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Mancuso Contract Renewal Summary

This study of the health and mortality of employees in AEC laboratories and in plants of AEC contractors provides a means of monitoring the health effects of employment in these facilities. Radiation is the factor of primary interest in the investigation. Since any effects that might result from exposure to radiation are likely to have a long latent period, modification of life span or mortality rate would become evident only after many years. The development of results in the study was accelerated by collecting data from past as well as current periods of employment in certain plants. This approach in effect dates the onset of the period of observation back to 1943-44 at Hanford and to various years between 1940 and 1950 for the different plants at Oak Ridge.

Much of the current work is directed to problems that have arisen in the course of the study or that were not attacked until recently. Since any radiation at any time might contribute to a radiation effect, the comparison of a study population with a control population requires the inclusion of all occupational radiation exposure, wherever incurred, in the employees' exposure records. To meet this need, a large effort to obtain documentation of employment periods for all employees in all AEC plants is in progress now and should be largely completed during the coming year. This project is accomplished by having the contractors forward the relevant data as it exists in their files to the Pittsburgh office. There it is transcribed to a standard format by clerical personnel. The information will be assembled into a master file later. It is our wish that this file be largely completed during the next contract year.

In another area, a suspicion of bias in forming the sibling group has arisen in the analysis of Hanford life span data. Results were different if the group of all employees were compared with all siblings as opposed to a comparison of the employees having identified siblings with their own siblings. If it exists, the bias would be caused by inadvertent comparison of both poorly and well educated workers with the siblings of well educated workers.

The investigators feel that they can eliminate the bias by increasing the percentage of discovery of siblings. They are, therefore, submitting the list of Hanford siblings to SSA again and will obtain death information on the enlarged group after identification of additional siblings. The second pass through SSA is expected to

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yield identification of a larger percentage of the listed siblings. The investigators anticipate that the group of newly identified siblings may contain a greater proportion of siblings of less well educated employees and thereby make the sibling group more representative. After the enlarged list of siblings is prepared, the Hanford life span data will be analyzed again.

The social security numbers of Oak Ridge employees were identified recently. During the coming year, processing of the Oak Ridge employees and siblings for identification of death will be performed. This will be followed by analysis of Oak Ridge data similar to the analyses of Hanford data. However, target dates for Oak Ridge analyses have not been set as yet.

Analysis of Hanford data by cause of death is projected for completion by November 1, 1972.

Progress of this study as measured in terms of usable results has been slow. The principal results produced thus far have been comparisons of life span for Hanford employees and their siblings. No breakdown by radiation exposure has been made, either with respect to exposed vs. nonexposed or by level of exposure. No comparisons of employees with controls for specific cause of death categories have been made. The investigators are now working on methodology for creating radiation exposure categories and on analysis by cause of death. Dr. Mancuso does not project early analyses relating radiation exposure to mortality, but the cause of death analyses are scheduled for completion later this year as stated above.

Expansion of ongoing data collection to other plants will be attempted next year. Retrospective data collection was begun early in 1972 at Mound Laboratories. The Mound facility is projected for inclusion in the main study in that data from past as well as current employment periods will be analyzed.

The importance of the study was reaffirmed during the past year. Need for assessment of the hazards due to radiation incidental to employment in the industry were emphasized by such diverse sources as the Commissioners, the General Advisory Committee and the Atomic Energy Labor-Management Relations Panel. The Study is also recognized as a unique source of data for ultimately relating quantified low level radiation to health experience. However, we are always faced with the qualification that the numbers studied may be insufficient to demonstrate the adverse effects of the low levels of radiation under consideration

if such effects do exist. A reason for proceeding with the study in spite of this qualification is that the exposed population will increase with expansion of the industry and may eventually reach a point where significant results are forthcoming. Perhaps, that point will be recognized only if the study is continued into the indefinite future while largely funded as an operational procedure.

Evaluation

Both the Commission and Division have expressed strong dissatisfaction with the progress of the study. In addition to the communication of this feeling to Dr. Mancuso during past years, a series of letters this spring has made explicit the unhappiness of the Division with the quality and paucity of reports emanating from the study (other than lengthy and difficult annual reports) as well as the slow rate of progress. The necessity of moving toward relating radiation exposure to mortality findings has been especially emphasized.

Care in the collection of data remains the principal investigator's greatest merit. In addition to points cited in the previous paragraph, his weaknesses include (a) loose administration and poor coordination of component parts of the study, (b) undue delay in analyzing data, thereby losing the opportunity to modify data collection to meet the needs of analysis, (c) poor judgment in deciding which factors are important in forming control groups and in projecting sensitivity of the study, and (d) lack of responsiveness to Commission needs in defining priorities within the program and in furnishing useful information to the Commission.

Recommendations

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A formal review is to be held later this year shortly after the next brief semiannual report to the Commission is received on November 1. Evaluation of the performance of the principal investigator will be held within the Branch after reports of the reviewers are received. At that time, a decision will be made to either renew the contract of the principal investigator or replace him with another P.I. In the meantime, contact will be made with other possible investigators to insure continuity of the study in the event that Dr. Mancuso is given a terminal period. In that case, overlap of the investigators would be provided to minimize dislocation during the period of transition.

If a change of investigator is made, the new investigator will be asked to centralize his operation. Economies of operation and more effective conduct of the study can probably be gained by having the computer and the programming staff at or near the administrative office rather than at Oak Ridge. The Oak Ridge staff office of the Pittsburgh operation, which collects death certificate information, would also be located at the central office. Centralization of the project should also effect economies of administration.

We recommend that Dr. Mancuso's contract be renewed for a year beginning August 1, 1972. During this contract period the above review process will be implemented. The recommended budget figure is \$191,930. We intend to furnish him a recommended budget and a list of priority projects and budgetary allocations. The priority projects are (a) the cause of death analyses and (b) development of the master file of employment periods for the compilation of lifetime occupational exposure records. The priority allocations are: (a) Dr. Mancuso's salary for 50% of his time (plus for indirect costs and fringe benefits); (b) Dr. LeGasse's salary for 25% of his time (plus for indirect costs and fringe benefits); (c) funds for the consultant services of Drs. Sanders and Elston; and (d) clerical help in the campus office and the service contract for the master employment file. The recommended budget involves a shift of some funds from such categories as consultant fees, travel and publications into priority categories like the partial salary of Dr. LeGasse, who has primary responsibility for the cause of death analyses. The bulk of the increase in the University of Pittsburgh budget is due to new expenditures such as Dr. Mancuso's salary and various items required for the master file. I believe that the recommended level of funding is necessary to the achievement of significant progress in the assembly of the master file.

The following is a breakdown of the revised FY 72 budget, Dr. Mancuso's FY 73 request and my recommended budget:

	<u>FY 72</u>	<u>FY 73 Request</u>	<u>Recommended</u>
Dr. Mancuso (50% of time)	-		
Indirect and fringe	-		
Dr. LeGasse (25% of time)			
Indirect and fringe			

	<u>FY 72</u>	<u>FY 73 Request</u>	<u>Recommended</u>
Support Staff (on campus)			
a. Administrative specialist	8,076	9,000	8,100
b. Secretary	5,000	6,500	5,000
c. Research technician	6,400	7,000	6,400
d. Clerks	<u>4,800</u>	<u>15,000</u>	<u>9,600</u>
Total	24,276	37,500	29,100
Indirect and fringe	19,834	31,275	24,270
Support Staff (Oak Ridge Office)			
a. Research assistant	11,200	12,000	11,200
b. Research technician	6,800	7,200	6,800
c. Clerk (part time)	<u>800</u>	<u>1,000</u>	<u>800</u>
Total	18,800	20,200	18,800
Indirect and fringe	11,825	13,050	12,150
Supplies	2,085	2,700	2,100
Publications	1,000	1,000	500
Repair of Equipment	250	250	250
Postage	500	500	500
Communications	3,250	3,600	3,250
Equipment for master file	-	2,000	2,000
Travel	10,000	12,500	6,250
Consultant	41,000	45,000	35,000
Service contract for master file	<u>-</u>	<u>19,250</u>	<u>19,250</u>
TOTAL	\$135,000	\$227,335	\$191,930

The recommended fund for consultants was reduced to \$35,000 rather than a lower figure because I believe that the continuation of Dr. Sanders' services on the same basis as in the past is essential to maintenance of the present rate of progress of the study. A study of this magnitude requires the services of a full time scientist-administrator. Although it would be advantageous to have an epidemiologist occupy that position, Dr. Sanders does function in that capacity. Dr. Mancuso was probably active in the original design and early phases of the study. However, I believe that his activities have been confined to organizing and fund raising during recent years. At this point, I doubt that he could function effectively as the scientific administrator of the study. If Dr. Sanders dropped out for personal reasons, progress in the study would probably slow down drastically until Dr. Mancuso could find a replacement (at the same or greater cost to the AEC than Dr. Sanders). Furthermore, I doubt that the _____ paid for Dr. Mancuso's services in the contract year beginning August 1, 1972, or the _____ that will be paid for his services during subsequent contract years (if his contract is renewed) will increase the level of his contribution to the study or diminish the need for Dr. Sanders' services. We may anticipate an annual expense of _____ for the combined services of Drs. Mancuso and Sanders after next year with only Dr. Sanders making a substantial contribution to the performance of the study unless a change in the administration of the contract can be made.

Other than Dr. Mancuso's and Dr. LeGasse's salaries, all increases in funding are related to the master file of employment periods. They include the hiring of an additional clerk (about \$9,000), equipment (\$2,000) and a contract for keypunching of information for the file and transfer to magnetic tape (\$19,250). The clerks in his supporting staff on campus would transfer information submitted to Pittsburgh from the contractors and laboratories to coded forms in preparation for keypunching. This is a laborious operation since much of the information arrives on microfilm. Dr. Mancuso requested the services of three clerks; two are provided in the recommended budget. If funding is not provided for adequate clerical help in the Pittsburgh office, there is no purpose in funding the service contract because the work provided under the contract cannot be started until the preliminary processing by the clerks is complete. The alternative to an adequate University of Pittsburgh budget is deferment of progress on the master file which in turn is likely to lead to a further delay in the analysis of life span and cause of death when employees are grouped according to the level of their lifetime occupational radiation exposure.

The recommended budget for SSA is as follows:

1. Complete ID of Hanford siblings	1,025
2. Complete ID of Oak Ridge siblings	7,905
3. Reprocessing of Hanford employees, siblings and nonstarts to identify deaths	15,675
4. Additional mortality data from payment centers	325
5. ID of deceased among Oak Ridge employees and siblings	40,000
6. Search for social security numbers for additional Hanford and Oak Ridge employees	2,000
7. Programming for above	<u>10,000</u>
TOTAL	\$76,930

A comparison of the total budget for this study between FY 72 and the recommended FY 73 budget is as follows:

	<u>FY 72</u>	<u>Recommended FY 73</u>
HEHF	43,000	60,000
Oak Ridge	160,000	130,000
Mound Labs.	30,000	30,000
SSA	120,000	76,930
Pittsburgh	<u>135,000</u>	<u>191,930</u>
TOTAL	\$488,000	\$488,860

SIDNEY MARKS