Michael Reese Hospital and Medical Center

Department of Medical Physics
29th Street and Ellis Avenue
Chicago, Illinois 60616

(312) 791-3180
Jacques Ovadia, Ph.D.
Chairman

October 30, 1981

U. S. Nuclear Regulatory Commission
Secretary of the Commission
Attention: Docketing and Service Branch
Washington, D.C. 20555

DOCKET NUMBER
PROPOSED RULE PR - Misc. Notice (Reg Guide)

Dear Sir:

This letter is a comment on the Draft Regulatory Guide and Valve/ Impact Statement issued August 1981 in Division 8 as Task OP 031-4 entitled: Proposed Revision 2 To Regulatory Guide 8.13, Instruction Concerning Prenatal Radiation Exposure.

Within Table 1 "Effect and Frequency of Certain Maternal Factors on Pregnancy Outcome" on page 8.13-8, there is a serious error in the rate of occurences enumerated for cigarette smoking. The referenced publication by M.B. Meyer and J. A. Tonascia, "Maternal Smoking, Pregnancy Complications, and Perinatal Mortality" states on page 495, "The perinatal mortality risk increased by 20 per cent among smokers of less than a pack per day and by 35 per cent among smokers of a pack or more per day." I believe the rate of infant death cited in the Draft Reg. Guide as 1 in 5 for smokers of less than one pack per day and 1 in 3 for smokers of a pack or more per day is a result of improper interpretation of the above statement.

To preserve the context of the Draft Reg. Guides rate of occurance data, I refer you to page 496, Table I of the reference. The rate of occurance of infant death may be properly cited as 1 in 36 for smokers of less than one pack per day and 1 in 30 for smokers of a pack or more per day using the data of "Perinatal Mortality" rate per 1,000 total births. In addition to citing the rate for smokers, I believe the rate of perinatal mortality among nonsmokers (1 in 43) should also be cited to allow realistic interpretation of the data.

In order to preserve creditability great care must be taken in the presentation of data. I hope that this comment will aid in this effort.

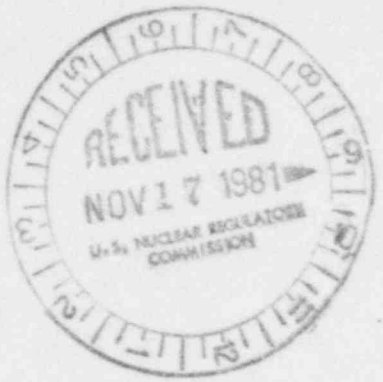
Sincerely,

Kevin J. Francis

Kevin J. Francis
Radiation Safety Officer

cw

D509
S.10
Add: Ed Hill



DOCKETED
USNRC

'81 NOV -4 P12:29

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

Evelyn Oden, M.D.
2001 Centrofamiliar, SW
Albuquerque, New Mexico, 87105
November 2, 1981

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch
Washington, DC 20555

DOCKET NUMBER
PROPOSED RULE PR-Misc. Notice (Reg Guide)

My name is Evelyn Oden, I am a pediatrician and a member of Physicians for Social Responsibility. The following comments are in response to the Nuclear Regulatory Commission's Draft Regulatory Guide and Value/Impact Statement. They address the Proposed Revision 2 to Regulatory Guide 8.13, Instructions Concerning Prenatal Radiation Exposure.

The sensitivity of the zygote, embryo and fetus is well described in the discussion of the guide. The embryo/fetus is stated to be more sensitive than a child. There is even more discussion on the rationale for the lower dose limits for workers under 18 years of age. However, with the 500 mrem exposure limit to the unborn, the regulatory position adopted by the NRC allows the sensitive embryo/fetus to be exposed to the same amount of radiation over 9 months as it does a working minor over a one year period. Even more alarming, the radiosensitive fetus would be allowed, over a 9 month period, almost 3 times the maximum recommended dose to the general population over a one year period. This is inconsistent with the proposed effort to protect the radiosensitive fetus from the harmful effects of ionizing radiation.

The 500 mrem exposure limit (distributed over a 9 month peroid) recommended by the NCRP is excessive and should be lowered for the following reasons:

1. There is insufficient evidence to prove that the recommended level of exposure will not result in an excess of miscarriages, stillbirths and infant morbidity/mortality.

Acknowledged by card. 11/4/81 emp

DS09
S 01 Add Ed Hill

2. There is evidence that in utero doseasges as low as 200 mrem may cause an excess of childhood deaths from cancer and leukemia with an increasing number of deaths with increasing exposure. There is strong evidence that there is a greater cancer hazard with exposure during the embryonic phase of development than for exposure later in prenatal life.[1] The women in the radioactive workplace will be exposed to ionizing radiation throughout their pregnancy. With the 500 mrem exposure limit, a considerable amount of exposure to ionizing radiation is allowed in the first trimester when the embryo/fetus is most vulnerable to the damaging effects of radiation.

3. The dose limit of 500 mrem/9 month period is unreasonable in that it assumes that the radiosensitivity of the population exposed is homogeneous. Bross and Natarajan have identified a susceptible group of children in which the same in utero radiation exposure can increase the relative risk of childhood cancer and leukemia by a factor of ten.[2] It is difficult to assess in utero which fetus' will be susceptible (i.e. those with allergic diseases such as asthma and hives). However, those pregnant workers with asthma or hives, or those who have a positive family history of allergic diseases will be at a higher risk of having an allergic child, increasing the risk of the subsequent development of cancer/leukemia in childhood.

4. Deaths from infectious diseases are not uncommon during infancy and childhood. Lileinfeld and co-workers have demonstrated a 2 fold increase in deaths from infectious diseases in white children exposed to X-Rays in utero, when compared to white controls.[3] This finding may be associated with damage to the developing immunological system of the embryo/fetus. Although the dose necessary to cause this damage is not known, the pregnant worker will be exposed to ionizing radiation during the period of differentiation and development of the fetal immune system.

5. The women in radioactive workplaces are not unlike the women of the general population. They are exposed to the same background radiation and environmental contamination with chemicals and heavy metals. They may also experience similar obstetrical complications as their piers. Hence, they too may need abdominal films, pelvimetry, for the diagnosis and treatment of problems that may arise during the course of the pregnancy, labor and delivery. Some of the pregnant workers will smoke, consume alcoholic and caffeinated beverages. The effects of the combination of these environmental factors has not been clearly delineated at this time, but one may discern that they may be synergistic leading to the greater possibility for a less than optimal outcome for the developing embryo/fetus.

Based on the preceeding discussion, I recommend that the NRC:

1. Lower the maximum exposure to the pregnant worker to a total of 150 mrem, paying close attention to the exposure in the first trimester of pregnancy. This will aid in reducing the risk of infant/childhood mortality from infectious diseases and cancer/leukemia.
2. Discuss the varying susceptibility of allergic persons in the Instructions Concerning Prenatal Radiation Exposure. This gives those pregnant workers who have allergic diseases themselves or in the family a chance to evaluate the additional risks of prenatal radiation exposure to the fetus. This would encourage more care to eliminate unnecessary exposure on the part of the pregnant woman and the employer.
3. Delete the Nagasaki and Hiroshima data. This data is now controversial. There is recent evidence to indicate that the accepted figures for the high LET (neutron) radiation at Hiroshima are overstated (perhaps by a factor of 6 to 10).[4] The women reading the guide may get a false sense of security by

only associating larger doses (100 to 150 rads) with adverse effects on the fetus in the form of mental retardation and birth defects.

4. Emphasize that the recommended dose limit is in addition to:

   (a) Natural background radiation

   (b) Emissions into the environment from the nuclear facility

   (c)Any environmental contaminants (chemical, heavy metals)

   (d) Any drugs ingested during pregnancy (aspirin, caffeine, alcohol, nicotine, etc.)

It is vital that the NRC strive to protect the mother and the unborn child from unnecessary and excessive exposure to ionizing radiation. I will conclude with a statement from a geneticist discussing the late effects of radiation;

> ...we must endeavor to protect our genetic heritage and to pass it on undamaged, or if possible, even improved upon. We should not be led into the false confidence that little or no harm is being incurred simply because the harm itself remains hidden..."[5]

Thank you for considering these comments.

Sincerely,

Evelyn Oden

Evelyn Oden, M.D.

FOOTNOTES

1. Stewart, A., and Kneale, G.W. Radiation Dose Effects in Relation to Obstetric X-Rays and Childhood Cancers. Lancet, June, 1970.

2. Bross, I., and Natarajan, N. Leukemia from Low Level Radiation. Identification of Susceptible Children. J. of Medicine. Vol. 287, No. 3.

3. Diamond, E.L., Schmerler, H. and Lileinfeld, A. The Relationship of Intra-uterine Radiation to Subsequent Mortality and Development of Leukemia in Children. Am. J. of Epidemiology. Vol 97, No. 5, May, 1973.

4. New A-Bomb Studies Alter Radiation Estimates. Science, Vol. 212, May 22, 1981.

5. Grahn, D. Late Effects of Radiation - Genetic Changes. Delivered at the Annual Life Sciences Symposium, Los Alamos Scientific Laboratory, Los Alamos, NM. Oct. 8 - 10, 1980.

HEALTH ENVIRONMENT department

"Equal Opportunity Employer"

STATE OF NEW MEXICO

ENVIRONMENTAL EVALUATION GROUP
320 Marcy Street
P.O. Box 968
Santa Fe, NM 87504-0968
(505) 827-5461

DOCKETED
USNRC

'81 NOV -4 P2:15

emp

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

October 30, 1981

- Misc. Notice
(Reg Guide)

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

Attention: Docketing and Service Branch

Dear Sir:

There are the Environmental Evaluation Group's comments on "Proposed Revision 2 to Regulatory Guide 8.13 Instruction Concerning Prenatal Radiation Exposure."

We concur in the need for such an instruction and with the general approach used. There are two specific items we wish to comment on:

1. There is no suggestion in the guidance that employers should make a reasonable effort to respond to a request to be reassigned to an area involving less exposure to radiation.

2. The continued exposure (after knowledge of pregnancy) at an annual exposure rate of up to 1.5 rem appears to be considered acceptable in the proposed guide.

Since such a small percentage of occupational workers are exposed to more than 1.5 rem/y (about 8% for all licensees) this criteria could probably be met without taking any precautions at all. However, only about 18% of all workers receive over 0.5 rem/y (these data are for 1976 and are from NUREG-0322). Consequently, it appears that many employers could respond to a request for reassignment to areas where the annual exposure is expected to be less than 0.5 rem without seriously impacting their operations. We recommend that serious consideration be given to inserting stronger language in the guide to really encourage both employees and employers to minimize exposure to the unborn.

Thank you for the opportunity to comment on this proposed Guide Revision.

Sincerely,

Robert H. Neill

D509
S/O

Add: Ed Hill

11/9/81 emp

Robert H. Neill
Director

RHN:eg

Washington Public Power Supply System

P.O. Box 968 3000 George Washington Way Richland, Washington 99352 (509) 372-5000

October 30, 1981
G02-81-439

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

Attention: Docketing and Service Branch

Dear Sir:

Subject: Proposed Revision 2 to Regulatory Guide 8.13

Attached for your use are the Supply System's comments regarding the proposed revision to Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure".

Please feel free to contact me if you have any questions regarding our comments.

Very truly yours,

GDB

G. D. BOUCHEY, Deputy Director
Safety and Security

GDB/KAH/sm
Attachments

cc: NS Reynolds D&L
J Plunkett NUS

D509
S1/1

Add: Ed Hill

11/9/81 emp

ATTACHMENT I

COMMENTS ON PROPOSED REVISION 2 TO REGULATORY GUIDE 8.13

"INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE"

1. The Regulatory Guide fails to provide enough emphasis on the individual's responsibilities. The following responsibilities should be included in the Regulatory Guide:

   a. Know and understand the risks.

   b. Make a decision with respect to pregnancy and radiation zone work.

   c. Inform management and request exposure status as soon as pregnancy is suspected.

   d. Track exposure status and ask for help from company Health Physics staff if necessary.

   e. Minimize exposure through good work practices.

2. In the third paragraph of the section entitled "Why the Unborn Are More Sensitive" is a sentence which states, "Other factors in the mother's life (including the exposure of the unborn to naturally occurring radiation) are thought to cause 6 out of 100 birth defects".

   The referenced sentence is very misleading and gives the impression that 6 out of 100 birth defects may be caused by natural background radiation. If 6% of birth defects were caused by natural background radiation, a few rem would be sufficient to cause a doubling of the birth defect rate and would be easily detectable from studies of medical x-ray exposures. Instead, current information supports the fact that x-ray and gamma ray radiation induced birth defects are not detectable below doses of 20 rem. It is recommended that the entire section be replaced with the attached discussion on interuterine irradiation of unborn children which appeared in an Academy Forum article entitled "Nuclear Radiation: How Dangerous is it?", September 27, 1979, National Academy of Sciences, Washington, D.C.

3. Table I is confusing because the rate of occurrence values mix relative ratios (such as 2 in 3 defects for German Measles) with absolute values (such as 1 in 230 for Down's Syndrome). The table should provide both the relative risk and the absolute risk, and explain the difference to avoid giving the impression that taking aspirin during pregnancy has a 1 in 13 chance of producing a child with a club foot.

ATTACHMENT II

The following is an excerpt of a discussion on interuterine irradiation taken from an Academy Forum article entitled "Nuclear Radiation. How Dange[illegible]F?", September 29, 1979, National Academy of Science, [illegible], D.C.

Now let's [illegible] unborn children, children who are not yet delivered at the time [illegible] radiation. Here again, there are conflicting observations. [illegible]ever, it is possible the fetus may be about 5 times more sensitive to radiation than adults. So if unborn children in 10,000 pregnant women each receive 1 rem of radiation, instead of 1 cancer death in 10,000 persons, there might be 5 cancer deaths in the 10,000 children before the age of 10.

There are two other effects which we must deal with; these are the genetic and the developmental defect problems in children, children who are born with some deformity following radiation.

The genetic effects are produced by the irradiation of either the father or the mother, and show up in their children. Estimates of the likelihood of such effects have not changed recently; the geneticists are fairly well agreed in their estimates. In 1 million children whose parents have received 1 rem of radiation, 10 times the annual background, it is predicted that somewhere between 5 and 75 of those 1 million children--5 to 75 is the range of uncertainty--will show a serious genetic defect, such as dwarfism or mental defectiveness in the child.

This should be compared with the known fact that of all the children born today, about 10 percent show some genetic defect. That is, out of the 1 million children, about 100,000 would show some genetic defect. That number is growing as medicine begins to recognize more genetic-type diseases in the population. So we're comparing 5 to 75 (say 25 as a middle estimate) from the 1 rem of radiation with the 100,000 genetic defects evident in an unexposed population.

Finally, let me mention malformations or birth defects which can develop in children who are irradiated while being carried by their mothers. These risks are about the same order of magnitude as the ones I've been discussing, but it is believed that there is a threshold dose for these effects for x-rays and gamma rays. The threshold for the more significant effects, such as skeletal deformities, may be 20 rem or more. It is not believed that there is a threshold for the densely ionizing radiation, the alphas and the neutrons.

One good example of such a defect is a child born with diminished-sized, small-sized head, which is usually accompanied by mental retardation. It is significant that following the dropping of the bomb in Nagasaki, where the radiation was from gamma rays, none of these cases occurred up to about 150 rems. So from this evidence it looks as if the x-and gamma rays carry a relatively low and perhaps zero risk at low doses. However, the neutron dose to the people in Hiroshima is associated with a much higher level of risk, down to rather low levels of neutron radiation such as a few rem. A good estimate is that about 1 case of microcephaly, as we call it, small head with mental retardation, would occur in 250 pregnancies where the mother received 1 rem; 1 case in 250. That's with the neutrons, not with the x-rays.