

524R



Department of Energy

Oak Ridge Field Office
P.O. Box 2001
Oak Ridge, Tennessee 37831-8614

707554

July 19, 1993

Dr. Clyde Dulin
Portsmouth Gaseous Diffusion Plant
Post Office Box 628
Building X-1000, MS 5020
Piketon, Ohio 45661

REPOSITORY OAK RIDGE OPERATIONS (ORO)
COLLECTION ENERGY PROGRAMS DIVISION, ER-11
BOX No. Active Records Gathered for Human Radiation Exp. P't.
FOLDER _____

Dear Dr. Dulin:

MORTALITY STUDY OF WORKERS AT THE FERNALD PLANT

Oak Ridge Institute for Science and Education (ORISE), which is managed and operated by Oak Ridge Associated Universities for the U. S. Department of Energy, has been funded by the National Institute for Occupational Safety and Health (NIOSH) to complete a mortality study of individuals employed at the Fernald Plant in Ohio. In the process of assembling the data necessary to complete this study, it has been determined that 18 individuals in the study group were also employed at Portsmouth Gaseous Diffusion Plant at one time. In order to have complete radiation exposure data for inclusion in the study, ORISE needs exposure records for individuals provided on the enclosed list. Name, social security number, birth date, and employment dates have been provided. The external exposure data provided should include shallow dose, deep dose, and neutron dose in the minimum available monitoring interval (i.e., weekly, monthly, quarterly, or annually). The internal exposure data should include raw bioassay data from in vitro and in vivo analysis. Please include information on quality factors, minimum detectable activities, units, etc. This information was recently requested from NIOSH, and the request was forwarded from John Cardarelli at NIOSH. A copy of the letter received at the Center for Epidemiologic Research from John Cardarelli is enclosed.

Please call Kathryn Robertson-DeMers at 615/576-9944, or Dr. Donna Cragle at 615/576-2866, if there are any technical questions regarding the data requested.

Sincerely,

for Thomas M. Jelinek, Director
Energy Programs Division

ER-113:McLaren

Enclosures

1021981

"Reading File" Copy

Dr. Clyde Dulin

- 2 -

July 19, 1993

cc w/o enclosures:
D. Cragle, ORISE
G. Davis, ORISE
J. Drewry, ORISE

93-0796.as

1021982

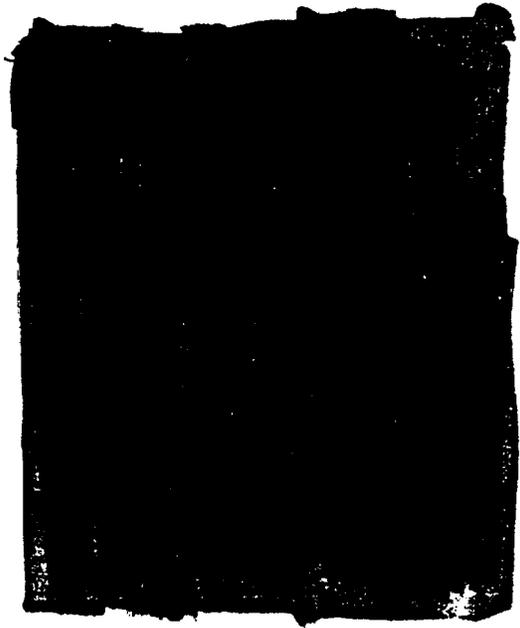
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PAUL JUUUJ

FILE: FERPOOP DATA G1 VM EXPRESS VM/ESA 370 FEATURE

FILE DESCRIPTION
(INDIVIDUALS IN THE FERNALD STUDY WHO ALSO
WORKED AT PORTSMOUTH GASEOUS DIFFUSION PLANT.)

CER ID	SOCIAL SECURITY NUMBER	BIRTH DATE	LAST NAME	FIRST NAME	MIDDLE NAME	HIRE DATE	TERM DATE
2-7							
10-18							
21-29							
32-46							
48-62							
64-75							
77-85							
08-96							
		04-SEP-26					31-JAN-57
		18-OCT-32					05-APR-62
		27-MAY-20					INFO USEFUL INFORMATION)
		08-OCT-31					10-JUN-57 30-JUL-65
		23-APR-38					18-FEB-57 27-JUN-58
		05-APR-20					01-DEC-54 25-AUG-55
		15-FEB-16					21-DEC-53 26-JAN-54
		21-AUG-19					27-SEP-57 31-MAR-84
		18-DEC-20					08-MAR-54 08-OCT-54
		18-SEP-24					11-MAR-57 27-JUN-58
		09-MAY-15					01-OCT-53 31-MAR-60
		16-FEB-10					01-DEC-54 15-OCT-56
		10-SEP-57					(WORKED AT FERNALD FOR
							ALL OF 78, 86, AND 87)
		10-FEB-25					26-OCT-70 28-FEB-73
		18-JUN-38					15-OCT-56 15-JAN-60
		07-MAR-37					19-NOV-56 15-JAN-60
		26-APR-08					20-DEC-54 04-MAR-55
		21-AUG-31					08-NOV-54 04-MAY-56



1021983



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
National Institute for
Occupational Safety & Health
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati OH 45226-1998

June 24, 1993

Ms. Kathryn Robertson-DeMers
Center for Epidemiologic Research
Oak Ridge Institute for Science and Education
P.O. Box 117
Oak Ridge, Tennessee 37831-0117

Dear Ms. Robertson-DeMers

This letter is in response to your request for radiation dosimetry data for 18 individuals that were previously employed at the Portsmouth Gaseous Diffusion Plant (PGDP). Several discrepancies were found in reviewing the data files. Below is a table illustrating the findings.

Review of PGDP Radiation Dosimetry Files for ORISE Study			
Data File	# with data	# without data	No data at all
External (Film and TLD)	11	7	6
In-vivo	1	17	
Urinalysis	10	8	

NIOSH is currently involved a study of this facility and is in the process of reviewing these data files. A verification and validation effort of these data have not yet been performed. Therefore, I recommend that you forward your request directly to PGDP Health Physics Personnel to retrieve the data you requested. I am providing a copy of the letter to Clyde Dulin at the PGDP and he should be able to respond to your request.

1021984

Page 2 - Ms. Kathryn Robertson-DeMers

If you have any problems in obtaining the information from PGDP or questions please contact me a (513) 841-4400.

Sincerely,



John Cardarelli II
Research Health Physicist
Energy-Related Health
Research Activity
Division of Surveillance, Hazard
Evaluations and Field Studies

cc:
Clyde Dulin, PGDP Health Physics

1021985

MEMORANDUM OF UNDERSTANDING
BETWEEN
DEPARTMENT OF ENERGY
AND
DEPARTMENT OF HEALTH AND HUMAN SERVICES

I. Background

The Secretary of Energy established an advisory committee to make recommendations on strengthening the Department of Energy's (DOE) epidemiologic research activities. This advisory committee—the Secretarial Panel for the Evaluation of Epidemiologic Research Activities (SPEERA)—recommended that DOE enter into a Memorandum of Understanding (MOU) with the Department of Health and Human Services (HHS) to manage and conduct analytic epidemiologic research (studies which test hypotheses). The Panel also recommended that DOE conduct descriptive epidemiologic studies, e.g., occupational health surveillance. The Secretary of Energy agreed with the Panel's recommendations and has requested that HHS enter into an MOU to implement them.

II. Purpose

This MOU sets forth the guidelines for coordination between DOE and HHS to carry out the recommendations of the SPEERA for the management and conduct of energy-related analytic epidemiologic health research by HHS.¹ This includes the authority, resources, and responsibility for the design, implementation, analysis, and scientific interpretation of analytic epidemiologic studies of the following populations: workers at DOE facilities; residents of communities in the vicinity of DOE facilities; other persons potentially exposed to radiation; and persons exposed to potential hazards resulting from non-nuclear energy production and use. This agreement is not meant to affect existing MOUs and Interagency Agreements (IA) between DOE and HHS or to preclude DOE and HHS agencies from entering into MOUs or IAs for other purposes.

¹This agreement does not apply to activities and facilities covered under Executive Order 12344 (42 USC 7158 note).

III. Authorities

- A. The Department of Health and Human Services/Public Health Service/Centers for Disease Control has legislative authority under Section 301(a) of the Public Health Service Act (42 U.S.C. Section 241) and under the Occupational Safety and Health Act [29 U.S.C. Section 669(a)] to conduct research into the health effects of a broad range of environmental and occupational hazards and to cooperate with other appropriate authorities in the conduct of such research.
- B. The DOE may enter into agreements with HHS for the management of epidemiologic research pursuant to Section 103 (3) and 103 (11) of the Energy Reorganization Act of 1974 [42 U.S.C. Sections 5813 (3) and 5813 (11)]; The Economy Act of 1932 as amended (31 U.S.C. Section 1535); and DOE Order 1280.1, MEMORANDUMS OF UNDERSTANDING, of 9-20-85.

IV. DOE Responsibilities

A. Access to DOE Data Sources

DOE will provide HHS with access to data and other documents that may be pertinent to the management and conduct of analytic epidemiologic studies and programs, including data on occupational and community exposures, and environmental releases.

DOE will solicit input from HHS on the development and maintenance of the Comprehensive Epidemiologic Data Resource (CEDR) and the selection of data to include in CEDR.

DOE will allow HHS personnel, contractors, and grantees with appropriate security clearances access to all DOE and DOE-owned, contractor-operated facilities for the purpose of independently reviewing or collecting any health or environmental information or samples that HHS determines are necessary for conducting analytic epidemiologic research.

To the extent that existing regulations, Privacy Act routine uses, or agreements with its own contractors preclude disclosure of data held by DOE or its contractors to HHS, or subsequent use by HHS under section V.G., below, DOE will amend the regulations and routine uses, and renegotiate the agreements, so as to permit such disclosure and use.

To the extent that existing agreements with other entities preclude disclosure of data held by DOE or its contractors to HHS, or subsequent use by HHS under Section V.G., below, DOE will take distinct affirmative steps to negotiate those agreements so as to permit such disclosure and use. All future agreements entered into by DOE governing data that may be useful for the studies to be conducted by HHS under this MOU will permit disclosure of that data to HHS and subsequent use under Section V.H., below.

B. Programs to be Transferred

The health research programs to be managed by HHS will include selected ongoing and future epidemiologic health studies that test hypotheses, e.g., cohort, case-control, and cross-sectional mortality and morbidity studies, including dose reconstruction and exposure assessment studies that are essential for conducting these epidemiologic studies. The ongoing studies and FY 1991 resources to be transferred are identified in Appendix A. See also Section V., below.

C. Classification of Documents and Security Clearances

As soon as possible following the effective date of this MOU, DOE will perform a classification review of documents and data necessary for HHS to conduct the studies and programs described herein. HHS personnel with appropriate security clearances will participate in this review which will include an examination of existing procedures for the classification of documents that will be needed to conduct analytic epidemiologic research. DOE will, wherever possible, declassify or downgrade these documents and data. DOE will expedite appropriate security clearances for designated HHS personnel, and when possible honor current HHS security clearances (Top Secret), so that HHS personnel may examine classified documents and enter DOE and DOE-owned, contractor-operated facilities as necessary.

D. Committee Representation

The DOE will participate in the development of the research agenda for analytic epidemiologic studies by having DOE representative(s) serve as non-voting member(s) of the HHS Advisory Committee which will provide advice to HHS in setting the research agenda and in conducting the research program.

E. Office of Management and Budget/Congressional Submissions

For FY 1992, DOE will forward to the Office of Management and Budget (OMB) for inclusion in the President's Budget a request for resources necessary to support the conduct of the aforementioned studies and programs.

F. Official Point of Contact

DOE designates the following individual as the official point of contact for this MOU:

Name: Paul L. Ziemer, Ph.D.

Title: Assistant Secretary for Environment, Safety and Health

Address: U.S. Department of Energy, Washington, DC 20585

Telephone: (202) 586-6151

V. HHS Responsibilities

A. HHS Advisory Committee

HHS will establish an Advisory Committee to provide advice to the Secretary of HHS in setting the research agenda and in conducting the research program. Members of the Advisory Committee will consist of representatives selected by the Secretary of HHS from non-federal employees and will include research scientists, public health officials, representatives of public interest groups, and representatives of affected parties (e.g., workers, community residents). Both HHS and DOE will have nonvoting members on this Committee.

This HHS Advisory Committee will have an open channel of communication with the DOE's Advisory Committee which will be established to advise DOE's Assistant Secretary, Environment, Safety and Health, on the conduct of its environmental, health, and safety programs.

B. Committee Representation

Representative(s) of HHS will serve as non-voting member(s) of the DOE Advisory Committee which will provide direction, oversight, and evaluation to the DOE's Office of Environment, Safety and Health.

Additionally, there exist currently DOE-funded host State health agreements. For these existing and future agreements, HHS representatives will provide technical and public health assistance to the host States, including participating on the Technical Review/Oversight Committees at the request of the host States. DHHS' role in future analytic epidemiologic studies conducted through States will be discussed by DOE with HHS prior to negotiations of their agreement with States.

C. Establishing the Research Agenda

The HHS Advisory Committee will provide advice and recommendations to HHS on establishing the research agenda. All energy-related analytic epidemiologic health studies proposed by DOE and HHS will be submitted to the HHS Advisory Committee. The HHS Advisory Committee will take into consideration information and proposals provided by DOE and its Advisory Committee as well as information and proposals from other agencies and organizations. HHS will then establish the research agenda and develop a research plan.

HHS will provide DOE the research plan for review and comment. The HHS research plan will be revised each fiscal year to incorporate changes in the research agenda and to reflect changes in available resources.

All DOE initiated analytic epidemiologic research projects, including dose reconstruction and exposure assessment studies essential for conducting these epidemiologic studies, would be offered first to HHS for consideration. However, DOE may conduct through alternate means an analytic epidemiologic study that it referred to HHS if the HHS Advisory Committee has recommended the study but HHS has chosen not to include it in its research agenda. Funding for such will come from a DOE source separate from that funding level set aside for HHS-managed studies to be conducted under this MOU.

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D. Conducting Research Activities

HHS will have sole responsibility for the design, conduct, analysis and scientific interpretation of the results for all transferred studies beginning at the time of transfer and for all future studies and programs covered under this MOU. HHS agrees to initially continue existing DOE grants and contracts listed in Appendix A. However, HHS will review all existing grants and contracts and continue, expand, or discontinue the projects based on this evaluation. This initial evaluation of current research activities and inclusion of those studies on a defined research agenda shall proceed with the advice of the HHS Advisory Committee and shall adhere to the principles specified in Section V.C. of this MOU.

HHS will decide which studies will be performed intramurally and which will move to open competition for all extramural research. HHS will develop a schedule for determining when continuing programs will be recompeted. HHS has the discretion to begin new intramural or extramural research consistent with the approved research agenda and resource availability.

E. HHS Data Sources

HHS will be responsible for the management of all data collected by HHS scientists, including data obtained from DOE. HHS will have access to all DOE and DOE-owned, contractor-operated facilities for the purpose of independently reviewing or collecting any health or environmental information or samples that HHS determines are necessary for conducting the analytic epidemiologic research consistent with the approved agenda.

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F. Procedures for Conducting Research

HHS will employ established HHS peer review procedures for awarding research grants and contracts. These mechanisms include open competition, peer review, a competitive system for project renewals, and quality assurance for research in progress. The National Laboratories would be eligible to compete in this process along with other applicants to the extent permitted by law and DOE policies.

Intramural research will be conducted in accordance with established mechanisms for assuring scientific peer review. After coordination with DOE, HHS will prepare and submit the necessary information collection proposals to OMB under the Paperwork Reduction Act. Representatives of populations being studied shall be included in review panels which will be established as appropriate for studies conducted under this MOU. These panels will allow for public comment on the design and conduct of all studies. Results of the studies will be communicated directly to the Secretary of DOE and HHS and openly communicated to all interested parties. Notification of workers will be performed through existing HHS procedures and coordinated through DOE if the workers are from DOE or DOE owned, contractor-operated facilities.

G. Classification of Documents and Security Clearances

As soon as possible following the effective date of this MOU, HHS personnel with appropriate security clearances will participate in a DOE classification review of documents and data necessary for HHS to conduct the studies and programs described herein. HHS will complete all necessary paperwork for appropriate security clearances for its personnel so that they may examine classified documents and enter DOE and DOE-owned, contractor-operated facilities.

H. Use and Disclosure of Information

Establishment of Privacy Act Systems

HHS will establish the necessary Privacy Act systems of records for information provided to HHS by DOE (or will include such information in existing systems). Before integrating DOE data into a HHS system of records, HHS will consult DOE about provisions of the system notice, including the routine uses, applicable to the DOE data in the system. Before establishing a new system of records for DOE data, HHS will consult DOE about the provisions of the system notice, including the routine uses.

Disclosure of Information to the Public Generally

Information provided to HHS under this agreement that is requested by the public under the Freedom of Information Act shall be made available by HHS in accordance with the Act, 5 U.S.C. Section 552 and implementing regulations, 45 C.F.R. Part 5. In making decisions about disclosure, HHS will consult DOE about any information provided by DOE and identified in advance by DOE as warranting such consultation.

Disclosure of Personally-Identifiable Information for Research Purposes

As provided under applicable laws, HHS will not use or disclose any personally-identifiable information obtained from DOE or its contractors except for research purposes. HHS will not use information in identifiable form to make any determination about the rights, benefits, or privileges of any individual. HHS will use and disclose this information in accord with agreements under which the personally-identifiable information was obtained by DOE or its contractors provided this is consistent with applicable law. Subject to applicable law and such agreements, HHS will provide this information to DOE's Comprehensive Epidemiologic Data Resource (CEDR) data base and otherwise may disclose this information outside HHS for research to persons or entities it deems qualified, after consultation with DOE and in accord with the provisions for disclosure in HHS Privacy Act notices. HHS shall notify DOE of any efforts on the part of anyone to obtain or use personally-identifiable information for purposes other than research and shall use and take appropriate steps to prevent improper disclosure. HHS will assist DOE as necessary in renegotiating (as required by section IV.A., above) any agreements that preclude disclosure to HHS of data held by DOE or its contractors.

1021993

I. Release of Data from Completed Studies

HHS will promptly disseminate results obtained through research covered by this MOU to the populations being studied. Public access, including DOE access, to data in HHS epidemiologic studies will be governed by applicable Federal laws and HHS implementing regulations. After HHS epidemiologic studies have been completed and reported, study data will be made available to the public and to CEDR without personal identifiers subject to the provisions of Sections V.G. and V.H. above.

J. Reports to DOE

HHS will report its progress to DOE on a quarterly basis for the first year of this MOU. After the first year, DOE and HHS will evaluate the reporting needs and determine the frequency of future reporting.

K. Responsible Official

HHS designates the following individual as the official point of contact for this MOU:

Name: William L. Roper, M.D., M.P.H.
Title: Director, Centers for Disease Control
Address: 1600 Clifton Road, N.E., Atlanta, GA
Telephone: (404) 639-3291 (FTS 236-3291)

VI. Implementation of MOU

The Secretaries of DOE and HHS will appoint a task force to oversee and assist in implementing this MOU, including transfer of the analytic epidemiologic research programs listed in Appendix A. This task force will be appointed for one year and will report to the Secretaries at the end of its term. The task force will consist of staff from DOE and HHS.

VII. Resources

DOE will provide and transfer resources to HHS for the purpose of managing the DOE energy-related analytic epidemiologic research program. The funding and full-time equivalent (FTE) employment levels will be determined annually by agreement between designated agency official points of contact for this MOU (for DOE, see Section IV.F.; for HHS, see Section V.K.) For FY 1991, funding for this program will be \$14,145,000 for grants and contracts and \$2,855,000 and 25 FTEs for program operations, and for FY 1992, program levels will be \$14,725,000 for grants and contracts and \$6,200,000 and 44 FTEs for program operations. Upon mutual agreement, resource levels may be amended at any time during the fiscal year, however in the event that HHS incurs extraordinary expenses as a result of DOE's action to amend or constrain this MOU, HHS will be entitled to reimbursement for these expenses upon demonstration that additional and extraordinary costs were necessarily incurred. A copy of the signed agreement can be used by DOE as the basis for DOE to request the allocation of FTEs to HHS to carry out the terms of this agreement.

The details of the levels of support to be furnished by DOE to HHS will be developed annually through a single interagency agreement. HHS will provide to DOE a description and justification for funding and FTE resource requirements for submission to OMB and Congress for the studies and programs described under this MOU. These submissions will be provided by HHS to DOE in a timeframe agreed upon that is consistent with DOE's budget cycle.

HHS will not accept responsibility for specific studies or undertake new programs unless the mutually agreed level of resources is sufficient to achieve the intended goals and objectives. If equipment is procured in order to provide service under this MOU, HHS will retain title to the equipment.

Any requirement for the payment or obligation of funds by DOE established by the terms of this Agreement shall be subject to the availability of appropriated funds.

For the purposes of studies conducted by HHS or its grantees and contractors, HHS will prepare the necessary information collection proposals for OMB approval under the Paperwork Reduction Act. These proposals will be submitted by HHS to OMB. In the event that OMB fails to approve the information collection or allow adequate burden hours, HHS will be under no obligation to undertake or complete individual studies but will advise DOE and work with DOE to secure OMB approval which may result in necessary modification of reporting requirements.

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VIII. Duration of Agreement

This agreement is effective when signed by both parties, shall initially remain in effect through FY 1995 unless amended by mutual written consent of both parties. The agreement is to be renewed annually thereafter by written mutual agreement. There is every intention to continue this agreement over the long-term.

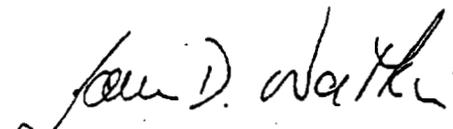
IX. Modification or Cancellation

This agreement, or any of its specific provisions, may be revised by signature approval of both of the parties signatory hereto, or their respective designees.

Cancellation of the agreement may be accomplished only at the expiration of 90-day advanced notification by either party.

DEPARTMENT OF ENERGY

DEPARTMENT OF HEALTH AND HUMAN SERVICES

By: 
James D. Watkins
Admiral, U.S. Navy (ret.)
Secretary

By: 
Louis W. Sullivan, M.D.
Secretary

Date 12/19/90

Date DEC 24 1990

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Appendix A

DOE Analytic Epidemiologic Studies and FY 1991 Resources
to be Transferred to HHS

The ongoing studies, which are the subject of this Memorandum of Understanding, are listed by contractor, year of expected study update*, program title (underlined), program funding level for FY 1991, and specific tasks.

HARVARD 1992 In vivo mutagenicity & clastogenicity of ionizing radiation.
\$200,000.

HEHF DOE Hanford Health and Mortality Study. \$383,000. Companion study to the PNL Statistical Health Effects Studies. HEHF is responsible for employment and medical records.

1991 Hanford health and mortality study. Deaths through 1984/5 for all states, and through 1989 for Washington State.

LANL Human health effects of plutonium. \$700,000.

1991 Analysis of mortality among employees of the Mound facility. Deaths through 1983.

1991 Cohort mortality surveillance among workers employed at the Los Alamos National Laboratory. Female subcohort completed; males scheduled for FY92.

1991 Investigation of mortality among employees of the Zia Company a subcontractor to the Los Alamos National Laboratory.

1991 Investigation of mortality among employees at the Rocky Flats nuclear weapons facility. Deaths through 1983.

1992 Analysis of mortality among plutonium exposed workers. Phase I of the pooled study including Rocky Flats and Mound. Deaths through 1983.

1992 Epidemiologic studies of Pantex workers.

Open Medical surveillance of Manhattan Project plutonium workers.

Open Mortality surveillance among 241 plutonium exposed workers.

Open Radiation exposure assessment study to support morbidity and mortality studies of workers.

LLNL

Melanoma studies at the Lawrence Livermore NL. Internal laboratory funding.

1021997

1993 A study of mortality among workers at the Paducah Gaseous Diffusion Plant.

1993 Mortality among workers at a uranium refining and processing plant (Mallinckrodt).

1993 Mortality among short-term workers at the Oak Ridge Gaseous Diffusion Plant.

Open Case-control study of renal disease among workers at a uranium processing plant (Fernald).

ORO 1992 CDC/Fernald dose reconstruction. \$6,100,000.

PNL Statistical health effects studies. \$295,000.

1991 Hanford health and mortality study. Deaths through 1984 for all states and through 1989 for Washington State. Joint HEHF/PNL project.

1992 Case-control study of childhood leukemia and non-Hodgkin's lymphoma and of late fetal deaths in populations around the Hanford Nuclear facility.

1992 LARC combined analyses of cancer mortality among nuclear industry workers. LARC and DOE scientists are involved in analysis of health effects and occupational exposure to external sources of irradiation. Dr. Gilbert is the DOE contractor representative for this activity.

RL 1993 Hanford dose reconstruction - Support to PNL. \$3,650,000.

* The year shown in the second column represents the estimated completion date of the initial or updated analysis. In general, this represents completion of a manuscript or submission of a study for scientific peer-review. "Open" implies that the work is on-going, a start date has not been assigned, or additional funding has not been provided.

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