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RADIATION STANDARDS FOR OCCUPATIONAL WHOLE BODY EXPOSURE

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I. Introduction

This Report is written in support of a petition by the Natural Resources Defense Council (NRDC) to the Nuclear Regulatory Commission (NRC) requesting a reduction in the maximum permissible occupational whole body radiation exposure. The present standards for occupational exposure are based on still current recommendations of the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP) adopted in 1958 and 1959, respectively. The NRDC petition and this Report were prompted by consideration of the latest information on the biological effects of radiation. This information indicates that the biological effects are greater than was assumed in 1958 and 1959 when the existing standards were recommended.

The latest data have been reviewed by a committee of the ICRP and by the BEIR Committee of the U.S. National Academy of Sciences (NAS).[1,2] The BEIR Committee was principally concerned with the exposure of the general population

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1/ ICRP Publication 14, Radiosensitivity and Spatial Distribution of Dose, Reports Prepared by Two Task Groups of Committee 1 of the International Commission on Radiological Protection, Pergamon Press, Oxford, 1969.

2/ NAS-BEIR Report, National Academy of Sciences, The Effects on Populations of Exposure to Low Levels of Ionizing Radiation. Report of the Advisory Committee on the Biological Effects of Ionizing Radiation (BEIR Report), Washington, D. C., November, 1972.

and, in this regard, indicated that the existing exposure standard was unnecessarily high.[3/] The ICRP Committee, while declining to make any recommendations, presented a calculation to demonstrate how the new data on the biological effects of radiation could be used to lower the existing whole body exposure standards by a factor of ten.[4/] The reduction requested in this Report corresponds closely to this factor of ten in the ICRP Committee analysis.

In January, 1971, while not recommending an overall change, the NCRP recommended that the occupational exposure of pregnant women be limited to one tenth the present exposure limit.[5/] The reduction requested in this Report would also fulfill this NCRP recommendation.

In the following section of this Report, we shall present an analysis of the risk of somatic and genetic injury at the current maximum permissible exposure limit and compare this risk with those encountered in other occupations. This analysis will serve to indicate that the exposure limit is too high. In Section III, we shall present our requested modifi-

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3/ Ibid., p.2.

4/ ICRP - Publication 14, op. cit., Appendix IV.

5/ NCRP Report No.39, Basic Radiation Protection Criteria, National Council on Radiation Protection and Measurement, Washington, D. C., 1971, pp.92-93.

cations of the exposure limits and an analysis of the reduced risk associated with these new limits. In the final section, we shall indicate how these requested reductions relate to the recommendation and suggestions of the ICRP, NCRP, and the NAS Committee on the Genetic Effects of Atomic Radiation.

II. Radiation Induced Risk at the Existing Occupational Whole Body Dose Limit

The latest and most comprehensive review of the biological effects of radiation on man is the NAS's 1972 BEIR Report. The BEIR Committee reviewed both the somatic and genetic risk associated with exposure to low levels of ionizing radiation. We shall discuss first the somatic and then the genetic effects.

A. Somatic Effects

Table 1 summarizes the BEIR Report estimate of the excess annual cancer and leukemia deaths per million people assuming whole body exposure to 5 rem/year (the current occupational standard).[6/]

6/ NAS-BEIR Report, *op. cit.*, p.170.

Table 1

Calculation of the excess annual number of cancer deaths for individuals exposed from 20 to 65 years of age

	ABSOLUTE RISK MODEL		RELATIVE RISK MODEL	
Exposure Conditions	Excess Deaths Due to:		Excess Deaths Due to:	
	Leukemia	All Other Cancer	Leukemia	All Other Cancer
10^6 people: 5 rem/yr.	81	(a) 300	181	(a) 601
		(b) 336		(b) 746

(a) 30 year plateau
(b) lifetime plateau

(Plateau region = interval following latest period during which the risk remains estimated).

Source: NAS-BEIR Report, p.170.

The risk estimates in Table 1 incorporate the assumption that the million people have an age and sex distribution identical to that of individuals 20 years and older in the U.S. population (1967 statistics). These figures do not represent a 20 year old individual's chance of eventually dying of radiation induced cancer(assuming exposure at the 5 rem/year limit). This chance can, however, be calculated by using the overall mortality rate for individuals over 20 years of age. This death rate in 1973 was 1500 deaths per 100,000 population. Hence, if this rate is divided into the frequency of cancer deaths given in Table 1, the chance of a worker, exposed at

5 rem/year from age 20, dying from radiation induced cancer is calculated to be from 1 in 16 to 1 in 40. We believe this level of risk is excessive.

A means of illustrating the excessiveness of the radiation risk to workers exposed at the maximum permissible dose rate is to compare this risk with the fatality rate associated with other occupations. This comparison is given in Table 2.

Table 2

Fatality Rate by Occupation

Occupation	Yearly Fatality Rate
Radiation Worker - exposed at the current maximum permissible dose rate [a] (from Table 1)	1 in 1000 to 1 in 2600
United States (1973)[b]	
All Industries	1 in 6000
Mining and Quarrying	1 in 900
England and Wales [c]	
All Occupations (males)	1 in 5000 to 1 in 10,000

a Due to cancer induced by occupational whole body exposure (at 5 rem/yr.) only.

b National Safety Council, Accident Facts, 1974 edition, 1974, p.23.

c Decannial Supplement for England and Wales, Registrar General's 1949-1953. Occupational Mortality. Part III, Vol.2. HMSO London (1958) as referenced in ICRP Publication 8, p.60.

In making the above comparison, we believe that the upper limit of the radiation induced risk should be used. The BEIR Committee cautioned that its estimate may be too high or too low.7/ One reason for suggesting that it is too low is that the linear hypothesis is used as a basis for extrapolating from high dose-high dose rate data to low dose-low rate situations. Recent evidence suggests that the linear hypothesis may underestimate the effect of low dose-low dose rate irradiation. The latest information has been summarized by Dr. Karl Z. Morgan who concluded:

> Frequently in the literature it is stated that the linear hypothesis is a very conservative assumption. During the past few years, however, many studies have indicated that this probably is not true in general and that at low doses and dose rates somatic damage per rad (and especially that from α-irradiation) probably is usually greater than would be assumed on the linear hypothesis.8/

Thus, there is little justification for relying on the lower estimate of the radiation induced risk and prudent health practice would indicate that the upper limit should be used. When this is done, inspection of Table 2 indicates that

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7/ Ibid., p.90.

8/ Morgan, Karl Z., Suggested Reduction of Permissible Exposure to Plutonium and Other Transuranium Elements, Journal of American Industrial Hygiene, August, 1975.

the estimated radiation exposure risk corresponds to that associated with mining and quarrying, a risk that is acknowledged to be far too high. The radiation exposure risk exceeds the average occupational risk by six fold. In this report, we are proposing a reduction in the risk of radiation induced cancer at the maximum allowable whole body exposure by a factor of 6 together with the request that the exposures be kept as far below the proposed new limits as is practicable. In making the above comparison and proposing this reduction, we do not mean to imply that all radiation workers are exposed to the maximum level of the current standards. We only mean to imply that the current exposure standard is an inappropriate guideline against which to apply the as-low-as-practicable rule.

It could be argued that it is not appropriate to set the maximum exposure limit at a level that corresponds to the average occupational fatality rate because the limit applies in practice only to the most exposed individuals. But it is precisely these most exposed workers about whom we must be concerned, and we see no reason why the nuclear industry should subject its workers to an above-average risk, certainly not when that risk is comparable to that in the mining and quarrying industry. Moreover, we believe this approach is appropriate because radiation workers are also subject to normal non-radiological occupational hazards, and hence the average risk in the industry will still be above the average for all occupations even with the adoption of our proposed changes. Thus, it would even be reasonable to argue that the risk of radiation induced cancer should be further reduced. Consequently, we see no justification for a higher risk, particularly since the above estimate of the cancer and leukemia risk does not include the additional risk associated with radiation induced genetic damage.

B. Genetic Effects

The BEIR Report estimated that the total incidence of all identified serious genetic diseases due to 5 rem per generation to a population of 1 million would be between 300 to 7,500 per year at equilibrium.[9/] In addition, the BEIR Report estimated that this same exposure at equilibrium would eventually lead to an increase of between 0.5% and 5% in the ill health of the population.

The approach for estimating the genetically significant dose (GSD) is to use that exposure accumulated by age 30. The existing exposure limit would allow a worker exposed at 5 rem/year from age 18 to accumulate a dose of 60 rem by age 30. Hence, based on the BEIR Report estimates

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9/ NAS-BEIR Report, *op. cit.*, p.51.

above, if one million workers were exposed from age 18 at the current 5 rem/year limit, between 3,600 and 90,000 identified serious genetic disease and a significant increase of ill-health would show up in the progeny of these workers, assuming an average of 2 children per worker. The increased incidence in ill-health would be equivalent to between 6% and 60% of the incidence in a population of 1 million, e.g., the first generation. This genetic risk can be compared with the somatic risk to the workers themselves. Thus, an individual worker exposed at 5 rem/year from 18 to 65 years of age would incur an additional risk of fatal cancer between 1 in 16 and 1 in 40, and an additional risk of between 1 in 10 and 1 in 300 that one of his progeny will incur a serious genetic defect. In terms of the raw numbers, the somatic and genetic risks overlap quantitatively. This simple comparison of the somatic and genetic risks associated with a single worker's lifetime exposure assumes equal weighting of the hurt or suffering associated with the somatic and genetic damage.

The genetic risk is different in that the effect is suffered not by the workers but by their offspring and by future generations. As a consequence, one can argue that the genetic risk should be given more weight because it is not assumed by the worker but involuntarily by their offspring and by future generations. Nevertheless, the biological data indicates that the risk of genetic damage is comparable to the leukemia and cancer risk and, therefore, is also too high regardless of any special weighting that it deserves.

Again, we strongly suggest that the upper limit estimate of the genetic risk be used in this comparison. The BEIR Committee suggested caution in the use of these estimates and began its Discussion section by stating:

> A major concern of the Subcommittee is the possible existence of a class of radiation-induced genetic damage that has been left out of the estimates. By relying so heavily on experimental data in the mouse we may have overlooked important effects that are not readily detected in mice, or the mouse may not be a proper laboratory model for the study of man.10/

As if to reemphasize this, the Committee concluded this section by stating:

> We remind all who may use our estimates as a basis for policy decisions that these estimates are an attempt to take into account only known tangible effects of radiation, and that there may well be intangible effects in addition whose cumulative impact may be appreciable, although not novel.11/

There is reason to suggest that the BEIR Committee should have implied an even more cautious approach to their

10/ *Ibid.*, p.57.

11/ *Ibid.*

estimates. In the experiments of Dr. William L. Russell at the Oak Ridge National Laboratory, it was observed that the induced mutation frequency at low dose rates was about 1/3 that observed at high dose rates. The factor of 1/3 was used by the BEIR Committee. However, Dr. Mary F. Lyon, et al., have analyzed the Russell data along with additional data from experiments at low dose rates.12/ Their analysis shows that as the dose rate drops below some 0.01 r./min., the induced mutation frequency begins to increase. They conclude:

> In future estimates of the genetic hazards of environmental radiation, therefore, it would be prudent to increase this last figure to a value above that seen in mice at 0.01 r./min., for which the maximum likelihood estimate given by the data considered here is 10 X 10^{-8}.13/

The value adopted in the BEIR Report was 2.5 X 10^{-8} mutations per locus per rem or a factor of 4 lower.

Thus, once again there is little justification for relying on the lower limit estimate and prudent health practices indicate that the upper limit estimate should be employed in establishing radiation protection standards. The upper estimate of the genetic risk (1/10) is comparable

12/ Lyon, Mary F., D. G. Papworth and Rita J. S. Phillips, "Dose-rate and Mutation Frequency after Irradiation of Mouse Spermatogonia," Nature New Biology, Vol.238, July 26, 1972, pp.101-104.

13/ Ibid., p.104.

to the upper limit estimate of the somatic risk of 1/16, and this genetic risk, like the somatic risk, is excessive. When somatic risk and genetic risk are combined (on an equal weight basis), the combination suggests that the existing exposure standard is at least 10 times too high. In this Report we are proposing a factor of 10 reduction in the genetic risk and a factor of 6 reduction in the somatic risk with the additional request as stated previously that the exposures be kept as far below the proposed new limits as is practicable.

III. Proposed Action

The NRC regulations governing permissible occupational exposure levels to radiation are embodied in the Code of Federal Regulations at 10 CFR 20.101. At present these 10 CFR 20.101 regulations limit the whole body dose to 1-1/4 rem per calendar quarter (5 rem/year), except a licensee may permit an individual to receive up to 3 rem/quarter whole body dose as long as the dose to the whole body when added to the accumulated occupational dose to the whole body, shall not exceed 5 (N-18) rem where "N" equals the individual's age in years.

The objective of the proposed action is to reduce the genetic risk associated with radiation exposure at the current occupational exposure level by a factor of 10 and reduce the somatic risk by a factor of 6. To meet the objective relative to the genetic risk, it is proposed that the current regulations be amended as follows:

1. For individuals under the age of M, where M is not less than 45, the whole body radiation exposure limit shall not exceed 0.5 rem in any calendar year and 0.3 rem in any calendar quarter.

To meet the objective relative to the somatic risk, it is proposed, in addition to the above, that:

2. For individuals equal to or greater than M years of age, a licensee may permit an individual to receive up to 3 rem/quarter whole body dose as long as the dose to the whole body shall not exceed 0.5 (M-18) + X(N-M) rem, where N equals the individual's age in years, and X is calculated to reduce the cumulative somatic risk by a factor of 6 below the cumulative somatic risk associated with exposure at 5 rem/year from age 18. It is proposed that the value of X be calculated using the relative risk model as described more fully in the BEIR Report.[14/]

14/ NAS-BEIR Report, *op. cit.*, p.171. It is proposed that the plateau region, *i.e.*, the interval following the latest period during which the risk remains elevated, for cancers other than leukemia be taken as the lifetime of the individual. The relative risk model with the lifetime plateau assumption gives the upper limit estimate of the risk.

It is further requested that:

3. The NRC institute hearings to determine the as-low-as-practicable extent to which the exposure can be maintained below the proposed new regulations.

The effect of these proposed changes will be to reduce the genetic risk from occupational radiation exposure at the limiting value by a factor of 10 to about 1 in 100 and reduce the risk associated with the induction of fatal cancers to about the same level. Again, it should be recognized that the ordinary occupational risks and the risk associated with other than whole body irradiation must be added to these whole body radiation risks. Nevertheless, the whole body radiation risk is still quite large and therefore, it is essential to maintain the actual exposures as far below these proposed new limits as is practicable.

IV. Additional Justification

The BEIR Committee of the NAS reviewed the more recent data on the biological effects of radiation. They were concerned mainly with the exposure of the general public. In this respect the Committee concluded that the current Radiation Protection Guide was unnecessarily high, [15/] a conclusion

15/ NAS-BEIR Report, *op. cit.*, p.2.

which in our judgment should be equally applicable to occupational exposure standards.

A Committee of the ICRP in 1969 reviewed the same material that formed the basis for the BEIR Report and indicated that the somatic effects of radiation were 5 to 6 times worse than was estimated previously. The ICRP made no recommendations relative to the exposure standards; rather, it stated:

> The choice between no change and a partial and tentative revision will depend, so it seems to us, not only on a scientific assessment of evidence, but also on practical considerations, such as the general desirability of stability in the recommendations over a period of years. The balance between practical considerations and incomplete scientific evidence is a matter for judgement outside the Task Group's frame of reference. Nevertheless, it seemed useful to give an example in Appendix IV of how our conclusions about relative tissue sensitivity to cancer induction by radiation might be used as a basis for setting dose limits for individual tissues and organs and perhaps for the whole body.16/

16/ ICRP - Publication 14, *op. cit.*, p.33.

In Appendix IV, the Committee analysis indicated that, when the somatic and genetic effects are combined, the whole body exposure limit should be reduced by a factor of 10. Thus, the changes proposed here are in accord with this ICRP Committee analysis.

Both the ICRP and NCRP have recommended that special consideration should be given to pregnant and fertile females. In fact, in January, 1971, the NCRP recommended:

> During the entire gestation period the maximum permissible dose equivalent to the fetus from occupational exposure of the expectant mother should not exceed 0.5 rem.17/

The changes proposed in this Report would in effect accomodate this recommendation of the NCRP.

The AEC, while acknowledging the greater sensitivity of the fetus, did not amend the dose limiting sections of the Commission's regulations (10 CFR 20). So far as pregnant or fertile women are concerned, the AEC noted difficulties in sex discrimination, right-to-work and right-to-privacy as reasons for not changing the limits.18/ The change proposed here, since it applies to both men and women below the age of 45 eliminates these difficulties.

In further justification for not changing the dose limits for pregnant and fertile women, the AEC stated in its

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17/ NCRP Report No.39, op. cit., p.92.

18/ Federal Register, Vol.40, No.2, Friday, January 3, 1975, pp.799-800.