

The University of Michigan

RADIATION CONTROL SERVICE
1101 NORTH UNIVERSITY BUILDING

1205 NORTH UNIVERSITY AVENUE
ANN ARBOR, MICHIGAN 48109

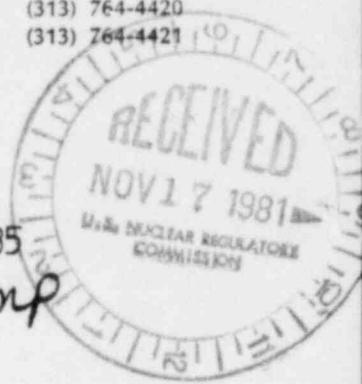
(313) 764-4420
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ARTHUR J. SOLARI
Director

DOCKET NUMBER
PROPOSED RULE **PR-Misc. Not.**
(Reg Guide)

November 3, 1981

DOCKETED
INSURE



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

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OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

Attention Docketing and Service Branch

Gentlemen,

The proposed revision of Regulatory Guide 8.13 on instruction concerning prenatal radiation exposure is a worthwhile improvement of the original guide. The inclusion of prenatal risks other than radiation establishes a background for comparison. However, the section on internal exposure should be expanded. Would it be possible to include a table of various radio-labeled compounds such as Na-1 (both I-125 and I-131), H-3 label thymidine or other DNA precursors with an estimate of the amount of the compound which if ingested would result in a 0.5 rem exposure to the unborn child, either by external radiation from the mother or by internal deposition in the fetus due to transport across the placental barrier.

I realize the data required to produce such a table is often not readily available, but some effort along this line would be very helpful. There are far more people working with labeled compounds than with x-ray machines or sealed gamma sources and guidance for them would be appreciated.

Some mention of skin absorption should be made. I have been informed by one experimenter that several organic compounds are readily absorbed through the skin and that this process can be nearly as effective a means of internal deposition of isotopes as ingestion.

I await the final revision with great interest. Thank you.

Sincerely,

A. J. Solari
A.J. Solari, Director
Radiation Control Service

DS09
5/10
Add: Ed Hill

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PDR REGGD
OB. 013 C PDR

11/9/81 emp

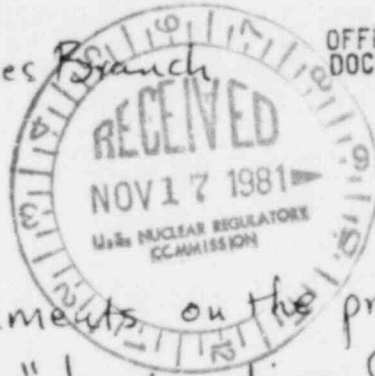
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PROPOSED RULE

PR-Misc. Notice
(Reg Guide)

13916 Castle Pkwy Apt 103
Silver Spring, Md. 20904
NOV. 4, 1981

'81 NOV -6 A8:36

Secretary of the Commission
Attn: Docketing and Services Branch
Washington, D.C. 20555



emp
OFFICE OF SECRETAR
DOCKETING & SERVICE
BRANCH

Dear Sir:

I offer the following comments on the proposed Revision 2 to Regulatory Guide 8.13, "Instructions Concerning Prenatal Radiation Exposure":

Section C Regulatory Position

Substitute "total maximum permissible dose equivalent" for "maximum permissible dose equivalent." Clarifies that the term is cumulative maximum not an instantaneous maximum.

Add the following to this section: "This position conforms to EEOC/DOL: 'Interpretive Guidelines on Employment Discrimination and Reproductive Hazards.' The inclusion of this statement adds balance to the position and may of itself prevent some employers from limiting all women to 0.5 rem for 9 months as my previous employer attempted in 1976 when Reg. Guide 8.13 was originally published (Ref my correspondence with Lester Regens circa 4/75, Robert Minogue, and Robert Alexander circa 2-6/76.)"

DS09 Add: Ed Hill
S/p

11/9/81 emp

Appendix to Reg Guide 8.13

¶2 The view of these "scientists" is one-sided and fails to acknowledge the socio-economic factors which could be more hazardous than radiation to the fetus and to the mother. I know that this is intentional. This paragraph and the following one have a tone that borders on arrogance.

Recommendations of Scientific Organizations

Eliminate "The scientific organization called"

Reason: Pompous and patronizing as well as redundant.

Reword the first sentence to define the antecedent of "their".

NRC Requirements

Eliminate "(down to zero)"

Its redundant as well as unachievable.

Your Responsibility

Reword: Item 1

Phrase 1 is argumentative and does not relate the information its

author. apparently intended.

Suggested words: "During the first three months of pregnancy, the development of your unborn child is affected by radiation exposure more than later in your pregnancy, so you should make the decision early whether or not to limit your exposure."

Why the Unborn are More Sensitive

Delete "prenatal" in "prenatal exposure to the unborn"; reason, redundancy

Put the table at the end of the text.

Please keep me informed about the outcome of this proposed revision.

Yours truly,
Mary Sullivan

GENERAL ELECTRIC

CASTLE HAYNE ROAD • P. O. BOX 780 • WILMINGTON, N. C. 28402 • (919) 343-5000

NUCLEAR ENERGY
PRODUCTS DIVISION

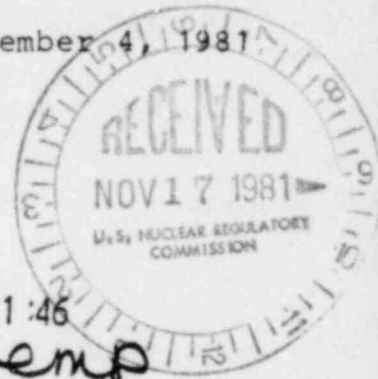
WILMINGTON MANUFACTURING
DEPARTMENT

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

November 4, 1981

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

DOCKETED
NRC



Attention: Docketing & Services Branch

'81 NOV -6 P1:46

Gentlemen:

Reference: NRC License SNM-1097, Docket #70-1113

U.S. NUCLEAR REGULATORY
COMMISSION
DOCKETING & SERVICE
BRANCH

Subject: Comments on Proposed Revision 2 to
Regulatory Guide 8.13

On September 10, 1981, General Electric received a copy of the proposed Revision 2 to Regulatory Guide 8.13, "Instructions Concerning Prenatal Radiation Exposure," for comment. Comments are due by November 5, 1981.

The General Electric Company fuel fabrication facility employs a number of radiation workers covered by 10 CFR 19.12 and, as a result, has had and will have in the future, extensive occasions to use past, current and future revisions of Regulatory Guide 8.13. It is within the context of GE's need and experience that the attached comments are included for consideration in revision of Regulatory Guide 8.13.

General Electric appreciates the opportunity to participate in the regulatory process concerning this proposed Regulatory Guide revision. We would be pleased to discuss any questions that you or your staff may raise related to our comments.

Very truly yours,

GENERAL ELECTRIC COMPANY

Charles M. Vaughan, Acting Manager
Licensing & Compliance Audits
M/C J26

CMV:bmw
Attachment
NSD-L

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Silo
Add: Ed Hill*

11/9/81 emp

Secretary of the Commission
November 4, 1981
Attachment - Page 1

Comments
Proposed Revision 2 to Regulatory Guide 8.13,
"Instructions Concerning Prenatal Radiation Exposure"

General Comments

General Electric finds the minor changes to the text of the guide to be beneficial in that they reduce some of the highly technical language making the guide much easier to follow.

Changes to the guide's appendix are extensive, increasing its volume by a factor of four and significantly increasing the technical content. General Electric feels that this makes the appendix counter-productive to use as an instructional tool, since most employees would not spend the time to read through the material in detail.

Furthermore, GE has not experienced any difficulty with the existing appendix as an instruction handout nor has anyone expressed a problem understanding it. The proposed revision contains extremely technical information that may not be easily understood by the average worker.

Specific Comments

- (1) It is understood that the objective of the guide is to educate potentially expectant mothers as to the relative risks from radiation exposure as it relates to them as a radiation worker and to advise them of their options. It should not address risks from such things as german measles, cigarettes, alcohol, bomb exposure, etc.

General Electric recommends that Table 1, "Effect & Frequency of Certain Maternal Factors on Pregnancy Outcome," not be included in the revised appendix. Alternately, this type of information could be made available to company and private physicians, and this should be accomplished through one or more of the NRC bulletin programs.

- (2) Discussion of the BEIR-80 report also appears potentially unnecessarily alarming to females and covers areas which do not have a direct relationship to the purpose of the guide.

Secretary of the Commission
November 4, 1981
Attachment - Page 2

General Electric recommends that lengthy discussions regarding the effects of Hiroshima, Nagasaki and medical x-ray examinations be deleted from the guide.

- (3) The section "Some Radioactive Material can be Inhaled or Swallowed" does not appear directly appropriate to this guide.

The first paragraph addresses issues which are a part of all radiation protection programs and the questions to be addressed are fundamental to the routine requirements a licensee has to address for all radiation workers. Likewise, the discussion of radioiodine does not appear universally appropriate.

General Electric recommends that this entire section be deleted.

In summary, General Electric feels that an appropriate appendix to Regulatory Guide 8.13 is one that is quite similar to the existing guide appendix in length and content. Only slight modifications, if any, appear to be necessary to the existing appendix.

If additional information is desired by female workers such as that contained in the proposed revision, this information could be made available to the licensee's medical staff to review with an expectant mother.

C. M. Vaughan
:bmw



Pennsylvania Power & Light Company

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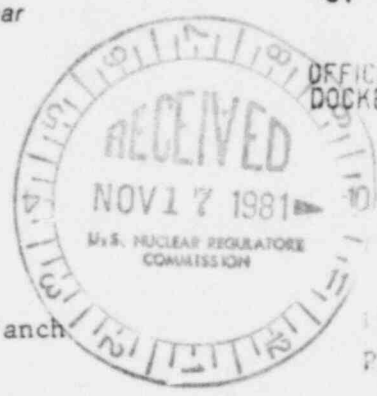
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Norman W. Curtis
Vice President-Engineering & Construction-Nuclear
215 / 770-5381

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November 2, 1981



OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH

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

(4)

PROPOSED RULE *PR - Misc. Notice*
(NUREG-0814)
(46 FR 44935)

SUSQUEHANNA STEAM ELECTRIC STATION
COMMENTS ON NUREG 0814 METHODOLOGY FOR
EVALUATION OF EMERGENCY RESPONSE FACILITIES-DRAFT
REPORT FOR COMMENT
ER 100450
PLA-951

FILE 834

This letter provides our comments on NUREG 0814 "Methodology for Evaluation of Emergency Response Facilities"-Draft Report for Comment, published in August, 1981.

The abstract of the report states that, when finalized, the questions in the report will be used by the staff to review the conceptual design of emergency response facilities. Many of the proposed questions are much too specific to be suitable for review of a conceptual design. Rather, the questions seem to be more appropriate for evaluation of the final design or the actual facilities.

For example, the information requested relative to the emergency response facility data system data acquisition hardware is so specific that until a vendor is selected, no answers can be formulated. An appropriate concern at the conceptual design stage might be whether the data acquisition scan rates proposed by the licensee are adequate to monitor safety parameters during rapid excursions, not what physical equipment will be utilized to satisfy the commitments.

In summary, we believe the details of design at the conceptual stage are the responsibility of the utility. The evaluation criteria, at the conceptual stage of design, should be limited to those items necessary to determine if the utility is satisfying its commitment for compliance to regulations. This draft report goes far beyond that concept.

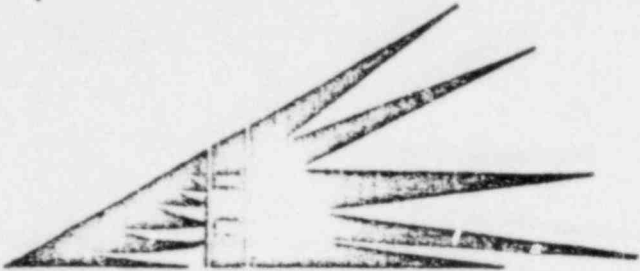
Very truly yours,
NW Curtis

N. W. Curtis
Vice President-Engineering and Construction-Nuclear

11/9/81 emp

WWW/mks

D509
S1/0 Add: *Steve Ramos*



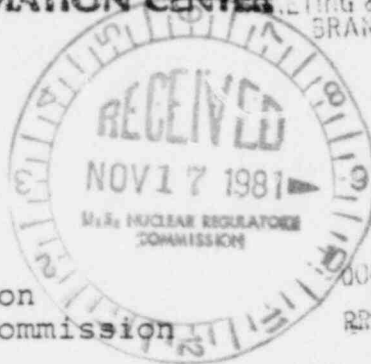
SOUTHWEST RESEARCH AND INFORMATION CENTER

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USNRC

'81 NOV -6 P1:46

emp

OFFICE OF SECRETARY
DOCKETING & SERVICE
BRANCH



November 1, 1981

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

DOCKET NUMBER
PROPOSED RULE

*PR - Misc. Notice
(Reg Guide)*

Attention: Docketing and Service Branch

Dear Sir/Madam:

Not acknowledged by card. 11/9/81... RMP

I am writing this letter to comment on Proposed Revision 2 to Regulatory Guide 8.13 Instruction Concerning Prenatal Radiation Exposure, August, 1981, which are being solicited by your office by November 5, 1981.

As an introduction, I wish to make two points which I plan to elaborate on further in the letter:

1) The recommended radiation level of 500 mr exposure to the unborn child by the NCRP (and especially the ICRP) are too high and do not afford adequate protection to the developing fetus from the harmful effects of radiation exposure.

2) The guide itself is inadequate in presenting to the woman nuclear worker an accurate, balanced picture of the risks associated with radiation to the unborn child, and hence provide no real incentives to voluntarily decrease radiation exposures in the nuclear workplace.

Studies on Very Low Levels of Radiation Exposure to the Unborn

- Alice Stewart's study (Radiation Dose Effects, Lancet, June 6, 1970) in relation to obstetric x-rays and childhood cancers indicates that in utero exposure between the 200-500 millirem range showed an excess in leukemia risk.

- Dr. Irwin Bross, (in Genetic Damage from Diagnostic Radiation, JAMA, May, 1977) indicates that between 500 and 5,000 millirads can cause leukemia in the descendants of the person exposed.

- Mole (1974 Antenatal Irradiation and Childhood Cancer: Causes or Coincidence, Brit. J. Of Cancer) and Pochin (1976 Radiology Now: Malignancies Following Low Radiation Exposure in Man, Brit. J. of Radio-

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Add:
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logy) states that in the range of 1 - 2 rads (1,000 - 2,000 millirads) from pelvimetry increases the risk of leukemia by 50%. This is particularly noteworthy in that the ICRP recommendation of 1.5 rads fetal exposure has been linked with an increase in leukemia by almost half.

- Dr. Irwin Bross (Leukemia from Low Level Radiation-Identification of Susceptible Children, July 20, 1972 NEJM) supports the hypothesis by others (ie. Burch in Principles of Radiation Protection NY R.E. Krieger '73) that a synergistic relationship exists between radiation exposure and a virus, or bacteria, or chemicals, where each insult "throws one switch", which may lead to a given type of leukemia or other malignancy. For example, Bross has shown that children with allergic diseases such as asthma or hives have a 300-400 percent increased risk of dying of leukemia compared with other children (one switch). Children who received in utero diagnostic x-ray exposure have a 40-50 percent increased risk of dying of leukemia, but children with two switches thrown (in utero exposure and later developing an allergic disease) have a 5,000 percent increase in risk of dying of leukemia.

These three studies and others are examples of what has not been taken into account by the proposed regulatory guide, at least in terms of discussion and reference. Greater protection must be afforded the unborn child if such low doses of radiation in the range of the recommended 500 mr have shown an excess of cancers.

Discussion of Table 1 on pp 8.13-3, 9.

Table 1 of the Guide discusses the risks to the unborn child from caffeine, alcohol and cigarette smoking as well as radiation. Although it is known these other agents increase risks to the unborn if taken during pregnancy, the risk increases (or decreases) with amount of intake. For example, the less alcohol, the less the severe effects on the child. But with radiation, even at natural background levels, the effect is not more or less severe, you either develop a cancer or leukemia or not. You don't develop a little bit of cancer or leukemia. This comparison of radiation to other harmful agents in this context is misleading and diffuses the issue of radiation effects.

The reference to the Hiroshima and Nagasaki data on p. 9 of the Table is also misleading. The data on children exposed in utero during the Hiroshima and Nagasaki bombings has been called into question for many reasons (See Morgan, Bulletin of Atomic Scientists, Sept. 1978). Among the criticisms are the unknown rate of spontaneous abortions and stillborns which may have occurred due to radiation. If the child had been born, it might have suffered a cancer or leukemia. Controversy exists over the actual radiation doses received by the mother. And not enough adequate study of other congenital abnormalities in those children exposed at Hiroshima and Nagasaki have been done to ascertain the rate of production of other abnormalities as a function of dose beyond "small head size".

Alice Stewart has noted that stillbirths, abortions, neonatal death or fatal infections may actually be pre-clinical cancers caused by radiation. This of course would underestimate the risk of radia-

tion due to the lack of data on how many of these fetal and neonatal deaths are the result of radiation exposure. It is well known that ionizing radiation readily induces chromosomes aberrations, the most common being deletions. It is also well known that chromosome aberrations are a major cause of spontaneous abortions, stillborns and birth defects. None of this is mentioned in the table or anywhere in the text of the regulatory guide.

Small head with severe mental retardation has occurred down to 10 rads in Hiroshima and Nagasaki. Nothing is mentioned about small head with less severe mental retardation at even lower doses. Small head is not a cosmetic problem which is to be slighted -- it is stunted growth of the most vital organ we have - the brain - which can lead to less severe, but equally important forms of retardation, lowered learning ability, lowered intelligence, etc. We must be concerned with the less severe of the abnormalities the unborn child faces with radiation exposure, where the full potential of the child is lost forever. No where is mention made of the less severe forms of abnormalities caused by radiation in the guide, and this should be included.

Radiation and Cancers - General

Radiation has been linked with virtually every type of cancer known to man - yet no specific examples are given in the Table or the guide. although great details are given the female nuclear worker on the risks of alcohol consumption, high altitude, etc. The cancers, which should be listed in the guide, include: brain, lung, pancreas, liver, thyroid, bone, stomach, esophagus, bladder, uterus, cervix, pharynx, skin, kidney, colon. Not all of these cancers would necessarily be fatal, but would present great pain and suffering to a child and its parents having to deal with the operations, treatments, and possible direct and indirect side effects from drugs, organ removal, etc. All the fatal and non-fatal types of cancers should be listed for full consideration.

Other Non-Cancer Problems

Radiation at low levels has been associated with much more subtle damage than fatal and non-fatal cancers and leukemias, or birth defects. Rosalie Bertell (X-Ray Exposure and Premature Aging, Journal of Surgical Oncology, 1977) puts forth an hypothesis of an aging effect of exposure to ionizing radiation in humans, with an equation of 1 rad being equal to one year of aging. The increased aging effect would impair the immune system's proper functioning, resulting in a person's greater susceptibility to all kinds of diseases (including cancer), general health degradation and onset of typical old age diseases at a much younger age (heart problems, pneumonia, etc.), thereby possibly taking years off a life or substantially lowering the quality of the life.

Pre-Conception Irradiation (Genetic)

No mention is made whatsoever of the risks associated with irradiation of the female nuclear worker before conception. According to Alice Stewart, an association exists between pre-conception radiation exposure and childhood leukemia as well as prenatal radiation exposure and childhood leukemia. Any exposure before con-

ception will be cumulative and act synergistically with irradiation after conception, increasing the risk that the unborn child will develop leukemia or cancer. Genetic injury to the reproductive cells of the female from pre-conception exposure can also lead to serious birth defects in the child, even if exposure after conception is kept at or even below the 500 mr range. The proposed recommendation should be established for all females of child-bearing age as well, before pregnancy. Even the BEIR and UNSCEAR reports indicate that radiation adds to all inherited afflictions of the unborn child, yet no discussion of preconception irradiation takes place in the guide.

Recessive Genetic Diseases associated with Radiation Exposure

No mention is made of recessive genetic diseases which may be incurred as a result of pre-conception (genetic) and prenatal (teratogenic) exposure to radiation. For instance, nobel prize winner H.J. Muller, in his study of genetic effects in flies, found that for every visible mutation due to radiation exposure (the mutation may lead to birth defects, cancer, etc.), there are 10,000 nonvisible or "small" mutations that result from each observed mutation. Muller stressed that it may be in the long run these small mutations result in a lack of vigor, susceptibility to disease, slight reduction in mentality and physique, etc. and will present a greater burden to society than the more easily identifiable dominant mutations. This is because the small mutations are eliminated from the gene pool very slowly.

The Proposed 500mr/per pregnancy Recommendation

The 500 mr per pregnancy on p. 8.13-11 is stated as a *having a* "reasonable safety factor" in protecting the unborn child from any adverse effects from radiation exposure. This is simply untrue and is greatly misleading. 500mr/yr was a standard actually set by the NRC for maximum radiation exposures to individuals standing at the boundary of a nuclear facility. The general public's average radiation exposure from nuclear facilities was set by the NRC at 170mr/yr. The EPA's new radiation standard was brought down from 170mr/yr to 25mr/yr from the nuclear fuel cycle, to account for potential harm to the unborn child and provide a "reasonable margin of safety. This last EPA standard I would call reasonably safe. Why should the unborn child of the pregnant female nuclear worker (which unborn should be considered a member of the general public) be allowed the maximum exposure annually as an adult at the boundary of the plant, and even worse, the average person in the public by law is required to receive less than 170 mr/yr, while the unborn can receive up to 500 or more during 9 months. Two points here: one, the 500 mr recommendation is far too high to adequately protect the unborn and two, the 500 mr is certain far from "reasonably safe".

Summary of recommendations

1. Discuss and reference studies of Stewart, Bross and Bertell, etal mentioned here which show that levels of radiation in the range of the proposed recommendation have increased risks of leukemia, cancer and birth defects.

2. Discuss the synergistic effects between low level radiation and other insults such as chemicals, alcohol, and even previous and future radiation exposure.

3. Discuss the shortcomings of the Hiroshima and Nagasaki data.
4. In Table 1 or elsewhere in the guide, include a description of all types of fatal and non-fatal cancers that radiation has been known to cause.
5. In Table 1 or elsewhere in the guide, include the different serious and less serious birth defects (besides small head and mental retardation) that radiation has been known to cause (cleft lip, palate, central nervous system damage, other organ maldevelopment and other malformations).
6. Discuss the potential 10,000 to 1 recessive diseases radiation may cause with result in aging, lowered resistance to disease, lack of vigor, aptitude, intelligence, etc.
7. Discuss the possibility of spontaneous abortions, still-borns and neonatal deaths that may be caused by radiation.
8. Change the recommended radiation exposure from 500 mr to the EPA general public radiation standard of 25mr/yr to ensure a reasonable safety margin. A compromise may be the 170mr/yr exposure the NRC itself has in effect from the general public exposure to nuclear fuel cycle irradiation.
9. Specifically, on p. 8-13.11 - take out the sentence in the second full paragraph - line 4 which begins "Therefore, the NCRP recommends . . ." all the way through ". . . a reasonably safety factor". This sentence is seriously misleading.
10. Develop specific wording which creates a real incentive for the female nuclear worker to voluntarily consider and follow the regulatory guide in protecting her unborn.

Summary

Generally, I find the entire guide misleading to the female nuclear worker for several reasons as outlined above. The risks of radiation are understated or not mentioned at all, and the risks of health problems from other agents are overstated and given great detail. (ie. the hazards of high altitude resulting in low birth weight - no mention is made that radiation exposure too could result in this). This reversed emphasis, ususally couched in "putting the risks of radiation in perspective" tends to discourage female nuclear workers from voluntarily abiding by the 500mr recommendation, let alone any more stringent recommendations. Following the above recommendations may give the female nuclear worker a fuller picture of the actuals to her unborn child and voluntary compliance would be facilitated.

PS. COULD YOU PLEASE FORWARD TO ME ANY FUTURE NOTICES SPECIFICALLY RELATING TO NRC REGULATORY GUIDES FOR RADIATION - RELATED ISSUES.

Sincerely,

Lynda Taylor
Lynda Taylor

Radiation and Health Project

J.S. NICHOLS EXHIBITORY COMMISSION
DOCKETING & SERVICE SECTION
OFFICE OF THE SECRETARY
OF THE COMMISSION

Exhibit Number

11/2/81

Number of Exhibits

1

Number of Exhibits

2

Ed Hill