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Report To The Congress

OF THE UNITED STATES

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Review Of The Department Of Energy's Controversial Termination Of A Research Contract

A contract to study the effects of low-level radiation on workers in the Department of Energy's nuclear facilities, begun in 1964, was conducted by a University of Pittsburgh researcher, Dr. Thomas Mancuso. On July 1, 1977, the contract was terminated and the study transferred to three contractors largely supported by the Department of Energy.

GAO's report discusses several controversial aspects of this matter, including the termination and the transfer of the study. It was undertaken at the request of the Chairman, Subcommittee on Health and the Environment, House Committee on Interstate and Foreign Commerce.



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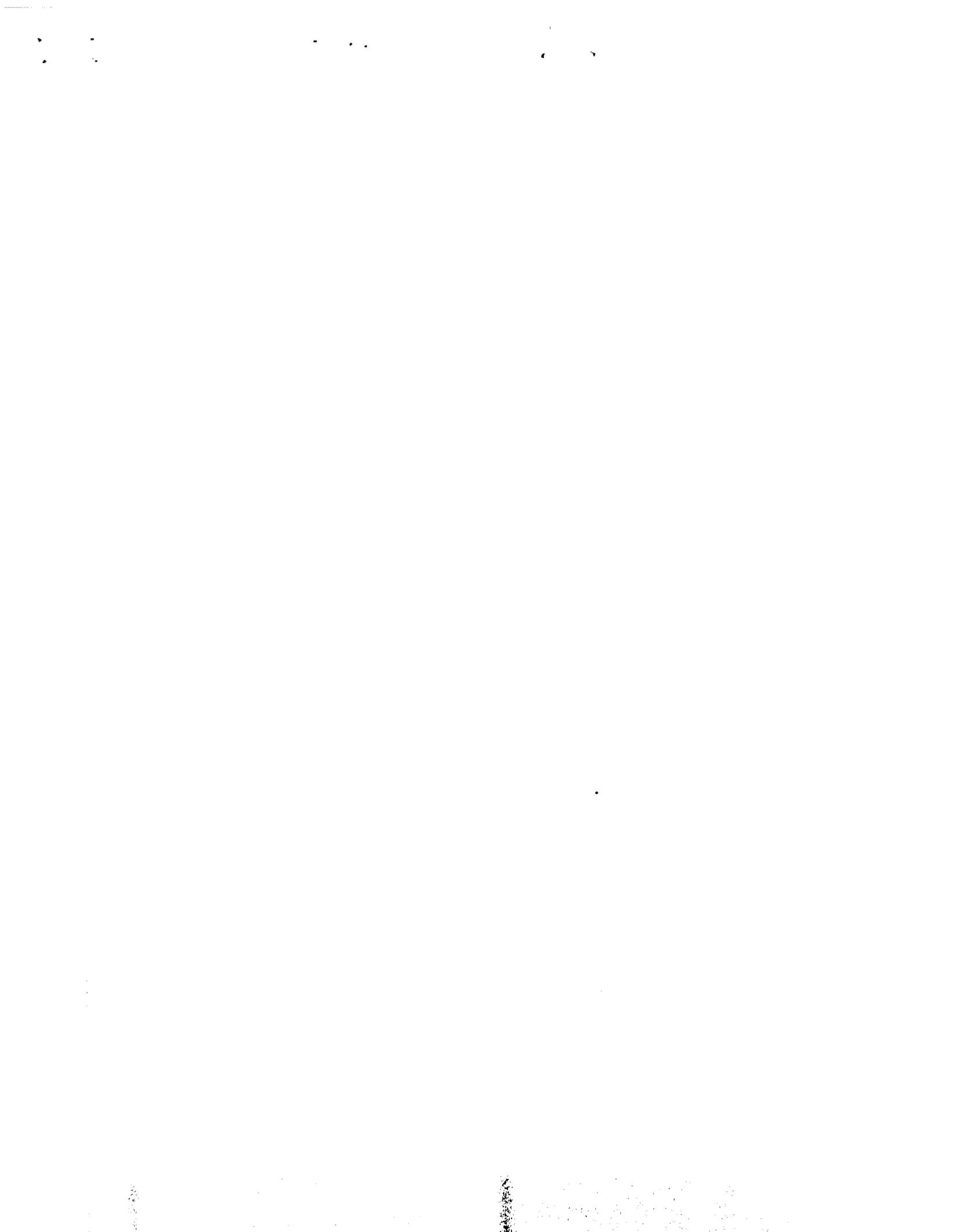


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Report Restr.

EMD-79-21

JANUARY 2, 1979





COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-164105

January 2, 1979

The Honorable Paul G. Rogers
Chairman, Subcommittee on
Health and the Environment
Committee on Interstate and
Foreign Commerce
House of Representatives

Dear Mr. Chairman:

In response to your request of August 17, 1978, here are the results of our review of the Department of Energy's termination and transfer of a research contract to study the effects of low-level radiation on human health. Our report also discusses an investigation of the termination and transfer conducted by the Office of Inspector General, Department of Energy.

We provided selected officials of the Department of Energy and the terminated contractor an opportunity to review a draft of this report. Their comments are contained in chapter 5 of this report. The report will be available for unrestricted distribution in 30 days unless you publicly announce its contents earlier.

Sincerely yours,

ACTING


Comptroller General
of the United States



COMPTROLLER GENERAL'S REPORT
TO THE CHAIRMAN, SUBCOMMITTEE
ON HEALTH AND THE ENVIRONMENT,
HOUSE COMMITTEE ON INTERSTATE
AND FOREIGN COMMERCE

REVIEW OF THE DEPARTMENT
OF ENERGY'S CONTROVERSIAL
TERMINATION OF A RESEARCH
CONTRACT

D I G E S T

In 1964 the Atomic Energy Commission, a predecessor agency to the Department of Energy, contracted with the University of Pittsburgh, with Dr. Thomas Mancuso as principal investigator, to study the health effects of low-level radiation exposure on workers at several Government-owned nuclear facilities. In 1977 Dr. Mancuso's contract was terminated but the study he started was continued by other Department of Energy contractors. (See pp. 1 to 3.)

GAO reviewed the

- termination of Dr. Mancuso's contract,
- transfer of the study to other Department contractors, and
- report on the matter by the Department's Office of the Inspector General.

TERMINATION OF THE CONTRACT

Background
The Department and Dr. Mancuso disagreed as to the reasons for termination of the contract. The Department claims that, essentially, Dr. Mancuso's work was unsatisfactory because the study was not producing results or conclusions for publication. Conversely, Dr. Mancuso claims that his contract was terminated because of his refusal to make public his preliminary findings, which the Department wanted to use to refute the 1974 findings of a Washington State researcher that showed excess cancers among workers in a nuclear facility. (See p. 5.)

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GAO found that documentation surrounding the reasons for terminating Dr. Mancuso's contract does not answer all questions. However, it is certain that the Department was very concerned about the conduct of Dr. Mancuso's study and was seriously considering replacing him years before the Washington State researcher's findings were known. It is also evident that the findings by the Washington State researcher and Dr. Mancuso's continued refusal to publish his own preliminary negative findings had a significant impact on moving the Department to take the steps to terminate his contract.

Why didn't the Department take this action years earlier when serious questions about Dr. Mancuso's study were being raised? For about the first 6 years of the contract, Department officials treated the contract with a "hands off" attitude because they believed the contract had the support of the highest level officials. Even though the Department's dissatisfaction with the study mounted and reached a point where it seemed that termination of the contract was imminent, the Department still did not act. In GAO's view, responsible Department officials found it easier to procrastinate rather than to act on an unpleasant matter which would likely result in questioning and adverse criticism of their action. (See pp. 11 and 12.)

TRANSFER OF THE STUDY TO DEPARTMENT CONTRACTORS

Responsibility for the study Dr. Mancuso started has been transferred to three other Department contractors. Documentation surrounding the consideration and selection of these contractors is sparse.

The contractors, however, were not necessarily bad choices. They appear capable of doing the job; potential weaknesses in their abilities have been identified; and solutions to correct these weaknesses are being sought. (See pp. 13 to 17.)

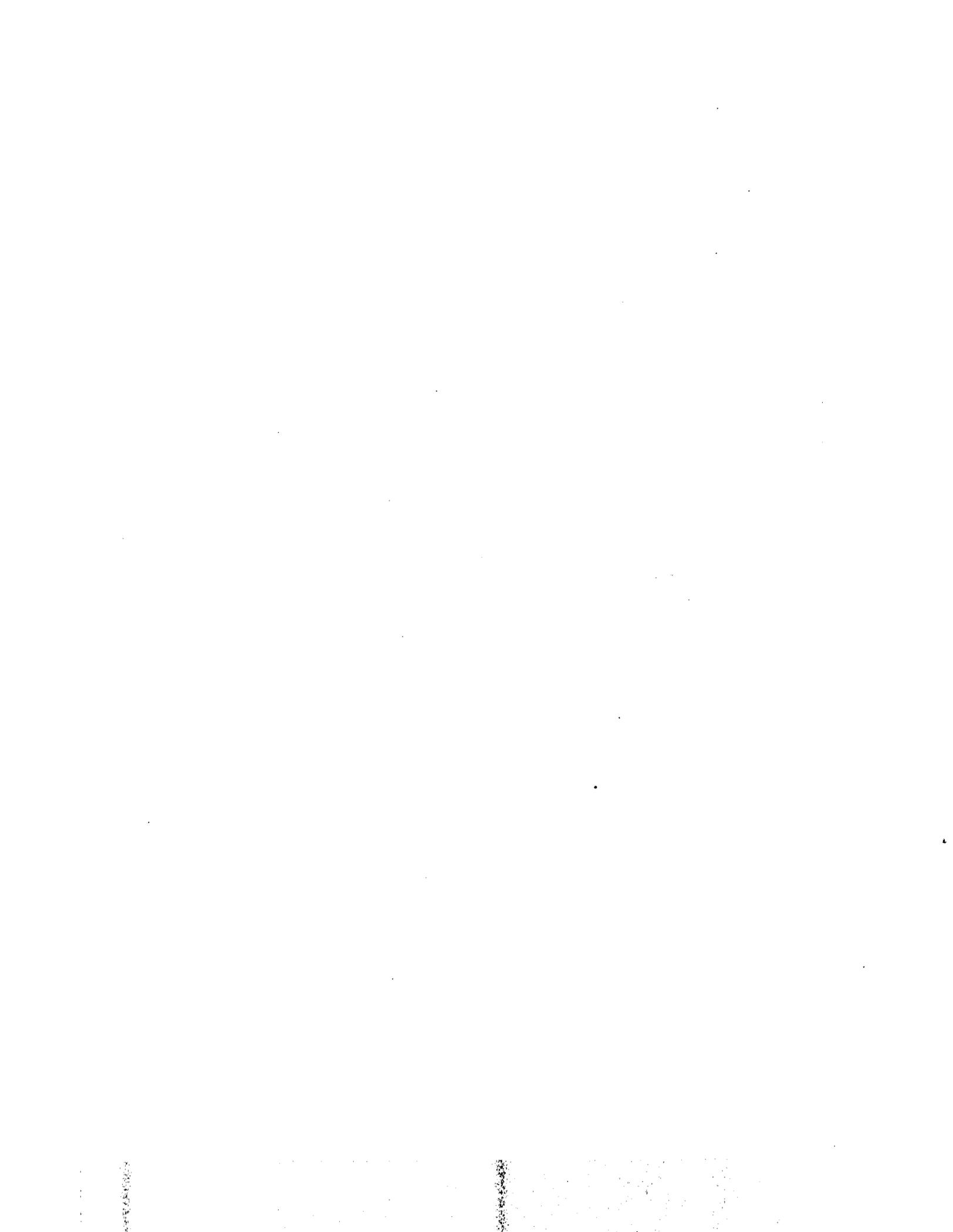
In GAO's view, the significant problem associated with the Department's selection is the image that results when the agency developing and improving nuclear power through contractors uses these same contractors to study the safety of nuclear power. The ramifications of this problem extend much beyond Dr. Mancuso's study to all of the similar Department research projects being carried out under these circumstances. (See p. 18.)

THE OFFICE OF INSPECTOR
GENERAL'S REPORT

In May 1978 the Office of Inspector General issued a report of its findings on the Department's termination of Dr. Mancuso's contract and transfer of the study he started. The investigation was limited to gathering factual information concerning specific allegations. The OIG's investigation disclosed that there was no validity to the allegations. In GAO's view, the report is a fair and comprehensive factual history of events surrounding the termination and transfer. (See p. 19.)

Comments on GAO draft report

GAO submitted this report for comment to the Department and to Dr. Mancuso. Their comments were received on December 14, 1978. The Department believed GAO's report appeared to be well balanced, with the facts presented in a clear, objective manner. However, the Department was critical of GAO's discussion of a conflict of interest over its selection of the new study contractors. Dr. Mancuso believed GAO's report was inaccurate and unresponsive to the questions raised by the House Subcommittee. GAO could find no evidence to support Dr. Mancuso's contentions regarding this matter. (See pp. 21 and 22.)



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ABBREVIATIONS

GAO	General Accounting Office
OIG	Office of Inspector General
ORAU	Oak Ridge Associated Universities

CHAPTER 1

INTRODUCTION

In a letter dated August 17, 1978, the Chairman, Subcommittee on Health and the Environment, House Committee on Interstate and Foreign Commerce, requested that we review and report on the Department of Energy's decisions to terminate the research contract of Dr. Thomas Mancuso, University of Pittsburgh, and to transfer the study he started to Department-supported contractors. Under the research contract, Dr. Mancuso, since 1964, had been studying the health effects of low-level radiation exposure on workers at several of the Department's nuclear facilities.

After his contract was terminated in 1977, Dr. Mancuso made serious allegations that suggested the Department deliberately attempted to suppress unfavorable findings of another study and to gain control over future analysis of his study data. On February 8, and 9, 1978, the House Subcommittee on Health and the Environment held hearings which addressed these allegations. In May 1978 the Department's Inspector General issued a report on the contract termination. The hearings and the Inspector General's report failed to totally resolve the allegations. Thus, the reasons for the Department's termination of Dr. Mancuso and the transfer of the research he started to Department-supported contractors remained unclear.

HISTORY AND BACKGROUND

Ever since man began to use radioactive materials, scientists have wondered what health effects result. More knowledge is available concerning the effects of large doses and high-level exposures, but the magnitude of many of the effects of low-level radiation remain uncertain. 1/

1/The health effects of low-level radiation exposure is the subject of broad-based, ongoing GAO study that should result in a report during the summer of 1979.

The Atomic Energy Commission 1/ a predecessor agency to the Department, had been involved in using radioactive materials since its inception. It recognized the need for information concerning the effects of low-level radiation, and as a result, approved in July 1964 a study designed to correlate lifetime radiation exposures with health and mortality data of Government contractor employees involved in nuclear work. The University of Pittsburgh, because of its excellence in epidemiology, 2/ was selected as the contractor and Dr. Thomas F. Mancuso was selected as principal investigator.

In 1964 a 1-year study was funded to assess the adequacy of information at various Government nuclear installations and to design a study approach. At the end of the 1-year study, which cost about \$72,000, Dr. Mancuso proposed to carry out a series of actual tests to validate the conclusion that it was feasible to carry out a useful epidemiological study. The proposal was for 5 years and included development of methodology, collection of data, data conversion and processing, and programs for statistical analysis.

Five installations were selected for the 5-year study including those located at Richland, Washington; and Oak Ridge, Tennessee. They were selected because their medical and radiological records were well organized and accessible.

From 1965 to 1974, the contract was reviewed annually for renewal by Department officials. During three of these reviews (1967, 1972, 1975), outside independent "peer reviews" of the study were obtained. The study was renewed each year with no substantive changes to the contract. During this period, the study found no indications of any adverse effect from radiation exposure.

1/In 1975 the Atomic Energy Commission became part of the Energy Research and Development Administration, which became part of the Department of Energy in 1977. Many of the statements and actions attributed to the Department were actually stated or performed by the Atomic Energy Commission and the Energy Research and Development Administration. For simplicity, however, the Department is usually referred to in this report.

2/The branch of medicine dealing with the study of the description and determinants of disease prevalence in man.

In May 1974 a limited preliminary mortality study conducted by the Washington State Department of Social and Health Services indicated a higher rate of some cancers among workers employed at the Richland facility.

In March 1975, Dr. Mancuso was informally advised by Department officials that effective July 31, 1977, his contract would be terminated and the study transferred to another contractor. In March 1976, formal notice of this decision was given to the University of Pittsburgh. The reason given by the Department for termination was simply that it was an "administrative decision." Neither Dr. Mancuso nor the University of Pittsburgh protested the action. About \$6 million of Federal funds had been expended on the study while it was directed by Dr. Mancuso.

During nearly all of the course of the contract (1965-76), analysis of study data by Mancuso's study team suggested no adverse impact on worker health from radiation exposure. Then, in the last year of the contract, Dr. Mancuso hired two new persons for the specific purpose of preparing for publication an analysis of the data. Dr. Mancuso's study team made an analysis of the Richland data and in October 1976 presented the preliminary findings at a national meeting of the Health Physics Society. ¹/ This analysis concluded that occupational radiation exposures at Richland were associated with an increase in cancer. This unexpected finding aroused national attention because occupational radiation protection standards had been thought to be well below levels where health effects could be detected.

After Dr. Mancuso reported his "positive" findings, the Department publicly criticized the study's analytical approach and the preliminary nature of the findings. In addition, the Department solicited other peer reviews of the study and provided data collected by Dr. Mancuso to the peer reviewers for analysis. While most peer reviewers were critical of Dr. Mancuso's study methods, his findings were described as interesting and deserving of continued study.

Even though the Department terminated Dr. Mancuso's contract, it has continued the study. Rather than continue the study with one contractor, the Department divided the work.

¹/An independent, professional organization whose charter is to develop scientific knowledge and a practical means whereby man and his environment are protected against the effects of harmful radiation.

That is, Department contractors located at the Richland, Washington, and Oak Ridge, Tennessee, facilities have been selected to perform the ongoing data collection activities and to develop the analytical methods required to determine if adverse health effects were or were not present. The Richland contractor has published two papers on Richland workers and the Oak Ridge contractor expects to publish preliminary results during fiscal year 1980.

Dr. Mancuso's study is one of many that the Federal Government has funded or supported during the last 25 years. According to Department records, about 20,000 studies or papers dealing with various aspects of the effects of low-level radiation have been supported by the Federal Government.

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The following are the results of our review of (1) the Department's justification for terminating Dr. Mancuso's research contract, (2) the events surrounding the transfer of Dr. Mancuso's contract to Oak Ridge and Richland contractors, and (3) the investigation of the matter by the Department's Inspector General.

CHAPTER 2

THE TERMINATION OF THE CONTRACT

The Department says that the reasons for terminating the contract were:

- The study team's lack of publication in scientific journals and lack of papers discussing the methodology for analysis.
- The reluctance of Dr. Mancuso to initiate any analyses until all data collection was complete.
- Unfavorable peer reviews given the study.

Dr. Mancuso stated that he believed the contract was terminated because of his refusal to make public his preliminary findings in 1974, which would have refuted the findings of the Washington State researcher that showed excess cancers among workers in a nuclear facility. He also said that the Department recognized that because the Washington State researcher had found a positive relationship, eventually his study would find the same. Because a similar finding by his study would be detrimental to the Department, he said, the Department terminated his contract so it could control his data.

CHRONOLOGY OF EVENTS LEADING TO TERMINATION

To assess the reasons behind the termination, it is necessary to discuss the origin and evolution of the project. The project began as a result of interest expressed by the Commissioners of the Atomic Energy Commission, who agreed that a study in the area was needed and requested that one be initiated. Because of the Commissioners' direct involvement, the Department program staff perceived the study to be totally supported by the Commissioners. Thus, the staff developed a kind of "hands off" attitude during the first 6 years of the study. For example, the contract renewals were not reviewed or presented for approval to the Department's research committee, as were other contracts, but were simply administratively approved by the program officials.

A peer review of the study was conducted in 1967 by five outside reviewers. The reviewers' critiques addressed the question of whether or not to expand the study to other Department installations. The reviewers unanimously agreed that the study should be limited to the installations being studied at that time. Three of the reviewers stated the study should

move as rapidly as possible toward analyzing the available data. Another reviewer suggested that if the study continued on its present course, then it should be terminated. The remaining reviewer suggested only that the study should be limited. One reviewer praised Dr. Mancuso's performance but was critical of the direction of the study. The other four reviewers did not address his performance in their critiques. Department files contain a letter to Dr. Mancuso dated December 15, 1967, in which the Department conveyed the principal criticisms of the peer reviewers. Dr. Mancuso told us that he was never told of the peer reviewers' comments. There is no way to prove that the Department sent the letter or that it was received by Dr. Mancuso.

In 1971 both the Joint Committee on Atomic Energy and a Commissioner began to show increased concern about when study results would be available. The Department's program staff consequently began to pressure Dr. Mancuso for results.

As a result, Dr. Mancuso presented a preliminary analysis of the Richland data in November 1971 at a health physics symposium. The analysis, which did not consider the effects of radiation exposure, showed no increased mortality among Richland workers. However, it was clearly pointed out that it was a preliminary analysis and the data was incomplete.

This analysis obviously did not satisfy the Commission because in a May 1972 letter to the Department's program staff, a Commissioner stated:

"It was my understanding * * * that we could expect to see a definitive program plan with a definite time in which results could be expected from the Mancuso project. Unfortunately, your memo indicates that the program for the next 1-3 years will continue essentially along the lines that it has since 1964. In my opinion, this is not satisfactory. It was my understanding that after seven years we should begin to see some results even if of a 'rough' nature rather than simply continuing along present lines of collecting and refining data."

The letter concluded by saying:

"I would appreciate being advised whether we can expect any results from this study in the near future. If not, then why a rough analysis based on data currently in the computers is not possible, and whether you feel that Dr. Mancuso is the appropriate one to continue this important study."

As a result, the program staff informed Dr. Mancuso of the need for prompt generation of information concerning the health effects of radiation on workers. During the ensuing months, the program staff established priorities and time frames for completing the study at Richland. The correspondence from the Department to Dr. Mancuso was forceful, even to the extent of threatening a change in the administration of the project if certain objectives were not met. A letter from the Department to Dr. Mancuso stated:

"Unless an acceptable plan to expedite development of the necessary results is forthcoming by August 1, 1972, and a semi-annual report in a form acceptable to the Commission is submitted by June 30, 1972, the Division will be obliged to consider a change in the administration of the project."

Dr. Mancuso disagreed with the time frames because much of his work was dependent on work being done for him by the Social Security Administration and various States.

The Department's program staff was caught in the middle of the Commission's wanting results and Dr. Mancuso's saying he was not able to produce them. The program staff sent to the Commission a memorandum dated July 27, 1972, the last three paragraphs of which describe the Department's perspective of the study at that time.

"At AEC request, Dr. Mancuso has submitted a list of target dates for completion of various phases of the study. In our opinion, the intervals from the start of data collection to his target dates are excessively long, notably the date for analysis based on grouping of employees by level of radiation exposure, which is scheduled for 1975 or 1976. For that and other reasons such as poor responsiveness to needs of the AEC for information, Dr. Mancuso's status as principal investigator for the study will be reviewed carefully during FY 73.

"Shortly after Dr. Mancuso's next semiannual report is submitted on November 1, 1972, a formal review of the study will be conducted at which Dr. Mancuso and his staff will present their methodology and findings. The review team will consist of DBER [program] staff and outside scientific reviewers. We plan to reach a decision as to retention or replacement of the principal investigator after reports of the reviewers are received and evaluated. If a decision for replacement is made, a new principal investigator will be sought in time

to be phased into the program during Dr. Mancuso's terminal contract period, which would then begin on August 1, 1973.

"Continuation of this project is considered essential to the best interests of the AEC. We recognize the obligation of the AEC to the large group of persons employed in this industry to establish the magnitude of their risk if any exists and is demonstratable. Moreover, whatever its limitations, this is likely to be the only available study of a human population of this size, exposed to low doses of radiation, for which reasonably accurate radiation dose information is available. Our present concern is with the manner in which the study is being conducted rather than the justification for its existence."

The program staff proceeded to identify potential replacements for Dr. Mancuso, if one were needed. The decision as to whether or not to retain Dr. Mancuso was to be made by the program staff following an assessment of the study by a peer review group.

THE 1972 PEER REVIEW

A peer review of the study was held on November 20, 1972. The review committee consisted of five outside reviewers. Five staff members and consultants from the study, including Dr. Mancuso, made the presentation of their study.

All the reviewers agreed that the study should continue. However, the results of the peer review were mixed as to whether or not to replace Dr. Mancuso. One reviewer, who was critical of Dr. Mancuso and his staff, addressed the issue pointedly:

"This is really the only firm recommendation--all others are contingent. It is that you should find another contractor, preferably a University Department of Epidemiology to take over the study after a terminal year."

Another reviewer stated that the consensus of the review committee was that the University of Pittsburgh should continue as the contractor. This reviewer also stated that some aspects of the study were disturbing and may well be cause for considering an alternate contractor. This reviewer considered the project to have "no overall direction" which might have resulted from the "apparent minimal involvement" in the project by Dr. Mancuso.

We found indications that Dr. Mancuso was minimally involved in the study. This was noted in peer reviews, Department correspondence, and by Dr. Mancuso's associates. Dr. Mancuso told us that he did not have complete involvement in the study, but that he did organize the study and give it direction.

One reviewer stated that the study should remain under Dr. Mancuso's direction, while the remaining two directed their comments to other problems of the study and did not address the issue of whether Dr. Mancuso should be replaced.

All five reviewers, however, did criticize the inability of the study to produce results. Four of the five reviewers recommended an early analysis of the available data.

We could not determine from the information available in Department files whether the Department discussed or communicated the review findings and recommendations to Dr. Mancuso. Department officials told us that the review was discussed with Dr. Mancuso but Dr. Mancuso told us that the results were never communicated to him.

In any event, the Department did not terminate Dr. Mancuso's contract at this time. Furthermore, we could not determine what Department actions regarding termination of Dr. Mancuso's contract transpired from early 1973 until the spring of 1974 regarding the problems the Department had with the study and its direction. Department officials told us that they recognized that Dr. Mancuso's contract should have been terminated at this time but did not take the steps that would lead to such an action. But in early 1974, an event occurred which we believe significantly influenced the Department's decision to take the steps needed to terminate Dr. Mancuso's contract.

THE WASHINGTON STATE RESEARCH FINDINGS

In May 1974, an epidemiologist with the State of Washington informed the Department and Dr. Mancuso of the results of a study he was conducting on the effects of radiation on Richland workers. His study results showed excess cancers among Richland workers. The study was based on 842 death certificates of Richland employees obtained from the State of Washington. The study cost about \$100,000 and was completed in a 3-year period.

At the request of the Department, one of Dr. Mancuso's associates, a statistician who had worked for Dr. Mancuso since the beginning of the study, met with the Washington State researcher in late June 1974. About 5 months later, Dr. Mancuso's statistician submitted a report to the Department which was inconclusive as to the validity of the Washington State researcher's findings. That is, he stated that he did not agree with the findings and had serious doubts about the study methodology used, but he acknowledged that an excess of cancer deaths existed among Hanford employees.

It is worth noting that, although Dr. Mancuso had never published an analysis of results, annual progress reports that he had been submitting to the Department indicated that no excess cancers existed among Richland workers. However, these reports were not made available by the Department for public dissemination. In 1970, Dr. Mancuso requested that the Department withhold the progress reports from public dissemination because he believed the information was preliminary, and he was concerned that it would be misinterpreted.

During this period the Department grew concerned that the Washington State researcher's results might be released to the public. The Department, in preparing a press response in the event a release to the public took place, consulted with Dr. Mancuso about using the negative results in his progress report. However, Dr. Mancuso maintained that his findings were preliminary and could not be used.

After the failure of Dr. Mancuso and his statistician to provide a conclusive critique on the validity of the Washington State researcher's findings, the Department requested the Battelle Pacific Northwest Laboratory at Richland to analyze the findings.

A draft of the Battelle report was given to the Department at a meeting in mid-July 1975. At this meeting, Battelle indicated that a conclusive answer still was unavailable and recommended expanding the study beyond the Washington State researcher's population base. The Department agreed and gave Battelle the approval to proceed with "an all-out study to complete the work." In 1976 preliminary results of the Battelle study indicated that while biases in early results of the Washington State researcher's study overstated the cancer mortality some cancers were still shown to occur more frequently than expected.

THE TERMINATION ACTION

In early December 1974, an internal Department memorandum was prepared which discussed the planned termination of the contract and transfer of the study. The formal termination date was set at July 31, 1977. The memorandum recommended that Dr. Mancuso be retained as a consultant to the study, but stated no reasons for the termination.

The Department invited Dr. Mancuso to Department headquarters to discuss the study. Because of conflicting schedules, a meeting could not be arranged until March 6, 1975. At this meeting, Dr. Mancuso was informed that his contract would be terminated and that responsibility for the study would be transferred to Oak Ridge Associated Universities at Oak Ridge, Tennessee.

CONCLUSIONS

Documentation surrounding the issue of the reasons for terminating Dr. Mancuso's contract does not answer all questions. However, certain facts are evident. It is certain that the Department was very concerned about the conduct of Dr. Mancuso's study and was seriously considering replacing him years before the findings of the Washington State researcher were known. It is important to note that, while the Department was considering replacing Dr. Mancuso, the progress reports he had been sending to the Department indicated no findings of a higher incidence of cancer among nuclear workers.

It is also evident that the positive findings by the Washington State researcher and Dr. Mancuso's continued refusal to publish his own negative findings had a significant impact on moving the Department to take the steps to terminate his contract.

Why didn't the Department take this action years earlier when serious questions about Dr. Mancuso and his study were being raised? For the first 6 years or so of the contract, Department program officials permitted the contract to continue without giving it the kind of reviews that were typically given to research contracts. As the Department's dissatisfaction with the study mounted and reached a point where it seemed that termination of the contract was imminent, still the Department did not act. In our view, the responsible Department officials found it easier to procrastinate rather than to act on an unpleasant matter which would likely result in questioning and adverse criticism of their action.

In our view, it took the expected public release of the Washington State researcher's findings to move the Department to terminate Dr. Mancuso's contract. What forces generated by the Washington State researcher's findings prompted the Department to terminate Dr. Mancuso's contract: did it represent a final, convincing indication to the Department that Dr. Mancuso had to be replaced, or did the Department want to control and publish Dr. Mancuso's study data to counteract the potential negative publicity that could be generated by the Washington State researcher's findings? There is no documentation or evidence to reach a conclusion on this. All that can be concluded is that if the Department had been decisive years earlier and taken the action it believed to be necessary, the question would not have arisen.

CHAPTER 3

TRANSFER OF THE STUDY

The Department's decision to terminate Dr. Mancuso in 1974 as principal investigator before the end of the study caused several problems for Department officials, the most important being obtaining a suitable and competent replacement to continue and expand the study. The Department selected and in 1977 awarded the contract for the study of Richland and Oak Ridge workers to Oak Ridge Associated Universities (ORAU), a long-time prime medical research contractor to the Department located at Oak Ridge, Tennessee. After the award of the contract to ORAU, responsibility for that part of the study involving analysis of Richland data was transferred to two Department contractors--Battelle Pacific Northwest Laboratories and Hanford Environmental Health Foundation--located at Richland. DLG00585
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DLG00584

Our review of the Department's actions in selecting these contractors and transferring study responsibilities to them follows.

METHODS USED TO SELECT NEW CONTRACTORS

The primary criteria for the selection of new contractors to continue the study started by Dr. Mancuso included experience in radiation effects studies and proximity to the data. In the case of ORAU, we found a 1974 draft memorandum in which Department officials recommended that all programs of public health and demographic surveillance around nuclear plants be centralized at Oak Ridge Associated Universities. Several reasons were cited for taking this action, including the need to take advantage of the past involvement of this contractor and other Oak Ridge contractors in the collection, processing, and compiling of radiation effects data. The analytical contribution of epidemiological and statistical personnel on the staff was specifically mentioned as one justification for the recommendation.

The selection of the Richland contractors to participate in the Richland portion of the study (1977) was based on the same justification. Battelle had been actively participating in an analysis of the Washington State researcher's study results and had expanded the analysis to Richland over a period of 2 to 3 years, beginning June-July 1974. Hanford Environmental Health Foundation had been involved in collecting data for the study.

While a Department official advised us that a limited attempt was made to develop interest for the study among

other contractors considered qualified, the effort was far from vigorous and immediately dropped when ORAU and the Richland contractors indicated they were interested.

Department officials responsible for the selection of the contractors indicated that actions taken were not unlike Department efforts on other projects. These officials advised us that the complex technical nature of these studies frequently precluded any competitive bidding (request for proposal). Thus the search for contractors is generally limited to making inquiries about parties that may be interested in the study. While we agree that these studies are of a highly complex and technical nature, we do not believe that this necessarily precludes competition. There may be a great many organizations and institutions with the necessary experience, capability, and interest to do human radiation exposure studies. For example, a great deal of interest recently was shown in response to a formal request by the Nuclear Regulatory Commission for proposals to analyze the data collected by Dr. Mancuso during his study. The Nuclear Regulatory Commission is sponsoring the studies to obtain an independent analysis of the data as part of the Commission's responsibility as a regulatory agency to find out if low-level radiation is hazardous to human health. A Nuclear Regulatory Commission official advised us that eight proposals were received from a wide range of sources. Three proposals were considered of sufficient quality and direction, and were backed by capable staff to justify selection. All three have been awarded contracts.

ABILITIES AND CAPABILITIES OF THE CONTRACTORS SELECTED

Peer review of ORAU programs and facilities

In May 1974, just before the Department's decision to transfer the study to ORAU, ORAU was reviewed to assess the scientific merits of individual programs and the specific investigators associated with the ORAU Medical Division. The review was one of a series of indepth peer reviews of national and onsite laboratories involved in research programs.

The results of the peer review indicated numerous deficiencies in ORAU programs and facilities. Most of the negative findings and comments were directed to clinical research and health care aspects of ORAU; in particular, the Oak Ridge facility hospital which ORAU had run since 1947. According to Department and ORAU officials, it was well known that the clinical program at ORAU was not viable and would eventually be phased out.

While the general tone of the peer review was negative concerning ORAU's clinical programs, it was very positive in its discussion of ORAU's involvement in human radiation exposure programs. These programs were considered high quality and staffed with extremely competent scientists.

In their report to the Department and to ORAU, the peer reviewers recommended phasing down some clinical programs but recommended continuing the human radiation exposure programs. In addition, the reviewers suggested that with improvements in areas such as computer services, it would be feasible to consider centralizing all information processing relative to radiation exposure programs at a facility such as ORAU.

In 1976, 2 years after the negative peer review report, an inhouse program review conducted by Department officials revealed that ORAU programs had been extensively overhauled under new leadership. In summary, the reviewers found the ORAU medical programs to be in good shape and growing in strong new directions under capable leadership.

Capability of ORAU staff to conduct study

The peer review conducted at ORAU in 1974 is very complimentary of the high quality of ORAU staff involved in human radiation exposure programs. However, the staff on board at that time were not considered to have the epidemiological qualifications requisite for conducting the study initiated by Dr. Mancuso.

At the time of the Department's decision to transfer the study to ORAU, it appeared that the responsible Department officials were cognizant of ORAU's epidemiological deficiencies. A central element in the Department's offer of the study to ORAU was the condition that it develop the necessary expertise in epidemiology and statistics.

The lack of expertise in the area of epidemiology at the time of the decision was not, according to Department officials, an overwhelming reason to refuse consideration of ORAU as a suitable candidate for the study. These officials cited the credible base of human radiation exposure staff experience as a more than adequate beginning and the 3-year time-frame (1974-77) for phasing out Dr. Mancuso as adequate time to develop (hire) additional epidemiological and statistical expertise.

According to the Chairman of ORAU's Medical Division, immediately following notification that ORAU might assume responsibility for the Mancuso study, a search was initiated

to hire an epidemiologist for the staff. In 1976, about 1 year before the transfer, a noted epidemiologist joined the ORAU staff as principal investigator. Her credentials are impressive and include responsibilities for epidemiological programs and studies at the Environmental Protection Agency and the U.S. Bureau of Radiological Health.

While it is generally accepted that her demonstrated capabilities could provide leadership to the study, it is interesting to note that she was the only candidate considered for the position. She had previously worked as a consultant with ORAU before the appointment, and ORAU officials stated that because of her previous work, they felt no strong need to look elsewhere. Department officials did not appear to have problems with ORAU's approach to the selection of this key study team member.

However, the principal investigator selected has not worked on the study since August 1978 and formally resigned on September 29, 1978, because of personal reasons. According to the Chairman of ORAU, as of December 1978, a replacement has not been selected. However, there is presently an epidemiologist working on the study.

Capability of Richland contractors to conduct study

Battelle Laboratories first became involved with the study in 1975, when it performed a quick analysis of the Washington State researcher's work for the Department. The analysis was primarily statistical in nature and was later expanded in 1975-76 to include Richland data collected and compiled by Dr. Mancuso.

In 1977 the Department decided to transfer the Richland portion of the study to Battelle and the Hanford Environmental Health Foundation. Before making the decision, Department officials made no attempt to independently assess the past performance or capability of either contractor's staff to conduct a complete epidemiological analysis and present findings. Department officials responsible for the transfer action have stated that a peer review at that time did not seem necessary. For example, Battelle's statistical work on the Washington State researcher's and Dr. Mancuso's data was being followed closely according to these officials and Battelle had demonstrated its capabilities in several papers and presentation of its findings.

The principal investigator assigned to the study at Richland has a strong biostatistical background but, according to Department officials, lacks the epidemiological credentials

required for a study of this type. However, several individuals with some epidemiology background are accessible to the investigator. Recently--in 1978--the Department approved a position for an epidemiologist for the Richland contractor's staff to be available for consultation on a part-time basis. The search to fill this position is now underway.

PROPRIETY OF MAJOR NUCLEAR CONTRACTORS
CONDUCTING RADIATION HEALTH EFFECTS RESEARCH

All of the contractors selected to continue Dr. Mancuso's health and mortality study--ORAU, Battelle, and Hanford Environmental Health Foundation--are located on or near Department facilities and have been contractually involved with the Department for some time. All are independent, nonprofit research organizations that have numerous ongoing projects involving nuclear and nonnuclear subjects. The majority of these projects are now funded by the Department. In fact, the contractors receive from 70 to 80 percent of their annual operating funds from the Department.

In addition, several of the projects being conducted by Battelle appear somewhat in conflict with the potential findings of the health and mortality study. These projects involve the study of ways to improve nuclear technology or develop new alternatives in nuclear areas in order to advance the use of nuclear energy. However, if the health and mortality study were to indicate adverse effects from low-level radiation, the future use of nuclear energy could be greatly impeded. Furthermore, in 1977, 1,000 of the 2,550 Battelle employees working at Richland were exposed to low-levels of radiation.

This situation has been described by several parties as being an apparent conflict of interest. These parties claim that the Department's control over a large portion of the contractors' funds and the pressure of studies designed to advance nuclear energy could possibly influence the outcome of efforts that might reflect badly on nuclear energy.

We could find no evidence to indicate that in selecting these two contractors, the Department deliberately attempted to either gain control or influence the outcome of the study. Moreover, there was no evidence that the Department attempted to exert control over these contractors through its funding of them. In fact, the Department has sought out several independent reviewers to perform additional analyses of study data similar to that being performed by the Department contractors. In addition, it has provided copies of the study data to British researchers and to the Nuclear Regulatory

Commission, which has contracted with independent reviewers for analysis of the data.

Regardless of whether the conflict of interest is apparent or real or whether it can be proved or not, the Department should be concerned with the image that this situation presents.

CONCLUSIONS

The decision by the Department to transfer the study to ORAU, Battelle, and the Hanford Environmental Health Foundation has been criticized. We believe that the primary cause for this criticism is that the Department did not establish or consider sound criteria for selection. Documentation concerning the consideration and selection of the contractors to replace Dr. Mancuso is sparse. The contractors, however, were not bad choices from a technical standpoint. All appear capable to do the job and potential problem areas have been identified and solutions to those problems are being sought. In the case of ORAU, the weak programs identified in a 1974 peer review have been dropped and strengths in radiation research vigorously pursued. Battelle had participated in the analysis of study data for 2 years before being given responsibility for the Richland part of the study. Hanford Environmental Health Foundation had been involved for many years. The contractors are actively pursuing epidemiologists to round out their study teams.

In our view, the significant problem associated with the Department's selection of these contractors is the image that results in an agency developing and improving nuclear power while at the same time using the same contractors to study the safety of nuclear power. The ramifications of this problem extend much beyond Dr. Mancuso's study to all of the similar research projects being carried out under these circumstances.

CHAPTER 4

THE OFFICE OF INSPECTOR

GENERAL'S REPORT

In May 1978, the Department's Office of Inspector General (OIG) issued a report of its investigative findings relating to the Department's termination of Dr. Mancuso's contract and transfer of the study he started. The investigation was initiated in November 1977 at the request of Department officials after serious allegations concerning the handling of the study were brought against the Department by a group of concerned citizen organizations. In summary, the allegations concluded that:

"This situation reflects a well-defined pattern of harassment and intimidation of scientists who do not agree with the opinion of promoters of radiation technologies that there are no adverse effects associated with exposures to low-level radiation."

The OIG's investigation was based on the allegations brought against the Department by the citizen organizations. The OIG also met with the staff of the House Subcommittee on Health and the Environment in February 1978 to identify additional areas of interest to the subcommittee. As a result of the meeting, the OIG's work focused on the events surrounding the transfer of the contract and the Washington State researcher's findings. The OIG advised us that it believed these were the two main areas of interest to the subcommittee. Consequently, much of the report is devoted to these two areas.

The specific allegations investigated by the OIG stated that;

- the decision to transfer the study was made secretly and for the purpose of assuring that no further independent analysis of the data would be made;
- Dr. Mancuso was faulted for not publishing his earlier negative findings which would have refuted the positive cancer findings of the Washington researcher; and
- the Department attempted to discredit and suppress the 1974 positive cancer findings of the Washington researcher.

The OIG investigation disclosed there was no validity to the allegations. The OIG did not follow up with opinions and conclusions concerning other basic questions relating to the

termination and did not address the appropriateness of the transfer. The OIG views its work as a fact-gathering exercise limited only to the specifically requested information--in this case the allegations.

In our work, we did not assess the conduct, thoroughness, or objectivity of the investigation. We generally limited our review to determining whether the OIG's report presented the facts properly and accurately. In our opinion, the OIG's report presents a fair and comprehensive factual history of events surrounding the termination and transfer. We also could not find any significant omission of facts or evidence in the report.

CHAPTER 5

COMMENTS ON OUR DRAFT REPORT

On December 8, 1978, we sent a draft of our report to Dr. Mancuso and to the Department and asked that they furnish us written comments. The Department and Dr. Mancuso furnished us their comments on December 14, 1978. (See apps. I and II.)

DEPARTMENT COMMENTS

The Department stated that our report appeared to be well balanced, with the facts presented in a clear and objective manner. However, it felt that several areas needed change or reinforcement to improve their clarity.

The Department expressed concern about our discussion of a conflict of interest over its selection of the new study contractors. The Department stated that ORAU and the Hanford Environmental Health Foundation are independent research organizations not involved in improving engineering aspects of nuclear power. The Department was also critical of our report's applying our point on conflict of interest to all of the Department's biomedical programs in general.

It is true that ORAU and the Hanford Environmental Health Foundation are independent research organizations not involved in improving the engineering aspects of nuclear power. But these contractors have historical ties to the Federal nuclear development agencies and now receive more than 70 percent of their funding from the Department. In our view, this situation raises a question about an appearance of a conflict of interest; and this question can be logically applied to similar Department biomedical research programs.

More questions can be raised regarding the involvement in the study of Battelle Pacific Northwest Laboratories. Unlike the other contractors, Battelle is involved in improving the engineering aspects of nuclear power and has employees at Richland that are being exposed to low-level radiation.

The Department had two other comments on relatively insignificant factual errors in our draft report. The first comment concerned selection of an epidemiologist at ORAU. We changed our report to reflect the fact that an epidemiologist has been selected, but that a principal investigator still has not. In response to the Department's second comment, we changed our report to state that the Hanford Environmental Health Foundation has an involvement in the Richland study.

DR. MANCUSO'S COMMENTS

Dr. Mancuso found our report inaccurate and unresponsive to the request of the House Subcommittee on Health and the Environment. A description of his major disagreements and our redressing comments on these disagreements follow.

Dr. Mancuso stated the reasons for the termination were that the Department knew that his study would eventually find a correlation between cancer and radiation, and that he had refused to cooperate in discrediting the Washington State researcher's finding. We would like to point out that at the time of the decision to terminate Dr. Mancuso's contract, the validity of the Washington State researcher's positive finding had not been determined; Dr. Mancuso's findings were negative, and; there was no indication that his negative findings would later change to positive. Also, we could find no evidence that supports Dr. Mancuso's statement that the Department wanted him to discredit the Washington State researcher's positive findings. The only information available indicates to us that the Department wanted Dr. Mancuso to supply a statement as to the validity of the finding. Dr. Mancuso did not provide such a statement.

Dr. Mancuso stated that the transfer of his study was made by the Department to "shape up" ORAU's program and to gain close control of the study. We could find no evidence to support this belief. The evidence shows and our report states that ORAU had the ability to perform work in human health effects. We could find no evidence that the transfer was a maneuver to control the study.

Dr. Mancuso stated that the OIG report has serious defects which we glossed over. We could find no serious defects in the OIG report and maintain that the report is fair and comprehensive factual history.

CHAPTER 6

SCOPE OF REVIEW

We conducted our review at the Department's offices in Germantown, Maryland; Richland, Washington; and Oak Ridge, Tennessee. We talked with officials at the Oak Ridge Associated Universities, Hanford Environmental Health Foundation, the State of Washington, and other interested organizations. We also interviewed Dr. Mancuso.

We reviewed all information which consisted of documents, studies, reports, and correspondence maintained by the Department. We were supplied other information by the above named organizations.



Department of Energy
Washington, D.C. 20545

December 14, 1978

Mr. J. Dexter Peach
Director, Energy Minerals
Division
General Accounting Office
441 G Street, N. W.
Room 5120
Washington, D. C. 20548

Dear Mr. Peach:

Enclosed are our comments on the draft of a proposed report entitled, "Review of the Department of Energy Controversial Termination of a Research Contract."

The report appears to be well balanced with the facts presented in a clear and objective manner. We feel, however, that several areas need some change or reinforcement in order to improve the clarity of the facts and to remove ambiguity.

I trust that these comments will be of help in clarifying the issues in the report. I appreciate the opportunity to be able to comment on the report.

Sincerely,


James L. Liverman
Deputy Assistant Secretary
for Environment

Enclosure:
As stated

COMMENTS ON "REVIEW OF THE DEPARTMENT OF ENERGY CONTROVERSIAL
TERMINATION OF A RESEARCH CONTRACT"

On page 1v, paragraph 3 and also on page 25, paragraph 2, it is stated that the contractors selected to continue the health and mortality study begun by Dr. Mancuso, have been contractually involved in the studies of ways to improve nuclear technology. The facts are that the Oak Ridge Associated Universities and the Hanford Environmental Health Foundation (and not Battelle as stated in the report) are independent research organizations not involved in improving engineering aspects of nuclear power who were selected by the Department of Energy (DOE) to engage in research on the medical and biological effects of radiation. It is misleading to convey the implication that the research contracts with these installations are of a nature that would promote the application of nuclear and non-nuclear energy technologies. Our constant attempt has been to ensure an independent look at the safety and health aspects of our DOE development programs. We plan to be very diligent in pursuit of such a goal and to support the efforts of independent investigators wherever they may be located to reveal to us the comparative hazards of energy activities.

The extension of this same concern for objectivity to the Department's biomedical programs in general is even more disturbing. Under the law DOE is charged with insuring that the energy systems we develop are done so safely and with full concern for both the general and the human environment. We have instituted aggressive programs during the past three years to insure entry into the procurement processes very early, to track the development of the energy systems with time. We have

also instituted procedures to insure that the research we are doing is fully coordinated with related research in other federal and state agencies, and that such research is adequate to answer all of the unresolved questions regarding the health and environmental impacts of energy activities on man and his environment. An important aspect of this effort is the fact that it is independent of the line organization development effort and yet closely coupled with that effort. We have a responsibility to the employees of the Department's programs whether they be civil servants or contractor employees. We must insure safe working conditions and adequate medical followup to confirm that safety. The one area in which we perhaps have been lax relates to highly visible external review procedures. We recognized much earlier that there is a need for an independent overview group who reports to the Assistant Secretary. The responsibility of this group is to review the efforts for their adequacy, their responsiveness, their independence, and their scientific excellence. More than six months ago, the National Academy of Sciences was requested to conduct an in-depth review of the scientific merit and adequacy of the current programs in radiation epidemiology and to create such an external review and oversight group. The first meeting of the review group is currently scheduled for early January 1979. Moreover, as has been recognized by the President, there is a need for a look at all of the epidemiological

studies on the effects of low-level radiation in humans irrespective of the agency of the Federal Government which may be supporting these efforts. A study directed by the President to review such efforts has been underway since mid-summer 1978 and is scheduled to be completed soon. One of the major points for discussion has centered around ways to insure adequate external review of the studies in this area. Thus, the conclusion is that not just DOE but all agencies need this overview.

On page 24, paragraph 2, it is stated that a replacement for the epidemiologist involved in the Oak Ridge Associated Universities (ORAU) health and mortality study has not been selected as of December 1978. The fact of the matter is that on June 20, 1978, a Ph.D epidemiologist and on July 10 a person with a Masters Degree in epidemiology joined the ORAU staff. In addition, it is our aim to find a mid-career epidemiologist, preferably an M.D., to assume the position of principal investigator.

On page 25, paragraph 2 and in a number of other places in the report, it is stated that either the Department transferred the study to Battelle or that the health and mortality study is conducted by Battelle. In a letter dated October 11, 1977 (copy enclosed), from the Manager of Human Health Studies Programs to Dr. P. A. Fuqua, Medical Director, Hanford Environmental Health Foundation (HEHF), it is clearly stated that "the health and mortality study of the Hanford workers is to be continued at the Hanford Environmental Health Foundation as an independent study..." and that "the effort with Hanford is to be a joint enterprise with PNL^{1/}" Our intent was,

^{1/}Battelle is a part of Pacific Northwest Laboratories (PNL)

and is, to have an independent study and it appears clear from this letter that the responsibility for conduct of the study is in the hands of HEHF with statistical backup from expertise on the staff at PNL. Any interpretation to the contrary is in error.

1 Enclosure

**University of Pittsburgh**

GRADUATE SCHOOL OF PUBLIC HEALTH
Department of Industrial Environmental Health Sciences

December 13, 1978

The Honorable B. Staats
Comptroller General of the U.S.
441 G Street, N.W.
Washington, D.C. 20548

Dear Mr. Staats:

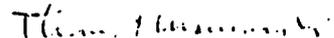
Enclosed are my comments on the draft GAO report, "Review of the Department of Energy's Controversial Termination of a Research Contract," which I received on December 9, 1978.

I am disappointed to find the report to be inaccurate and unresponsive to the serious questions raised by the House Sub Committee on Health, and the Environment, concerning the Department of Energy's (DOE's) action on my research project and DOE's, subsequent internal investigation of the matter.

The questions and critiques, which accompanied the Sub Committee's request for this GAO investigation, are attached as appendix 'A' to my comments.

I appreciate this opportunity to present my views on the GAO investigation and to have these comments and GAO's responses included in the final report.

Sincerely,


Thomas F. Mancuso, M.D.
Research Professor

COMMENTS OF DR. THOMAS F. MANCUSO ON DRAFT GAO REPORTIntroduction

In these comments, I refer to and quote documents contained in the Department of Energy's (DOE's) files on the Study of the Lifetime Health and Mortality Experience of Employees of ERDA Contractors (Health and Mortality Study), of which I was the principal investigator. These files, which I requested under the Freedom of Information Act on May 18, 1978, were made available to me, with minimal deletions, on November 28, 1978. I wish to acknowledge the assistance of Michael Bancroft, my attorney in this matter, in preparing these comments and to thank the GAO for providing him with a copy of the draft report.

The draft GAO report paints a picture of AEC staff dissatisfaction with my performance of the contract, dating back years before the decision to terminate the contract. However, supposedly because of the staff's perception of Commission support for my project, the staff "procrastinate[d]" and did not act on its long-standing negative evaluation until 1974. What this GAO overview leaves out is the purpose the AEC had for the study in the early years, what happened in 1974 to change this perception, and an independent evaluation by the GAO of the validity of the AEC's pressure on me to publish meaningless and misleading negative results.

1. AEC Purpose for the Health and Mortality Study

The AEC initially believed that the Health and Mortality Study could not find any adverse health effects of the doses of radiation experienced by the numbers of workers being studied. This attitude, and the reasons that the AEC found the study useful nevertheless, is reflected in numerous statements of the staff and its consultants

over the years. For instance:

It seems to be highly probable that if one went through the mechanics of calculating the kinds of radiation effects which a study of the present magnitude might detect, one would be led to conclude that the undertaking is a hopeless one. However, as earlier recognized, it may have other merit in that it may provide a firmer basis for settlement of claims against the Atomic Energy Commission....

Letter from Professor William J. Schull to Dr. Leonard A. Sagan, AEC,
November 8, 1967.

In my opinion this study does not have, never did have, and never (in any practical sense) will have, any possibility of contributing to knowledge of radiation effects in man.

I recognise that much of the motivation for starting this study arose from the "political" need for assurance that AEC employees are not suffering harmful effects. ... This is a collection of information that should be of great value in assuring whoever needs to be assured regarding harmful effects to employees.

Letter From Professor Brian MacMahon to Dr. Leonard A. Sagan, AEC,
November 13, 1967.

It was the unanimous opinion of the group that, aside from a certain "political" usefulness, it is very unlikely that new information on radiation effects will accrue from this study.

Memorandum from Dr. Leonard A. Sagan to John R. Totter, Director, Division of Biology and Medicine, AEC, November 20, 1967.

The study probably will not confirm or refute any important hypotheses but should permit a statement to the effect that a careful study of workers in the industry has disclosed no harmful effects of radiation (if the results are negative as they are likely to be). That statement, supported by appropriate documentation, would seem to justify the existence of the study.

Comment prepared by Dr. Sidney Marks attached to a memorandum from John R. Totter to S. G. English, Assistant General Manager for Research, AEC, February 28, 1972.

It is against this AEC perception of the usefulness of the Health and Mortality Study that the GAO should have approached its evaluation of the validity of the "failure to publish" criticism and of the AEC's reasons for deciding to terminate my contract in the critical year, 1974.

2. Evaluation of the AEC Shift in 1974

In March 1974, Dr. Samuel Milham, of the State of Washington Department of Social & Health Services, informed the AEC that he had found a marked cancer excess among Hanford employees. In the GAO's discussion of the effect of Dr. Milham's findings, there is no mention of the memoranda of officials of the AEC field office in Hanford describing the frenzy of activity which the Milham study produced in the AEC. The memoranda of Robert Fasulo and Alex Fremling express the view that "[i]n essence, where we are is that we hoped to get a good answer to the Milham report, and, instead, it looks like we have support for it." Although the GAO draft mentions my refusal to cooperate with AEC plans to issue a press release discounting Dr. Milham's findings, the GAO does not evaluate the validity of my reasons for doing so, which are discussed in the next section.

Thus, by the summer of 1974, the AEC knew from Dr. Milham's positive cancer findings that the Health and Mortality Study might find a correlation between cancer and radiation among atomic workers and had my refusal to cooperate in discrediting Dr. Milham. I am convinced that this led to the decision to take the project away from me and to move it in-house, where the AEC could control the data. Given this context, what reasons do the responsible officials give for the termination, and what scrutiny does the GAO give to those reasons?

Dr. James Liverman, who was responsible for the decisions of the AEC and its successors on the Health and Mortality Study, wrote in 1977 that the decision to terminate my contract was based on my "imminent retirement." In 1974, I was 62 and did not have to retire from the University of Pittsburgh until age 70 if I had external funding. Dr. Liverman has since retracted the "imminent retirement" rationale and now says the decision was based on adverse peer reviews and failure to publish. Yet the December 2, 1974 staff memorandum, on which

Dr. Liverman claims to have based his decision to transfer the project, does not mention peer reviews or publications, nor indeed is there in it any criticism of my work or performance of the contract. The shifting reasons given by Dr. Liverman further heighten GAO's obligation to exercise independent judgment of the validity of the DOE's central criticism of my performance.

3. Implications of Publication

a. 1971 Health Physics Society publication

In 1971, Drs. Sanders, Brodsky, and I presented a paper to a Health Physics Society symposium on radiation protection standards. This 186 page monograph, entitled "Methodology and Some Preliminary Findings Limited to Mortality for Hanford Employees," was distributed to members of the Health Physics Society and was available to the public. Dr. Sidney Marks, the contract officer at the time of the termination decision, sent copies of this monograph to the peer reviewers in 1972, referring to it as "Dr. Mancuso's latest publication."

b. Long latent period of radiation induced cancers

The GAO draft recognizes the difficulty presented in studying the carcinogenic effects of low-level radiation, in that the latent period between exposure and manifestation of cancer is 20 to 30 years. The actual figure, particularly for solid tumors, is near the upper end of this range and possibly greater. This latency had just begun to be fulfilled for the earliest workers at Hanford and Oak Ridge at the time the radiation and employment data was sent to me by the AEC contractors in the early and mid-1970's.

The latency factor and its relation to premature analysis has been recognized by DOE. On March 29, 1977, Dr. Mark's successor, Dr. Walter Weyzen, wrote to Ms. Pat Borchmann that, because of "latency

periods of up to several decades," and "costly and time consuming data collection," "it would have been extremely difficult to conduct meaningful analysis at an earlier time." DOE's recognition that the results would have been bound to be negative from an earlier analysis, whether there was an effect or not, taken with the government's consistent praise of my care and skill in collecting and testing the data, does not support the AEC's pressure on me to publish my preliminary negative findings.

c. Dates of obtaining necessary data

In any event, earlier publication of results on causes of death would have been based on the sketchiest of data, if not physically impossible, because the major data on employment histories, radiation exposures, and deaths were not available until about the time the termination decision was made. This fact is demonstrated in the excerpt from my testimony to the Subcommittee on Health and the Environment, which is attached as Appendix B and which I stressed to the GAO investigators. This tabulation shows the late date of transmittal of vital information from the AEC contractors on whom I depended.^{*/}

d. Quality of early statistical analysis

I have learned that there was considerable AEC and peer reviewer criticism of the skill and methodology of the actuary who was the statistical consultant to the project from the outset until 1976. The AEC staff never suggested to me that this defect might jeopardize continued support for the study. Why was the AEC staff so anxious to have published preliminary negative findings based on the analysis of a

^{*/} The GAO's reference to the Social Security Administration and the states as causes of delay is incomplete and misleading. These entities generally responded with dispatch, while for many years the AEC contractors were the bottleneck.

statistician whose skill and approach they were dubious of?

e. Refusal to contradict Dr. Milham

The GAO draft states that I refused to let my preliminary findings be used in a proposed AEC press release in response to Dr. Milham's results. The GAO does not even present, to say nothing of evaluating the validity of, my reasons for believing that my data was not inconsistent with Dr. Milham's findings. Because Dr. Milham's study was limited to deaths in the State of Washington, he had deaths from more recent years (and thus farther into the latency which was at a critical stage) than mine which had to go through the Social Security Administration. Furthermore, his study included reactor maintenance workers who had received occupational radiation exposure and were not included in my study.

4. Transfer of Study to ORAU and Battelle

It is gratifying that the GAO takes a critical view of the decision to transfer the Health and Mortality Study to laboratories overwhelmingly dependent on DOE funding. The GAO report also sees the conflict of interest arising from the fact that ORAU and Battelle Pacific Northwest Laboratories (Battelle) are affiliated with facilities which promote nuclear technology and employ workers exposed to low-level radiation. Although the GAO notes the anomaly of the choice of ORAU when the immediately prior peer reviews were negative on its capability for this study, without a proposal or principal investigator (indeed, without even discussing the transfer with ORAU in advance of the decision), the GAO does not consider whether the decision was influenced by a bureaucratic desire to shore up a client lab facing the scaling down of its clinical program and to obtain close control of the Health and Mortality Study. Finally, the GAO should have considered the specific apparent conflict of interest where Dr. Marks, who was influential in the decision to terminate my contract, wound up with supervision of the

Hanford part of the Health and Mortality Study after moving to Battelle.

5. DOE Inspector General's Report Not "Fair and Comprehensive"

The GAO draft concludes, without providing any basis, that the Inspector General's (IG's) report is "fair and comprehensive." One example, which I pointed out to the GAO investigators, will illustrate the IG's lack of fairness. The IG erroneously claims that I stated "that the decision to terminate the contract was due, in part, to the July 1976 positive cancer findings." No citation is given to the transcript of my interview, included as an exhibit to the IG's report, because I never said any such thing. It would have been a foolish and damaging mistake of logic if I had claimed that a decision in 1974 was influenced by a 1976 event.

The IG's report is biased in its use of documents, interviews, and quotations. For instance, the IG's report, refers to, but does not include or summarize, the Fasulo and Frembling memoranda and the December 2, 1974 memorandum discussed in section 2 above. It is puzzling that the GAO glossed over the serious defects of the IG's report in light of the substantial critique of that report provided to the GAO by the Subcommittee on Health and the Environment (Appendix A).

The GAO draft reports, without comment or criticism, the IG's view of "its work as a fact gathering exercise limited only to the specifically requested information--in this case, the allegations." I would have expected the GAO to compare this view with the mandate given the IG by Congress in the Department of Energy Organization Act:

It shall be the duty and responsibility of the Inspector General--
(4) to keep the Secretary and the Congress fully and currently informed...concerning fraud and other serious problems, abuses, and deficiencies relating to the administration of programs and operations administered or financed by the Department, to recommend corrective action concerning such problems, abuses,

and deficiencies, and to report on the progress made in implementing such corrective action.

42 U.S.C. § 7138(b).

6. Attitude of GAO Investigators

The GAO report makes the surprising statement that "the effects of low-level radiation remain unknown." There is scientific literature dating back to the 1950's which contradicts this statement. There is, to be sure, a range of uncertainty in the estimates of the risk of low-level radiation. The erroneous "unknown" statement suggests that the GAO investigators have absorbed the views of those who prefer to exaggerate scientific uncertainty rather than to confront known dangers.^{*/}

In counting up the comments of the 1972 peer reviewers, the author of the GAO draft displays a critical misunderstanding of how the government chooses scientific contractors. The GAO draft interpolates a phrase into the comments of one reviewer that the consensus of the reviewers was to continue the University of Pittsburgh as the contractor, "--not necessarily Dr. Mancuso." Research contracts are given on the basis of the abilities of the principal investigator and project staff. The university administers the contract and accounts for the money received. There is no validity to the suggestion that this reviewer perhaps meant that someone else at the University of Pittsburgh should take over the study. This mistake is repeated in the GAO's statement that "[t]he University of Pittsburgh, because of its excellence in epidemiology, was

*/ The GAO statement that there is not a good record of exposures is in apparent conflict with the statement that Hanford and Oak Ridge were chosen because their records were "well organized and accessible." In fact, the truth is in between. The records are available and reliable, but require considerable processing, tabulation and checking. In any event, Hanford and Oak Ridge were chosen because of the latency problem and the fact that they are the oldest AEC facilities.

selected as the contractor...." (Emphasis added.) It is clear from the statements of the AEC and its advisors that the choice was on the basis of my reputation and development of the methods used in the Health and Mortality Study, in particular the Social Security method of tracing industrial populations over several decades.

The GAO draft cites DOE records to show that "about 20,000 studies or papers dealing with various aspects of the effects of low-level radiation have been supported by the Federal Government."^{*/} Without explanation of what the studies concerned, this figure is meaningless. Furthermore, it is misleading to suggest that the Health and Mortality Study is just one out of 20,000. During my direction of the Health and Mortality Study, it was one of a very few occupational epidemiological studies of low-level radiation, the one with the largest and best monitored industrial population, and the only one on chronic exposure of employees of AEC contractors.

*/ Was all this financial support wasted if the effects of low-level radiation remain "unknown?"

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