearings will be held at the following locations, beginning no earlier than 60 days following publication of this notice: Washington, D.C., Chicago, Illinois, San Francisco, California, Houston, Texas. We will publish the times and addresses for these hearings shortly.

3. Instructions of interest to those who wish to appear at the public hearings are given below under the heading "Public Hearings."

ADDITIONAL INFORMATION: We will be happy to send a copy of a background report which provides additional information on these proposed recommendations to anyone requesting it. Please send requests to Mr. Luis F. Garcia at the address below. This report is also available for inspection and copying at EPA's Central Docket Section and ten Regional Offices (addresses below).

ADDRESSES: Written comments should be addressed to the Director, Criteria and Standards Division (ANR-460), U.S. Environmental Protection Agency, Washington, D.C. 20460. Attention: Docket No. A-79-48. These comments and the public hearing record will be filed under the above docket number and will be available for inspection and copying at the U.S. Environmental Protection Agency's Central Docket Section, Room 2903B, Mail 401 M Street, S.W., Washington, D.C. 20460, and at the Agency's library in each of its ten regional offices: *Region I:* JFK Building, Room 2100-B; Boston, Massachusetts 02203 (Tel. 617-223-5791); *Region II:* 26 Federal Plaza, Room 1002, New York, New York 10278 (Tel. 212-264-2881); *Region III:* Curtis Building, 6th & Walnut Streets, Philadelphia, Pennsylvania 19106 (Tel. 215-597-0580); *Region IV:* 345 Courtland Street, N.E., Atlanta, Georgia 30365 (Tel. 404-881-4216); *Region V:* 230 South Dearborn Street, Room 1417, Chicago, Illinois 60604 (Tel. 312-353-2022); *Region VI:* First International Building, 1201 Elm Street, 28th Floor, Dallas, Texas 75270 (Tel. 214-767-7241); *Region VII:* 324 East 11th Street, Kansas City, Missouri 64106 (Tel. 816-374-3497); *Region VIII:* Radiation Program Office (in lieu of library), 1860 Lincoln Street, Second Floor, Denver, Colorado 80203 (Tel. 303-837-2221); *Region IX:* 215 Fremont Street, 6th Floor, San Francisco, California 94105 (Tel. 415-556-1841); *Region X:* 1200 Sixth Avenue, 12th Floor, Seattle, Washington 98101 (Tel. 206-442-1289).

FOR FURTHER INFORMATION CONTACT: Contact Mr. Luis F. Garcia, U.S. Environmental Protection Agency (ANR-460), Washington, D.C. 20460 (Telephone 703-557-8224), about these proposed recommendations or the public hearings.

SUPPLEMENTARY INFORMATION:

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 88-373 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 taken the form of qualitative and quantitative "Radiation Protection Guidance." 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).

Previous Actions by EPA

We began this review of the 1960 radiation protection guidance for workers in 1974. The most recent notice of this activity listed the principal issues being addressed and announced our intent to hold public hearings on proposed recommendations (44 FR 53785, Sept. 17, 1979).

We have sponsored two major studies in support of this program. First, the Committee on the Biological Effects of Ionizing Radiations, National Academy of Sciences—National Research Council, has reviewed the scientific data on the health risks of low level ionizing radiation developed since its 1972 report. Second, we have carried out a study of occupational radiation exposures and published our findings in a report entitled: "Occupational Exposure to Ionizing Radiation in the United States: A Comprehensive Summary for the Year 1975." We have also considered recent recommendations of the National Council on Radiation Protection and Measurements.

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. These agencies are the Occupational Safety and Health Administration, the Nuclear Regulatory Commission, the Mine Safety and Health Administration, the Department of Defense, the Department of Energy, the Department of Transportation, the Food and Drug Administration, the National Aeronautics and Space Administration, the National Institute for Occupational Safety and Health, and

[1] Radiation Protection Guides.

[2] A *rad* is a unit of measure for dose, i.e., the amount of ionizing radiation energy absorbed per unit weight of tissue. Thus, the same energy absorbed by twice as much tissue gives only one-half the number of rads. The rem, a unit for dose equivalent, is a rad multiplied by factors which describe how damaging the type of radiation is.

[3] In this notice we henceforth use "dose" to mean "dose equivalent."

the National Bureau of Standards. These agencies, which have not formally endorsed these recommendations, will formally review final proposals when they are developed following public review.

Issues Addressed

The principal issues we addressed in formulating these recommendations were identified in the advance notice cited above. They were:

1. Are the doses currently received by workers and the maximum doses permitted under existing guidance adequately low? In this regard, a) how adequate is the basis used for estimating risks to health from radiation exposure, and b) what are the appropriate bases for judging maximum individual and collective radiation doses in the work force and the tradeoffs between these two indices of the health impact of occupational exposure?

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

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

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

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

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

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

Additional issues suggested since publication of the advance notice include:

8. Should the guidance include numerical values for the factors (called "quality" and "modifying" factors) used to convert dose (measured in rads) to dose equivalent (measured in rem)? If so, should this be developed now or issued later as supplementary guidance?

9. What guidance should apply to workers who do not use radiation sources, but who are exposed to radiation due to the activities of workers under the control of other employers?

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

Many of these issues are addressed below. However, for a more complete and extensive discussion please refer to the background report cited above under the heading "Additional Information."

Risks From Occupational Exposure

There are three kinds of risks from the low levels of ionizing radiation characteristic of occupational exposures. The most important of these is cancer, which is fatal at least half the time. Another risk is the induction of hereditary effects in descendants of exposed persons. The severity of these effects ranges from fatal to inconsequential. We assume that at low levels of exposure the risk of cancer and hereditary effects is in proportion to the dose received, and that the severity of any induced effect is independent of the dose level. That is, while the probability of a given type of cancer occurring increases with dose, such a cancer induced at one dose is equally as debilitating as that same type of cancer induced at another dose. Thus, for these effects we assume that there is no completely risk-free level of radiation exposure.

The third type of risk includes a variety of other effects on workers and on the children of women exposed during pregnancy. These effects range from serious effects on children, such as mental retardation, to less serious effects on workers, such as opacification of the lens of the eye and temporary impairment of fertility. For these effects we believe the degree of damage (i.e., the severity) depends to some extent on the dose level. At the dose levels allowed by current radiation protection guides, we believe that none of the effects on workers themselves occurs to a degree sufficient to be clinically detectable. At these levels, however, effects on children exposed in utero may be serious.

The risks of effects on health from low level ionizing radiation were reviewed for EPA by the National Academy of Sciences (NAS) in reports published in 1972 and in 1980. We have used these studies and others to estimate the risks associated with the current and proposed Federal guides for limiting radiation dose. Details of these and other risk estimates we use are provided in the accompanying background report.[1]

A worker who received the largest lifetime dose allowed under present guides (5 rem per year from age 18 to assumed retirement at age 65, or 235 rem) would have a lifetime risk of about 3 to 8 in 100 of dying from radiation-induced cancer, and numerically comparable chances both of nonfatal cancer and, for male workers, of mutational effects in his descendants.[2] Risks of mutational effects from exposure of female workers are assumed to be three to four times smaller. However, in our recent national survey of exposures for the year 1975, 99% of all workers received less than half of, and only 0.13% exceeded, an annual dose of 5 rem. Based on these and other data, we believe that only a few workers involved in accidents have received close to the current maximum allowed lifetime dose.

The average worker exposed to radiation sustains only a small risk of death from radiation. The estimated average risk of death due to radiation-induced cancer is smaller, for example, than the risk of job-related accidental death in the safest of all major occupational categories, retail trades, for which the annual death rate was 60 per million workers in 1975. We estimate that the collective dose to the more than one million workers potentially exposed to radiation in their workplace for that same year will not lead to more than 15–36 premature cancer deaths. Other ways of expressing this risk are that the exposure of an average worker to radiation in 1975 represented an average lifeshortening of about two to three and a half hours, or an average increase in his chance of cancer death of about one to three in 100,000. In 1975 about one sixth of United States deaths were from cancer.

The comparative time-loss associated with nonfatal cancer is also estimated to be very small. The average time lost by

[1] Our estimated ranges of risk for cancer death are based on absolute and relative linear risk models used by the 1972 BEIR Committee and the assumption that the risk of incurring most radiogenic cancers continues throughout the lifetime of exposed persons. The 1980 BEIR report, which was just published, gives estimates based on a variety of risk models, some of which yield lower and some higher values. Based on our preliminary review, we do not believe that the differences between these values and those we have adopted here would lead to any changes in these proposals.

[2] Mutational effects here mean those hereditary effects included by the BEIR Committee in their 1972 report as serious disabilities. Examples are congenital malformations leading to premature death, hemophilia, sickle cell anemia, cystic fibrosis, diabetes, schizophrenia, and epilepsy.

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U.S. workers due to all occupationally-related injuries and illnesses over a working lifetime is one month. For radiation-induced nonfatal cancers it is estimated to be about four days for a hypothetical individual receiving the largest lifetime dose allowed (235 rem), and for the average worker it is about two hours.

Limitation of Whole Body (External) Exposure

Based on these observations, risks due to occupational exposure to radiation do not appear to be unreasonably high for the average worker. They are comparable to risks of accidental death in the least hazardous occupations. However, a worker exposed to the current maximum allowed dose year after year would sustain substantial risks. The proposed radiation protection guidance contains provisions to avoid the accumulation of large lifetime doses through reduction of the maximum allowed annual dose and through specific minimum radiation protection requirements for workers in high-dose work situations. These include on-the-job radiation protection supervision for high-dose jobs, maintenance of lifetime dose records, and an admonition that exposure of workers should be managed so that their lifetime doses do not exceed 100 rem.

Existing Federal guidance permits doses up to 3 rem per quarter (or 12 rem per year), within an overall cumulative limit of 5(N-18) rem, where N is the age of the worker. This flexibility, which allows annual doses greater than 5 rem, does not permit specific tasks that require doses to individuals of more than 5 rem (since the 3 rem per quarter limit prohibits this), but it does permit the same worker to accomplish several tasks requiring doses at or near this quarterly limit in a given year. In view of the risks, it is our judgement that repeated exposures in a year at such levels should not occur, and these recommendations would eliminate this flexibility. One appropriate solution in cases where workers with specific skills are in short supply is to train additional workers, rather than to impose higher risks on a few individuals.

Because we assume that any exposure carries some risk, we believe that it is important to avoid unnecessary exposures at any exposure level. Although more than 97% of all workers in our survey received annual doses less than one rem, these same workers accumulated about half of the collective dose received by the entire work force. Many of these workers, because their doses are low compared to the limits, may receive only minimal training, supervision, and monitoring for radiation protection. Many also work in situations where there is no need for exposures to ever approach the existing or the proposed new RPGs. On the other hand, some exposures at higher doses are justified. The proposed recommendations, therefore, provide a graded system of radiation protection which would establish minimum radiation protection requirements for each of three different ranges of exposure within the basic guides for maximum allowed dose to all workers. We anticipate that maximum exposure of the vast majority of workers would be effectively limited to the lowest of these ranges (less than approximately 0.3 rem to the whole body per year) through the deterrent of requirements for increased justification, on-the-job radiation protection supervision, and monitoring in the two higher ranges. In addition, the recommendations encourage regulatory agencies to establish more restrictive regulatory limits for work situations not requiring the maximum doses allowed under the basic guides.

The proposed guidance leaves agencies considerable discretion in implementing the minimum radiation protection requirements for justification of exposure of workers in each of the various ranges. We are considering additional guidance which would recommend the establishment of more explicit requirements for the highest range (Range C). These requirements could include establishment of criteria for use of Range C or prior application to and approval by the regulatory agency of Range C exposure (either for specific or more general job situations). We request specific comments on these and similar approaches to further restrictions on the exposure of workers at these higher levels.

We have considered both higher and lower alternatives to the proposed 5 rem/year RPG for whole-body exposure. This value is proposed because (a) it is the current internationally-accepted value, (b) there appear to be essential jobs requiring near 5 rem per year, and (c) the risks to the few workers in these jobs are not high compared to other industrial hazards. In addition, the costs for levels significantly lower (one rem/year or less) appear to be unwarranted, both in terms of increased collective dose to the entire workforce (in return for a few lower individual doses), and in terms of increased economic costs.

In 1975 the National Council on Radiation Protection and Measurements took the position that no change was required in the recommendation given by it in 1971. That recommendation is that "The maximum permissible prospective dose equivalent for whole body irradiation from all occupational sources shall be 5 rems in any one year" (NCRP Report No. 39, Jan. 15, 1971). Likewise the International Commission on Radiological Protection in 1977 recommended a basic dose-equivalent annual limit of 5 rem for whole body exposures to ionizing radiation (ICRP Publication 26, Jan. 17, 1977). In support of its recommendation the ICRP states that "The Commission believes that for the foreseeable future a valid method for judging the acceptability of the level of risk in radiation work is by comparing this risk with that for other occupations recognized as having high standards of safety. * * *." The radiation risk factors given in ICRP Publication 26 in arriving at its recommendation were reviewed by ICRP in May 1978 and no changes were made (ICRP Publication 28, 1978).

Nevertheless, these recommendations are all value judgments; there is not now compelling evidence for any particular value and it is hard to get such evidence. In judging the acceptability of the risks involved, it is necessary to identify (a) activities that cannot be performed at particular maximum dose levels, (b) skilled professionals and workers in limited supply whose numbers would be difficult to quickly increase in order to reduce average annual doses, and (c) the costs for additional workers and equipment that would be needed to meet different limits. For example, we are aware of a small number of maintenance tasks at nuclear power stations that could not be done under some limits less than 5 rem/year. There may be many more examples of professions, principally in medical areas, with limited labor pools. These include cardiologists performing catheterizations using fluoroscopy; and radiologists, neuro-radiologists, and nuclear medicine technologists with large patient loads for special procedures. Finally, studies by the Department of Energy and the nuclear power industry report that large costs and many more workers would be needed to greatly reduce the dose limits for many operations. Their projections of costs and personnel requirements increase expotentially with decreasing limits. We therefore request, in addition to comment on reduction of the current RPG of 3 rem/quarter to our proposed recommendation of 5 rem/year, comment on the above factors for reduction of the current RPG to 0.5 rem/year, 1 rem/year, and 3 rem/year.

Limitation of Partial Body Exposures

Exposure of portions of the body can occur through localized irradiation of

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extremities (such as hands in glove boxes), or by breathing or swallowing radioactive materials, which then migrate to different organs of the body.

Current guidance limits such exposures through separate numerical guides for organs and for individual parts of the body that are easily exposed, such as hands and feet or lens of the eye. Some organs recognized as easily subjected to high doses or as particularly sensitive to radiation have specific guides.

These current guides are applied separately. For example, even though a worker has received the maximum allowed dose to his thyroid, he may also receive doses to his lungs, skin, or any other organ, as long as no single organ receives more than the dose specified by its guide. We assume that the risks associated with such multiple doses are additive.

An alternative approach is to limit the total risk of fatal cancer in all exposed organs. This method has been adopted by the International Commission on Radiological Protection (ICRP). It is also adopted in these recommendations, but only when it leads to a greater degree of protection than limiting the dose to critical organs. Specifically, the recommended guidance provides that (a) either the combined risk of fatal cancer from all doses to individual organs not exceed the risk permitted under the whole body guide or (b) the dose to the most significantly exposed organ not exceed its guide, whichever is more restrictive. The recommendations also provide, when workers receive both external doses from whole-body exposure and internal doses from radionuclides, that the sum of the risks of fatal cancer from external whole-body doses and those due to breathing or swallowing radioactive materials not exceed the risk of fatal cancer allowed by the whole-body guide.

The numerical weighting factors chosen to relate risks to individual organs to whole-body risk are discussed in the background report cited above. In general, they are consistent with recent determinations of risk of fatal cancer by national and international scientific bodies, such as the NAS and the ICRP.

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

It is usually impractical to directly monitor the dose received by a worker who breathes or swallows radioactive materials, but it is useful to be able to predict doses that may be received from breathing contaminated atmospheres or swallowing contaminated materials. To make decisions about radiation protection of such workers possible, it is necessary to calculate the amounts of different kinds of radioactive materials which, when breathed in or swallowed, give the maximum dose allowed by the RPGs. Those calculations require complex models of metabolism and dosimetry. We propose that these limiting amounts of radioactivity be designated the "Radioactivity Intake Factors" (RIFs), and that they replace the currently used "Radioactivity Concentration Guides."

Recent advances in modeling metabolism and dosimetry have produced significant changes in the doses calculated for radioactive materials in the body. For many radioactive materials the changes in the RIFs due to changes in the models are considerably larger than the changes due to the proposed new RPGs. These new models more often reduce allowable intakes than raise them. However, for those cases where the RIF for any specific radionuclide would be increased, the question arises whether regulations adopted by implementing agencies should retain existing values, in accordance with proposed Recommendations 2 and 3. We believe that, for existing applications, experience gained over the past two decades shows that current values can be reasonably achieved. Accordingly, in cases where the RIF for any specific radionuclide would be increased under the proposed guidance, we recommend that the value adopted in regulations governing existing applications be no higher than that now in use. A summary of the changes due to the new models and to the proposed new guides is provided for the more significant radionuclides in the background report.

Limitation of Risk From Mutations

The current guides for limiting dose to the gonads are identical to those for the whole body. For a given annual dose, the risk of mutational effects in all of a male worker's descendants combined is believed to be numerically comparable to his lifetime risk of fatal cancer. The risk to a female worker's descendants is smaller. The medical severity of these hereditary effects is usually less than, and, at worst, comparable to, death from cancer. For these reasons we do not believe that a more restrictive guide is required for the gonads than for the whole body. The proposed new guide for gonadal dose is therefore identical to that proposed for the whole body. This guide is specified separately and not included in the scheme proposed above for weighting partial-body doses because the risks involved are of a fundamentally different nature: the affected individual is not the one exposed to radiation and the effects include different types of harm.

Limitation of Risk to the Unborn (Fertilized Oocyte, Embryo, and Fetus

Protection of the unborn from radiation is an already well-established principle: the purpose of the guide for gonadal exposure is to limit mutational effects in children conceived after the exposure. However, those conceived but not yet born, the "unborn," are also at risk. Their risks are greater, for a given dose, than the risks to those not yet conceived. Current guidance does not contain a dose limitation to protect the unborn from these risks.

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

There are several factors which mitigate this situation. First, the exposure of most workers under annual limits is relatively evenly distributed over the year, so that only a quarter of a worker's annual dose is delivered to the unborn during any trimester. Second, the mother's body provides considerable shielding of the unborn for most types of exposure. Finally, the total period of potential exposure is small for the unborn compared to that for a worker—a period of months compared to a working lifetime.

It is difficult to provide for protection of the unborn without affecting the rights of women to equal job opportunities. This difficulty is compounded because the critical period for most harm to the unborn occurs soon after conception—during the second and third month after conception, when a woman may not know that she is pregnant. Based on our assessments of the risks and the other factors noted above, we believe that the maximum dose to the unborn should be a factor of ten below the maximum permitted adult workers in any year. This is also the current recommendation of the National

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Council on Radiation Protection and Measurements. In Recommendation 8 we propose four alternatives which would, with varying degrees of certainty, achieve this objective.

The first two alternatives rely upon voluntary compliance and, therefore, should have less impact on equal job opportunities for women. The first assumes a woman knows she is pregnant within six weeks of conception, and will then, along with her employer, take appropriate protective action. It therefore does not guarantee that doses to the unborn during the critical early stages of pregnancy will be less than 0.5 rem.

The second alternative adds a voluntary limit on dose rate to women who can bear children in order to protect the unborn whose existence is not yet known. It permits women to hold any job, but encourages women able to bear children not to take those few jobs which potentially involve high dose rates.

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

The final alternative would restrict the exposure of all workers, male and female, to a level which would protect the unborn at the level of the first alternative. This alternative preserves equal job opportunity for women at the cost of causing more total harm. Studies of several high exposure activities show that decreasing the dose limits to this extent would significantly increase the collective dose to workers, and that some current activities would not be possible.

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

Limitation of Other Risks

The risk of nonfatal cancer is not only intrinsically less important than that of fatal cancer, but is very much smaller than other nonfatal occupational risks. Thus, we believe the protection provided against fatal cancers includes adequate protection against nonfatal cancers.

While adequate protection against cataracts of the lens of the eye might be provided by a higher maximum average annual dose than the 5 rem now allowed, no operational difficulty is reported with use of 5 rem as an annual limit. That value is therefore retained in these proposals.

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

Other Considerations

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.

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

In many jobs diagnostic x-ray examinations are a routine part of periodic or pre-employment physical examinations. Some of these examinations are a condition of employment and some are not. Federal radiation protection guidance on use of diagnostic x-rays was issued by the President on February 1, 1978 (43 FR 4377). These recommendations provide that, in general, use of such x-ray examinations should be avoided unless a medical benefit will result to a worker, considering the importance of the x-ray examination in preventing and diagnosing diseases, the risk from radiation, and the cost. Although all of the recommendations in that guidance may be usefully applied to x-ray examinations of workers, Recommendations 1 through 4 are particularly pertinent. Because this matter has been addressed by separate Federal guidance, exposure from such diagnostic x-ray examinations is not included in this guidance for occupational exposure.

Current Federal guidance provides that occupational doses to minors (those below the age of eighteen) be limited to one tenth the RPGs for older workers. We propose no change.

No other general types of exposed workers are singled out for special protection by these recommendations. However, one special class of workers—underground uranium miners—is already subject to a separate Federal guide (36 FR 12921). That guide limits exposure of their lungs to radioactive decay products of radon gas. The Mine Safety and Health Administration regulates exposure of all underground miners in accordance with this guide. We expect to review the guide on the exposure of miners to decay products of radon in the future. Exposure of miners to other radiation is governed by the Federal radiation protection guidance in these proposed recommendations.

We have not addressed the issues of emergency exposures or of whether overdoses in one year should lead to additional restrictions on doses in future years. Such situations must be dealt with on the merits in each case and under the regulatory mandate of the controlling Federal agency. We do not consider it either practical or reasonable to prejudge or prescribe general conditions for such situations beyond the general principles which apply to all radiation exposure that are set forth below in Recommendations 1 and 2.

We recognize, in addition, that some situations may exist which justify planned exposures exceeding the guides. Recommendation 9 provides for this. It requires that the controlling Federal agency fully consider and disclose the reasons for any such exposures.

Estimated Impact of These Proposals

We estimated above that the exposure of 1.1 million workers in 1975 (the latest year for which we have complete statistics) will lead to 15–38 additional premature cancer deaths and comparable numbers of serious mutational effects and nonlethal cancers. If this new guidance is adopted, workers should be harmed less in the future. We are not able to quantify the improvement because we cannot predict how efficiently the guidance will be implemented and we do not know how much of existing exposure is unjustified. However, the proposed recommendations provide a framework of graded minimum requirements to cut down the amount of unjustified exposure, and a recommendation that implementing agencies establish lower regulatory limits for workers who can operate significantly below the new maximum limits. We believe that most workers can. The proposals also reduce the maximum annual and lifetime dose that any workers can get by about 60%.

We have made only a limited assessment of the costs of implementing this proposed guidance. We do not believe it would be prudent to attempt a detailed analysis, because agencies developing regulations to carry out this guidance may use different means, and their specific proposals will be subjected to public review and economic analysis when they are developed.

The principal cost will be that associated with reduced RPGs. In order to comply with a reduced RPG an enterprise can hire more workers, reassign (and, if necessary, retrain) present employees, improve its procedures or technology, or curtail the activity. In general, a mix of these will be used, depending on the value of the reduced RPG, on the cost of each alternative, and on other factors. Since we do not know what mix will be used, for the purpose of developing rough numberical estimates of the upper bounds of costs we have used a simple model based on the costs for hiring new workers only.

From the distribution of doses found in our national survey of exposures for the year 1975, we computed the total excess collective dose between the old RPG of 3 rem per quarter and the proposed RPG of 5 rem per year. Dividing this excess by the value of the proposed new RPG gives the minimum number of workers that must be hired to absorb this dose. The average labor cost, including overhead, for each additional worker was assumed to be $41,000 per year. This method yields a cost of about $35 million per year. We believe the actual cost of meeting the new RPG will be much less.

We have also attempted to evaluate costs if existing workers now receiving lower doses are retrained to do high-dose jobs instead of hiring new workers. Some workers are very difficult to replace (e.g., medical professionals, such as cardiologists and radiologists; and workers in small enterprises with very limited labor pools). However, we believe that most workers can be relatively easily retrained (e.g., medical technicians and skilled laborers, such as welders and pipe fitters) to handle tasks which cause higher exposures. We estimate that workers that can be reassigned to these jobs would require training varying from a few days to a few months. For these workers, the costs are expected to range from a few percent to a few tens of percent of the annual cost of new hires. In addition, these costs are incurred only once instead of annually, as in the case of new hires. We therefore estimate that the costs based on the above new hires model may be as much as ten times too high, for the first year, and an even greater over-estimate in succeeding years. We welcome comments on the costs of implementing these proposals, on whether or not the costs are reasonable, and why.

Proposed Recommendations

We propose nine recommendations as guidance to Federal agencies in the formulation of Federal radiation protection standards for workers, and in their establishment of programs of cooperation with States. In all cases but one we have made single recommendations for public comment. The exception, Recommendation 2, addresses protection of the unborn during gestation. Because this recommendation involves issues that go beyond simple radiation protection of workers, including equality of employment rights and the rights of the unborn, we have proposed four alternatives for public consideration. The recommendations follow:

1. All occupational exposure should be justified by the net benefit of the activity causing the exposure. The justification should include comparable consideration of alternatives not requiring radiation exposure.

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

3. The radiation dose to individuals should conform to the numerical Radiation Protection Guides (RPGs) specified below. Individual doses should be maintained as far below these RPGs as is reasonably achievable and consistent with Recommendation 2.

Radiation Protection Guides

a. The sum of the annual dose equivalent [4] from external exposure and the annual committed dose equivalent [5] from internal exposure should not exceed the following values:

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

b. Non-uniform exposure of the body should also satisfy the condition on the weighted sum of annual dose equivalents and committed dose equivalents.

H_{nu} that

$$H_{nu} = \Sigma_i w_i H_i < 5\text{rem}.$$

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

Breast—0.20
Lung—0.15
Red bone marrow—0.15
Thyroid—0.04
Bone surfaces—0.03
Skin—0.01
Other organs [6]—0.08

c. When both uniform whole-body exposure and nonuniform exposure of the body occur, in addition to the requirements of 3a, the annual uniform whole-body dose equivalent added to the sum of weighted annual dose equivalents from additional nonuniform exposure, H_{nu}, should not exceed 5 rem.

4. The following Minimum Radiation Protection Requirements should be established by appropriate authorities and carried out in the workplace, on the basis of the range of doses anticipated in individual work situations. The numerical values specifying the dose ranges may be adjusted to fit the needs of specific situations by implementing agencies.[7]

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[4] "Dose equivalent" means the quantity expressed by the unit "rem," as defined by the International Commission on Radiation Units (ICRU).

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

[6] Applies only to each of the five other organs with highest doses.

[7] Suggested numerical ranges are: Range A, less than 0.1 RPG. Range B, 0.1–0.3 RPG. Range C, 0.3–1.0 RPG.

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Minimum Radiation Protection Requirements

Range A

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

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

c. Instruct workers on basic hazards of radiation and radiation protection principles, and on the levels of risk from radiation and appropriate radiation protection practices for their specific work situations. The degree of instruction appropriate will depend on the potential exposure involved.

Range B

The above requirements, plus:

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

e. Provide individual monitoring and recordkeeping.

Range C

The above requirements, plus:

f. Justify the need for work situations which are expected to make a significant contribution to exposure in Range C and provide professional radiation protection supervision before and while such jobs are undertaken to assure that collective and individual exposures are as low as is reasonably achievable.

g. Carry out sufficient additional monitoring of workers to achieve Recommendation 4f.

h. Once a worker has been exposed in Range C, maintain a lifetime dose record, including at least all subsequent annual doses (as specified in Recommendation 3c) in Ranges B and C.

i. Maintain lifetime doses as low as is reasonably achievable. The accumulation of doses (as recorded under Recommendation 4h) by individual workers should be managed so that their lifetime accumulated dose is less than 100 rem.

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

b. When a RIF for a specific radionuclide in a specific chemical or physical form determined on the basis of part (a) is larger than that currently in use, a value no greater than that in current use should be adopted in regulations governing work situations identical or similar to those currently in existence.

6. Federal agencies should establish limits and administrative levels that are below the RPGs and the RIFs, when this is appropriate. Such limits or levels may apply to specific categories of workers or work situations.

7. In addition to any other Federal restrictions, the occupational exposure of individuals younger than eighteen should be limited to one tenth of the Radiation Protection Guides for adult workers.

8. Exposure of the unborn [19] should be restricted more than that of workers. This should include special consideration of ALARA practices for women. Women able to bear children should be fully informed of current knowledge of risks to the unborn from radiation. In addition, employers should assure that protection of the unborn is achieved without loss of job security or economic penalty to women workers. Due to the complexity of the issues involved, we propose four alternative recommendations on numerical limitation of dose to the unborn for public comment. We would be glad to receive other recommendations for dealing with exposure of the unborn.

a. Women are encouraged to voluntarily keep total dose to any unborn less than 0.5 rem during any known or suspected pregnancy; or

b. Women able to bear children are encouraged to voluntarily avoid job situations involving whole-body dose rates greater than 0.2 rem per month, and to keep total dose to the unborn less than 0.5 rem during any known pregnancy; or

c. Women able to bear children should be limited to job situations involving whole-body dose rates less than 0.2 rem per month. Total dose to the unborn during any known period of pregnancy should be limited to 0.5 rem; or

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

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

The following notes clarify application of the above recommendations:

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

2. When the uniform external whole-body exposure occurs in addition to exposure from radioactive materials taken into the body, the requirement of Recommendation 3c may be satisfied by the condition that

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

where H_{ext} is the annual external whole-body dose equivalent, RPG_{wb} is 5 rem, I_j is the intake of radionuclide j, and RIF_j is defined as in Recommendation 5.

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

4. Numerical guides for emergency exposures are not provided by this guidance. Agencies should follow the general principles established by Recommendations 1, 2, 7, 8, and 9 in dealing with such situations.

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

6. Limits for periods other than one year may be derived by Federal agencies from the annual RPGs and RIFs when necessary for administrative

[19] "Unborn" here means the fertilized oocyte, the embryo, and the fetus.

purposes. Such limits should be consistent with Recommendation 2 and the three ranges in Recommendation 4.

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

These proposed recommendations would provide general guidance for the radiation protection of workers. They would replace that part of existing guidance (see 25 FR 4402 of May 13, 1960) which applies to workers. Individual Federal agencies, with their knowledge of specific worker exposure situations, would use this guidance as the basis upon which to develop detailed standards and regulations to meet their particular statutory obligations. We propose to follow the activities of the Federal agencies as they implement the final Guidance, to issue any necessary clarifications and interpretations, and to promote the coordination necessary for an effective Federal program of worker protection.

Public Hearings

Public hearings on these proposed recommendations will be held as indicated above under the heading "Dates." Because of their major responsibilities to regulate radiation exposures in work places, the Nuclear Regulatory Commission (NRC) and the Occupational Safety and Health Administration (OSHA) will participate in sponsoring these hearings. The following conditions and procedures will govern the conduct of the hearings:

1. Purpose, Type, and Scope

These hearings are to provide additional opportunity for people to express opinions and provide factual information to aid EPA, OSHA, and NRC in carrying out their respective responsibilities for guidance on and regulation of occupational exposure to ionizing radiation. The hearings will be informal and legislative in nature rather than adjudicatory or formal rulemaking hearings. Technical rules of evidence, discovery, subpoena powers, testimony under oath, and similar formalities will not apply.

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 ...idance and standards. The subject ...er of these hearings encompasses the issues raised in those petitions (See 40 FR 50027 of October 29, 1975).

2. Presiding Officer and Panel

The hearings will be conducted by a presiding officer. A six member panel consisting of representatives of EPA, OSHA, and NRC will assist the presiding officer. A principal responsibility of the panel will be to clarify the testimony by eliciting views, comments, and factual information from participants. Members of the panel will not present views or respond to questions on behalf of their agencies. The membership of the panel may vary from time to time.

The presiding officer and panel shall have the joint responsibility to assure a fair and impartial hearing and to encourage the development of testimony that will contribute to informed decision-making. It will not be the function of the presiding officer or the panel to issue an opinion or to make decisions at the conclusion of the hearings. The presiding officer shall conduct the hearings in an orderly, fair, and expeditious manner and make procedural decisions. His functions shall include, but not be limited to, the following:

a. Regulating the course of the hearings and the conduct of participants, including establishing reasonable time limits for the hearings, establishing the sequence and length of presentations and questioning, and opening and closing each hearing session;

b. Making determinations concerning procedure and similar matters;

c. Assuring that questioning of speakers by panel members and others is consistent with the nature and purpose of these hearings;

d. Making determinations on the relevance of oral testimony and questions to the issues identified as within the scope of the hearings, or, in consultation with the panel, to additional issues pertinent to the proceedings; and, as necessary, terminating irrelevant presentations;

e. Ruling on late requests to participate;

f. Deciding how long the hearing record will remain open for written comments and additional data after the end of the oral proceedings.

3. Participation in the Hearings

Persons or organizations who wish to give presentations longer than ten minutes or present extensive data and evidence must give written notice to the Director, Criteria and Standards Division (ANR-460), U.S. Environmental Protection Agency, Washington, D.C. 20460, no later than 28 days prior to the scheduled date of a hearing. The notice should include: (1) the name, address, and telephone number of the participant; (2) the hearing at which they wish to testify; (3) the organization (if any) that they will represent; (4) the amount of time requested; and (5) which of the issues they want to address. Oral presentations will generally be restricted to 30 minutes. Detailed or lengthy material should be summarized orally and presented in full in written submissions. Requests for longer times for oral presentations will be considered only on the basis of a detailed summary of the material to be presented. The Agency will notify participants in advance if their allocated time is less than that requested.

An opportunity will be provided each day of the hearings for persons who have not submitted a notice as specified above to make brief oral statements. A register will be provided at the beginning of each hearing for this purpose. A minimum period will be set aside for such statements in the agenda for each hearing, and the presiding officer may allocate additional time, as necessary. The maximum time allowed for such statements will depend on the number of registrants and the availability of time, but will generally be limited to periods of no more than 5 to 10 minutes each. In order to assist the management of the hearings, persons wishing to make such statements are encouraged to register promptly at the beginning of the hearing.

Attendance at the hearings will be open to all members of the public, and seating will be made available on a first-come first-served basis.

4. Testimony and Written Submission

a. The oral proceedings will be recorded verbatim and a transcript made available promply for inspection and copying, as specified below under the heading "The Public Hearing Record." It will help the panel if speakers supply copies of their oral testimony before they give it. However, this is not required.

b. Fourteen copies of any written statements and documents on which speakers intend to base their oral statements must be submitted to the Director (see "Addresses" above) no later than 14 days before the beginning of the hearing in which they will testify. We would appreciate if speakers would also provide eight additional copies for the use of the panel.

c. Questions may be directed to speakers by the hearing panel, by other speakers, and by other members of the public. Speakers may respond or not, as

they wish. Questions should be designed to elicit relevant information and should not be repetitious of questions asked by others. The views of questioners should be expressed in their statements and not as prefaces to questions. Such informal questioning will be at the discretion and under the control of the presiding officer.

d. Members of the public who are not able to attend the hearings or prefer not to ask questions themselves may suggest questions to the hearing panel to ask of speakers. These must be submitted no later than 14 days before any hearing to the Director (see "Addresses" above). The panel will decide whether or not to ask these questions.

e. Members of the public may also submit comments during the post-hearing comment period set by the presiding officer. These post-hearing comments should be confined to responses to data and opinions submitted at the hearings or to written comments received by the Agency.

f. In addition to these public hearings, we would appreciate any written comments on these proposals. These will be given equal consideration in formulating final recommendations. The procedure for submitting such written comment is given above under the headings "Dates" and "Addresses." Participants in the hearings may refer to and comment on such written comments, which will be available for public inspection and copying as specified below under "The Public Hearing Record."

5. Opening Statement

At the opening of each hearing, EPA will provide a summary statement of the proposed recommendations and of the major issues involved. At that time speakers and other members of the public can ask questions of the EPA representatives in order to clarify the proposed recommendations and the reasons why EPA is proposing them.

6. The Public Hearing Record

The procedures for filing documents in these hearings will be specified by the presiding officer, except as already provided herein.

The hearing record will include the transcript of oral statements by speakers, the questions and answers, and all written materials filed in connection with these hearings. Items in this public hearing record will be filed under EPA Docket No. A-79-48 and will be available for public inspection and copying as soon as possible following their receipt, at the Environmental Protection Agency's Central Docket Section, Room 2903B, M Street, S.W., Washington, D.C. 20460, and at each of the Agency's ten regional offices (see "Addresses" above).

Dated: January 16, 1981.

Douglas M. Costle,

Administrator.

[FR Doc. 81-2268 Filed 1-22-81; 8:45 am]

BILLING CODE 6560-26-M

Enclosure I

ENCLOSURE II

Mr. Walter C. Barber
Acting Administrator
U.S. Environmental Protection Agency
401 M Street, SW., A-100
Washington, D.C. 20460

Dear Mr. Barber:

Enclosed for your consideration are the Nuclear Regulatory Commission comments on the proposed "Federal Radiation Protection Guidance for Occupational Exposure," published on January 23, 1981 (46 FR 7836).

We recognize the difficulties faced by EPA in developing new guidance for radiation protection of workers. Our response is intended to be constructive and to assist you in your efforts to develop the final guidance. In summary, while we agree in principle with many of the proposed recommendations, we suggest a number of substantive changes.

Although we do not suggest adopting all of the recommendations in ICRP Publication 26, we now strongly recommend adoption of the system of dose limitation as recommended by the ICRP. That system is logical and self-consistent, and appears to be based on the best scientific information available. The proposed EPA guidance endorses summation of external dose and internal committed dose equivalent, as does the ICRP system. However, the proposed EPA guidance also incorporates major departures from the ICRP system, including changes in organ dose limits and changes in weighting factors which, in our view, would impair the usefulness of the system.

We recognize that the EPA proposed guidance reflects endorsement of the interim position taken by the Commission in October 1979 on retaining current limits for internal radiation exposure in the workplace. However, since publication of the ICRP recommendations in 1977, additional information regarding the bases for these recommendations has become available. Open discussions of those bases have led to a more complete understanding of the ICRP system which, in turn, has resulted in a more complete endorsement of the ICRP system by the international radiation protection community and the NRC staff. The Commission believes that the ICRP system is based upon the best scientific information and methodology currently available and that the ICRP's general approach is consistent with the Commission's policies regarding (1) the appropriate application of risk-based methodology in regulatory decision making and standards setting and (2) the necessity for vigorous application of the ALARA concept in radiation protection activities. Accordingly, the Commission requests that EPA adopt the ICRP system of dose limitation intact as a sound basis for quantifying relative risk, regulating exposures to radiation, and as one which would be consistent with that used in other countries.

The Commission is also concerned that implementation of some of the EPA proposed guidance would infringe on the personal privacy of women who choose to work in a workplace where they might be exposed to radiation and might interfere with the career options of persons who, during the course of their work, could receive greater-than-average doses during their working lifetimes.

In its Federal Register notice (46 FR 7836), EPA requested views on (1) the desirability or necessity for a reduction of the 5-rem radiation protection

guide (RPG) on effective dose equivalent and (2) the provision of additional EPA guidance that would establish more explicit requirements on exposure of individuals. The Commission does not consider any reduction in the 5-rem RPG or additional guidance by EPA to be necessary, justifiable, or desirable. The Commission supports the approach of providing all workers with information on which to base informed individual decisions on the acceptability of the risk associated with employment involving radiation doses.

Enclosed are both general and specific comments on the proposed EPA guidance. The specific comments are numbered to correspond to the numbered recommendations as they appeared in the Federal Register notice.

Sincerely,

Joseph M. Hendrie

Enclosure: NRC Comments

NRC COMMENTS ON PROPOSED FEDERAL RADIATION PROTECTION GUIDANCE FOR OCCUPATIONAL EXPOSURES PUBLISHED JANUARY 23, 1981 (46 FR 7836)

A. GENERAL COMMENTS

The NRC's evaluation of the proposed EPA guidance has identified a number of issues that would introduce substantial problems for the NRC--and perhaps, for other agencies. One of the key issues is the proposed adoption of a system of dose limitation resembling the ICRP system of dose limitation, but which includes a number of departures that, in our view, would impair the usefulness of the system. The NRC endorses the adoption of the ICRP system of dose limitation. Our endorsement of the ICRP system is in recognition of some very desirable features of that system. The ICRP system:

(1) is based on a contemporary radiation protection philosophy that would require (a) justifying why persons are to be exposed to radiation (b) ensuring that any exposures are as low as reasonably achievable, and (c) using appropriate dose limits;

(2) is based on an "acceptable risk" rationale that is derived from the statistics of job-related risks to workers in the "safer" industries, excluding nuclear;

(3) provides a method (a) to combine doses to multiple organs, doses from multiple radionuclides, and doses from internal and external exposures and (b) to express these doses in terms of a whole-body dose equivalent on the basis of risk considerations, which may be compared to the dose limits;

(4) incorporates the state-of-the-art knowledge of biological, physical, and dosimetric information in deriving "annual limits of intake" (ALI) and "derived air concentration" (DAC); and,

(5) provid appropriate dose limits for normal working conditions, which are generally more restrictive than previous limits; but provides flexibility for exceptional operational difficulties when it is in the public interest to exceed the primary limits.

The new ICRP analytical models are so complex that sophisticated computers are required to calculate those quantities (such as ALIs and DACs) needed to implement radiation protection programs and to regulate the use of radioactive material by industries and others. Owing to the complexities of the calculations and the interdependence of the features of the ICRP system of dose limitation, it is not possible to arbitrarily change some selected parts of the system without destroying the continuity and coherence of the whole, which would be the effect of the proposed EPA guidance. If the proposed EPA guidance is promulgated in its present form, all of the calculations and tables provided by the ICRP must be replaced, and the implementation by all U.S. agencies would be made extremely difficult. In addition, communication with radiation scientists of essentially all other countries with radiation programs could be extremely difficult because the U.S. would have different definitions for the same concepts. The ICRP system has been adopted or is in the process of being adopted by the IAEA, the Commission of European Communities, the OECD Nuclear Energy Agency, and most countries with radiation programs. The selection of a

specific system of dose limitation has a direct impact on international agreements, cooperative efforts, and guidelines, related to radiation doses to workers and members of the public.

Another area of concern to us is that some of the differences between the ICRP system and the EPA recommendations are changes that EPA justifies on the basis of demonstrated practicability. We believe that the current experience does not demonstrate practicability, but does demonstrate technical feasibility. This difference is significant. Primary dose limits and DACs must be met regardless of the costs which might be involved. In contrast, practicability (in the sense of "as low as practicable"--now "as low as reasonably achievable") requires consideration of the costs for achieving a particular level of radiation protection. This distinction is the heart of the ICRP system of dose limitation, and we believe that many of our problems with the proposed EPA guidance stem from mixing of ALARA issues with the issues dealing with selection of primary dose limit values.

An additional problem that we have identified is one of semantics. Terms such as "should," when used in regulations, usually indicate a substantial amount of flexibility (i.e., that options are afforded to those regulated); the term "shall" indicates that action is required without options. However, when the EPA recommendations appear in the Federal Register over the President's signature, the word "should" may have the impact of the word "shall" for Federal agencies. With this in mind, we have noted that several of the proposed EPA recommendations, that would seemingly permit substantial flexibility for affected Federal agencies, might actually result in de facto limits and requirements that were not intended.

B. SPECIFIC COMMENTS

Recommendation 1:

EPA's first recommendation would require the justification of all occupational exposure. This is consistent with ICRP recommendations, and we concur in this recommendation.

Recommendation 2:

The second recommendation would require that collective doses be as low as is reasonably achievable. This is also in agreement with ICRP recommendations, and we concur in this recommendation.

Recommendation 3:

Recommendation 3, would provide radiation protection guides (RPGs) that are not consistent with ICRP recommendations. In our view, recommendation 3 constitutes a major and undesirable departure from the ICRP system of dose limitation.

Key differences between the ICRP system and that proposed by the EPA are as follows:

1. Differences between EPA and ICRP recommended dose limits are shown in the following table:

Organ	Annual Dose Limit	
	EPA	ICRP
Gonads	5 rems	-- (a)
Eye lens	5 rems	15 rems (b)
Others	30 rems	50 rems (b)

(a) No value given by ICRP, but 20 rems may be inferred from the weighting factor for gonads.

(b) The ICRP provides these dose limits to avoid non-stochastic effects.

2. As shown in the table of weighting factors below, EPA is proposing the exclusion of the risk to gonads in calculating the weighting factors, but is proposing the inclusion of skin.

Tissues	Weighting Factors (Wt)	
	EPA	ICRP
Gonads	-	0.25
Breast	0.20	0.15
Red bone marrow	0.16	0.12
Lung	0.16	0.12
Thyroid	0.04	0.03
Bone surfaces	0.03	0.03
Skin	0.01	-
Remainder (other organs)	0.40[a]	0.30[a]

3. The EPA guidance states that the value of an ALI (or equivalent) currently in use is not to be increased in regulations governing work situations identical with or similar to those currently in existence although information provided in ICRP Publication 26 and its companion volume, Publication 30, would support increasing some ALIs as well as decreasing others.

The ICRP system of dose limitation would (1) combine the doses from internal and external exposures, (2) add contributions from several internal organs in a "weighted" manner, and (3) impose an overall combined limit for the whole body of 5 rems or its equivalent in terms of dose to body parts or organs. The ICRP system of dose limitation makes use of a series of "weighting factors," W_T, by which the dose to <u>each</u> organ would be multiplied to give an effective dose that would be equivalent to a whole body dose with respect to risks. The ICRP system requires that the "effective dose equivalents" for <u>each</u> organ be

[a] Five other organs with highest dose. The factor for each of the other organs is then 0.06 (ICRP) or 0.08 (EPA).

summed (along with any external whole-body doses) and that the sum should not exceed 5 rems.

The ICRP does not recommend an annual dose limit for a single internal organ. However, an annual dose limit for a single organ may be inferred from the ICRP W_T values if it is assumed that (1) there is no external exposure and that (2) no other organs receive any dose during intake, transport through the body, and elimination of the radionuclide. In this case, the dose required to yield a risk equal to that associated with whole-body irradiation might be so high that some nonstochastic (prompt, nonrandom) biological effects might occur. In order to avoid these nonstochastic effects, which are related to dose in a "threshold" manner, the ICRP recommended a constraint that the annual doses to any internal organ not exceed a conservatively established value of 50 rems. Thus, the 50-rem dose constraint should not be compared directly with the dose limits for "critical organs" that are currently being used. The ICRP limits for the lens of the eye and for skin are also based on avoidance of nonstochastic effects.

Since the 30-rem dose constraint proposed by EPA for all internal organs presumably would be used to avoid nonstochastic effects, and since the 50-rem dose constraint of the ICRP system and the 30-rem dose constraint of the EPA are both below the threshold for such effects, it would appear that the lower dose value selected by EPA would represent an unnecessary added factor of conservatism that is not supported by either biological information or cost-benefit analyses, and would cause confusion in relationship to practices in other countries. This is also true of the differences in do es to the lens of the eye and the dose to the skin, which EPA chose to include in the W_T table.

While the ICRP system of dose limitation, which combines doses from external and internal doses, would, in general, be more restrictive than the current standards, some derived air concentrations based on the ICRP system would be somewhat higher than the current values in 10 CFR Part 20 (based on FRC guidance) for a variety of reasons. For example, the ICRP values are based on quantification of risks; they are derived using contemporary biological models; and some organs are less important radiocarcinogenically than others. The ICRP system of dose limitation, which includes justification, ALARA requirements, and dose limits, is based on a logical scientific rationale that is internally consistent. Compared to current EPA (FRC) standards, some annual intake limits (and their reflection in the derived air concentration values) would increase, some would decrease, and others would remain essentially unchanged. The primary dose limit of 5 rems per year would not change. We believe that the EPA guidance should reflect the new values for the intake limits and DACs independent of the direction of the change.* We believe that any restrictions on exposures below the basic limits, particularly those that would be selected based on operating experience, are ALARA issues. Such matters, can best be handled by the regulatory agencies who can judge whether any adjustments are needed, and if so, by how much, and the justification for doing so.

By removing "gonads" from the list of organs that are included in the derivation of W_T values, the proposed EPA guidance would increase all but one of the W_T values for the remaining organs. Since the doses to each organ are

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*Clearly, if questions occur concerning a particular issue, such as what the MPC value should be when chemical toxicity restrictions might be more limiting than the radiotoxic restriction, or should the NCRP or others identify any problems that we have not anticipated, the issues should be resolved before the new values are implemented.

multiplied by the W_T value for that organ in order to obtain the effective dose equivalent, the effect of the EPA change would be to add an additional factor of conservatism without justification. By limiting the annual dose for gonads to 5 rems, another factor of conservatism is introduced by EPA for that organ.

If the U.S. adopts a variation of the ICRP system, as proposed by EPA, the U.S. derived effective dose equivalents will not be comparable to those determined on the basis of the ICRP system which is being implemented by essentially all countries with nuclear industries throughout the rest of the world. Further, there will not be a simple way of translating from one system to the other for comparison purposes.

All ALI and "derived air concentration" (DAC) values in ICRP Publication 30 are based on the ICRP system. If the proposed EPA system is adopted in the U.S., an entirely different set of values for ALI's and DAC's will have to be established (calculated) for use only in this country.

We feel that a cost-benefit analysis would not support the departures from the ICRP system proposed by EPA. Moreover, departures from the broad, generally applicable guidance that are more conservative than the primary dose limits should be seen in the context of ALARA and should continue to be the prerogative and responsibility of the individual Federal regulatory agencies.

For the reasons stated above, the NRC requests that EPA revise its recommendation 3 to conform exactly to the ICRP's risk-based system of dose limitation.

If the EPA concludes that it is necessary to achieve greater radiation safety by arbitrarily adjusting parameters, the NRC believes that the RPG values should be adjusted rather than the components of the formulae and procedures used to calculate the "effective dose equivalent" values. In this way, at least the basic biophysical data developed by the ICRP could be used and the ability to communicate on radiological matters with scientific and regulatory peers in the world community would not be sacrificed as a consequence of the EPA having modified some of the key elements of the system of dose limitation.

Recommendation 4:

Recommendation 4 contains a set of graded radiation protection actions correlated with three exposure ranges. It is our view that the form of the set of graded radiation protection requirements could result in greatly increased costs and personnel requirements that are not likely to be justified by the dose saving, if any dose saving is to be realized. We believe that a cost-benefit analysis should be made as part of the basis for the final decision of EPA with respect to this recommendation.

We agree that protective measures should be commensurate with the potential risk in the work-place as indicated in recommendation 4. In fact, the Commission's present regulations include this approach. However, the NRC requests that the implication of de facto limits ("Ranges") in recommendation 4 be avoided by making a change in the wording to replace the term "requirements" with the term "actions" so that the first sentence reads:

"The following minimum radiation protection actions should be established by appropriate authorities and carried out in the workplace on the basis of the range of doses anticipated in individual work situations."

Recommendation 4:

Recommendation 4.i. pertaining to a career dose limit would have the effect of requiring that each worker's lifetime occupational dose be limited to 100 rems. Although NRC-EPA staff discussions indicated that the language of recommendation 4.i. would be hortatory, the use of the words "should be managed" in this recommendation, when signed by the President, may, as a practical matter, leave no room for discretion on the part of the implementing agencies. This would have the effect of requiring that each worker's lifetime occupational dose be limited to 100 rems.

Such a dose limit would be, in effect, a two- to three-fold reduction of the maximum lifetime dose permitted by recommendations of the ICRP and NCRP, which allow an average of 5 rems per year. This proposed career limit is based on EPA's premise that maximum potential lifetime risks from occupational exposures to radiation should be limited to a value comparable to average risks from other occupational hazards. We consider this approach to the establishment of radiation risk limiting standards to be unjustified.

Serious questions would be raised by imposition of such a career limit. Clearly, it could impact significantly on a person's employability, job continuity, and ability to plan and pursue a career. An individual's career, for which extensive training and experience are required, could be terminated prematurely, regardless of the individual's willingness to accept continuing

exposures and the associated risks. Indeed, we are not aware of any valid epidemiologic study that demonstrates any observable increase in health effects at the radiation exposure levels found in the workplace. In addition, a significant career impact may result if a worker has accrued a higher total dose than others competing for the same job. An employer could be expected to hire selectively those workers with the lowest career doses regardless of their skill level or other positive attributes.

The accumulation of 100 rems would likely occur at an age when, because of latency considerations for radiogenic cancer, the risk per unit of dose is actually decreasing and when hereditary considerations are declining. The career limit might, in effect, selectively remove those individuals from the work force who are at least risk from additional exposure. Further, it must be remembered that 100 rems does not represent a dividing line between absolute safety and unacceptable risk. Under the "linear hypothesis," the 101st rem presents no more risk than any other, earlier, 1 rem dose. Also, current data indicate that only a very small number of workers are likely to exceed a dose of 100 rems during their working lifetimes.

Based on these considerations, a requirement for limiting career doses to 100 rems, with its potential for career interference, does not seem justified. It appears that requirements for justification of dose and ALARA efforts would accomplish essentially the same objective. The NRC suggests that recommendation 4.i. be recast to read: "Maintain lifetime occupational doses as low as is reasonably achievable. Individual workers should be instructed on the levels of risk from radiation and encouraged to maintain career cumulative dose as low

as is reasonably achievable." NRC regulations require that workers be informed of the risks associated with the radiation exposure so that each worker can make an informed decision in this regard.

Recommendation 5:

Recommendation 5 pertains to the regulation of occupational radiation hazards from breathing, swallowing, or immersion in media containing radionuclides and introduces the term "radioactivity intake factors." The term "radioactivity intake factors" should be replaced with the ICRP term "annual limits of in. .." The introduction of the additional term "radioactivity intake factor" is unnecessary and can lead to confusion and misunderstanding.

Also, it is suggested that recommendation 5.b, pertaining to the retention of existing radioactivity intake factors (or their equivalent), where they are smaller than such factors calculated on the basis of the new proposed system, be deleted. As stated above with respect to recommendation 3, we feel that justification for departures from the broad, general system of guidance in such areas as exposure limits that are more conservative than the guidance should be the prerogative and responsibility of the implementing agencies. We believe that this is a matter that could best be handled by implementing ALARA requirements, as presented in recommendation 2, with which we concur.

Recommendation 6:

Recommendation 6 states that "Federal agencies should establish limits and administrative levels that are below the RPGs and the RIFs, when this is appropriate...." The Commission believes that this recommendation is unnecessary and should be withdrawn. We believe that Federal agencies have such

authority now. To the extent that the recommendation is read by some Federal agencies to require establishment of lower limits it could result in the imposition of different standards by the several agencies. If, after reconsideration, EPA concludes that it is necessary to make a recommendation of this nature, we request that the word "should," in the first sentence, be replaced with "may." Use of the word "may" would recognize the responsibility of individual agencies to take actions appropriate to optimization or ALARA and to justify such actions, including actions such as those covered by proposed Recommendation 5.b., discussed above, which should be recognized as an ALARA issue.

In addition, if Recommendation 6 is retained, it should be revised to encourage interagency cooperation and consistency in setting standards, particularly where two or more agencies have responsibilities for different facets of a particular activity or operation. Examples of this are the authorities of MSHA and NRC over uranium milling, and the authority of OSHA over naturally-occurring and accelerator-produced radioactive materials (NARM) that are frequently used in the same programs as byproduct, source, and special nuclear materials regulated by NRC. Differences between agency standards could pose a significant problem for States having formal agreements with both OSHA and NRC for the assumption of certain regulatory controls. This is because those agreements require a finding that the State regulations are compatible with the Federal agency's regulations.

Recommendation 7:

The NRC concurs in the recommendation that workers under 18 years of age be limited to one-tenth of the RPG for adult workers.

Recommendation 8:

In recommendation 8, which pertains to exposure of the fertilized oocyte, the embryo, and the fetus, EPA has proposed four alternatives for comment. Based on much deliberation in this area, we consider a voluntary approach, such as alternative "a," as the only practical approach. Alternative "d" appears to establish an RPG for whole-body dose of 1 rem per year for all workers (i.e., 0.5 rem per six-month period), which is inconsistent with the RPG of 5 rems per year given in recommendation 3.a. In addition, such an RPG would probably fail a practical cost-benefit test and appears to be an unreasonable constraint on necessary operational flexibility. Alternatives "b" and "c," are discriminatory towards women, unduly burdensome in their restrictions and, for reasons given below, are probably not capable of being fully implemented.

Although recommendation 8.a. seems to embrace a purely voluntary approach, it contains what amounts to an exhortation to limit the dose to a woman suspected of being pregnant to 0.5 rem during the pregnancy. The NRC cannot disagree with the intent of this part of the recommendation, but we are concerned that the inclusion of the 0.5 rem figure is likely to be interpreted as a de facto limit and result in serious limitations on women's employability and implementation problems for regulatory agencies.

A requirement that a female employee be removed from or limited in her performance of work involving exposure to radiation because she is fertile, or because she is pregnant, raises both Constitutional and statutory questions. In addition, such a requirement implies an obligation on the part of the licensee, and perhaps the NRC, to determine, as a condition of employment, who

is fertile and who is, or is likely to be, pregnant. Any mechanism to accomplish this involves a potential for infringement of the individual's right to privacy.

The present NRC approach to protection of the fertilized oocyte, the embryo, and the fetus encourages the instruction of all radiation workers about the risks to these entities associated with occupational exposure. This permits each individual to make a decision as to whether or not to accept (or continue to accept) those risks associated with exposure to radiation, based on the best available radiological information.

We request that the guidance not contain any language that may be interpreted as establishing or recommending the establishment of special limits for fertile and/or pregnant women, but rather that it encourage fully informing both men and women with respect to the risks involved before they accept radiation work. In effect, the recommendation should be based on an "informed consent" approach with fertile or pregnant women being free to decide for themselves whether or not to accept work involving radiation exposure after being instructed as to the risks associated with such exposure.

Recommendation 9:

We agree with the general nature of recommendation 9 that, in some cases, doses exceeding RPGs can be justified. The obvious example is an action that, although resulting in doses above the RPGs, results in preventing much larger doses to others on a collective or individual basis. Those workers accepting work that involves the potential for receiving doses in excess of RPGs should

be aware of the potential risks involved and should be free to decide for themselves whether to participate in such work.

It is anticipated that circumstances requiring doses above the RPGs would occur infrequently. In many cases, these circumstances would develop in such a manner that they could not reasonably be foreseen so as to permit a long period of planning preceding the necessary action. In other words, the prevention of major harm may depend on rapid and decisive action by responsible management at the scene. In such cases, it would be unreasonable to expect the licensee to notify the NRC, provide detailed information, and await a case-by-case evaluation by the staff. We believe that provision can be made for such actions in NRC regulations without involvement of the NRC staff in lengthy evaluations of each such action before the licensee is authorized to take the necessary actions. Therefore, the NRC requests that EPA recommendation 9 be reworded to avoid the implication that a case-by-case evaluation of each and every action that may result in exceeding the RPGs is necessary prior to such an action. This could be accomplished by revising the existing recommendation to read:

> "In exceptional circumstances, the RPGs may be exceeded, for cause. Provision for doing so may be established on a generic basis by the Federal agency having jurisdiction where clear and specific criteria are provided as a basis for permitting such doses, including the requirement that such doses are permitted for the purpose of mitigating circumstances that might, otherwise, result in greater harm to other workers or the general public."

C. NOTES CLARIFYING RECOMMENDATIONS:

We have two suggestions concerning the notes following the recommendations. The first concerns the manner of compliance with subitem e of recommendation 4 (individual monitoring and recordkeeping), and the second pertains to recommendations 2 and 3 and the implementation of the ALARA concept.

1. Note Clarifying Recommendation 4.e:

The most direct, and perhaps the most desirable, way of determining committed internal dose is by means of determining the amount and location of internally deposited radionuclides by bioassay methods. However, bioassay methods (including whole body and organ counting; breath, urine, and fecal analyses) are not always practicable at exposure levels encountered in the workplace. In order to clarify EPA's acceptance of other more indirect methods for estimating and controlling internal exposure, we request that an additional note, perhaps designated 2.a., be inserted between notes 2 and 3 to read:

> "With respect to the requirement in subitem e of recommendation 4 for the provision of individual monitoring and recordkeeping, it is recognized that, under some conditions of exposure, monitoring individual exposures by means of bioassay procedures will not be feasible or necessary. Therefore, regulatory agencies may provide for alternative monitoring and recordkeeping procedures such as monitoring and recording of concentrations of radioactive materials in air to which the individual is exposed and the duration of that exposure."

Even this alternative might prove to be difficult to implement in Range B where levels might be as low as 10-percent of the RPG from both internal and external exposures.

2. Implementation of ALARA

We are concerned that the EPA proposed guidance may be read as requiring a rigorous quantitative implementation of ALARA. The difficulties involved in a rigorous quantitative approach to implementation of ALARA are recognized in ICRP Publication 26. The NRC has studied this problem and concluded that, while quantification of the cost-benefit analyses associated with reducing the exposure of workers to radiation and optimization of radiation protection provisions are desirable goals, the implementation of ALARA should not be delayed while the problems associated with such a quantitative approach to ALARA implementation are solved, but should proceed on a qualitative basis. That is, the elements of optimization analyses, which would include the costs as well as technical practicability and benefits, would be considered in judging ALARA.

A quantitative optimization analysis can be costly. Some applications are too trivial to justify quantitative analyses. In these cases, qualitative analyses are adequate. What is important is that the elements of an optimization analyses be factored into the decision-making process.

We, therefore, request that EPA clarify its guidance with respect to ALARA implementation by adding a note to the effect that ALARA implementation should not be delayed while a rigorous, quantitative implementation procedure is perfected, but should proceed on a structured qualitative basis.

D. OTHER COMMENTS:

1. EPA requested comments on approaches to further restrictions on the exposure of workers in Range C, which is defined in EPA recommendation 4. As indicated above, we have serious reservations concerning the overall value of the proposed set of graded minimum radiation protection requirements as proposed in recommendation 4. It does not appear that EPA guidance that would require further restrictions on exposures within any range below the RPG could be justified on a rational cost-benefit basis. It is our view that each individual regulatory agency is in the best position to determine the justification for and the specific nature of any such requirements. As expressed above, it is our position that the 5-rem annual RPG as proposed by EPA and as recommended by ICRP will result in radiation protection that provides an adequately low level of risk relative to those found in other safe industries. With the requirement for justification and ALARA efforts at all levels of exposure, any further restrictive requirements seem to be without merit and verging on stultification.

2. EPA requested comments on the possible reduction of the 5 rem annual RPG. The NRC has published proposed amendments* to 10 CFR Part 20 that would eliminate the 5(N-18) formula and the 3 rem per quarter standard that allows up to 12 rems per year. We see no reason to reduce the annual dose standard (RPG) below 5 rems at this time. The staff has done an extensive analysis of the pros and cons associated with a proposed dose-limiting standard reduction. It was concluded that any significant reduction would result in very substantial

* 44 FR 10338, Published 2/20/79.

costs and that a reduction to 0.5 rem per year would result in wholly unacceptable impacts, including, for some activities which NRC regulates, a significant increase in collective (person-rem) dose, when considered in light of the theoretical benefits. Further consideration of any such reduction by EPA should include a thorough and carefully developed cost-benefit analysis.

ENCLOSURE III

SUPPLEMENTARY INFORMATION IN SUPPORT OF

PROPOSED NRC COMMENTS TO EPA

A. Background

By memorandum of October 30, 1979, S. J. Chilk to L. V. Gossick, the staff was informed that the Commission "has, as an interim position, concurred with the staff's recommendation to retain current NRC limits for internal radiation in the work place." The proposed guidance published by EPA reflects the Commission's interim position.

B. Current Staff View

It is now clear that the majority of the technical staff recommends a change from the Commission's interim position to a position that the ICRP system of dose limitation, including W_T values and limits to avoid non-stochastic effects, be adopted by EPA and NRC exactly as proposed by ICRP.*

As indicated in the proposed comments to EPA (Enclosure II), the majority of the NRC staff endorses the adoption of the ICRP system. Although the EPA proposed guidance bears some resemblance to the ICRP system of dose limitation, it includes a number of departures which significantly impair the usefulness of the ICRP system.

* Clearly, if questions occur concerning a particular issue, such as what the MPC value should be when chemical toxicity restrictions might be more limiting than the radiotoxic restriction, or should the NCRP or others identify any problems that we have not anticipated, the issues should be resolved before the new values are implemented.

The staff believes that the ICRP system is based upon the best scientific information currently available and that its general approach is consistent with the Commission's current policy regarding the appropriate application of risk-based methodology in regulatory standards and actions.

The bases for the staff's current view are discussed below.

C. Bases For Current Staff View

The ICRP system of dose limitation is the heart of the controversy between the NRC staff and EPA regarding the proposed guidance. Although the ICRP system was published in 1977, relatively few persons are familiar with the details of its features and the differences between the ICRP system and the current NRC dose limits.

A general understanding of the ICRP system is necessary to appreciate why valid simple comparisons of different systems (ICRP-26, NRC and EPA) cannot be provided. Attachment A presents a very brief summary of the principal features of the ICRP system of dose limitation. Attachment B is a copy of a Nuclear Safety article that contains a more comprehensive summary of the entire ICRP recommendation, including the system of dose limitation.

Since the time that the ICRP recommendations (ICRP-26) were published, additional information regarding the bases for those recommendations has become available. Open discussions of those bases have led to a more complete understanding of the ICRP system. This, in turn, has resulted in a more complete endorsement of the ICRP system by the international

community and by the NRC staff. A number of the principal facets of the ICRP system are discussed below.

The ICRP system of dose limitation, which includes justification, ALARA requirements, and dose limits, is based on a logical scientific rationale that is internally consistent. The system includes derived limits using (a) contemporary biologic and dosimetric analytical models and parameters and (b) the sum of weighted internal doses and external doses. Compared to current NRC standards, some annual intake limits (and their reflection in the derived air concentration values) would increase, some would decrease, and others would remain essentially unchanged. The primary dose limit of 5 rems per year would not change.

The dose limits of the ICRP system would not necessarily increase the current dose limits. Some of the ICRP dose limits would reduce the maximum annual dose values that would be permitted by the current NRC (FRC) limits. For example, present NRC regulations do not require any reductions in the internal organ dose limits because of exposure to external radiation sources, or any reduction in external dose limits because of the dose from radioactive material deposited in the body. Thus, current regulations would not prohibit up to 42 rems per year to the bone and thyroid (30 rems internal, 12 rems external) and up to 27 rems per year to the other single internal organs (15 rems internal, 12 rems external). The ICRP system would (1) combine the doses from internal and external exposures, (2) add contributions from several internal organs in a "weighted" manner, and (3) impose an overall combined limit for the whole body of 5 rems or its

equivalent in terms of dose to body parts or organs. (See further discussion in Attachment A.)

While the ICRP system, which combines doses from external and internal doses, would be more restrictive generally than the current standards, some derived air concentrations based on the ICRP system would be somewhat higher than the current values in 10 CFR Part 20 for a variety of reasons. For example, the derived air concentrations are based on quantification of risk, they are derived using improved contemporary biological models, and some organs have been found to be more important radiocarcinogenically than others.

The consensus of the technical staff is that the primary dose limits should be based on the best scientific information available. Whether values for derived limits rise or fall, the values that result from a scientifically based, coherent system should be used for the standards.

The actual intake by workers or the concentrations in the working environment do not depend entirely on the primary limits in the standard. It has been recognized for several decades that a key element of an effective radiation protection program is the ALARA effort. This is reflected in recommendations of the ICRP, NCRP, FRC, EPA, and others. The implementation of the ICRP system would make ALARA a <u>requirement</u>, rather than an admonition, and we endorse this feature. The implementation of ALARA, rather than the dose limits, effectively establishes the level of radiation protection. The levels of protection achieved by licensees (at considerable

expense) in the past should not be a principal determinant in reaching subsequent decisions on limits. Rather, the limits should be internally consistent. The staff believes that any restrictions on exposures below the basic limits, particularly those that would be selected based on operating experience, are ALARA issues. Such matters can best be handled by the regulatory agencies who can judge whether any adjustments are needed, and if so, by how much, and the justification for doing so.

Licensees are required to meet primary safety standards regardless of costs. On the other hand, the costs of efforts to stay ALARA below the limits must be considered. While licensees are operating well below current limits, including MPC values, this demonstrates technical feasibility but it does not demonstrate practicability (in the ALARA sense) because the costs might not have been factored into the consideration. It would not be appropriate to restrict the changes in primary standards when the new values would permit some relaxation if the licensee could demonstrate that alternative design or operating procedures would satisfy ALARA conditions.

The ICRP system makes use of "weighting factors," W_T. The dose to each organ is multiplied by the appropriate W_T to give an effective dose value equivalent to whole body dose with respect to risks. The ICRP system requires that the "effective dose equivalent" for each organ be summed (along with any external whole-body doses) and that the sum should not exceed 5 rems. The ICRP does not recommend an annual dose limit for a single internal organ. However, an annual dose limit for a single organ may be inferred from the ICRP W_T values if it is assumed that (1) there is no external exposure and that (2) no other organs receive any dose

during intake, transport through the body, and elimination of the radionuclide. This "limit" would restrict risks of fatal somatic effects (cancers), which are assumed to be proportional to dose. However, the dose required to yield a risk equal to that associated with whole body irradiation might be so high that some nonstochastic (prompt, nonrandom) biological effects might occur. In order to avoid these nonstochastic effects, which are related to dose in a "threshold" manner, the ICRP recommended a constraint that the annual doses to any internal organ not exceed 50 rems. Thus, the 50-rem dose constraint should not be compared directly with the dose limits for critical organs that are currently being used.

The ICRP system is based on an "acceptable" risk value derived from data on industrial fatalities in "safe" industries. Non-fatal cancers and additional hereditary considerations are different end-points which could have been chosen, e.g., non-fatal cancers might have been compared to illnesses caused by chronic exposure to chemicals or non-fatal accident statistics. Other end-points such as statistical loss of lifetime could also have been used rather than fatalities. The rationale of the ICRP for the selection and the method used to reflect this risk in terms of dose limits is discussed in Attachment B.

Four reasons were set forth in SECY-79-1B in support of the position advocating no increase in permissible organ doses or radionuclide intakes:

(1) Reporting requirements would be relaxed;

(2) Facility and process design decisions would permit higher exposures for many future years;

(3) Licensees are currently meeting present standards, including MPC's, therefore practicability has been demonstrated; and

(4) There is uncertainty about risks attendant to exposures to low level radiation.

As indicated above, the staff believes that the regulations should reflect the new values for the intake limits independent of the direction of the change.

(a) Reporting Requirements

Reporting requirements should be reevaluated in light of the new limits and either tightened or relaxed depending on the reasons for requiring the reports in the first place. The reporting requirements should not be a reason for influencing the selection of the values used for secondary dose limits within an otherwise coherent system of dose limitations.

(b) Facility and Process Design

Facility and process design decisions might indeed be influenced by the values of the dose limits and derived limits. It seems reasonable that they should be so influenced in order to reflect changes in either direction. Actually, the design and operating decisions are much more closely related to ALARA requirements rather than to the dose limits. For this reason, it is doubtful that increasing selected intake limits would be reflected in a relaxation of design features.

(c) Current Practice

This issue was discussed previously.

(d) Uncertainties in Risk

There is more scientific evidence on the hazards of ionizing radiation, than on most, if not all, other environmental agents that affect humans.

Comprehensive periodic reviews on national and international levels have been published by the U.S. National Academy of Science (NAS), the (U.S.) National Council on Radiation Protection and Measurements (NCRP), the International Commission on Radiological Protection (ICRP), the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), and others. There appears to be close agreement among these and similar expert organizations that the current state of knowledge concerning low-level exposures is quite adequate to serve as the technical base for a system of dose limitation such as that recommended by the ICRP. Most expert advisory groups have expressed more concern that too much conservatism in the selection of a system of dose limitation might result in the use of alternatives that could produce greater detriments to humans than exposures to radiation. Indeed, the dose limits recommended by the ICRP are generally viewed as being a conservative, but not excessively conservative, basis for radiation protection.

ATTACHMENT A

TO

ENCLOSURE III

FEATURES OF THE ICRP SYSTEM OF DOSE LIMITATION

The ICRP System of Dose Limitations is presented in ICRP Publication 26 (1977). The main features of the system are:

"(a) no practice shall be adopted unless its introduction produces a positive net benefit;

"(b) all exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account; and

"(c) the dose equivalent to individuals shall not exceed the limits recommended for the appropriate circumstances by the Commission."

For convenience, the feature stated as item (a) is often termed "justification," item (b) is termed "ALARA," and item (c) the "dose limitations."

In implementing this system, justification can be judged by applying cost-benefit techniques* in either a quantitative or a qualitative manner. Implementation of ALARA can also be achieved through the use of cost-benefit techniques. In order to determine whether a reduction in exposure is "reasonably achievable," it is necessary to consider on the one hand the increase of

*Basically, the net benefit resulting from the practice is equal to the gross value of the practice (which includes the value of the product plus tangible and intangible social and other benefits) minus the production costs (including the costs to society of nonradiological detriments and the costs to protect against the nonradiological hazards), minus the cost of radiation protection, minus the cost assigned to the radiation detriment involved in the operation. Realistic, rather than conservative cost estimates and collective doses must be used in the cost-benefit analyses in order to avoid distortions that might bias the decision-making in favor of an alternative that is not evaluated conservatively.

benefits from such a reduction and on the other increase of cost involved in its achievement. The process of analyzing the costs and benefits of incremental changes in the level of radiation protection to determine the maximum degree of protection which is justifiable is termed "optimization" assessment. The optimum radiation protection system permits the maximum benefit from a practice involving radiation exposures, while satisfying all dose limit requirements, at the minimum overall cost. Such a condition is, by definition, as low as reasonably achievable (ALARA).

Since, for radiation protection purposes, any exposure to radiation is assumed to involve some degree of risk, all exposures should be kept ALARA. The basic requirement can be met in a qualitative or quantitative way. In particular, the quantitative approach is recommended when formulating quantitative requirements such as setting an authorized limit for prescribed actions. The aim of the quantitative analysis should be to assess how far exposures can be reduced before further reduction would not justify the incremental cost required to accomplish it. This assessment can be made by a differential cost-benefit analysis, i.e., an optimization assessment.

A quantitative optimization analysis can be costly. Some applications are too trivial to justify quantitative analyses. In these cases, qualitative analyses are adequate. What is important is that the elements of an optimization analyses, e.g., consideration of alternative measures, their costs, and their effect on the levels of exposure, must be factored into the decision-making process.

Dose Limits

For radiation protection purposes, it is assumed that for random (stochastic) somatic effects:

(a) the probability of a health effect occurring is proportional to dose over the exposure range encountered by radiation workers; and

(b) the severity of the health effect is independent of the magnitude of the dose.

A range of "acceptable" risks for workers was selected based on the risk of fatalities from industrial causes in "safe" industries. Information concerning the distribution of doses to radiation workers was considered in conjunction with the relationship between dose levels and probability of health effects to select the annual dose limit for radiation workers, e.g., 5 rems for uniform irradiation of the whole body.

The quantity of radionuclide which, taken into a body, would yield a risk equal to that of a 5-rem whole body external dose was calculated using contemporary dosimetric and biologic models and parameters, and the available data to estimate the relationship between doses to specific internal organs and health effects. Values of the weighting factor, W_T, by which doses to individual organs can be multiplied to yield a whole body effective dose equivalent were calculated based on risk considerations.

In those cases where the internal organ has a relatively low risk of fatal cancer induction, additional constraints were provided to avoid prompt non-

stochastic (nonrandom) health effects. Such effects are related to dose in a threshold manner, i.e., they have not been observed below a particular dose magnitude. The ICRP selected 50 rems per year as the value that would prevent nonstochastic health effects in internal organs. Nonstochastic effects for external organs are avoided by using special dose limits for the lens of the eye (15 rems per year) and for skin (50 rems per year).

Doses from internal and external exposure modes can now be added with the use of the weighting factors, W_T, and the resulting sum, "effective dose equivalent" values, can be expressed in units of rem (or sievert).

Derived Limits

The ICRP has provided tables of "annual limits of intake" and "derived air concentrations." These tables* contain values derived using the best available analytical models and parameters, ICRP W_T values, and ICRP internal organ dose constraints.

*Values are currently available for radionuclides of 21 elements. Values for the remaining elements are being calculated at the present time and will be available by the time the system can be implemented by getting the regulations in place.

ATTACHMENT B

TO

ENCLOSURE III

NUCLEAR SAFETY ARTICLE

"RECOMMENDATIONS OF THE
INTERNATIONAL COMMISSION ON RADIOLOGICAL PROTECTION"

Recommendations of the International Commission on Radiological Protection

Adapted by the *Nuclear Safety* Staff

[Editor's Note: The following adaption by the *Nuclear Safety* Editorial Staff was made from a much longer report of the same name *(ICRP Publication 26)*. The report is an authoritative source of information on risk estimates of ill health associated with ionizing radiation and provides an established basis for radiation protection actions and policies both in this country and elsewhere. A summary is presented here to provide a penetrating insight into this important area.]

As one of the commissions established by the International Congress of Radiology, the International Commission on Radiological Protection (ICRP) has continued its close relationship with succeeding Congresses, and it has also been looked to as the appropriate body to give general guidance on the more widespread use of radiation sources caused by the rapid developments in the field of nuclear energy. The ICRP continues to maintain its traditional contact with medical radiology and the medical profession generally, and it also recognizes its responsibility to other professional groups and its obligation to provide guidance within the field of radiation protection as a whole. Details of the ICRP rules, membership, and relationship with other bodies are in the appendix to *ICRP Publication 26*.

In 1966 the ICRP published its recommendations *(ICRP Publication 9)* which had been adopted in 1965;

they were amended in 1969 and 1971. During the last decade new information has emerged which has necessitated a review of the Commission's basic recommendations; the present report results from the examination of such new information by the ICRP and its committees and task groups. The recommendations made in this report supersede the former basic recommendations published by the Commission, but not necessarily those of its committees.

As in its previous recommendations, the ICRP deals only with ionizing radiations in this report.

The Commission wishes to reiterate that its policy is to consider the fundamental principles on which appropriate radiation protection measures can be based. 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. The ICRP recognizes that the individual experts responsible for putting radiation protection into practice need guidance that is sufficiently flexible to allow for national, regional, or other variation. For this reason the ICRP recommendations are intended to provide an appropriate degree of flexibility. Because of this, the form in which the recommendations are worded will not necessarily be suitable, and may often be inappropriate, for direct assimilation into regulations or codes of practice.

OBJECTIVES OF RADIATION PROTECTION

Radiation protection is concerned with the protection of individuals, their progeny, and mankind as a whole, while still allowing necessary activities from which radiation exposure might result. The detrimental effects against which protection is required are known as somatic and hereditary; radiation effects are called "somatic" if they become manifest in the exposed individual himself and "hereditary" if they affect his descendants.

"Stochastic" effects are those for which the probability of an effect occurring, rather than its severity, is regarded as a function of dose without threshold. "Nonstochastic" effects are those for which the severity of the effect varies with the dose and for which a threshold may therefore occur. At the dose range involved in radiation protection, hereditary effects are regarded as being stochastic. Some somatic effects are stochastic; of these, carcinogenesis is considered to be the chief somatic risk of irradiation at low doses and is therefore the main problem in radiation protection.

Some nonstochastic somatic effects are specific to particular tissues, as in the case of cataract of the lens, nonmalignant damage to the skin, cell depletion in the bone marrow causing hematological deficiencies, and gonadal cell damage leading to impairment of fertility. Other nonstochastic effects may arise in the blood vessels or connective tissue elements that are common to most organs of the body and therefore require that, as a precautionary measure, a dose-equivalent limit should apply for all body tissues to ensure that nonstochastic effects do not occur in any such tissue. For all these changes the severity of the effect depends on the magnitude of the dose received, and there is likely to be a clear threshold of dose below which no detrimental effects are seen.

The aim of radiation protection should be to prevent detrimental nonstochastic effects and to limit the probability of stochastic effects to levels deemed to be acceptable. An additional aim is to ensure that practices involving radiation exposure are justified.

The prevention of nonstochastic effects would be achieved by setting dose-equivalent limits at sufficiently low values so that no threshold dose would be reached, even following exposure for the whole of a lifetime or for the total period of working life. The limitation of stochastic effects is achieved by keeping all justifiable exposures as low as is reasonably achievable, economic and social factors being taken into account, subject always to the boundary condition that the appropriate dose-equivalent limits will not be exceeded.

Most decisions about human activities are based on an implicit form of balancing of costs and benefits leading to the conclusion that the conduct of a chosen practice is "worthwhile." Less generally, it is also recognized that the conduct of the chosen practice should be adjusted to maximize the benefit to the individual or to society. In radiation protection it is becoming possible to formalize these broad decision-making procedures, although it is not always possible to quantify them. However, the application of these procedures does not always provide sufficient protection for the individual. It is therefore necessary, for this reason also, to establish dose-equivalent limits in situations where the benefits and detriments are not received by the same members of the population.

For the above reasons the ICRP recommends a system of dose limitation, the main features of which are as follows:

Attachment B

1. No practice shall be adopted unless its introduction produces a positive net benefit.

2. All exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account.

3. The dose equivalent to individuals shall not exceed the limits recommended for the appropriate circumstances by the Commission.

In applying these recommendations, we must recognize that many present practices give rise to dose equivalents that will be received in the future. These dose-equivalent commitments should be taken into account so that necessary developments of present or future practice would not be liable to result in undue exposure of any members of the public.

Although the principal objective of radiation protection is the achievement and maintenance of appropriately safe conditions for activities involving human exposure, the level of safety required for the protection of all human individuals is thought likely to be adequate to protect other species, although not necessarily individual members of those species. Thus the ICRP believes that if man is adequately protected, then other living things are also likely to be sufficiently protected.

BASIC CONCEPTS

Detriment

The deleterious effects of exposure to radiation may be of many kinds. Among the effects on health, there may be both stochastic and nonstochastic effects in the exposed individual and stochastic effects in later generations. In addition, there may be deleterious effects not associated with health, such as the need to restrict the use of some areas or products.

The ICRP has introduced the concept of detriment to identify and, where possible, to quantify all these deleterious effects. In general, the detriment in a population is defined as the mathematical "expectation" of the harm incurred from an exposure to radiation, taking into account not only the probability of each type of deleterious effect but also the severity of the effect. These deleterious effects include both the effects on health and the effects not associated with health. On some occasions it is convenient to deal separately with the effects, or the potential effects, on health. These are then characterized by the concept of detriment to health. For effects on health, if p_i, the probability of suffering the effect i, is small and the severity of the effect is expressed by a weighting factor g_i, then the detriment to health, G, in a group of P persons is given by

$$G = P \sum_i p_i g_i$$

Dose Equivalent

The absorbed dose,[1] D, is insufficient by itself to predict either the severity or the probability of the deleterious effects on health resulting from irradiation under unspecified conditions. In radiation protection it is convenient to introduce a further quantity that correlates better with the more important deleterious effects of exposure to radiation, more particularly with the delayed stochastic effects. This quantity, called dose equivalent, is the absorbed dose weighted by the modifying factors Q and N.

The dose equivalent, H, at a point in tissue, is given by the equation

$$H = DQN$$

where D is the absorbed dose, Q is the quality factor, and N is the product of all other modifying factors specified by the ICRP. At the present time the ICRP has assigned the value 1 to N. The special name for the unit of dose equivalent is the sievert (Sv);

$$1\ \text{Sv} = 1\ \text{J kg}^{-1}\ (= 100\ \text{rems})$$

The quality factor, Q, is intended to allow for the effect on the detriment of the microscopic distribution of absorbed energy. The Q factor is defined as a function of the collision stopping power (L_∞) in water at the point of interest. Interpolated values of Q as a function of L_∞ can be obtained by using the values shown in the table below.

L_∞–Q Relationship

L_∞ in water, keV/μm	Q
3.5 (and under)	1
7	2
23	5
53	10
175 (and above)	20

For a spectrum of radiation, an effective value, $\bar{Q}$, of Q at the point of interest can be calculated.[2]

When the distribution of radiation in L_∞ is not known at all points in the volume of interest, it is

permissible to use approximate values for $\bar{Q}$ related to the various types of primary radiation. For this purpose the ICRP recommends the following values of $\bar{Q}$ to be used for both external and internal radiation:

X rays, gamma rays, and electrons	1
Neutrons, protons, and singly charged particles of rest mass greater than one atomic mass unit of unknown energy	10
Alpha particles and multiply charged particles (and particles of unknown charge) of unknown energy	20
Thermal neutrons	2.3

Committed Dose Equivalent

Another quantity used in the ICRP recommendations is the "committed dose equivalent," H_{50}, to a given organ or tissue from a single intake of radioactive material into the body. This quantity, which may be considered to be a special case of dose-equivalent commitment, is the dose equivalent that will be accumulated over 50 years, representing a working life, following the intake:

$$H_{50} = \int_{t_0}^{t_0+50y} \dot{H}(t)\,dt$$

where $H(t)$ is the relevant dose-equivalent rate and t_0 is the time of intake.

DOSE–RESPONSE RELATIONSHIPS

The relationship between the dose received by an individual and any particular biological effect induced by irradiation is a complex matter on which much further work is needed. For radiation protection purposes, it is necessary to make certain simplifying assumptions. One such basic assumption underlying the ICRP recommendations is that, regarding stochastic effects, there is, within the range of exposure conditions usually encountered in radiation work, a linear relationship without threshold between dose and the probability of an effect. The simple summation of doses received by a tissue or organ as a measure of the total risk and the calculation of the collective dose equivalent as an index of the total detriment to a population are valid only on the basis of this assumption and that the severity of each type of effect is independent of dose.

The added risk from a given dose increment will depend on the slope of the dose–response relationship. If the dose–response relationship for stochastic processes is in fact highly sigmoid, the risk from low doses could be overestimated by making a linear extrapolation from data obtained at high doses.

There are radiobiological grounds for assuming that the dose–response curve for low-LET* radiation will generally increase in slope with increasing dose and dose rate over the absorbed dose range up to a few gray.† For many effects studied experimentally, the response in this range can be represented by the expression‡

$$E = aD + bD^2$$

where E denotes the effect, D the dose, and a and b are constants. The quadratic term (bD^2) in this expression predominates at high absorbed doses (generally above 1 Gy) and high absorbed dose rates (of the order of 1 Gy/min); however, the linear term (aD) and the slope that it represents come to predominate as the dose and dose rate are reduced. Although a relationship of this form has been documented for a variety of effects, the relative values of the parameters a and b vary from one observation to another.

For human populations in particular, knowledge of dose–response relationships is too limited to enable confident prediction of the shapes and slopes of the curves at low doses and low dose rates. Nevertheless, in a few instances the risk estimates can be based on the results of irradiation of human populations involving single absorbed doses, of the order of 0.5 Gy or less, or such doses repeated at intervals of a few days or more. In these cases it can be reasonably assumed that the frequency per unit absorbed dose of particular harmful effects resulting from such exposures is not likely to overestimate greatly the frequency of such effects in the dose range of concern in radiation protection, even though the latter may be received at much lower dose rates.

In many instances, however, risk estimates depend on data derived from irradiation involving higher doses delivered at high dose rates. In these cases, it may be appropriate to reduce these estimates by a factor to allow for the probable difference in risk. The risk factors discussed later have therefore been chosen as

*LET = linear energy transfer.

†1 gray (Gy) = 1 J kg^{-1} (= 100 rads).

‡At high doses this expression would have to be modified to take account of the decreased tumor risk caused by cell sterilization. This effect is not significant at the doses encountered in normal exposure conditions. (However, see the discussion of hot spots under Significant Volumes and Areas.)

far as possible to apply in practice for the purposes of radiation protection.

The use of linear extrapolations from the frequency of effects observed at high doses, leads to an overestimate of the radiation risks, which in turn could result in the choice of alternatives that are more hazardous than practices involving radiation exposures. Thus, in the choice of alternative practices, radiation risk estimates should be used only with great caution and with explicit recognition of the possibility that the actual risk at low doses may be lower than that implied by a deliberately cautious assumption of proportionality.

IMPLICATIONS OF ASSUMPTIONS ABOUT DOSE–RESPONSE RELATIONS

Significant Volumes and Areas

From the assumption about the proportionality between dose and response, it would follow that for stochastic effects it would be justifiable to consider the mean dose* over all cells of uniform sensitivity in a particular tissue or organ. This use of the mean dose has practical advantages in that the significant volume can usually be taken as that of the organ or tissue under consideration.

When the irradiation of a tissue is nonhomogeneous, the use of the mean dose over the tissue ceases to be strictly valid if doses to individual cells differ more widely than the range of doses over which the dose–response relationship for the tissue can be regarded as linear. An example of this may be the irradiation of the lung by radioactive particulates. However, on the basis of theoretical considerations and of available epidemiological evidence, the ICRP believes that, for late stochastic effects, the absorption of a given quantity of radiation energy is ordinarily likely to be less effective when due to a series of "hot spots" than when uniformly distributed because of the effect of high doses in causing the loss of reproductive capacity or the death of cells. Thus, with particulate radioactive sources within a tissue, to assess the risk by assuming a homogeneous dose distribution would probably overestimate the actual risk. Moreover, for nonstochastic effects the limited amount of cell loss that might result at moderate dose levels would be most unlikely to cause any impairment of organ function.

For exposure of the skin, either to external sources or as a result of skin contamination, it is not generally appropriate to average the dose equivalent over the entire skin.

Rate of Dose Accumulation

The ICRP believes that it is sufficient to set annual dose-equivalent limits and does not recommend any further restrictions either on the instantaneous rate or on the rate at which the dose equivalent may be accumulated, except in the case of occupational exposure of women of reproductive capacity and pregnant women.

TISSUES AT RISK

For the purposes of radiation protection, it is necessary to specify a number of organs and tissues that have to be considered because of their susceptibility to radiation damage, the seriousness of such damage, and the extent to which this could be treatable.

Some of the quantitative risk factors are clearly age- or sex-dependent, as for example those for the development of breast cancer or for the induction of hereditary defects. In addition, the risk factors for the occurrence of malignancies are reduced in older persons because of the long latent periods involved in the development of these effects. For these reasons the total risk from an individual exposure will vary somewhat with age and with sex, although in fact the variations from the average value for all ages and both sexes are not considerable. Thus for protection purposes sufficient accuracy is obtained by using a single dose-equivalent limit for each organ or tissue for all workers regardless of age or sex. These limits, which are discussed under The System of Dose Limitation, are based on the average risk levels listed in Table I for the various organs or tissues. The same principle applies also for different members of the general public.

The risk factors for different tissues are based on the estimated likelihood of inducing fatal malignant disease, nonstochastic changes, or substantial genetic defects expressed in liveborn descendants. It is recognized that the appropriate basis for quantifying detriment should include the evaluation of all other forms of hurt and suffering that may result from exposure. This problem is the subject of a task group report being prepared for the ICRP. It appears likely that the forms

*Unless specifically qualified, the term "dose equivalent" refers to the mean dose equivalent over the entire organ or tissue.

Table I Risk Factors for Radiation Protection Purposes

Organ or tissue	Risk factor, Sv^{-1}	Effect
Gonads	10^{-2}	Hereditary ill health within first two generations
Red bone marrow	2×10^{-2}	Leukemia mortality
Bone	5×10^{-2}	Bone cancer mortality
Lung	2×10^{-2}	Lung cancer mortality
Thyroid	5×10^{-2}	Thyroid cancer mortality
Breast	2.5×10^{-2}	Breast cancer mortality
All other tissue	5×10^{-2}	Cancer mortality
Any other single tissue	$<1 \times 10^{-2}$	Cancer mortality
Uniform whole-body irradiation	10^{-2}	Cancer mortality
Uniform whole-body irradiation	4×10^{-2}	Hereditary effects within first two generations
Uniform whole-body irradiation	8×10^{-2}	Hereditary effects in all subsequent generations

of detriment mentioned above would be regarded as the dominant components of the harm which may be caused by radiation and those on which risk factors should most appropriately be based.

Children and Fetuses

Exposure before birth or during childhood may interfere with subsequent growth and development, depending on such factors as dose and age at irradiation. Susceptibility to the induction of certain malignancies also appears to be higher during the prenatal and childhood periods than during adult life.

Tissues of Low Sensitivity

It is now established that there are various tissues, such as muscle and adipose tissue, in which the development of malignancy following irradiation seems to be very rare, as evidenced by the fact that epidemiological surveys have so far not shown excess rates of malignancy in such tissues. For these tissues, dose limitation is based on the possibility of vascular or other deleterious changes. There may also be some tissues, for example, those containing nonnucleated cells, the irradiation of which can be ignored for the purpose of radiation protection.

Other Effects

Other than the specific effects already discussed, there is no good evidence of impairment of function of organs and tissues at the levels of dose normally encountered in radiation work. The evidence for life-shortening from effects other than tumor induction is inconclusive and cannot be used quantitatively. Moreover, it seems unlikely that any major hazard from irradiation at recommended levels has been overlooked, as judged by the evidence from heavily irradiated populations, observed for periods up to 30 years.

THE SYSTEM OF DOSE LIMITATION

The ICRP recommends a system of dose limitation, the main purposes of which are to ensure (1) that no source of exposure is unjustified in relation to its benefits or those of any available alternative, (2) that any necessary exposures are kept as low as is reasonably achievable, (3) that the dose equivalents received do not exceed certain specified limits, and (4) that allowance is made for future development.

It may thus be necessary to make subjective value judgments in order to compare the relative importance of the costs imposed on human health by radiation exposure with other economic and social factors. In this respect, radiation is not unique, and the same statement could be made in respect to a number of other agents to which mankind is exposed.

Dose-Equivalent Limits: General

The total absorbed dose rate in most human tissues from natural radiation is about one-thousandth of a gray per year, but absorbed dose rates up to one-hundredth of a gray per year or more have been reported from certain limited areas of the world.

Man-made modifications of the environment and man's activities can increase the "normal" exposure to natural radiation. Examples of this include mining, flight at high altitudes, and the use of building materials containing naturally occurring radioactive nuclides. Even living within a house is often sufficient to increase radiation exposure because restricted ventilation tends to lead to an accumulation of radioactive gases and their decay products.

In radiation protection the Commission's recommended dose-equivalent limits have not been regarded as applying to, or including, the "normal" levels of natural radiation, but only as being concerned with those components of natural radiation that result from man-made activities or in special environments.

Moreover, it should be emphasized that, on the premise that the frequency of radiation effects is

Attachment B

linearly proportional to the dose received, such harm as may be caused by natural radiation could be regarded as independent of, and simply additive to, the amount of harm that may be caused by any of the man-made practices involving radiation exposure to which the Commission's limits apply. In this sense, regional variations in natural radiation are regarded as involving a corresponding variation in detriment in the same way as, for example, regional variations in meteorological conditions or volcanic activity involve differences in the risk of harm in different areas. On this basis, there is no reason why differences in natural radiation should affect acceptable levels of man-made exposure, any more than differences in other natural risks should do.

Medical Exposures of Patients and Dose-Equivalent Limits

Medical exposure is, in general, subject to most of the ICRP's system of dose limitation, that is, unnecessary exposures should be avoided; necessary exposures should be justifiable in terms of benefits that would not otherwise have been received; and the doses actually administered should be limited to the minimum amount consistent with the medical benefit to the individual patient. The individual receiving the exposure is himself the direct recipient of the benefit resulting from the procedure. For this reason it is not appropriate to apply the quantitative values of the Commission's recommended dose-equivalent limits to medical exposures. With certain medical exposures, a very much higher level of risk may in fact be justified by the benefit derived than by the level judged by the ICRP to be appropriate for occupational exposure or for exposure of members of the public.

Dose-Equivalent Limits for Workers

The ICRP believes that for the foreseeable future a valid method for judging the acceptability of the level of risk in radiation work is by comparing this risk with that for other occupations recognized as having high standards of safety, which are generally considered to be those in which the average annual mortality due to occupational hazards does not exceed 10^{-4} (Ref. 3).

The Commission believes that the calculated rate at which fatal malignancies might be induced by occupational exposure to radiation should not in any case exceed the occupational fatality rate of industries recognized as having high standards of safety.

It should be mentioned that an accidental death appears to involve an average loss of about 30 years of life in many industries and to be associated with an approximately equal total loss of working time from industrial accidents. A fatal malignancy induced by occupational exposure to radiation would be expected to involve the loss of about 10 years of life, owing to the long latency in the development of such a condition, without appreciable associated time loss from accidents.

In many cases of occupational exposure where the Commission's system of dose limitation has been applied, the resultant annual average dose equivalent is no greater than one-tenth of the annual limit.[4] Therefore the application of a dose-equivalent limit provides much better protection for the average worker in the group than that corresponding to the limit. For example, in the case of uniform exposure of the whole body, in circumstances where the ICRP's recommendations, including the annual dose-equivalent limit of 50 mSv, have been applied, the distribution of the annual dose equivalents in large occupational groups has been shown very commonly to fit a lognormal function, with an arithmetic mean of about 5 mSv, and with very few values approaching the limit. The application of the risk factors given in Table I to the above mean dose indicates that the average risk in these radiation occupations is comparable with the average risk in other safe indust

Recommended Dose-Equivalent Limits. The ICRP recommendations given in Table 2 are intended to prevent nonstochastic effects and to limit the occurrence of stochastic effects to an acceptable level. The Commission believes that nonstochastic effects will be prevented by applying a dose-equivalent limit of 0.5 Sv (50 rems) in a year to all tissues except the lens, for which the Commission recommends a limit of 0.3 Sv

Table 2 Recommended Annual Dose-Equivalent Limits

Recommended limit	Application	Tissue or organ
0.5 Sv (50 rems)	Workers	All tissue except lens of eye
0.3 Sv (30 rems)	Workers	Lens of eye
50 mSv (5 rems)	Workers	Uniform irradiation of whole body
5 mSv (0.5 rem)	Individual members of the public	Whole body
50 mSv (5 rems)	Individual members of the public	Any one organ or tissue including skin and lens of eye

(30 rems) in a year, as indicated in Table 2. These limits apply irrespective of whether the tissues are exposed singly or together with other organs, and they are intended to constrain any exposure that fulfills the limitation of stochastic effects.

For stochastic effects the ICRP's recommended dose limitation is based on the principle that the risk should be equal whether the whole body is irradiated uniformly or whether there is nonuniform irradiation This condition will be met if

$$\sum_T W_T H_T \leq H_{wb,L}$$

where W_T is a weighting factor representing the proportion of the stochastic risk resulting from the irradiation of tissue (T) to the total risk when the whole body is irradiated uniformly; H_T is the annual dose equivalent in tissue (T); and $H_{wb,L}$ is the recommended annual dose-equivalent limit for uniform irradiation of the whole body, ..e., 50 mSv (5 rems).

Table 3 Tissue Weighting Factors

Tissue	Weighting factor (W_T)
Gonads	0.25
Breast	0.15
Red bone marrow	0.12
Lung	0.12
Thyroid	0.03
Bone surfaces	0.03
Remainder	0.30

The values of W_T recommended by the ICRP are given in Table 3. The value of W_T for the remaining tissues requires further clarification. The Commission currently recommends that a value of $W_T = 0.06$ is applicable to each of the five organs or tissues of the remainder receiving the highest dose equivalents and that the exposure of all other remaining tissues can be neglected. (When the gastrointestinal tract is irradiated, the stomach, small intestine, upper large intestine, and lower large intestine are treated as four separate organs.)

Although the ICRP no longer proposes separate annual dose-equivalent limits for individual tissues and organs irradiated singly, the implied values of such limits can be obtained, if required, by dividing the dose-equivalent limit by the relevant value of W_T. Such values would be subject to the limits, based on nonstochastic effects, given in Table 2.

Occupational Exposure of Women of Reproductive Capacity. When women of reproductive capacity are occupationally exposed under the recommended limits and when this exposure is received at an approximately regular rate, it is unlikely that any embryo could receive more than 5 mSv during the first 2 months of pregnancy. Having regard to the circumstances in which such exposures could occur, the ICRP believes that this procedure will provide appropriate protection during the essential period of organogenesis.

Occupational Exposure of Pregnant Women. It is likely that any pregnancy of more than 2 months' duration would have been recognized by the woman herself or by a physician. The ICRP recommends that, when pregnancy has been diagnosed, arrangements should be made to ensure that the woman can continue to work only where it is most unlikely that the annual exposures will exceed three-tenths of the dose-equivalent limits.

Dose-Equivalent Limits for Individual Members of the Public. Radiation risks are a very minor fraction of the total number of environmental hazards to which members of the public are exposed. Thus it seems reasonable to consider the magnitude of radiation risks to the general public in the light of the public acceptance of other risks of everyday life.

An example of such risks is that of using public transport. From a review of available information related to risks regularly accepted in everyday life, it can be concluded that the level of acceptability for fatal risks to the general public is an order of magnitude lower than for occupational risks. On this basis a risk in the range of 10^{-6} to 10^{-5} per year would be likely to be acceptable to any individual member of the public.

The assumption of a total risk of the order of 10^{-2} Sv^{-1} (Table 1) would imply the restriction of the lifetime dose to the individual member of the public to a value that would correspond to 1 mSv per year of lifelong whole-body exposure. Because the application of an annual dose-equivalent limit of 5 mSv to individual members of the public is likely to result in average dose equivalents of less than 0.5 mSv, provided that the practices exposing the public are few and cause little exposure outside the critical groups, the ICRP's recommended whole-body dose-equivalent limit of 5 mSv (0.5 rem) in a year, as applied to critical groups, has been found to provide this degree of safety, and the Commission recommends its continued use under the conditions specified in *ICRP Publication 26*.

in the calculation of the dose equivalent incurred by members of the public from intake of radionuclides, account must be taken of differences in organ size or metabolic characteristics of children. Data on such differences are in the report of the task group on Reference Man *(ICRP Publication 23)*.

As with workers, an increase in the average dose to members of the public could result from any large increase in the number of sources of exposure, even though each satisfactorily met the criteria of justification and optimization and caused no exposures above the recommended limits. National and regional authorities should therefore keep under surveillance the separate contributions from all practices to the average exposure of the whole population so as to ensure that no single source or practice contributes an unjustified amount to the total exposure and that no individual receives undue exposure as a result of membership in a number of critical groups.

Exposure of Populations

In these recommendations the ICRP does not propose dose limits for populations. Instead, the Commission wishes to emphasize that each man-made contribution to population exposure has to be justified by its benefits, and that limits for individual members of the public refer to the total dose equivalent received from all sources (except as already noted). The limit for irradiation of a whole population is thus clearly seen as the total reached by a summation of minimum necessary contributions and not as a permissible total apparently available for apportionment. Thus the Commission's system of dose limitation is likely to ensure that the average dose equivalent to the population will not exceed 0.5 mSv per year.

Accidents and Emergencies

Under conditions in which accidental exposures occur, questions arise as to what remedial actions may be available to limit the subsequent dose. In such cases the hazard or social cost involved in any remedial measure must be justified by the reduction of risk that will result. Because of the great variability of the circumstances in which remedial action might be considered, it is not possible for the ICRP to recommend "intervention levels" that would be appropriate for all occasions. The setting of such levels for particular circumstances is considered to be the responsibility of the national authorities. However, with certain types of accident that are to some extent foreseeable, it may be possible to gauge, by an analysis of the costs of the accident and of remedial action, levels below which it would not be appropriate to take action. The Commission's recommended limits are set at a level that is thought to be associated with a low degree of risk; thus, unless a limit were to be exceeded by a considerable amount, the risk would still be sufficiently low as not to warrant such countermeasures as would themselves involve significant risks or undue cost. It is therefore clear that it is not obligatory to take remedial action if a dose-equivalent limit has been or might be exceeded.

GENERAL PRINCIPLES OF OPERATIONAL RADIATION PROTECTION

Responsibilities for achieving appropriate radiation protection fall on the employers, the statutory competent authorities, the manufacturers and the users of products giving rise to radiation exposure, and in some cases the exposed persons. The management of an institution must provide all the necessary facilities for the safe conduct of the operations under its control. In particular, it should designate persons with special duties for protection, such as members of radiation protection teams.

It is important to distinguish between distinct types of protection standards, i.e., basic limits (dose-equivalent limits and secondary limits), derived limits, authorized limits, and reference levels.

Limits

The *dose-equivalent limits* apply to the dose equivalent, or, where appropriate, to the committed dose equivalent, in the organs or tissues of the body of an individual or, in the case of exposure of the population, to the average of one of these quantities over a group of individuals.

Secondary limits are given for external irradiation and for internal irradiation. In the case of external irradiation of the whole body, the secondary limit applies to the maximum dose equivalent in the body at depths below 1 cm. The secondary limits for internal exposure are the annual limits of intake by inhalation or ingestion.

In practical radiation protection it is often necessary to provide limits which are associated with quantities other than dose equivalent, committed dose equivalent, or intake, and which relate, for example, to environmental conditions. When these limits are related to the basic limits by a defined model of the situation and are intended to reflect the basic limits, they are

called *derived limits*. Derived limits can be set for such quantities as dose-equivalent rate in a workplace, contamination of air, contamination of surfaces, and contamination of environmental materials. The accuracy of the link between derived and basic limits depends on the realism of the model used in the derivation.

Limits laid down by a competent authority or by the management of an institution are called *authorized limits*. In general such limits should be below derived limits, although, exceptionally, they may be equal to them. Where an authorized limit exists, it will always take precedence over a derived limit.

Reference Levels

Reference levels can be established for any of the quantities determined in the course of radiation protection programs, whether or not there are limits for these quantities. A reference level is not a limit and is used to determine a course of action when the value of a quantity exceeds or is predicted to exceed the reference level. The most common forms of reference levels are recording levels, investigation levels, and intervention levels.

APPLICATION TO OCCUPATIONAL EXPOSURE

The main responsibility for the protection of workers rests with the normal chain of management in an institution possessing any radiation source that causes exposure of workers. It is necessary to identify technically competent persons to provide advice on all relevant aspects of radiation protection, both inside and outside the institution, and to provide such technical services as are needed in applying appropriate recommendations for radiation protection.

Conditions of Work

For the purposes of this article, occupational exposure comprises all the dose equivalents and intakes incurred by a worker during periods of work (excluding those due to medical and natural radiation). The scale and form of the problems of radiation protection of workers vary over very wide ranges, and there are practical advantages in introducing a system of classification of conditions of work. Conditions of work can be divided into two classes:

1. *Working Condition A*. This describes conditions where the annual exposures might exceed three-tenths of the dose-equivalent limits.

2. *Working Condition B*. This describes conditions where it is most unlikely that the annual exposures will exceed three-tenths of the dose-equivalent limits.

The value of three-tenths of the basic limits for occupational exposure is thus a reference level used in the organization of protection: it is not a limit.

The main aim of the definition of Working Condition A is to ensure that workers who might otherwise reach or exceed the dose-equivalent limits are subject to individual monitoring so that their exposures can be restricted if necessary. In Working Condition B, individual monitoring is not necessary, although it may sometimes be carried out as a method of confirmation that conditions are satisfactory.

The practical application of this system of classification of working conditions is greatly simplified by introducing a corresponding system of classification of workplaces. The minimum requirement is to define controlled areas where continued operation would give rise to Working Condition A and to which access is limited.

It is sometimes convenient to specify a further class of workplace. It is called a "supervised area" and has a boundary chosen so as to make it most unlikely that the annual dose equivalents outside the supervised area will exceed one-tenth of the limits.

There is no simple parallelism between the classification of areas and the classification of working conditions, because the classification of areas takes no account of the time spent by workers in the area during the course of the year and because conditions are rarely uniform throughout an area.

Individual workers are usually classified to simplify the arrangements for medical supervision and for individual monitoring. In principle, this can be done in terms of the class of working conditions in which they operate, but in practice it almost always must be done in terms of the areas where they work, the type of work done, and the time to be spent in the area, if this can be forecast with sufficient reliability.

Provisions for Restricting Exposure

As far as is reasonably practicable, the arrangements for restricting occupational exposure should be those applied to the source of radiation and to features of the workplace. In general, the use of personal protective equipment should be supplementary to these more fundamental provisions. The emphasis should thus be on intrinsic safety in the workplace and only secondarily on protection that depends on the worker's own actions.

Since there is no ICRP recommendation on individual monitoring in Working Condition B (i.e., where it is most unlikely that the exposure will exceed three-tenths of the appropriate dose equivalent, secondary or derived limits), it is often appropriate to use this figure of three-tenths in setting investigation levels for individual monitoring. However, for an investigation level to be useful, it should be set in relation to a single measurement, not the accumulated dose equivalent or intake in a year. In addition, the investigation level should be based on the fraction of three-tenths of the limit corresponding to the fraction of a year to which the individual monitoring measurement refers. The monitoring is associated with a single event, although not necessarily a unique one, and the choice of an investigation level depends on the expectation of the number of occasions on which similar events will occur during the year. In *ICRP Publication 10* the ICRP recommends that the investigation level should correspond to one-twentieth of the annual dose-equivalent limits, if it is assumed that events requiring a program of special monitoring may occur in relation to a single individual about six times in a year.

Although investigation levels are suitable for initiating investigations into specific situations, it may be convenient to record dose equivalents at somewhat lower levels. The ICRP recommends that the recording levels should be based on an annual dose equivalent or intake of one-tenth of the annual dose-equivalent limit or intake limit.

For the special case of monitoring of skin, two situations occur in routine practice. In one situation, for external radiation, a dose equivalent is measured by one or two dosimeters, and the results are treated as representative of the whole skin or of substantial areas of the skin. No problem of averaging then arises, and the results are related directly to the relevant dose-equivalent limit. In the other situation the irradiation results from surface contamination on the skin. Surface contamination is never uniform and occurs preferentially on certain parts of the body, chiefly the hands. However, surface skin contamination does not persist over many weeks and does not always occur again at exactly the same places. For routine purposes it is adequate to regard the contamination as being averaged over areas of about 100 cm^2. Routine monitoring for skin contamination should therefore be interpreted on this basis and the limit applied to the average dose equivalent over 100 cm^2.

In accidents or suspected accidents, more detailed information should be sought on the distribution of absorbed dose, dose equivalent, or contamination. An estimate should be made of the average dose equivalent over 1 cm^2 in the region of the highest dose equivalent. This dose equivalent should then be compared with the dose-equivalent limit. If the dose distribution is extremely nonuniform, as is that from very small particles in contact with the skin, the local distribution of absorbed dose should be assessed and used to predict possible local skin reactions. It is inappropriate, however, to relate such localized absorbed doses to the absorbed doses corresponding to the dose-equivalent limit.

Medical Surveillance

The medical surveillance of workers exposed to radiation is based on the general principles of occupational medicine. The aims are (1) to assess the health of the worker, (2) to help in ensuring initial and continuing compatibility between the health of the workers and the conditions of their work, and (3) to provide a baseline of information useful in the case of accidental exposure or occupational disease.

Workers designated as operating in Working Condition A should be given a preoperational medical examination before starting this kind of work.

Following a preoperational examination, consideration should be given to the need for a continuing surveillance of the health of workers.

The ICRP considers that, with the present dose-equivalent limits, no special administrative arrangement is appropriate for workers as far as radiation risks are concerned. In particular, no special arrangement is required with respect to working hours and length of vacation.

Intervention in Abnormal Situations

Arrangements should be made for dealing with abnormal situations, not only with respect to their detection and the assessment of dose or intake but also with respect to the form of intervention that may have to be applied. The intervention levels and the appropriate actions for limiting exposure should be the subject of operating instructions. Provision should be made for special medical surveillance and, if necessary, treatment following exposure substantially in excess of the dose-equivalent limits.

APPLICATION TO OTHER EXPOSURES

The various contributions to other exposures may be grouped into broad categories to which the general principles of protection may apply but which call for

different technical approaches. These categories are (1) exposure due to the dispersion in the environment of radioactive materials; (2) direct exposure to radiation sources used in industry, medicine, and research; (3) exposure resulting from the use in everyday life of widely distributed products containing sources of ionizing radiation; (4) exposure to natural sources of radiation and to practices in everyday life that cause an increase in the level of dose resulting from the natural background of radiation; and (5) exposure due to the use of radiation sources in teaching.

Assessment of Exposures

Application of the system of dose limitation to any practice involving such exposures requires assessment of both the individual dose equivalents and the collective dose equivalents. For the purpose of comparing individual dose equivalents with the appropriate limits, the doses from the normal natural radiation background are not included.

The dose equivalent to a specified organ or tissue in a given population group will usually be determined on the basis of a representative sample. The spread of the observed values will be an indication of the homogeneity of the sample, and thus of the group, and will provide a statistical basis for judging whether the group has been suitably defined.

It is often possible to identify population groups with characteristics causing them to be exposed at a higher level than the rest of the exposed population from a given practice. The exposure of these groups, known as critical groups, can then be used as a measure of the upper limit of the individual doses resulting from the proposed practice.

In some cases it is also useful to assess the dose-equivalent commitment or the collective dose-equivalent commitment.

These assessments require the use of models of various degrees of complexity, representing the movement of radioactive materials through the environment from the source to man. These models have to take into account the nature and the physical and chemical forms of the radioactive materials, together with their methods of release. The models then have to reflect the characteristics of the environment and of man which influence the consequent exposure of individuals and groups. To make such models detailed and realistic requires extremely complex studies involving a considerable effort, and it is reasonable in practice to adjust the magnitude of this effort to the importance of the particular problem.*

REFERENCES

1. International Commission on Radiation Units and Measurements, *Radiation Quantities and Units*, ICRU Report 19, Washington, D. C., July 1, 1971.
2. International Commission on Radiation Units and Measurements, *Dose Equivalent*, ICRU Report 19(Suppl.), Washington, D. C., Sept. 1, 1973.
3. International Commission on Radiological Protection, *Problems Involved in Developing an Index of Harm*, in preparation.
4. United Nations Scientific Committee on the Effects of Atomic Radiation, Medical Irradiation, Annex F of *Sources and Effects of Ionizing Radiation—1977 Report to the General Assembly*, United Nations, New York, 1977.

*This topic is discussed in detail in a report being prepared by ICRP Committee 4.

Attachment B

ENCLOSURE IV

FIRST MINORITY OPINION

The comments prepared by the NRC staff on EPA's proposed guidance to Federal agencies contain two recommendations in which R. E. Alexander, Chief, Occupational Health Standards Branch, Office of Standards Development, did not entirely agree.

First, the comments request recasting of Section 4.i. of the proposed guidance in a manner which would eliminate a proposed 100-rems lifetime dose limit and state instead that lifetime doses should be maintained ALARA and that workers should be instructed on the levels of risk from radiation. It is Mr. Alexander's position that the EPA's proposal for a lifetime dose limit is too stringent, while the staff majority proposal is too lax. Mr. Alexander believes that the Commission should recommend that the EPA establish a mandatory informed consent procedure which would involve considerably more than training workers on radiation risks, but which would not limit their opportunities to obtain and retain employment. The informed consent procedure would consist of notifications to workers when their lifetime risk reached a pre-set value; the workers would then make their own decisions about accepting additional radiation risks. Mr. Alexander believes this procedure to be more in keeping with the risk associated with continued annual radiation doses near the 5-rems-per-year limit. His position is developed in more detail in Section I of this enclosure.

Second, the proposed comments to EPA request that subsection 5.b of the proposed EPA guidance be deleted. This subsection states, essentially, that Federal agencies should not adopt concentration values for airborne radionuclides that are less restrictive than those currently in use. Deletion of this statement

would leave the Commission free to allow higher radionuclide concentrations in air as recommended by the ICRP. It is Mr. Alexander's position (1) that compliance with ICRP recommendations is not necessary in the United States and is undesirable to the extent that such compliance would result in less protection for workers, and (2) that the Federal government should not take action which would reduce the degree of protection currently being provided for workers when the only justification for such action is compliance with ICRP recommendations. For these reasons Mr. Alexander proposes that subsection 5.b. of the proposed EPA guidance be accepted by the Commission. His position is developed in more detail in Section II of this enclosure.

I. RISK FROM EXTERNAL RADIATION SOURCES

Summary

The EPA has proposed a lifetime radiation dose limit of 100 rems to the whole body. This constraint is described by the EPA as being necessary to limit the risk for those workers who are exposed on a long-term basis to annual doses near 5 rems per year. The constraint could result in career interference for affected workers--workers who could find difficulty in obtaining acceptable employment in nonradiation industries. Therefore, it is proposed that each worker be allowed to decide for himself/herself whether or not to accept additional risk after a limit such as 100 rems has been achieved. Under this proposal it would be necessary to establish a mandatory notification system to let affected workers know when the limit had been achieved, although no work restrictions would be imposed. It is further proposed that a risk notification system be established rather than a dose notification system. This approach would permit consideration of the number of years of life at risk following an annual dose, an important factor which would be neglected by a dose system. The approach would also permit consideration, with respect to cancer induction, of the age-dependent aspects of the dose/effect relationship.

Risk Notification System

In relatively recent developments the ICRP and EPA have recommended or proposed 5 rems per year as the limit for occupational radiation dose to the whole body. However, both of these organizations take the position that a worker actually

receiving 5 rems per year over a long period might incur a risk that would be considered high in relation to other occupational risks. The ICRP position is stated in paragraphs (101) and (102) of ICRP Publication 26:

> "Exposures consistently near the limits would be comparable with a situation where a higher-than-average risk has been identified for certain individuals in non-radiation industries."
>
> "Long-continued exposure of a considerable proportion of the workers at or near the dose-equivalent limits would only be acceptable if a careful cost-benefit analysis had shown the higher resultant risk would be justified."

The present EPA position appears on page 99 of the background report for their newly proposed guidance to Federal agencies (EPA 520/4-81-003):

> "However, a worker who received the maximum allowed annual dose every year throughout a working lifetime could accumulate a lifetime risk higher than that of average workers in the three highest risk major occupational categories not normally exposed to radiation--mining, quarrying, construction and agriculture."

The EPA position is predicated on the observation that a comparison between those maximally at risk in one industry, and those exposed to the average risk in another, is informative. Unfortunately, risk data for workers maximally at risk in industries such as mining and quarrying have not become available.

The EPA background report states on page 92 that:

> "The maximum lifetime risk of death from radiation-induced cancer allowed under the 1960 guide was estimated to fall between 3 and 6 in a hundred."

The 1960 guide established an average annual dose limit of 5 rems per year. This risk estimate, which states that 3% to 6% of workers so exposed would die of radiation-induced cancer, was based on risk factors published in the 1972 BEIR report. Using age-dependent risk factors published in the 1980 BEIR

report, the risk estimate for the incidence of radiation-induced cancer is 6.5 in a hundred for male workers exposed for a working lifetime at the rate of 5 rems per year. It is often assumed that one-half of such cancers would be fatal. Thus, for the linear hypothesis, the two BEIR reports are in essential agreement.

The ICRP bases the acceptability of its 5-rems-per-year limit on the fact that, as shown by experience, under this limit the mean (or average) annual dose is near 0.5 rems per year, an acceptable level. This position may be found in paragraph (100) of ICRP Publication 26:

> "In the case of uniform exposure of the whole body, in circumstances where the Commission's recommendations, including the annual dose-equivalent limit of 50 mSv (5 rems), have been applied, the distribution of the annual dose equivalents in large occupational groups has been shown very commonly to fit a log-normal function, with an arithmetic mean of about 5 mSv (0.5 rem), and with very few values approaching the limit. The application of the risk factors given in paragraphs 40-60 to the above mean dose indicates that the average risk in these radiation occupations is comparable with the average risk in other safe industries..."

The position of the EPA, which may be found on pages 97 and 94 of the background report, is similar:

> "...based on experience for the past 15 years, the risk of death from radiation induced cancer for the average worker is low in comparison with risks of accidental death in other occupations. For this reason we do not find it necessary or justified to lower the whole-body Radiation Protection Guide below 5 rem to provide greater protection from radiation-induced fatal cancer to the work force, taken as a whole."

Thus, it is concluded that both the ICRP and EPA accept the 5-rems-per-year limit on the rationale that experience with the limit has indicated an acceptable degree of protection for the average worker, who receives only about 10% of the limit. Neither organizations endorses 5 rems per year as a limit pro-

viding the desired degree of protection for workers exposed at that level for long periods of time.

In an effort to provide additional protection for the small group of workers who receive annual doses considerably above the average (e.g., some nuclear power plant transient workers and some medical workers), the EPA is proposing a lifetime dose limit:

> "...in order to achieve the objective of limiting maximum lifetime risks to a value comparable to average risks from other occupational hazards, a two- to three-fold reduction of the maximum lifetime dose permitted by an RPG of five rems per year is required."

According to the EPA proposal, this objective is to be achieved through management of individual worker dose accumulation in a manner avoiding lifetime doses greater than 100 rems. Although the overall objective of lowering the risk for highly exposed workers is necessary and should be achieved, several disadvantages are associated with the EPA proposal. Among these the following three are outstanding:

(1) The recordkeeping burden;

(2) Potential career interference (which could occur at a particularly disrupting time in life); and

(3) Control of dose rather than risk.

In the following discussion an alternative approach to meeting the objective is proposed; this approach would remove the final two disadvantages. It should be noted that EPA would recommend this degree of recordkeeping for the small number of highly exposed workers whether a lifetime dose limit is imposed or not.

In attempting to achieve comparability in worker safety with other industries, it does not appear essential to eliminate completely exposures at the maximum lifetime level. Mine safety regulations and procedures do not absolutely prevent all of the higher-risk tasks, such as prevention of lifetime doses greater than 100 rems would do. However, it is believed that miners in general understand the risks they are taking, and accept the risks voluntarily on an informed basis for reasons of their own. In operations involving long-term radiation exposures near the limits a comparable situation could be achieved by a system of notification. Under such a system individual workers would receive a written notification from their employers at the time the lifetime dose (or risk, as discussed below) reached a predetermined accumulated level. The notifications would explain the associated risk in sufficient detail to permit an informed decision by the worker as to whether additional occupational exposure should be accepted.

A risk notification system of this nature has the following advantages:

(1) Those workers receiving an annual dose near 5 rems per year on a long term basis would not be subjected to a sense of false security;

(2) The government would not terminate a worker's career in activities involving radiation exposure;

(3) At the worker's own, informed option, work could be performed as usual until terminated by other causes such as retirement;

(4) Workers would have the opportunity to make a change in their future occupational radiation exposure situation if they chose to do so;

(5) No one would be incurring an accumulated risk greater than the preselected value without knowing it in advance;

(6) It is likely that affected workers would make an improved effort to avoid reaching the preselected level, since it would have a special significance for them;

(7) It is likely that many employers would be more willing to endure added costs for protection in order to avoid sending such notifications; and

(8) Workers with small accumulated risks would not be affected; only the higher-risk personnel would be notified.

These advantages indicate that most of the desirable effects of a lifetime dose limit would be made available by the proposed risk notification system.

The risk notification system should employ a risk level rather than a dose level. The dose is only one component of the risk. The other two components are the risk factor (cancers per rem per year) and the number of years at risk after the dose is received. These three numbers may be multiplied together to estimate the risk for the dose received during a given year. The lifetime risk is obtained by adding all of the annual risks already incurred.

The ICRP has provided guidance regarding an acceptable, occupational lifetime risk level. In paragraph (96) of ICRP Publication 26 the following statement appears:

> "The Commission believes that for the foreseeable future a valid method for judging the acceptability of the level of risk in radiation work is by comparing this risk with that for other occupations recognized as having high standards of safety, which are generally considered to be those in which the average annual mortality due to occupational hazards does not exceed 10^{-4}."

If it is assumed that a person works in some industry for 50 years, and that the average annual risk associated with this work is 1×10^{-4}, the lifetime accumulated risk would be the product of these numbers, i.e., 5×10^{-3}. In other words, work in which 5 such people out of a thousand die as a result of their jobs is considered to have a high standard of safety, sufficiently high to use as a standard of excellence for radiation work. This number, 5×10^{-3}, could be used as the notification level for those in radiation work. The radiation risk incurred by each worker during a year would be estimated at the end of the year. This annual risk would be added to the annual risk for previous years. The risk from radioactive material deposited in the body would be included as well as the risk from external sources. As soon as the total reached 5×10^{-3}, the worker would be notified. The notice would state that, in accordance with currently accepted scientific opinion, the risk of radiation-induced cancer as caused by occupational exposures received during his/her entire working lifetime had reached a significant level. The level would be described as sufficiently high that additional exposure could place the lifetime risk in a category similar to that of occupations not considered to have high standards of safety.

A key question that arises is the notification age, i.e., under various conditions of exposure, at what age would a worker be notified that the significant risk level (5×10^{-3}) had been reached? The table below provides a few pertinent answers obtained using age-dependent risk factors for cancer incidence from the 1980 BEIR report. For this table it is assumed that the workers are

exposed until age 65, that they live to age 75 and that the risk factor is applicable to every year of life following the annual exposure.

The table presents the age at which workers would be notified if they received annual doses of 0.5, 1, 2, 3, or 5 rems. Notification ages are shown for workers who start their radiation work at ages of 20, 30 or 40 years. The table makes several significant points:

(1) For workers receiving 5 rems per year, the risk notification criterion (5×10^{-3}) is reached very quickly, even for those who do not start until age 40;

(2) For workers receiving 3 rems per year, the criterion would be reached in a relatively short period of time;

(3) Workers receiving 2 rems per year or more would receive a notification if they continued their radiation work for as long as 10 years.

(4) Workers receiving 1 rem per year would not be likely to receive a notification unless they continued in radiation work for 18 years or more.

(5) Very few workers receiving the average annual dose (about 0.5 rem) would ever receive a notification.

It appears that this risk notification system would provide ample opportunity for workers to evaluate their own risk status; it also appears that such a system is badly needed for those who receive annual doses near the 5 rems per year limit.

NOTIFICATION AGE FOR VARIOUS CONDITIONS OF EXPOSURE*

(years of age)

Starting Age (years)	Average Annual Dose (rems)				
	0.5	1	2	3	5
20	55	38	30	26	23
30	> 75	48	40	36	33
40	> 75	58	50	46	43

*Male workers

II. RISK FROM INTERNAL RADIATION SOURCES

Summary

The EPA has proposed new standards for protecting workers from airborne radioactive materials. Some of these standards would allow higher concentrations in air, but the EPA is recommending that Federal agencies continue to use present standards in these cases. The EPA rationale is that present standards are acceptable to employers, and that, under such conditions, government agencies should not take action to reduce the degree of worker protection presently afforded. It is proposed that the NRC accept this recommendation.

Recommendations for NRC Position

Using newly recommended calculational techniques (modified slightly) and data recently published by the ICRP (ICRP Publication 26, ICRP Publication 30), the EPA is proposing new guidance to Federal agencies which would significantly change the concentration of radioactive material in air that would be permitted in the workplace for most of the radionuclides of interest to the NRC and its licensees. Some concentration values would be reduced, while others would be increased. The reason for these changes is that some radionuclides have been found to present a greater risk than was previously thought, while others now appear to present less risk.

The actual risk that is being incurred by the workers is determined, of course, by the quantity and type of radioactive material taken into their bodies, rather than by current scientific opinion. If these quantities are allowed to increase,

the actual risk will increase accordingly, even though the nuclide in question may be less hazardous than previously thought. Thus a question arises as to whether, as a result of new information, increases in these quantities should be allowed.

Some health physicists believe that it is necessary to avoid governmental action that would permit higher concentration values than those presently permitted. The major reasons for this position are:

(1) The relaxation of overexposure reporting requirements. In general, licensees are very sensitive about overexposure reports and will go to great lengths to avoid them, much to the benfit of the worker. Significant relaxation of overexposure reporting requirements would result in a concomitant relaxation of protection effort on the part of the licensees. In addition, the Commission's inspectors would not be notified of many incidents that are now reportable, and would thus lose the opportunity for special investigations of breakdowns in the licensees' safety programs.

(2) Facility and process design decisions. The long-range impact of higher intake limits would lie in the area of facility design and process planning. Design and planning decisions are very dependent on the magnitude of the regulatory concentration values, and those decisions virtually dictate what the worker exposures will be for many years to come. The higher the concentration values the fewer protective features, and the higher the exposures.

(3) Practicality of present concentration values. NRC licensees apparently are having little difficulty in complying with present standards, and more permissive standards could allow increased risks to the workers with no justification other than compatibility with ICRP recommendations and, in some cases, decreases in operating costs.

(4) Present uncertainty about low-level radiation. It would not be prudent to raise limits while the Government is in the process of assessing whether the biological effects of low-level radiation are more likely to occur than previously believed, at least not without compelling justification. To relax the standards now would, to many people, have the appearance of irresponsible governmental action.

These four reasons are considered by some to be adequate justification fo ~ot increasing permissible organ doses or radionuclide intakes at this time.

Based on considerations of this nature, the EPA has included in its proposed guidance the following statement (5.b):

> "When a RIF for a specific radionuclide in a specific chemical or physical form determined on the basis of part (a) is larger than that currently in use, a value no greater than that in current use should be adopted in regulations governing work situations identical or similar to those currently in existence."

For the purposes of this discussion the acronym RIF may be used interchangeably with the term concentration value. In the Federal Register notice proposing the new guidance (46 FR 7836) the following statement appears in support of this part of guide.

> "We believe that, for existing applications, experience gained over the past two decades shows that current values can be reasonably achieved. Accordingly, in cases where the RIF for any specific radionuclide would be increased under the proposed guidance, we recommend that the value adopted in regulations governing existing applications be no higher than that now in use."

From these quotations it is apparent that the EPA does not believe that it would be appropriate for Federal agencies to take action that would increase the concentration values where they are presently being applied. However, the higher concentration values could be used in new applications. Thus, it is the position of the EPA that, where employers have accepted present concentration values, higher values should not be allowed, with associated higher risks, in order to comply with new calculational techniques and data.*

It is proposed that the NRC accept the EPA position and refrain from raising any of the concentration values presently appearing in 10 CFR Part 20. There appears to be little or no evidence that compliance with the present concentration values is a source of serious concern among NRC licensees. The licensees have been able to conduct their businesses under these constraints for many years. And, from the regulatory viewpoint, the only apparent justification for relaxing constraints, at the expense of worker health protection, is compatibility with ICRP recommendations.

*The views of the Utility Workers Union of America are given in the attached letters to EPA.

UTILITY WORKERS UNION OF AMERICA

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815 SIXTEENTH STREET, N.W.
WASHINGTON, D.C. 20006
(202) 347-8105

May 27, 1980

Mr. Douglas M. Costle, Administrator
U. S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Costle:

The Utility Workers Union of America, AFL-CIO, represents the workers in a number of the nuclear generating plants in various parts of the United States. As the Representative of these workers we are very concerned about the exposure to radiation involved in such work.

We recently became aware that the Office of Radiation Programs - Federal Guidance Branch of the Agency has developed a proposed (draft) - Standards for Occupational Exposures to Ionizing Radiation.

We have not had the opportunity to review the draft of the proposed standards and we have been informed that such a review is not possible as the draft must be reviewed and approved by the department heads responsible for this activity. Therefore, our information might be considered as hearsay at this point but we have been able to obtain some general information from a source we consider to be most reliable and the information we do have has raised very serious concerns.

It is our understanding that the standards drafted by the EPA staff follows the new ICRP 26 approach for establishing airborn radioactivity limitations in the work environment, with some minor exceptions. The adherence to the concept

expressed in ICRP 26 would permit and, in all probability, result in increased exposures to airborn radioactivity for nuclear workers in the generating plants as well as other licensed facilities and, if I understand the implication of the EPA's role in setting such standards, the application would include other facilities where radiation is involved even if not licensed by the NRC.

We have, therefore, within our own Councils, arrived at a conclusion that the standards being proposed by the EPA staff will increase exposure to airborn radioactivity greater than is presently permitted by 10 CFR Part 20. Until we are shown clearly in the proposed standards that such is not the case, we will proceed on the assumption that our conclusions are correct.

While we are understanding of the fact work can be performed in nuclear facilities in such a manner that workers are reasonably protected from serious harm from low levels of radiation, over the many years we have represented nuclear workers, we have accepted the standards in 10 CFR Part 20 as adequate. We have never agreed to or accepted the fact the exposure levels were too low and we do not now feel that the existing standards are set too low. We would oppose most vigorously any attempt to permit increases in the levels of airborn radioactivity in work areas where our members would be required to perform.

Since there is no overriding consideration either economically, technically, or scientifically to suggest a necessity for increasing the permissible levels of airborn radioactivity we implore you as the Administrator and we implore the Environmental Protection Agency to re-examine the proposed standards and make appropriate revisions to take full advantage of the ICRP 26 approach in those areas where worker protections are strengthened and to reject those areas where protections would be reduced or weakened.

As an organization having substantial responsibility and interest in standards applicable to workers in the nuclear industry, we respectfully request that we be given the opportunity to review the proposed standards and possibly arrange a meeting with the EPA staff to more thoroughly and explicitly explain our position on the matters expressed in this letter.

Sincerely,

Marshall M. Hicks

Marshall M. Hicks
National Secretary-Treasurer

MMH:njs
opeiu #2
CC: UWUA Executive Committee
AFL-CIO Department of OSHA
IBEW - AFL-CIO
IUD OSHA Director
OCAW, AFL-CIO
R. E. Alexander, NRC

UTILITY WORKERS UNION OF AMERICA

Affiliated with A.F.L.-C.I.O.

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PRESIDENT

JAMES JOY, JR.
EXECUTIVE VICE PRESIDENT

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July 17, 1980

Mr. David G. Hawkins, Assistant Administrator
United States Environmental Protection Agency
Office of Air, Noise and Radiation
Washington, D. C. 20460

Dear Mr. Hawkins:

On May 27, 1980, I wrote to Mr. Costle, Director of the Environmental Protection Agency, to register the concerns and objections of the Utility Workers Union of America to the EPA's proposed draft for "Standards for Occupational Exposures to Ionizing Radiation".

It is apparent from the response received from you, dated June 20, 1980, that the objections stated in our communication were not understood as we had meant them to be. At the time we submitted the objections and voiced our concerns we felt that we did have a full and complete comprehension of changes that would be effected. We had studied ICRP 26, including the statement from the 1978 Stockholm meeting. And, in addition, we had considered other information and had reviewed our understandings with others.

We have accepted without disagreement that the conclusions reached by the International Commission on Radiological Protection are the best scientific knowledge available. We did not, and do not, argue with the conclusion that it is possible in the case of certain radionuclides to allow or permit an increase in the "Maximum Permissible Concentrations" without surpassing the dose limit to the whole body. Our argument and objections were derived from the fact we see no need whatsoever to make such increases in the MPCs when it has already been clearly

proven that we have the technical and engineering capability to maintain the lower levels for the maximum permissible concentrations because it has been done for a number of years. To merely raise the MPCs because it has been deemed possible without surpassing the whole body dose limits appears to be totally ridiculous.

We attempted to make the point that the MPCs should not be raised for any radionuclide unless there was a clearly established and compelling economic, technical or scientific necessity to do so. If it were not possible, for instance, to establish an environment at the limits previously established, then some consideration for raising the MPCs seems reasonable and your analysis may have some merit.

However, the idea that such limits should be increased based on nothing more than a newly reached conclusion that such increases will not surpass the arbitrarily established whole body dose limit is contrary to the basic "objectives of Radiation Protection" as stated in ICRP 26.

> "(9) The aim of radiation protection should be to prevent detrimental non-stochastic effects and to limit the probability of stochastic effects to levels deemed to be acceptable. An additional aim is to ensure that practices involving radiation exposure are justified.
>
> (12) (b) All exposures shall be kept as low as reasonably achievable, economic and social factors being taken into account."

There can be no question that the previously established Maximum Permissible Concentrations are "reasonably achievable" and a standard that would permit or allow higher concentrations are not "justified".

Mr. Hawkins
July 17, 1980

It is hoped these additional comments make the position and objections of the UWUA clearer and the EPA will be convinced it should take a closer look at its proposed standards and failing to find justification for raising the standards for "maximum Permissible Concentrations" a conclusion will be reached to retain the previously established limits.

Sincerely yours,

Marshall M. Hicks

Marshall M. Hicks
National Secretary-Treasurer

MMH:njs
opeiu #2
CC: UWUA Executive Committee
AFL-CIO Department of OSHA
IBEW, AFL-CIO
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ENCLOSURE V

SECOND MINORITY OPINION

Certain important issues are not addressed with sufficient clarity by the staff position in the opinion of C. A. Willis, Leader, Applications Section, Effluent Treatment Systems Branch, NRR. Consideration of these issues emphasizes the importance of careful evaluation and justification before making fundamental changes in the bases for the radiation protection regulations. These issues are addressed briefly in this enclosure.

1. There is no health and safety justification for changing the bases for the radiation protection regulations. Neither the EPA nor the ICRP have contended that a problem exists. Further, according to the most authoritative determinations available, the occupational risks from radiation are far less than the risks from other carcinogens (Table 1).

2. No major reduction in occupational radiation exposure or risk can be expected from changing the regulations as would be required by adoption of either the EPA proposal or the ICRP recommendations. Neither the EPA nor the ICRP has suggested that exposure reductions are to be expected. In fact, neither has offered any practical benefits from the proposed changes.

3. The only known reasons for considering a fundamental change in the radiation protection regulations are:

   (a) to make the limits consistent with current risk estimates, and

   (b) to make the U.S. limits consistent with the limits of other countries.

   These are desirable results but it is not self-evident that they provide benefits commensurate with the costs. Neither the ICRP nor the EPA has addressed this question.

Adopting the ICRP recommendations would help achieve these results. The EPA proposal would not help on either count.

4. The proposed changes in the bases for the radiation protection regulations have the potential for being very costly. NRC regulations affect tens of thousands of licensees with millions of employees and with hundreds of billions of dollars in facilities and equipment. Under these conditions even simple terminology changes can be costly; it could easily cost the NRC millions of dollars just to revise the regulations as would be necessary to use the ICRP-recommended terminology (gray, sievert, becquerel, ALI, etc.). The costs to the agreement states and to the licensees could be even more substantial. Of course, terminology changes would wreak havoc with public information programs.

The potential for increasing costs is illustrated by one feature common to both EPA and ICRP; they would reduce the air concentration limit for thorium by a factor of 50 (Table 2). This could have a major cost impact on breeder reactor programs. If such a change is necessary, it should be made explicitly so interested parties would have the opportunity to fully address the issues.

The inevitable cost of diverting scarce resources from more serious problems is particularly objectionable at this time.

It seems that no systematic effort has been made to identify the potential costs of either the EPA proposal or the ICRP recommendations. Nevertheless, there is evident potential for high costs.

Conclusion: The NRC should oppose implementation of either the EPA proposal or the ICRP recommendations without a full evaluation of the potential costs and the potential benefits.

TABLE 1

OCCUPATIONAL RISKS
(Events per year per 100,000 workers)

	Mining & Quarrying	All U.S. Industries	Trade	Radiation Exposure
Fatal Accidents[1]	63	14	6	0
Disabling Injuries[1]	5040	2460	1850	0
Delayed Effects				
Actual	readily Observable	Occasionally Observable	Not Observable	not Observable
Estimated	?	Includes 115-219 lethal cancers[2]	?	Includes 4-6 lethal cancers[3]

(1) 1976 data, from "Accident Facts, 1977 Edition," National Safety Council.

(2) Estimates from "Toxic Chemicals and Public Protection, A Report to the President by the Toxic Substances Strategy Committee," Council on Environmental Quality, Government Printing Office, May 1980. Minimum estimates are 6 to 29.

(3) Estimates from BEIR-III, 1980, assuming an average radiation worker exposure rate of 0.5 rem/yr; exposure at the limit, 5 rems/yr, would yield an estimate of from 37 to 63 lethal cancers per year per 100,000 workers.

TABLE 2

COMPARISON OF THE AIR CONCENTRATION LIMITS OF
10 CFR 20 TO THOSE OF ICRP-30 FOR 40 HOUR/WK OCCUPATIONAL EXPOSURE

Nuclide	Limit,* Ci/m^3 DAC (ICRP-30)	MPC (10 CFR 20)	Ratio DAC/MPC
H-3	2E-5	5E-6	4
P-32	2E-7	7E-8	3
Mn-56	5E-6	5E-7	10
Co-60	1E-8	9E-9	1
Kr-85	1E-4	1E-5	10
Sr-90	2E-9	1E-9	2
Zr-95	5E-8	3E-8	2
Nb-95	5E-7	1E-7	5
Mo-99	5E-7	2E-7	2
Te-127m	1E-7	4E-8	2
Te-132	8E-8	1E-7	0.8
I-131	2E-8	9E-9	2
Cs-137	5E-8	1E-8	5
Ce-141	2E-7	2E-7	1
Po-210	3E-10	2E-10	1
Ra-226	3E-10	3E-11	10
Th-232	5E-13	3E-11	0.02
U-235	2E-11	1E-10	0.2
Pu-239	2E-12	2E-12	1
Am-242	3E-8	4E-8	0.8
Cm-244	5E-12	9E-12	0.6
Cf-251	2E-12	2E-12	1
U-238	2E-11	7E-11	0.3

*In each case the lowest limit is given; the other chemical forms have higher or equal limits.

ENCLOSURE VI