

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

BEFORE THE ATOMIC SAFETY AND LICENSING BOARD

In the Matter of)
HOUSTON LIGHTING & POWER COMPANY) Docket No. 50-466
(Allens Creek Nuclear Generating)
Station, Unit 1))

AFFIDAVIT OF REGINALD L. GOTCHY CONCERNING
THE NEPA IMPACTS OF LOW LEVEL RADIATION

My name is Reginald L. Gotchy. I am employed at the U.S. Nuclear Regulatory Commission as a Senior Radiobiologist in the Radiological Assessment Branch. A statement of my professional qualifications is attached.

The purpose of this affidavit is to address the merits of the following contention which was reworded by the Licensing Board and admitted by Order dated September 26, 1980.

The health effects* of low level radiation emitted during normal operation of the plant, even though meeting the "as low as is reasonably achievable" standards of Appendix I, if included in the NEPA balancing of costs and benefits, would alter this benefit to the extent that costs would outweigh benefits.

*Health effect: include impacts upon humans, animals, and plants.

By way of background to this response, it should be noted that 10 C.F.R. §§50.34a and 50.36a provide that an application for a permit to construct a nuclear power reactor shall include a description of the preliminary design of equipment to be installed to maintain control over radioactive materials in gaseous and liquid effluents produced during normal reactor operations, including expected operational occurrences. The application must also identify the design objectives, and the means to be employed, for keeping levels of radioactive material in effluents to unrestricted areas "as low as is reasonably achievable."

After a lengthy rulemaking proceeding initiated in 1971, the Commission adopted Appendix I to 10 C.F.R. Part 50 in 1975. See In re Rulemaking Hearing, Numerical Guides for Design Objectives and Limiting Conditions for Operation to Meet the Criterion "As Low As Practicable" for Radioactive Material in Light-Water Cooled Nuclear Power Reactor Effluents, CLI-75-5, 1 NRC 277 (1975). Appendix I provides numerical guides for design objectives and limiting conditions for operation of LWRs to keep radioactivity in effluents as low as is reasonably achievable. Design objectives and limiting conditions for operation conforming to the guidelines of Appendix I shall be deemed a conclusive showing of compliance with the "as low as is reasonably achievable" requirements of 10 C.F.R. Part 50.

In addition to the design objectives for annual doses for any individual in an unrestricted area from both liquid and gaseous effluents, a further requirement

is imposed by Appendix I that the applicant include in the radwaste system all items of reasonably demonstrated technology that, when added to the system sequentially and in order of diminishing cost-benefit return, can for a favorable cost-benefit ratio effect reductions in dose to the population reasonably expected to be within 50 miles of the reactor. As an interim measure, the Commission accepted \$1000 per total-body person-rem for making the necessary cost-benefit analysis and indicated that this represented a "conservative value" subject to modification at a later date. 1 NRC 277 at 284.

In sum, the Appendix I guidelines were designed specifically to limit the maximum exposure of radiation a person might receive from the operation of LWRs. Any facility conforming to the guidelines would be considered a conclusive showing of compliance with the "as low as is reasonably achievable" requirements of 10 C.F.R. Part 50.

The thrust of the instant contention is that the health effects of such radiation meeting the Appendix I guidelines would, if included in the cost-benefit analysis, result in an unfavorable NEPA balance for the Allens Creek facility. The following analysis will show that based on current health effects models, the consideration of Appendix I health risks in the NEPA cost-benefit balance results in such a de minimus impact that it would not alter the balance.

A. Background

The health effects of the NRC Staff's proposed Appendix I rule was discussed in some detail in the Final Environmental Statement (FES) prepared for that rulemaking. (WASH-1258, July 1973). That assessment was based on the BEIR I Report.^{1/} However, only population dose commitments for people living within 50 miles of the power plants were considered. Subsequent evaluations by the Staff indicated that most of the population dose commitments from individual plants occurred outside the 50-mile radius. The best examples for such generic calculations were presented in the FES prepared for the rulemaking on the use of mixed oxide fuel in LWRs, the so-called GESMO proceeding. "Final Generic Environmental Statement on the Use of Recycle Plutonium in Mixed Oxide Fuel in Light Water Cooled Reactors," NUREG-0002 (August, 1976). Those assessments, which included 1,000 MWe LWRs using a variety of fuels, indicated that LWRs meeting Appendix I design objective doses would result in population dose commitments of about 100 person-rem to the entire population of the United States for each year of operation.

Thus, the health effects judgments generically hinge on two considerations: (1) individual risk at doses of 5 mrem per year (or less) to the total body or 15 mrem per year (or less) to any organ of members of the public; and (2) collective risk to the U.S. population at annual population doses of 100 person-rem per year.^{2/}

^{1/} "The Effects on Population of Exposure to Low Levels of Ionizing Radiation," BEIR Committee, National Academy of Sciences (November, 1972).

^{2/} Most estimates are now below 50 person-rem per year.

Risks to plants and animals from radiation exposures have been shown to be of secondary importance relative to man. For example, BEIR I concluded:

In regard to possible effects of radiation on the environment, it is felt that if the guidelines and standards are accepted as adequate for man then it is highly unlikely that populations of other living organisms would be perceptibly harmed." BEIR I Report, p. 3.

This response will therefore concentrate on the potential effects of exposure to individuals and the general public from Appendix I levels since such effects on man dominate the total impact on the environment from low level radiation exposure.

In order for the NEPA balancing of costs and benefits to be altered by health effects considerations, the NRC models used to calculate potential somatic effects (cancer) and genetic effects would have to seriously underestimate the risks. Therefore, the validity of the NRC health effects models will be analyzed in the next discussion followed by a generic assessment of potential risks using current health effects models.

B. Validity of NRC Health Effects Models

In development of its models, the NRC Staff has relied heavily on the BEIR Reports (BEIR I Report (1972), supra, and BEIR III Report (1980)) and the Reactor Safety Study health effects models which were essentially updated

BEIR I models. Since the 1972 report, the EPA, the NRC, and other federal agencies have generally used the BEIR guidance in assessing the risks of ionizing radiation. BEIR is regarded as one of the most outstanding groups of experts on the medical and biological risks of radiation exposure. The BEIR I Report and the NRC health effects models have been subjected to considerable public exposure and debate and have withstood all challenges. See, e.g., Tennessee Valley Authority (Hartsville Nuclear Plant, Units 1A, 2A, 1B, and 2B), ALAB-463, 7 NRC 341 (1978). BEIR III deals with the scientific basis of effects of low-dose radiation and encompasses a review and evaluation of scientific knowledge developed since the BEIR I Report concerning radiation exposure of human populations.

It should be stated at the outset that these models produce estimates of risk that are generally characterized by most radiobiologists as tending to be upperbound (i.e., overestimates of the actual risk). Indeed, both BEIR committees (1972 and 1980) noted that the lower bounds of the risk from exposure to low level and low LET radiation (the type emitted from LWRs) could include zero.^{3/}

Most of the challenges to the conventional beliefs of the radiation bio-effects community have come from a few studies that have been roundly criticized for

^{3/} See, BEIR I, p. 88; BEIR III, p. 187.

reasons ranging from dishonesty to poor statistical methods. Following are direct quotes from the BEIR I and BEIR III reports regarding some of these studies.

1. Drs. Gofman and Tamplin:

The conclusion, therefore, is that the figures generated by Gofman et al. (20) are overestimates: The reasons for their overestimates are:

- (i) An overestimation of the relative risk of solid tumor induction following irradiation of 0-9 year olds by a factor of 4-5, and by a factor of 10 for all other ages.
- (ii) The unreasonable assumption of a life-long plateau region following in utero irradiation. (BEIR I, p. 188).

2. Dr. Sternglass:

The evidence assembled by Sternglass has been critically reviewed by Lindop and Rotblat (5) and by Tompkins and Brown (6). It is clear that the correlations presented in support of the hypothesis depend on arbitrary selection of data supporting the hypothesis and the ignoring of those that do not. (Emphasis added). In several regards, the data used by Sternglass appears to be in error. One of the most vital assumptions in that model - that without the atomic tests the infant mortality rate would have continued to fall in a geometrically linear fashion - is without basis either in theory or in observation of trends in other countries and other times. The dose of strontium-90 used in the experiments referred to by Sternglass were of the order of 100,000 times greater than those received by humans from all the atomic tests. . ." (p. 178, BEIR I).

Part of Dr. Sternglass' presentation (to the BEIR III Committee) alleged that fallout from Chinese bomb-testing in 1976 led to an increased amount of radioactivity in milk in some areas of the United States. He concluded that there was an increase in infant mortality in the eastern-seaboard states from Delaware to New England shortly after these events--an increase that he ascribed to the radioactivity. Although Dr. Sternglass stated that his analysis was incomplete, the Committee received no further data on this subject. We have concluded that the alleged association did not fit the time course for radioisotope movement into the cow-milk food chain, nor was there clear evidence of a universally applicable change in infant mortality rates. Thus, the Committee did not believe that the allegation was substantiated. (p. 561, BEIR III).

3. Dr. Bross, et al:

The NRC Staff is aware of and recognizes the possibility that genetic differences among individuals may result in some people being more sensitive to the effects of radiation than others. However, it is also possible that other persons are less sensitive to radiation. The large population of Japanese bomb survivors involved all ages, sexes, and wide genetic heterogeneity. As a result, the risk estimators used by the NRC Staff (which are based heavily on those data) include susceptible and less-susceptible members of the population. The BEIR III Committee (1980), reviewing recent claims by Bross, et al., regarding the question of susceptibility concluded:

The "susceptible subgroup" model, although it may contain some grain of truth, nevertheless imposes so little structure on the inferences possible from analysis of dose-response data that it is unlikely that usable estimates can be obtained with it from available data. The applications by Bross, et al have been clearly incorrect, and they provide no evidence that the risk of cancer from low-dose radiation is greater than indicated by conventional estimates. (BEIR III, p. 559).

4. Dr. Mancuso et al. (The Hanford Study):

Mancuso, Stewart, and Kneale have reported finding dose-related excess cancer mortality among occupationally exposed workers, monitored with radiation badges, at the Hanford works in Richland, WA. Their risk estimates are much higher than estimates derived from studies of the Japanese atomic-bomb survivors and the populations exposed to ionizing radiation for medical reasons. . .

* * *

[T]he risk estimates for multiple myeloma and pancreatic cancer were extremely high--so high that they can be discounted on logical grounds; such high estimates imply an improbably large causal role for background radiation in the etiology of these diseases among the general population.

It is highly relevant to note that, if the risk estimates for multiple myeloma and pancreatic cancer were not extremely high, they would not satisfy conventional requirements for statistical significance. This necessary numerical relationship is a consequence of the limited sample size and low individual radiation doses of the Hanford workers. Compared with the great majority of studies of irradiated populations, the Hanford study is distinctly lacking in statistical power. That is, assuming the conventional estimates to be representative of the true risks of radiation-induced cancer, the Hanford study could be expected to yield risk estimates that are negative with probability around 40%, positive but statistically nonsignificant estimates with probability around 50%, and statistically significant but highly exaggerated estimates with probability around 10%. Thus, the low statistical power of the Hanford study, according to conventional studies of risk estimates, detracts considerably from the challenge posed by the study's results and from the validity of these estimates.

Other observations support the interpretation of the Hanford study results as small-sample phenomena. The emergence of multiple myeloma and pancreatic cancer

(but not myeloid or lymphocytic leukemia) as the cancers most closely related to radiation, the observed (non-significant) negative associations of dose with the lymphomas, lymphocytic leukemia, and stomach cancer in the first analysis and with myeloid leukemia in the second, and the fact that the risk estimates obtained in the second, expanded analysis were lower than those obtained in the first are all consistent with great statistical instability.

Published criticisms of the Hanford study findings have suggested alternative explanations for the observed dose associations, including confounding of radiation exposure with exposures to other carcinogens and inadequate dosimetry. Only further study can determine the validity of these suggestions.

At present, however, there seems to be little reason to abandon the body of epidemiologic evidence on radiation-induced cancer that, although based on greater exposures, yields consistent and statistically stable estimates. (BEIR III, pp. 553-556, footnotes omitted).

6. Dr. Najarian and Dr. Colton (The Portsmouth Study):

The report by Najarian and Colton was based on interviews with next of kin for 525 (of 1,722) certified deaths at ages under 80 among former workers at the Portsmouth Naval Shipyard in New Hampshire. . . . After the publication of their report, the authors were provided by the National Institute of Occupational Safety and Health with employment and radiation-exposure records from the Portsmouth Naval Shipyard for the 1,722 names in the original collection of death certificates. . . . The analysis revealed that the decedents whose next of kin were contacted in the original study did not constitute a representative sample of those actually exposed. In particular, it was more likely that the next of kin would be contacted, and the decedent would be correctly identified as a nuclear worker, for exposed workers who died of cancer, compared with those who died of other causes.

* * *

[S]uccessive analyses of proportional mortality among Portsmouth Naval Shipyard workers [have contributed] little to our understanding of health risks from low-level radiation. However, they do provide a remarkable illustration of the dangers of response bias in epidemiologic studies. (BEIR III, pp. 559-560, footnote omitted).

The report was reevaluated by Colton in a July 9, 1980 report prepared for National Institute for Occupational Safety and Health (NIOSH). Personal communication with NIOSH^{4/} indicated that the Colton reevaluation was released to the public for information but was not endorsed by NIOSH. A Staff review of the study does not indicate any statistically meaningful basis for developing a dose response relationship for radiogenic cancer. In fact, at all dose levels except one, the cancer risks appear lower among radiation workers than among the unexposed control population of workers. It should be noted that a detailed study by NIOSH is nearing completion.

6. Other Areas of Dispute

The following discussions are relevant to some of the arguments just discussed. However, they have been raised by several people (including some of the above) and deserve separate consideration.

The first argument is that as the dose rate declines, the health risk per unit dose increases. BEIR III disagrees, concluding:

^{4/}Mr. Phillip Beirbaum, Deputy Director, Division of Surveillance, Hazard Evaluations and Field Studies, September 9, 1980 telecom.

The available data relative to the effects of low-dose or low-dose-rate exposures on carcinogenesis in humans and experimental animals do not, in general, support the hypothesis of an increased probability of induction at low dose rates. Increasing the duration over which a given dose of low-LET radiation is administered, either by decreasing the dose rate or by fractioning the dose, has been generally found to decrease oncogenic effects of ionizing radiation. (BEIR III, p. 565).

The second argument is that the risks of radiation exposure increases in a multiplicative manner (i.e., inferring synergism) when accompanied by exposure to other carcinogens or toxic materials. The NRC Staff recognizes such a possibility. However, it should be noted that if such effects exist (e.g., from cigarette smoking), they must first be identified before anything can be done about them. The BEIR III Committee, in reviewing the most recent data on possible synergism between cigarette smoking and exposure to radon-222 decay products, concluded the following:

. . . it is of interest that emerging data in man indicate that cigarette-smoking does not contribute as strongly to the risk of bronchial cancer induced by radiation as had previously been thought, although smoking shortens the latent period. (BEIR III, p. 390).

Based on the foregoing discussion, it is apparent that the BEIR Committee has considered and discredited most of the studies that have criticized the conventional wisdom regarding radiation bio-effects. Thus, the Staff believes that the BEIR III Report can be considered the latest authoritative guidance or the best scientific evidence available with respect to health effects from radiation exposure. Therefore, the validity of the health effects models used by the NRC can be determined by a comparison with the BEIR III Report.

In such a comparison the Staff finds that the most probable risk values cited by the BEIR III Report are only slightly lower than those currently used by the NRC Staff--120 cancer deaths per 10^6 person-rem versus 135. With regard to estimates of genetic effects in future generations, the BEIR III Report yields a slightly lower risk than estimated by the NRC Staff--220 effects per 10^6 person-rem versus 258. Based on these comparisons with the BEIR III Report, the Staff believes that the validity of the NRC health effects models is confirmed.

C. Evaluation of Potential Health Effects Associated with Operation of LWRs Meeting Appendix I Design Objectives

Since we have concluded that the health effects models used by the NRC Staff are in agreement with the latest authoritative guidance, they will now be applied to evaluate the potential health risks associated with LWRs operating in accordance with Appendix I design objectives.

1. Risks to Individuals

In the first case, exposures to individuals, the health risks are proportional to the Appendix I doses.

I. <u>Liquid Effluents</u>	App I Design Objectives (per Unit)	Lifetime Risk per Year of Exposure at App. I Dose Levels	
		<u>Cancer Mortality</u>	<u>Genetic Effects</u>
Total body	3 mrem/yr	0.4 chances in a million	0.8 chances in a million
Any organ *			
a. Thyroid	1 mrem/yr	0.1 chances in a million	3 chances in a million (gonad dose only)
b. Bone marrow	1 mrem/yr	0.07 chances in a million	
II. <u>Gaseous Effluents</u>			
Total body	5 mrem/yr	0.7 chances in a million	1 chance in a million
Any organ *			
a. Thyroid	15 mrem/yr	0.2 chances in a million	4 chances in a million (gonad dose only)
b. Lung	15 mrem/yr	0.3 chances in a million	
c. Bone marrow	15 mrem/yr	0.1 chances in a million	

* All other organ risks are smaller than those shown.

In order to place the preceding risk values in perspective, the table below lists some lifetime risks of mortality that are numerically equivalent to one chance in a million:

<u>Source of Risk</u>	<u>Lifetime Mortality Risk Equivalent to one chance in a Million ^{5/}</u>
Cigarette smoking (primarily lung cancer and cardiovascular disease)	1.5 cigarettes
Drinking wine (chirrosis of the liver)	0.5 bottle
Automobile driving (accidental death)	50 miles
Air travel (accidental death)	250 miles
Rock climbing (accidental death)	1.5 minutes
Canoeing (accidental death)	6 minutes
Typical factory work (accidental death)	1-2 weeks
Being a man aged 60 (cancer and heart disease)	20 minutes
Being pregnant (ages 20-34)	20 hours

The average annual risk of mortality is on the order of 14 chances in 1,000; or about 10,000 times greater than the potential lifetime risk of annual radiation doses at Appendix I levels.

Another comparison can be made with exposure to background radiation. Background radiation varies from about 80 mrem/year for some low level areas (e.g., Florida) to about 200 mrem/year in the high mountains of Colorado. In other words, people are exposed to normal variations in background radiation exposure in the U.S. that are 1,000% or more in excess of the Appendix I design objective

^{5/}Sir E. E. Pochin, "The Acceptance of Risk," Br. Med. Bull. 31, No. 3, p. 184 (1975).

levels. Since most experts believe background radiation accounts for a few percent or less of the total lifetime risk of cancer death (cancer accounts for about 20% of the total lifetime risk of mortality), the overall risk of cancer mortality would not be significantly changed by exposures at the Appendix I levels.

2. Risk to Populations

A second type of potential risk comes from cumulative population doses from LWRs operating at Appendix I design objectives. As mentioned previously, a reasonable estimate of the dose to the U.S. population (delivered at average rates that are about 0.0005% of background rates) is about 100 person-rem.^{6/} Current health effects models would predict on the order of 0.01 potential cancer death (i.e., none) among the entire U.S. population during the remainder of their lives. In other words, there might be as much as one death in the years ahead for each year the U.S. operates 100 large LWRs. Thus, if the 220 million Americans now living were continuously exposed to the radioactivity released from 100 large LWRs for the life of those plants (about 30 years/plant), about 40 people might die from cancer due to the operation of the LWRs among 4.4 million people who would die from cancer due to all other causes (i.e., about 0.0009% of the total from all other causes).

^{6/} Person-rem is the unit of collective population dose; it is the sum of the doses to each person in the exposed population. For example, one millirem given to 1,000 people is one person-rem. Most assessments estimate 100 person-rem.

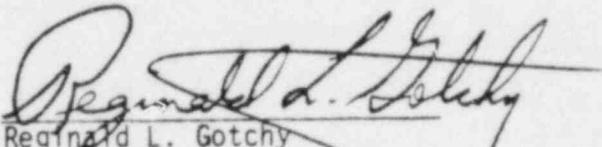
In the case of genetic effects, the collective risk of a genetic defect occurring during the next 5 generations is about twice that of the risk of cancer mortality. Most of the genetic effects, while tragic, would be relatively insignificant compared to the current estimated risk of about 6% per generation^{7/} from all other causes (i.e., about 0.001% of the total from all other causes).

D. Conclusion

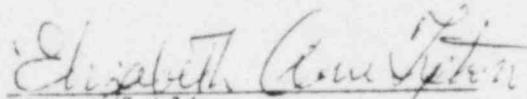
Based on the foregoing discussion concerning the current health effects models, it is concluded that health risks to present day populations from cancer, and to future populations from genetic effects associated with normal operations (Appendix I levels) of large LWRs in the U.S. are insignificant relative to naturally occurring events. As a result of the de minimus nature of Appendix I health risks, the NEPA cost-benefit balance cannot be significantly affected by them and, thus, result in an unfavorable NEPA conclusion regarding the construction of the facility. Accordingly, this contention that normally operating LWRs which meet the Appendix I design objectives can result in health costs that would alter the NEPA cost-benefit analysis must be rejected on the basis of the best scientific evidence available.

^{7/}BEIR I, p. 56.

The foregoing affidavit was prepared by me and I swear that it is true and correct to the best of my knowledge, information and belief.


Reginald L. Gotchy

Subscribed and sworn to before me
this 26th day of November, 1980.


Notary Public

My Commission Expires: July 1, 1982

DR. R. L. GOTCHY

Professional Qualifications

My name is Reginald L. Gotchy. I am a Senior Radiobiologist on assignment with the Radiological Assessment Branch in the Office of Nuclear Reactor Regulation. In this capacity, I am responsible for coordinating the technical review and evaluation of the environmental radiological impact of nuclear facility operations.

I received a B.S. in Zoology from the University of Washington in 1958, an M.S. in Radiation Health from the Colorado State University in 1966, a Ph.D. in Radiation Biology from the Colorado State University in 1968, and attended the University of Washington Graduate School 1958-1959 as an AEC Radiological Physics Fellow.

I have 19 years of professional experience in health physics, industrial hygiene, radiation physics, radiation biology, environmental sciences, project coordination of research and development programs, and development of AEC and NRC standards. This experience has included operational and safety responsibilities, and review and coordination of facility operations under contract to the AEC. I have been employed by the Lawrence Radiation Laboratory, the U.S. Public Health Service, Reynolds and Electrical Engineering Company, the AEC Nevada Operations Office, and the NRC Office of Standards Development prior to my assignment in the Office of Nuclear Reactor Regulation in 1975. I was an adjunct professor of Radiation Health Technology at the University of Nevada, Las Vegas (1969-1972).

I am a member of Sigma Xi (Research Society of North America), the American Nuclear Society, the Health Physics Society and the International Radiation Protection Association, and the Radiation Research Society. I am a past member of the American Association for the Advancement of Science and the American Industrial Hygiene Association.

I am certified by the American Board of Health Physics, and served as a member of the Panel of Examiners (1972-1976). I remain active in the development of examination questions and updating my professional standing by periodic post-graduate work and training.

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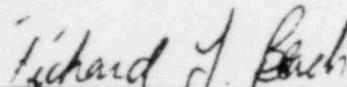
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