August 1, 1978

Note to: Accession Unit
Room 050
Phillips Building

From: **Robert B. Minogue**

Please place the attached document in the PDR using the following file and file points:

PDR File (Select one and enter number)		Additional Info (Enter if appropriate)	
Proposed Rule (PR)		ACRS Minutes No.	
Reg. Guide		Relates to Proposed Rule (PR)	
Petition (PRM)	PRM 20-6	Relates to Reg. Guide	
Effective Rule (RM)		Relates to Petition (PRM)	
ANSI		Relates to Effective Rule (RM)	
IAEA		Federal Register Notice	
		SD Task No.	
		NUREG Report	
		Contract No.	

Subject: Lowering of Occupational Radiation Exposure

~~July 5, 1978 ltr from Andrew Hull, Sec.,~~ Scientists for Enlightenment on Nuclear Sources of Energy with August 1, 1978 acknowledgement ltr from Minogue

cc:
Central Files
Secretariat

[redacted]

7810270184

SENSE 1-78

Scientists For Enlightenment
on Nuclear Sources of Energy
P. O. Box 413
Upton, N. Y. 11973

Letter to Dr. Joseph D. Hendrie
Chmn. U. S. Nuclear Regulatory Commission
Re: Implications of Recent Studies
of Low-Level Radiation for
Occupational Dose Limits

July 5, 1978

[redacted]

No. 78-1060 Logging Date 7/26/78

NRC SECRETARIAT

TO:
- ☐ Commissioner ____ Date ____
- XXX ☐ Exec. Dir./Oper.
- ☐ Cong. Liaison
- ☐ Public Affairs
- ☐ Gen. Counsel
- ☐ Solicitor
- ☐ Secretary
- ☐ ____

Incoming: Andrew Hull
From: Brookhaven National Lab.

To: Hendrie Date 7/5/78
Subject: Implications of recent studies of low-level radiation for occupational dose limits

- ☐ Prepare reply for signature of:
  - ☐ Chairman
  - ☐ Commissioner ____
  - ☐ EDO, GC, CL, SOL, PA, SECY
  - ☐ Signature block omitted
  - ☐ ____
  - ☐ Return original of incoming with response

- ☐ For direct reply*
- XXX ☒ For appropriate action
- ☐ For information
- ☐ For recommendation

Rec'd OGC, EDO 7/27/78
Date ____
Time 9:20

Cys to: RF

July 5, 1978

Dr. Joseph R. Hendrie, Chmn
U. S. Nuclear Regulatory Commission
Washington, D. C. 20555

Dear Dr. Hendrie:

It is our understanding that the Nuclear Regulatory Commission has before it a petition calling for the lowering of the occupational dose limits by a factor of 10, that is from the current basic occupational dose limit of 5 rem/year for radiation workers in NRC licensed facilities to 0.5 rem/year. Within recent months, three studies[1-3], which purport to show a greater than hitherto recognized dose-effect relationship for low-level radiation have been widely publicized and have apparently been advanced as evidence in support of the above petition. Although they are suggestive of areas which merit more careful study, we find these studies scientifically unconvincing, compared to the number of preexisting more thorough studies upon which the current standards are based. Consequently, we write to urge that the Commission adopt a careful and deliberate attitude in this matter.

In our view, the Commission should give great consideration to the considerable body of biological evidence which has been assessed over many years by prestigious and competent scientific bodies as the basis for their recommendations. We find that preliminary analyses have indicated methodological problems and/or limitations in all of these recent studies. This suggests to us that immediate action by the Commission is not in order, but rather that it should await peer review of these studies and their evaluation by the knowledgeable scientific bodies, such as the ICRP, UNSCEAR and NCRP. We also counsel that the Commission should act in concert with the other governmental agencies which have a counterpart concern for occupational radiation exposure, such as HEW-BRH, EPA and OSHA, rather than adopt a lone position.

The three recent studies to which we refer are those by a) Mancuso, Stewart and Kneale (MSK), b) Bross and c) Najarian and Colton. Although we have not made an independent critique of any of them, we have made an attempt to be informed about the principal points raised by each and about the principal points raised by the currently available critiques.

The current standards are largely based on human dose-effect data from observation of Japanese exposed to atomic weapons and of patients exposed to x-ray for treatment of a condition known as ankloysing spondylitis. Their individual exposures were generally in the region of from 10 to a few hundred rads, with aggregate population doses of 1 to 10 million person rads. All three of these most recent studies are based on generally smaller average exposures, between 1 to 10 rads, smaller populations and therefore on very much smaller aggregate person rem doses.

[redacted]

As the individual average exposure and the aggregate population dose decreases, it becomes much more difficult to sort out the "signal" in the form of excess cancer rates due to the radiations of interest from the competing "noise" of the occurrence of the same kinds of cancer that would have existed in the absence of this signal and due to a variety of other causes, i.e., other radiations, chemicals, racial and genetic factors, etc. Ideally, one would select a control population alike the "exposed" one in every respect save the exposure to the radiation of interest. Outside the laboratory and in the real world, this is well nigh impossible. However, there are a variety of statistical models which may be applied to test for an association and to establish its strength. Each suffers from the risk of confounding the variable of interest with some other variable(s), which risk increases as the number of cases and/or size of the population under study decreases.

With regard to the analysis of the Hanford data by Mancuso, Stewart and Kneale, we are particularly convinced by the evaluations by Brodsky[4], (who worked on the study on analysis is based), that the authors have not made a scientifically convincing case. We are made additionally doubtful about the validity of their analysis and findings, in that more conventional analyses by Marks and Gilbert[5,6] find no positive correlation of overall cancer mortality with radiation exposure. Although their studies found a positive correlation for two specific cancers, neither has previously been suggested to be in particularly radiosensitive tissues. We are particularly impressed that no such positive association was found for leukemia, which many previous studies have suggested to be most strongly identifiable if in excess, due to its relatively low otherwise occurring rate.

Although drawing heavily upon the above critiques, Sagan[7] has raised additional questions about the MSK dose estimates, and their methodology. A review by Reissland and Dolphin[8] and comment by Cohen[9] reinforce our skepticism of the MSK conclusions.

From these critiques, we find in particular that a proportional mortality comparison with a standard U.S. white male population, as utilized in the MSK study of the Hanford employees, does not adequately take into account the likely bias (toward finding a relative excess of cancer) which is introduced by the "healthy worker" effect (who are not as comparatively at risk due to most other diseases, as is the general U.S. population). Furthermore, their retrospective finding of a slightly greater average dose for the "exposed" workers who have died of cancer, as compared to the "unexposed" workers, is not in our view adequately controlled for other influences; i.e., comparable or even greater exposures to radiation such as natural background, medical procedures and other occupational increments at other nuclear facilities, relative age distribution, socio-economic factors or differential exposure to other carcinogens.

The existence of widely varying rates of overall and specific types of cancer, both within the U.S. and between the U.S. and other countries, raises considerable doubt about the relevance of the concept of a doubling dose, as set forth by MSK. In this connection, we call your attention to the observation by Reissland and Dolphin that some of the smaller doubling doses for older workers promulgated by MSK cannot be reconciled with their accrued background radiation dose.

[redacted]

Although we respect the scientific credentials of the authors of the MSK study, we consider that their objectivity in this investigation is impugned by their adoption of a questionable statistical analysis, when the data for other surer methods were available to them. It is further jeopardized by their making of what we find to be excessive claims for the certainty of their conclusions.

We find that the paper by Bross consists for the most part of arguments that he has previously advanced[10,11]. In our view, he has not responded adequately to published criticisms that his analyses do not unambiguously support his conclusions[12,13]. Additionally, we agree with the recent comments by Rothman[14], that Bross has employed circular reasoning and that he has not in fact presented a dose-response curve of leukemia risk.

In our view, the study by Najarian and Colton suffers from many of the previously indicated impairments of the MSK study, especially insofar as it is based upon relative proportional mortality (to a U.S. white male population). Additionally, it relies on an imprecise definition about the composition, employment history and radiation experience of their "exposed" and "unexposed" populations of shipyard workers.

All three of these studies relate to occupational radiation exposures which appear to be comparable to those from medical and background radiation, each of which may have amounted to a few rads over one or two decades. Even if the observed effects are relatable to radiation, it remains difficult to conclude which source is responsible, in the absence of careful quantitative establishment of all three. We would furthermore observe that studies of the incidence of cancer with the variation of background radiation (which is about) rad/decade in the low background areas of the U.S. and over 2 rads/decade in the highest background states) have been if anything negative, that is the incidence of most forms of cancer appears lower in the high background states[15-17].

Finally, with regard to these studies, we note that the Department of Energy proposes to continue and to expand the Hanford study to include most of its other contractor sites. According to newspaper reports, the Navy has asked DOE to conduct a counterpart study of shipyard workers. Questions having been raised, we feel that the Hanford and Portsmouth situations should be further examined for alternative explanations of the observed data. However, we feel that there should be a careful appraisal of the prospective costs and benefits of the expansion of such studies to include larger numbers of occupationally exposed persons. We note that much larger numbers are differentially exposed to comparable average levels of background radiation. That differential rates of cancer are not apparent to them casts doubt on the usefulness of studies of still smaller populations of radiation workers.

Since we find no scientific basis for making any distinction between various low-level radiations (when RBE is considered, that is in rems), we feel that there should be a consistent regulation for all kinds, i.e., nuclear, medical or technologically enhanced. Accordingly, we counsel that the Commission should act in concert with the other involved governmental agencies, such as BRH-HEW, EPA and OSHA in formulating any change in its existing occupational dose limits. As low as reasonably achievable recommendations should be made on a consistent cost-benefit basis for the total averted dose in person-rems.

[redacted]

Finally, we believe that a record should be kept of all exposures of radiation workers, including medical x-rays. The present procedures, under which an industrial firm keeps records solely of exposures due to its own activities is inadequate because:

a) it does not preclude a company from employing someone for a month only during which he/she may incur a year's dose, following which some other company may employ the individual who may incur another year's dose the next month,

b) without such information, future epidemiology studies may be vitiated, as are the current studies in its absence, and

c) it would make the employee safety conscious and ultimately only the employee can protect his own health.

We hope these thoughts will be useful to you.

Yours sincerely,

SENSE

sls

1. T. F. Mancuso, A. Stewart and G. Kneale, "Radiation Exposures of Hanford Workers Dying from Cancer and Other Causes", Health Physics, 33:5 pp. 369-385 (1977).

2. I. D. J. Bross, "Hazards to Persons Exposed to Ionizing Radiation (and to their children) from Dosages Currently Permitted by the Nuclear Regulatory Commission", Presentation to NRC (4/9/78).

3. T. Najarian and T. Colton, "Mortality from Leukemia and Cancer in Shipyard Nuclear Workers", Lancet, 1:8072 p. 1018-1020 (1978).

4. A. Brodsky, "Evaluation of Paper by Mancuso, Stewart and Kneale", submitted to NRC (1/12/78).

5. S. Marks and E. S. Gilbert, "Comments on 'Mortality Experience of Workers in Atomic Energy Industry' by Mancuso, Stewart and Kneale", BNWL-SA-6012 (1976).

6. E. S. Gilbert, Testimony to U. S. House of Representatives Committee on Interstate and Foreign Commerce, Subcommittee on Health and Environment, PNL-SA-6341-Rev. (1978).

7. L. A. Sagan "Low-level Radiation Effects: The Mancuso Study", available from Atomic Industrial Forum, Washington, D.C. (1978).

8. J. A. Reissland and G. W. Dolphin, "A Review of the Study of Mortality Among Radiation Workers at Hanford", Radiation Protection Bulletin No. 23, NRPB Harwell (1978).

9. B. L. Cohen, "Lows of Statistics Ignored by Statisticians", in publication address: University of Pittsburgh (1978).

10. I. D. J. Bross and N. Natarajian, Leukemia from Low-Level Radiation: Identification of Susceptible Children", N. Eng. J. Med., 287:107-110 (1972).

11. I. D. J. Bross and N. Natarajian, "Genetic Damage from Diagnostic Radiation", JAMA 237:22 pp. 2393-2401 (1977).

12. P. G. Smith, M. C. Pike, L. D. Hamilton, "Multiple Factors in Leukemiogenesis", Letter in BMJ (May 26, 1973).

13. L. V. Gould, T. R. Bledsoe, C. F. Land, B. E. Oppenheim, Letters in JAMA 238:10 pp. 1023-1024 (1977).

14. K. J. Rothman, "Review of Dr. Irwin Bross's Presentation on Radiation Exposure and Risk", to Nuclear Regulatory Commission (4/7/78).

15. N. L. Frigerio, "Carcinogen Hazard from Low-Level, Low-Rate Radiation", ANL/ES-26 Part 1 (1973).

16. T. J. Mason and R. W. Miller, "Cosmic Radiation at High Altitude and U. S. Cancer Mortality, 1950-1969", Radiation Research, 60:302-306 (1974).

17. A. P. Jacobson et.al., "The Role of Natural Radiations in Human Leukemogenesis", AJPH 66:1, pp. 31-36 (1976).

[redacted]

AUG 1 1978

PRM 20-6

Dr. Andrew Hull, Secretary
Scientists for Enlightenment on
Nuclear Sources of Energy
P. O. Box 413
Upton, New York 11973

Dear Dr. Hull:

Thank you for your letter of July 5, 1978 to Chairman Hendrie regarding the implications of recent studies of low-level radiation for occupational dose limits.

Your letter has been forwarded to staff for consideration in its preparation of recommendations to the Commission regarding effective ways to reduce occupational exposure. I assure you that your comments will receive appropriate consideration.

Sincerely,

Original signed by:
ROBERT B. MINOGUE

Robert B. Minogue, Director
Office of Standards Development

bcc: K. R. Goller, w/inc.
I. C. Roberts, w/inc.
R. E. Alexander, w/inc.
PDR, w/inc.
Secretariat, w/inc. for docketing
Chairman Hendrie, w/inc.

Distribution:
Central Files
SD Rdg
SD Alpha
EDO Rdg
RBMinogue
SD Task NO.

OFFICE ➔	SD	SD:DIR				
SURNAME ➔	SFlory:sf	RBMinogue				
DATE ➔	7/31/78	8/1/78				

NRC FORM 318 (9-76) NRCM 0240

☆ U.S. GOVERNMENT PRINTING OFFICE: 1976 — 626-624