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REPORT OF THE STAFF COMMITTEE TO STUDY THE PAPER "RADIATION EXPOSURES OF
HANFORD WORKERS DYING FROM VARIOUS CAUSES"

The committee was established on October 27, 1976 to study the subject document, to evaluate its methodology and results, to recommend if any NRC action should be initiated over the short term and to present a report of these findings and recommendations.

The committee was composed of S. Yaniv, D. Rubinstein, A. Brodsky and M. Parsont. M. Parsont was selected as the coordinator of the project under the supervision of J. Kastner.

The committee met on 3 separate occasions at which times the planning of approach, discussion of comments and review of draft inputs were accomplished.

The investigation of the document was as thorough as was possible given the nature of the data and form of the Mancuso paper. (Dr. Mancuso was not available to provide assistance) There were many comments - few in some support of the paper, most critical. The extent and complexity of these comments ranged from "nits" to reanalyses made of one of the tables.

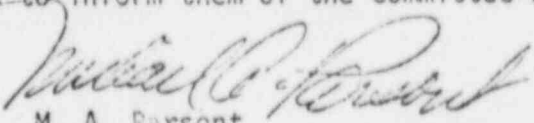
The consensus of the committee was that the results drawn by Mancuso et. al. could not be supported by the information presented in their document, and that no immediate NRC action need be taken in addition to this current review. It was recommended that the NRC support the continuation of collection and analysis of the Hanford and other similar data and to participate in some appropriate manner.

The committee study presents a distillation of some of the important comments. Attached to this study are more detailed comments compiled by A. Brodsky and a recommendation of H. Peterson of future action.

The members of the committee will make themselves available for comment on details of the study as is necessary.

Since the results of the Mancuso paper will be appearing at hearings and other occasions, it is recommended that at least one meeting be conducted with interested parties within NRC to inform them of the committee's work.

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Enclosure:
Report of Staff Group to Study
Mancuso Paper with attachments

REPORT OF THE STAFF GROUP TO STUDY THE MANCUSO, STUART, KNEALE PAPER ON LOW LEVEL RADIATION EFFECTS

Introduction

On October 13, 1976, Drs. Thomas Mancuso, Alice Stewart and Mr. George Kneale presented a paper (hereafter called the "Mancuso paper") at a Health Physics Society Symposium in Saratoga Springs, New York.^{1/} The authors purported to demonstrate a causal and numerical relationship between low level radiation and the mortality from four cancer types in former employees of the Hanford Laboratories of Richland, Washington. Also presented at this meeting was a paper by Dr. S. Marks and E. Gilbert^{2/} of Battelle Northwest Laboratories pointing out what they considered to be serious deficiencies in the Mancuso paper and calling for a peer review of the Mancuso paper.

Using data from human death certificates and radiation exposure records, the authors reported an apparent association between the proportion of specific cancer mortalities and the amount of occupational radiation exposure received. The authors claimed the results indicated a much more pronounced radiation effect than had been concluded from previous studies in man and laboratory animals. If valid, the findings of this study would indicate significant implications for our assessment of radiation effect on the health and safety of the public. This applies not only to NRC-licensed activities, but also other radiation exposure sources such as natural background radiation and medical diagnostic X-rays. Therefore, a technical group was established to study the Mancuso paper, to provide technical judgments of its analyses and conclusions and to recommend what further

action, if any, should be taken by NRC. The group was composed of a radiobiologist, a health physicist, a biostatistician-health physicist and a mathematical statistician. The Mancuso paper was reviewed for competence of technical content, presentation and analytical techniques. The group relied on the summary tables and graphs as given. Unfortunately, the original Hanford data used by the authors were not available for the initial study. The review also considered pertinent scientific literature, the paper of Marks and Gilbert ^{2/} and a review by Bair for the Atomic Industrial Forum.^{3/}

The following results represent a consensus of the findings of the group with representative illustrations for clarification.

Group Findings

The use of a retrospective epidemiological analysis by Mancuso et al. is thought to be a poor approach in light of data already collected and available to the authors. A prospective approach, in which groups of exposed and nonexposed workers would be followed with respect to the number and causes of mortality, could have permitted the study of actual mortalities and specific causes of death rather than ratios of causes of death. Primarily, the authors investigated relative mortalities.

Cancer incidence and mortality are complex phenomena involving such things as demographic factors, age, geographical areas, latent periods, and exposure to various carcinogenic agents including ionizing radiation from

all sources (natural, medical, occupational, etc.). An analysis that deals with only one or two of these factors at a time cannot be conclusive because it does not treat the interrelationships of the other factors. By and large, the authors used a one variable at a time approach which led to the confounding of these factors -- this is a major deficiency.

To give a simplified example of confounding, and the resulting bias: Older workers are more likely to die of cancer. Since older workers are also more likely to have accumulated a larger radiation dose, some age related cancer mortalities might be erroneously attributed to the larger dose.

In addition, small sample size is frequently a problem in studies of this type, and particularly in the authors' retrospective analyses, which compare average radiation exposures among cancer deaths with that of other deaths. Since the distribution of radiation doses is highly skewed, the few cases with large doses tend to dominate the averages and can lead to inappropriate conclusions.

A prospective analysis had been outlined by Dr. Mancuso in previous reports on this project. Such analysis would facilitate control of the many factors affecting cancer rates.

The Data and Conclusions

There are specific instances where group review indicated that the authors' conclusions could not be supported by either their analysis or their presented

data. There are several instances in which tabular material presented allows for multiple interpretation of the data. Reasoning similar to that which the authors used to make their conclusions can yield contradictory interpretations of equal merit. Tables which are particularly vulnerable to this criticism are 1 and 6. For example, from Mancuso's Table 1, the ratio of cancer to non-cancer mortalities in males is lower than the similar ratio in females whereas the average occupational radiation exposure of males is higher. This holds true for all males ($670/2851 \times 100 = 23.5\%$) compared to all females ($111/251 \times 100 = 44.2\%$) as well as for exposed males ($441/1739 \times 100 = 25.3\%$) compared to exposed females ($32/76 \times 100 = 42.1\%$). This result is not consistent with U. S. cancer mortality data compiled by the National Cancer Institute for cancers resulting from all causes.

If anything, these data suggest a lower cancer mortality among exposed women (which we do not claim). This staff conclusion is similar to that of Marks and Gilbert 2/ and Bair.3/

The group carried out some cursory analyses using the Mancuso data. These analyses per force also ignored many factors of cancer etiology and depended in part on small samples and were therefore also grossly deficient. Although one of the group's analyses suggested an apparent increase in cancer deaths among exposed males, it was considerably different from that given in the paper by Mancuso et al. A similar analysis for women shows no increase of cancer deaths among exposed women. In fact, some of the Mancuso et al.

tabulations of the data indicate this inconsistency and thus are contrary to their own conclusions. The conclusions that can be drawn from both the group's and the Mancuso et al. analyses are that different statistical treatments of the presented data yield different results, and none can be definitive unless all relevant factors are considered.

A View of the Literature

The results of the Mancuso paper are in disagreement with a large body of data on cancer risks as summarized in 1972 in the BEIR Report^{4/}--a report compiled under the auspices of the National Academy of Sciences by acknowledged experts in the field of radiation effects.

In contrast with the Mancuso report, we understand that the National Council on Radiation Protection and Measurements in its report No. 40, soon to be published, will support the conclusion that the effects of low dose and dose rate radiation is about one-fifth as damaging as was previously suggested in the BEIR Report.

The independent analysis of the Hanford data by Marks and Gilbert^{2/} resulted in entirely different conclusions than those of the Mancuso paper.

Conclusions and Recommendations

The finding of this analysis, based on the above discussion, is that the conclusions reached by Mancuso, Stewart, and Kneale cannot be justified by the information given in their paper. We find that there is insufficient information in the paper for independent and thorough analysis of the data. However, on the basis of the information provided, the presentation

is, in part, self-contradictory, unclear, and probably incorrect in several important areas. Based on these findings, the initiation of any immediate regulatory action by NRC is not warranted.

We are convinced, however, that the Hanford data and data already collected on other plants may eventually offer valuable epidemiological conclusions about the effects of low level ionizing radiation. We know that these data are only a portion of that which have been collected by the AEC Health and Mortality Study and which are available for analysis. There is a real need to study and evaluate the total content and impact of the Hanford and other pertinent data. The NRC should carefully and expeditiously analyze the Hanford and other data of this type. This should be a project of highest priority. In addition, knowledgeable groups such as the National Council on Radiation Protection, National Academy of Sciences, and Energy Research and Development Administration, or independent authorities or organizations such as the National Cancer Institute and Environmental Protection Agency should be encouraged to continue work in the general scientific area of study represented by the Mancuso project. The NRC should maintain active liaison with all groups involved in such study.

REFERENCES

- (1) T. F. Mancuso, A. M. Stewart, and G. W. Kneale, "Radiation Exposures of Hanford Workers Dying from Various Causes," ERDA Contract No. E(11-1) 3428 presented at the Tenth Midyear Symposium of the Health Physics Society, Sarasota Springs, New York 11-13 October 1976.
- (2) S. Marks and E. Gilbert, comments on the paper by Mancuso, Stewart, and Kneale (Ref. 1) to be published in the same proceedings of the Tenth Midyear Symposium of the Health Physics Society.
- (3) W. J. Bair "Press Response to New York Times Article by David Burnham Monday, October 25, 1976." Battelle, Pacific Northwest Laboratories, Richland, Washington 99352, October 27, 1976.
- (4) Report of the Advisory Committee on the Biological Effects of Ionizing Radiations, "The Effects on Populations of Exposure to Low Levels of Ionizing Radiations," National Academy of Sciences - National Research Council, Washington, D. C., 1972.
- (5) T. F. Mancuso, B. S. Sanders, and A. Brodsky, 1971, "Study of the Lifetime Health and Mortality Experience of Employees of AEC Contractors, Part I: Methodology and Some Preliminary Findings Limited to Mortality for Hanford Employees," presented at the November, 1971 topical symposium of the Health Physics Society in Richland, Washington, and published in Volume III of "Proceedings, Radiation Protection Standards: Quo Vadis," Columbia Chapter, Health Physics Society, 1972.