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DEPARTMENT OF RADIOLOGY Radiological Research Laboratories RARAF--Nevis



P.O. Box 21

Secretary of the Commission U.S. Nuclear Regulatory Commission Washington, D.C. 20555

Dear Sir:

I wish to make the following comments relevant to the proposed revision of 10 CFR Part 20.

- A. General Comments
- 1. Justification

While it is certainly a major obligation of NRC to protect workers and the public from the harmful effects of ionizing radiation such efforts must be tempered by the realization that radiation is a minor pollutant in the USA. Although it is not established that--apart from substantial doses incurred in accidents or in radiotherapy--exposure to radiation has failed to cause injury or death it is generally agreed that after exposures within the limits which have been in force for several decades any deleterious effects must have been small.

The proposed revision would result in quite minor dose reductions and the decrease in any deleterious effects would be small indeed. It would seem that the principles of justification and optimization which are invoked with regard to radiation exposure should also apply to regulatory actions. NRC should be expected to analyze the cost-effectiveness balance between the degree of death and suffering prevented and expenditures which it estimates to total 0.1 Billion Dollars. The result should make the following comments redundant.

2. Timeliness

A footnote on p.52000 refers to the fact that at this point the data on the epidemiology of Japanese bomb survivors are questionable. While some experts may believe that the re-analysis will not result in substantially different risk estimates, I am by no means alone in my uncertainty on the outcome. Like other sources of information the Japanese data are subject to limitations (such as the high dose rates involved) but they are of cardinal significance because of the large number of individuals exposed. Other data can be fitted with various functional relations between dose and effect but it was the Japanese data that raised

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substantial doubts regarding proportionality (especially for leukemia) by me and most other members of the BEIR III Committee.

It would seem quite inadvisable to proceed with any changes (and in particular with minimal alterations) in radiation protection standards until the A-bomb survivor data have been analyzed on the basis of a revised dosimetry.

3. Balance

There is a very serious lack of perspective if the same document expresses concern whether adult members of the public should be permitted to be exposed to levels of radiation that are a fraction of those of background, but permits exposure of the far more sensitive embryo/fetus (which hardly can be considered a radiation worker) to levels that are more than 100 times higher.

4. Validity of Assumptions

The first paragraph in section IV contains a tautology. It is not merely a "presumption" (inherent in any assumptions on the dose-effect relation) that there must be an effect at any dose if there is no threshold. The next sentence correctly acknowledges that proportionality may not be supported by the best scientific evidence but disposes of this vital point within parentheses. It is particularly appropriate to stress the uncertainties involved if there is a linear extrapolation over some 4 or more orders of magnitude.

5. Quantities

It is desirable that an official NRC document be precise not only in its legal but also its scientific terms. Perhaps the term "dose" should be eschewed also if the meaning is implied by the unit (but even that is often not the case). Frequently the term "dose equivalent" is employed when "effective dose equivalent" is meant.

ICRU has defined the deep dose equivalent index as the maximum dose equivalent at depths greater than 1 cm in a tissue equivalent sphere of 30 cm diameter. There seems no reason why this could not be employed in the document. At any rate the dose equivalent at a depth of 1 cm (the "deep dose equivalent") depends not only on body geometry but also on orientation with respect to the radiation source(s) and the adjective "maximum" would certainly be needed. The term "whole body dose equivalent" is undefined. It should also be made clear that the "dose" to an organ is to be considered the average dose equivalent in the organ.

6. Units

The SI units are being rapidly adopted by the scientific community and journals are, or will shortly be, rejecting papers in which the old special units appear. The proposed format would become rapidly obsolete. While values in terms of the old units may well be useful it would be better if they appeared in parentheses following the SI units rather than the other way around.

7. De minimis

The establishment of de minimis (effective) dose-equivalents is to be welcomed but a level of 10 μ Sv (corresponding to the effective dose equivalent received from background radiation within a few days in Salt Lake City) is very low indeed. Annual variations that are ten times larger are experienced by many (if not most) individuals of the population, not only in travel but also in local variations of terrestrial radioactivity. Since background radiation has not been shown to be correlated with deleterious effects and its variations hardly ever influence activities by the public a de minimis level of 100 μ Sv is likely to be accepted by the great majority of persons.

The arguments against a <u>de minimis</u> level that are presented on p.52014 appear to be inconsistent with statements on p.52012. Licensees should indeed not institute changes in operating procedures, and radioactive materials could indeed be widely used, if <u>de minimis</u> levels are not exceeded. On the other hand "inadequate evaluations" are obviously prohibited whether they involve de minimis levels or not.

The comments on the proposed application of <u>de minimis</u> to collective dose equivalents are contradictory. In the second paragraph on p.52014 the term "per person" indicates an <u>average</u> dose equivalent while in the third paragraph the limit is expressed in terms of dose equivalent rates and thus represents a <u>maximum</u> for any individual. The latter position if taken in § 20.304. Why should such an individual limit apply only when employed in collective dose equivalent calculations?

A <u>de</u> <u>minimis</u> limit is needed not only for the general population but also for radiation workers if only to discount doses (that are less than measurab — ith personal dosimeters) in exposure records.

8. Complexity

Fig. 1 (p.52013) refers to no less than 4 limits (plus one range) for exposure of the public (although I do not understand the reason for any difference between the lowest 2). The "reference level" is yet another regulatory complication imposed for exposures near background levels.

Contrary to assertions in several paragraphs this and various other innovations must create further requirements of reports, variances, records, etc. and thus entail substantial additional efforts and costs.

9. Q

A few years ago NCRP released the "Neutron Statement" recommending reduction of neutron exposures. A joint Task Group of the ICRP and ICRU (of which I am the Chairman) has just recommended an increase in Q and this is about to appear in an ICRU report. It in effect raises Q for neutrons of maximum effectiveness to 25 (and reduces it to 0.5 for hard gamma radiation). As an interim measure ICRP has already recommended a doubling of Q for neutrons.

No statement seems to be made on Q for alpha radiation (for which the Task Group also recommended a value of 25).

B. Specific Comments

Page Column p*

51992	3	1	To my knowledge no major scientific body has ever "inferred" a threshold for radiation injury although no "clinical effects" have been demonstrated at dose equivalents near those deemed permissible at any time. What is now called ALARA has always been urged.
52000	3	3	The statement in the last sentence is especially dubious when applied to high-LET radiation. It also conflicts with the statement in parentheses in (2) in the second column of p.52007.
52003	2	3&4	This does not seem to fit the heading X.
52007	2	3	In addition to the previous comment this also appears to be self-contradictory.
52010	1	2&3	Apart from the relatively lesser objection that the dose to the embryo/fetus could be even larger than the effective dose equivalent to the mother I consider a regulation that could permit a dose equivalent as high as 10 rem to the fetus/embryo to be quite unacceptable.
52010	1	6	Here and in other places a dose limit for the calendar year implies the possibility of receiving twice the dose in a few days. While this is unlikely to occur, it might be better to state limits in terms of the dose received in 12 consecutive months.

*Paragraph (including incomplete paragraphs).

January 31, 1986

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This review is primarily limited to scientific aspects of the proposed revision and does not extend beyond Section XVIII.

Yours sincerely,

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Harald E. Rossi Professor of Radiology

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