UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

FEB 26 1979

Dr. Dade W. Moeller
Member Committee 4
International Commission on Radiological Protection
Harvard University School of Public Health
Kresge Center for Environmental Health
665 Huntington Avenue
Boston, Massachusetts 02115

Dear Dr. Moeller:

By letter dated June 30, 1978, you invited Mr. Robert E. Alexander, Chief, Occupational Health Standards Branch, NRC, among others, to provide identification of those recommendations contained in ICRP Publication 26 "which may be difficult to implement in practice." A comparable invitation was extended to all members of the Health Physics Society by an announcement published in the Health Physics Society NEWSLETTER, August 1978. I am aware that Mr. Alexander has submitted individual comments in response to those invitations.

Enclosed are comments that reflect the coordination of considerations by the several Offices within NRC. The enclosed comments do not reflect formal consideration by the Commission. No proposed amendments to the Commission's regulations have been recommended to the Commission by the staff to implement the recommendations in ICRP Publication 26. The ICRP recommendations are under study, but implementation has been delayed pending resolution of the problem areas identified in the enclosed comments. Note, also, that the Environmental Protection Agency has not yet provided any changes to the (Federal Radiation Council) guidance on radiation protection to Federal agencies as a result of the publication of ICRP 26. We anticipate the development of proposed amendments to NRC regulations soon after the new EPA guidance is issued.

Sincerely,

(Signed) Lee V. Gossick

Lee V. Gossick
Executive Director for Operations

Enclosure:
Comments

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Enclosure A

RECOMMENDATIONS IN ICRP PUBLICATION 26 THAT MAY BE DIFFICULT FOR THE NUCLEAR REGULATORY COMMISSION TO IMPLEMENT IN PRACTICE

Change in Internal Dose Standards

The United States Nuclear Regulatory Commission (NRC) regulations regarding exposure to radioactive materials, as set out in Title 10, Code of Federal Regulations, Part 20, are expressed in terms of intake. They are based on the calculated committed dose equivalent to the "critical organ." For example, iodine intake is limited so that it does not result in a dose greater than 300 mSv (30 rems) to the thyroid in a year, at equilibrium, with no consideration being given to the lower doses received by other organs or the whole body.

The control procedure recommended in ICRP Publication 26 would limit internally committed dose equivalent on the basis of overall risk to several affected organs. This risk must be no greater than that associated with the recommended external whole-body dose standard. In order to calculate the concentration value for an airborne radionuclide, the committed dose equivalent to each of the several organs is determined, each such dose is weighted by a factor W_T according to the relative risk, and the results are added. The sum must be less than 50 mSv (5 rems) whole body equivalent risk per year and the (unweighted) committed dose equivalent to

each organ must be less than 500 mSv (50 rems) per year. This technique recognizes that a given radionuclide may contribute dose to a number of organs and provides a mechanism for summation of those contributions. The technique also provides a mechanism for summing the doses that would be received in the event that a number of different radionuclides are taken into the body. Most importantly, this technique provides for summation of "risk" due to internal and external dose. The dose limits for stochastic effects are based on summed risks. In principle, we consider this approach useful and logical.

The relative risk factors W_T are based on new biophysical data which are to be presented in subsequent ICRP publications. In the absence of the detailed biophysical data (discussed below), it is difficult to determine whether the procedure recommended in ICRP Publication 26 is more or less conservative than current NRC requirements for control of internal dose commitment. It appears that the effect of the ICRP recommendations could be to increase slightly the amount of many radionuclides that may be taken into the body. Such a change seems unwise at a time when present limits are achievable and the numerical values of risk associated with exposure to ionizing radiation are uncertain.

We do not expect the impact of this change to be great in the working areas. However, the need to calculate committed dose equivalent and total risk, rather than MPC-hours or intake will create problems. We believe that many NRC licensees may not have the technical capability to perform the required calculations and probably would have to be provided extensive

guidance or have to hire someone to perform the work for them. It may be feasible to incorporate the recommendations into our regulations in a manner that would permit the continued use of intake or MPC-hours by these licensees. Presumably such use could be somewhat more restrictive than the ICRP recommended action. Further, depending on the guidance that may be developed for Federal agencies in the United States by the Environmental Protection Agency and the resulting implementing amendments to 10 CFR Part 20 of our regulations, we anticipate that these ICRP recommended actions may require significant increases in air sampling, in bioassay programs, and in record keeping.

In the procedure where W_T values are estimated by summing all organ risks and normalizing this total to 1.0, adjustments may be required in the future on the basis of new risk assessments or new risk estimates for organs not prevously considered. If these W_T values are internal to the calculations of the annual limits of intake (ALI), the ALI values may not be readily modified to accommodate such changes. Also, the risks underlying the W_T values are primarily the induction of fatal cancers. For thyroid irradiation, the low mortality rate may not be an adequate measure of the detriment. Further, only about half of all cancers are fatal; thus, postulated nonfatal cancers constitute a substantial additional risk.

Considerable concern has been expressed regarding the societal acceptability of certain implied organ dose limits which may be derived using the weighting factors. As noted above, those factors appear to allow increased

dose to certain organs, when irradiated individually, which in practical application does not appear necessary. It has been suggested that the biophysical data being prepared by ICRP should be used to derive values for annual intake or limiting concentrations in air that would result in annual committed dose equivalents no greater than those currently permitted. In view of the ability of the industry to meet the existing radiation standards, and the continuing question as to the risk associated with the doses at the existing standards, it would appear unwise to implement less restrictive control values.

Concern has been expressed about the availability of new biophysical data on some (large) fraction of the nuclides that may be in use. We feel that all of these data must be available to the public prior to the promulgation of NRC regulations implementing the ICRP Publication 26 recommendations.

Summation of External Dose and Internally Committed Dose Equivalent

Because of the technical difficulties involved, the regulations in 10 CFR Part 20, give one set of dose-limiting standards for exposure to radioactive materials (§ 20.103, in terms of intake or MPC-hours) and another for external dose (§ 20.101), with no provision or requirement for summation. ICRP Publication 26 provides a technique for the summation of external dose and the weighted internally committed dose equivalents and recommends one limit for the sum. This change is very desirable in principle. However, based on experience and the information available to us at this time, it appears that this change will be relatively unimportant from the

standpoint of limiting the activities of individual workers. Apparently few workers receive significant doses from both external and internal exposure. However, a potential problem could develop in the implementation of the recommendation into the regulations. Again, the potential problem is one of added burden on licensees of additional monitoring (air sampling and bioassay), additional capability for personnel needed to perform the calculations and summations, and additional record keeping.

ICRP Publication 26 recommends that records be kept only of those doses that exceed 10% of the annual limits. The use of such a criterion for the recording of daily, weekly, or even monthly accrual of external dose and internally committed dose equivalent would neglect a very high percentage of doses that are relatively uniformly distributed over time. Additional guidance is needed regarding increments of dose that may be neglected from day-by-day records.

The regulations in 10 CFR Part 20 (§ 20.202) currently require the provision of monitoring equipment if it is likely that an individual will exceed 25% of specified quarterly standards, i.e., 1/16th of the annual dose standards for external exposure. When assessment of an individual's intake of radioactive material is necessary, the regulations (§ 20.103(a)(3)) provide that intakes less than those that would result from inhalation for 2 hours in any one day or for 10 hours in any one week at MPC need not be included, provided that for any assessment in excess of these amounts the entire amount is included.

Deletion of Quarterly Dose Limiting Standards

ICRP Publication 26 does not recommend any quarterly dose limitations. Informed members of the scientific community believe that there is little or no biological advantage, except for an embryo or fetus, in limiting the dose rate for annual doses on the order of 50 mSv (5 rems). However, we are concerned that, in the absence of quarterly limits and the associated regulatory overexposure reporting requirements that give early indication of possible loss of control by a licensee and the opportunity to require correction of an undesirable situation, a potentially inadequate safety program may be allowed to continue for a year or until a routine inspection occurs. Also, the absence of quarterly limits, while providing additional flexibility to licensees to use their workers, increases concern for the potential overexposure of transient and moonlighting workers during multiple employments.

ICRP Publication 26 would permit planned special exposures resulting in doses of up to 100 mSv (10 rems) whole body or equivalent provided that the situations occur infrequently, that only a few workers are so exposed, and that no worker receives more than 5 such special exposures in the worker's lifetime. This provision would be useful on occasion to licensees in that it would permit the kind of flexibility to use employees to accomplish essential work that involves relatively high doses that is currently available under the dose-averaging formula 5(N-18). The provision for special exposures would present complications for a regulatory agency in developing regulations and standards to implement the recommendation.

Occupational Exposure of Women of Reproductive Capacity and Pregnant Women

Paragraph (115) of ICRP Publication 26 states that when women of reproductive capacity are occupationally exposed to radiation within the 50 mSv (5 rems) per year dose limit, and when this dose is received at an approximately uniform rate, it is unlikely that the embryo could receive a dose of more than 5 mSv (0.5 rems) during the first 2 months of pregnancy. ICRP indicates that this will provide appropriate protection during the essential period of organogenesis. From the standpoint of a regulatory agency, it is also necessary to consider conditions in which a woman of reproductive capacity may be exposed at a very non-uniform rate, e.g., a transient worker at a nuclear power plant. Thus the ICRP recommendations appear to be incomplete.

Paragraph (116) continues by recommending that, when a pregnancy has been diagnosed, arrangements should be made to ensure that the woman can continue to work only in Working Condition B, that is, where the annual doses are most unlikely to exceed three-tenths of the annual dose-equivalent limits. The impact of these recommendations will depend on the way they may be implemented through regulatory requirements, if any. If licensees establish Condition A zones and exclude women from them during pregnancy or other times, this could have a significant impact on the employability of women and will constitute discrimination on the basis of sex. While recognizing the need to protect the embryo and fetus, the NRC has been advised by the United States Office of Equal Employment Opportunity that establishing

dose standards for women that are lower than dose standards for men would violate existing laws.

Following long and careful consideration of these matters the NRC has advised licensees to instruct women, their supervisors, and the co-workers of the risk associated with exposure to embryos and fetuses. It has also provided in Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure," the information that the Commission staff feels should be presented on this matter . The Commission has carefully avoided any differentiation between women and men in its regulations.

ICRP Emphasis on Occupational Radiation Protection

The ICRP's emphasis on occupational radiation protection does not provide sufficient guidance for application to protection of the general population. For example, the stochastic risk values in Section D do not provide guidance related to the possible variation of biological sensitivity with age. This emphasis on the adult also influences the definition of the committed dose equivalent. For infants and other nonadult members of the general population, the 50-year committed dose equivalent may not be appropriate and longer-term values may be required. Hopefully, the forthcoming annual limits of intake (ALIs) and associated uptake and retention data will permit age-dependent committed dose equivalents to be readily calculated without having to resort to the original literature.

In paragraphs (43), (60), and (80), consideration of the genetic risk is limited to the first two generations. We do not agree with the rationale for this limitation (copy enclosed) set forth in paragraph (43)(a) of ICRP Publication 27, "Problems Involved in Developing an Index of Harm." It is our opinion that the genetic risk should consider the effects that may result in all subsequent generations. The ICRP indicates that this would require doubling of the risk assigned.

SI Units

ICRP Publication 26 replaces the so-called "special units" (the rem, rad and curie) with a new set of units (the sievert, gray and becquerel, respectively). These new units are, and probably will continue to be, a source of irritation to many and will complicate communications for years. We are uncertain as to the extent of the impact of the new units, but serious concern has been expressed regarding the potential for misunderstanding and overexposure of patients in medical diagnosis and therapy.

However, it is the intent of the NRC to convert to the SI system at a rate at least paralleling that being achieved by United States industry in the various disciplines.

of a Canadian nuclear facility, and it seems likely that of the order of 50% of the full risk will be expressed following exposure at working ages. (It may be emphasized that these are age-weighted mean values. The variation of risk with the age or sex of the *individual* are discussed in paragraphs 65–67, and Table 13.)

(40) The contribution to harm by induction of malignancies includes a number of components:

(a) The 10–15 years loss of life due to fatal malignancies as discussed above (see paragraph 13);

(b) The period of illness prior to death from a fatal malignancy. The median period of survival from diagnosis to death for cancers of all sites, including leukaemia, is quoted as 26.4 months for about 7 000 patients in whom radical treatment was possible and 5.3 months in 21 000 in whom it was not, giving a value for all patients of about 11 months.[17] This figure should probably be increased slightly to express mean rather than median survival;

(c) The period of illness or disability, including any operation, in cancers that are not fatal, and the anxiety as to a recurrence of the cancer after treatment.

(41) The risk of non-fatal cancer is likely to be comparable with that for fatal cancers, the great majority being those of skin, thyroid or breast. For skin, the severity of symptoms, operation and, probably, anxiety are all likely to be relatively slight. For thyroid, the same is likely to apply to symptoms and to operation in most cases, and the risk of either substantial or prolonged clinical disability is probably comparable with the risk of fatal malignancy in this organ ($5\ 10^{-4}$ rem^{-1}). For breast, the total average frequency of non-fatal cancers is likely to be about equal to that of fatal ones ($25\ 10^{-4}$ rem^{-1}), but there will be periods of treatment in all cases and of additional disability in some of them.

(42) It is obviously impossible to give any exact weighting to the three components described in paragraph 40, but some approximations seem possible. The first component involves a 10^{-4} rem^{-1} risk of a complete loss of 10–15 years of life, and the second carries an equal risk of about 1 year's loss of health. The third probably involves an average risk in the order of $2\ 10^{-4}$ rem^{-1} of several years of disability, and of a rather higher risk of a somewhat longer period of anxiety after apparently successful treatment. It seems reasonable to suppose that most people would regard the first component as dominant in its impact, with more importance attaching to 10–15 years loss of life than to the corresponding periods of 1 year's terminal illness or substantially smaller chances of rather longer periods of temporary illness or of continuing anxiety in some cases. If so, this would suggest that the total impact of somatic effects of radiation would, as regards duration of loss of life or health, lie in the region of $1.5\ 10^{-4}$ rem^{-1}.

RADIATION-INDUCED GENETIC EFFECTS

(43) The harm attributable to genetic effects of radiation in the descendants of the exposed person depends critically upon a number of decisions which are essentially matters of opinion.

(a) In estimating the harm experienced by a worker exposed to radiation (as distinct from that contributed to the population as a whole), should account be taken only of genetic damage expressed in his children, or of that in his grandchildren also, or of that in all future generations? The worker's own experience of congenital abnormalities which

might be due to his own exposure will be limited to the first two generations. The worker's anxiety, and that of the worker's wife (or husband) will probably also be largely in regard to these generations rather than to all their posterity. In considering limits for occupational radiation exposure therefore in terms of the harm that may result, it may seem reasonable to include genetic harm expressed within the first two generations only, although of course the total harm to all generations requires to be included when the harm to the whole population resulting from occupational exposure is considered.

(b) What "weighting" would be given to harm to be expressed, not in the worker, who recognizes some personal initiative in accepting employment involving possible harm to himself, but in his offspring who may be harmed from infancy because of his exposure and without their personal choice in the matter? The possibility of such harm being expressed in his own children from their birth might clearly have a much heavier weighting with him and with his wife than would apply to equal injury expressed in himself. It might, therefore, appear reasonable to apply a weighting to each non-fatal but substantial genetic defect, which was equal to that of a loss of life from a fatal malignancy in the worker himself.

(c) Genetic abnormalities induced by radiation may:
- —if severe, cause failure of development or of implantation of the fertilized ovum;
- —be severe enough to cause abortion of a non-viable foetus;
- —permit development to a viable stage and be expressed in a liveborn child.

What relative weights should be given to these possibilities?

(44) The opinion could be held that the first two of these conditions involved a greater loss of potential life than the third, and should be given greater weighting. Equally, and perhaps more probably, the view might be taken that injury expressed and experienced in the liveborn only should be taken into account and that, to the worker or to his wife, the failure of implantation is recognized only as the missing of a menstrual period, and that an early and non-viable abortion could be regarded as the failure of a disabled life to occur.

(45) There is clearly considerable latitude for differences of opinion on these points, which require discussion. Meanwhile, however, it would be valuable to obtain estimates of the frequency with which chromosomal aberrations or point mutations are likely to be expressed in each of these, or any other, modes. It may, however, be considered provisionally that genetic injury contributes to the harm of occupational exposure essentially by such major defects as are expressed in the liveborn of the first two generations of offspring of the exposed individuals.

(46) The risk of such defects is estimated from the frequencies observed in the offspring of irradiated animals, particularly mice, with corrections to allow for the size of the human genome or, in the "doubling dose" method, for the natural frequency of hereditary defects in man. The risk rate for mice is that for defects expressed in all progeny occurring subsequent to the irradiation of fertile animals. The corresponding risks inferred for man, of 10^{-4} rem^{-1} (of serious hereditary ill-health during the first two generations,[18] is therefore that which would apply to a population of fertile individuals irradiated prior to conception of their offspring.

(47) For working populations of ages 18–65, most exposures will be received at ages at which the subsequent child expectancy is reduced, and some exposure will have no genetic impact because of the lack of children conceived subsequently; although at young ages, when the subsequent child expectancy

TABLE 10. GENETICALLY SIGNIFICANT COMPONENT OF CONSTANT ANNUAL EXPOSURE OF WORKING POPULATIONS, AGES 18–65

	Males			Females		
Age group	Relative child expectancy*	% of population	Product	Relative child expectancy*	% of population	Product
18-	0.984	7.1	7.0	0.931	17.2	16.0
20-	0.566	12.2	10.6	0.730	22.7	16.6
25-	0.584	10.8	6.3	0.401	10.5	4.2
30-	0.293	10.1	3.0	0.155	6.3	1.0
35-	0.121	9.7	1.2	0.046	6.4	0.3
40-	0.044	10.3	0.5	0.003	7.5	0.1
45-	0.015	11.0	0.2	0.001	5.9	—
50-	0.005	9.4	—	—	—	—
55-	0.002	10.0	—	—	—	—
60-	0.001	9.4	—	—	—	—
		100	28.8		100	38.2
Genetically significant fraction			0.29			0.38

*Mean subsequent child expectancy in age group, relative to value of unity at age before parenthood.

remains nearly maximal, the risk of impairment in offspring will approach the figure of 10^{-4} rem^{-1}.

The average fraction of occupational radiation exposure that is genetically significant, therefore, depends critically upon the age structure of the working population concerned, and on the age at which exposures are received. (The variation with age in the individual is discussed in a later section.)

(48) Table 10 gives values for the mean subsequent child expectancy in groups of males and females, relative to a value of unity at ages prior to parenthood. The table also gives the distribution with age between 18 and 65 of a working population (all those registered as employed in U.K. 1970[113]). The products of the percentage of this population and of the child expectancy in each age group allow the mean risk of genetic injury to be compared with the value to be expected if all workers were at ages when a full child expectancy still applied. For a population with the age structure examined, the mean risk for males would be 0.29, and for females 0.38, times the risk—of 10^{-4} rem^{-1}[111]—which would apply for complete expression of genetic effects in the first two generations of all members of the population. The estimation assumes a uniform radiation exposure with age, as appears to be approximately true, although a

TABLE 11. GENETICALLY SIGNIFICANT FRACTION OF AVERAGE ANNUAL OCCUPATIONAL EXPOSURE, AS DETERMINED BY AGE STRUCTURE OF POPULATIONS

Nation	Occupation	Fraction
Males		
U.K.	All employed	0.29
	Power generating corporation	0.21
	Nuclear plant	0.19
	Reprocessing plant, 1950	0.32
	Reprocessing plant, 1974	0.16
	Radiochemical facility	0.24
	Industrial radiographers	0.27
Canada	Power generating corporation	0.23
	Nuclear plant	0.20
Japan	Reactor operation	0.25
	Fuel processing	0.35
	Reactor maintenance	0.42
	Reactor operation	0.37
	Industrial processes	0.26
	Medical staffs	0.08
	Research and education	0.16
Females		
U.K.	All employed	0.38
	Radiographers	0.61
Canada	Nuclear plant	0.24
Japan	Medical staff	0.09
	Research and education	0.14
Australia	Radiographers	0.43
	Radiological assistants	0.39
	Nursing staff	0.39
	Nuclear medical staff	0.48

OPTIMIZATION

There are four difficulties with "optimization" that, from the staff's viewpoint, are collectively prohibitive:*

1. Selection of a dollars-per-manrem criterion would be arbitrary; the value selected would be tied inextricably to a monetary value for human life, e.g., $10,000,000 to save a life is associated with 1,000 $/manrem, $1,000,000 with 100 $/manrem, $500,000 with 50 $/manrem, etc.

2. The establishment of a dollars-per-manrem criterion by the Federal government would likely result in hazard pay for workers based on the number of rems received; this situation could promote a non-cooperative attitude from workers regarding their own protection and could lead to the substitution of premium pay for protective measures that are more expensive.

3. Whatever the value selected for the dollars-per-manrem criterion, implementation of the "optimization" procedure would eliminate the use of some protective measures that have been commonly employed by

*The term "optimization" refers, for all practical purposes, to a procedure for decisionmaking, on questions of occupational ALARA, which requires the use of a dollars-per-manrem criterion. The term was first introduced in ICRP Publication 26, although the report does not suggest a value for this criterion.

licensees for many years on a voluntary basis; in these cases, the Federal govenment would be taking regulatory action that would reduce the degree of worker protection now provided.

4. To implement the "optimization" concept, it is necessary to calculate the number of manrems that will be saved, to divide this number into the cost, and to compare the result against the dollars-per-manrem criterion. Example calculations performed by the staff have revealed (a) that a pre-selected value for the number of manrems saved may be obtained by varying the assumptions used in the calculation, and (b) that values selected in this manner for the assumptions can usually be made to appear reasonable. The "optimization" concept does not, therefore, provide a sufficiently sound technical basis for a regulatory program.