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ROBLEY D. EVANS
4621 EAST CRYSTAL LANE
SCOTTSDALE, ARIZONA 85253

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

Attention: Docketing and Service Branch

Subject: Comments on "Standards for Protection Against Radiation", 45 FR 18023-18026 (March 20, 1980), re 10CFR Part 20

Gentlemen:

The final paragraph of the subject notice begins with the welcome caveat "It must be emphasized that the items listed above do not represent decisions or commitments.". This, I hope, is applicable to all items in the entire notice, in spite of the possible impression that the final paragraph is only a closing remark in the section on "Areas in Part 20 That Need Improvement".

Recalling that the first comprehensive revision of 10CFR20 as published in 22 FR 548 on January 29, 1957 had been in gestation since the notice for public comment in July 1955, and recognizing the enormous complexities in the advances since then in radiobiological knowledge, the present revision is bound to be a long and complex undertaking. I am pleased and fully concur with your plan to utilize the information and guidance available through the NCRP, ICRP, and UNSCEAR, and to coordinate with the EPA, OSHA, and the FRPC. The current difficulties with BEIR III seem to have been recognized by its omission. A great deal of relevant information is "in the mill" in NCRP's Scientific Committee No. 57, on internal emitters, ably chaired by Dr. J. Newell Stannard.

Perhaps the most troublesome problems will revolve around the stated basic assumption that for radiation protection purposes "there is within the range of exposure conditions usually encountered in radiation work, a linear relationship without threshold between dose and probability of stochastic effect;" (page 18024, para. a(1)).

It will be important to temper the linear nonthreshold hypothesis with recognition of the effects of LET, protraction, and of dose rate for some stochastic end points. An unequivocal example of dose-rate effect is seen in the genetic studies by William L. Russell and others. Important well-controlled studies at the Mayo Clinic of the (nonelevated) leukemia occurrence in patients subjected to diagnostic and therapeutic low-level radiation (0 to 300 rads to the bone marrow) are in press at The New England Journal of Medicine. A clear example of distinct nonlinearity is seen in the 46-year studies of radium-burdened

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humans at MIT, and in the independent confirmation by the observations at ANL-ACRH and the continuing empirical and theoretical studies at ANL/CHR.

It is important to recall the historical origin and development of the linear nonthreshold model. This model was introduced and quantified gradually between about 1950 and 1964 in connection with biopolitical problems arising from the atmospheric testing of nuclear weapons. It was not based on radiobiological data but was chosen specifically on grounds of mathematical simplicity and manageability in population-related estimates. It had the virtue of prudence as an estimator of the upper limit of risk (not the risk) in the low-dose domain, for effects which only have been observed and partially quantified in the higher-dose domain.

A useful summary of the development and application of the linear nonthreshold model from 1950 to 1972 is given on pages 448-453 of the chapter on "Radiogenic Effects in Man of Long-Term Skeletal Alpha-Irradiation" by R. D. Evans, A. T. Keane, and M. M. Shanahan in the symposium book RADIOBIOLOGY OF PLUTONIUM edited by B. J. Stover and W. S. S. Jee, University of Utah (1972). A reprint of this chapter is enclosed for ease of reference.

This chapter also deals with the clearly nonlinear dose-response relationship for Ra-226 and Ra-228 in man. See also R. D. Evans, Health Physics 27, 497-510 (1974), J. H. Marshall and P. G. Groer, Radiat. Res. 71, 149-192 (1977), and R. E. Rowland, A. F. Stehney, and H. F. Lucas, Jr., Radiat. Res. 76, 368-383 (1978). Among more than 1700 studied persons, exposed decades ago to internal burdens of radium, no radiogenic malignancy (bone sarcoma, sinus or mastoid carcinoma) has been found at a skeletal average dose below 1000 rads as computed on the Marshall retention function (ICRP No. 20), although many would be predicted on a linear nonthreshold model and several would be predicted on a dose-squared model. Linearity is strongly excluded.

There is of course a growing body of evidence on a variety of radiobiological effects which favors a dose-square model or a combination of linear and dose-square terms. It is to be hoped that the comprehensive revision of 10CFR20 will utilize the best available radiobiological evidence. Recourse to linear nonthreshold models, with slopes appropriate to low-level protracted exposures, and metabolic retention functions appropriate to the particular radionuclide, would seem suitable as prudent estimates of the upper-limit of risk primarily in situations where sound radiobiological evidence is lacking.

While utilizing the linear nonthreshold model as a general basis EPA has stated as its policy (41 FR 28409, July 9, 1976) "in special situations to utilize the best available detailed scientific knowledge in estimating health impact when such information is available for specific types of radiation, conditions of exposure, and recipients of the exposure.". Examples of the application of this excellent policy have been difficult for me to find. In particular, it has been my opinion that the available definitive knowledge concerning the human metabolism and lifetime risks of ingestion of radium-226 and radium-228 were not utilized adequately in setting the maximum permissible level for these radionuclides in community water systems (40CFR Part 141, 41 FR 28402, July 9, 1976). This regulation also has an impact on the permissible concentrations in effluent water from such industrial sites as uranium mines and mills in the western states.

Regardless of the dose-response models chosen, I interpret the proposals on Radiation Protection Principles (page 18024, column 3) to imply that risks will be estimated on the basis of absolute risk, and not on relative risk. I heartily concur.

Dose limitations for combined internal and external exposures are mentioned on page 18025, column 2, item b(1). Here it should be recalled that the combined risks are not always simply additive. For example, the absolute risk of lung cancer per working level month (WLM) of exposure is derived primarily from epidemiological studies on uranium miners exposed to high levels of radon-222 daughter products during the early years of uranium mining in the U.S. These miners were simultaneously exposed to whole-body gamma radiation, hence the derived lung cancer risk already includes the effect on the lung of the external radiation. It would be a mistake in this case to add an assumed risk of lung cancer from whole-body external radiation because it has already been included in the derived risk per WLM.

In some other cases of combined external and internal exposure care must be taken to identify the target organs. They may be different, e.g., lung for radon daughters but red bone marrow for whole-body gamma radiation, and require special pro rataing as implied in paragraph 105 of ICRP Report No. 26. Thus ICRP regards the stochastic risk to lung as only 12% of the stochastic risk to the whole body in the case of whole-body exposure to external radiation.

Provision should be made somewhere for the rational disposal of small activities of radionuclides used in diagnostic nuclear medicine procedures. As Rosalyn Yalow and many others repeatedly have pointed out this situation is at present chaotic.

The application of ALARA principles is fine, but substantial problems could arise if quantitative guidelines are contemplated which are significantly below those which could be justified on grounds of estimated radiobiological risk factors integrated over affected populations and generations. This could be especially aggravating in cases such as the management of uranium mill tailings and other disposal problems, especially if the violation of a quantitative ALARA guideline were to become a reportable and penalizable offense. I could not be sure of the intent of item a(2) in column 2 of page 18025 in this regard.

The proposed transition from air and water MPC values to annual limits of intake (column 3 of page 18025) has my full support. Too many people are unaware that many MPC values were derived to represent averages over a time span of at least a calendar quarter, some for a year, and some for a lifetime.

With respect to the adoption of SI units I, for one, am strongly in favor of retaining our present conventional units (rad, rem, curie, WLM, MeV, etc.) as being understood and meaningful to our operational and regulatory people. For example, OSHA, the Bureau of Mines, EPA and all uranium and phosphate mining companies who deal with radon-222 and its daughter products are comfortable with the working level (WL) unit of concentration and the working level month (WLM) unit of exposure as embodied in all current Federal and State regulations. The corresponding SI unit of exposure to radon-222 and its daughter products is the joule-hour-per-cubic-meter ($J \cdot h/m^3$). The relationship between the conventional and SI units is 1 WLM = 0.0035 $J \cdot h/m^3$. It would involve much unnecessary effort and expense as well as considerable time for the U.S. mining industry and its cognizant agencies to visualize radon daughter exposures in units of $J \cdot h/m^3$.

To facilitate the acquisition of a feeling for the SI units, to aid our people in translating SI units in current ICRP publications, and to assist overseas readers who are forced to use SI units, I favor showing in U.S. documents the corresponding SI values in parentheses following the specification in conventional units.

I appreciate the opportunity to comment and will look forward to some degree of participation in this latest comprehensive revision of 10CFR Part 20.

Sincerely,

Robley D. Evans

Robley D. Evans
Professor of Physics, Emeritus
Mass. Institute of Technology

RDE:mms
enc.
xc w/enc: Robert E. Baker, NRC
William A. Mills, EPA