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Executive
Office

August 9, 1985

Mr. Wayne Range
A M Information
U. S. Department of Energy
Oak Ridge, Tennessee 37831

Subject: REQUEST FROM DOROTHY LEGARRETA

Dear Mr. Range:

Enclosed is a copy of a request received from Dorothy Legarreta, Ph.D., for a document prepared by Dr. C. C. Lushbaugh under the ORAU-DOE contract. We are also enclosing a copy of the document in question.

We have no objection to your releasing this document. However, it could be properly characterized as an intra-agency memorandum as that term is used in the Freedom of Information Act.

Sincerely yours,

ORIGINAL SIGNED BY
Phillip M. Kannan
General Counsel

PMK:psr

Enclosure w/attachment

cc: W. P. Snyder ✓
C. C. Lushbaugh

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PERSONNEL -1
FCIA
National Assn.
of Radiation
3913

NATIONAL ASSN. OF RADIATION
SURVIVORS
78 El Camino Real
Berkeley, CA 94705
415-654-0100



NATIONAL ASSOCIATION OF
RADIATION SURVIVORS

Rec. 7/29 85

July 25, 1985

Dear Sirs,

Please send me the report of the 1982 DOE Workshop, held in Rockville, MD., entitled, "The Development and Present State of the DOE Health and Mortality Studies", as summarized by Clarence Lushbaugh, of ORAU.

Thank you for your assistance.

sincerely,

Dorothy Legarreta

Dorothy Legarreta, Ph.D.

Administrative Director

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7/20/82
Sent to Headquarters
2 changes 2/13/82

The Development and Present State of the DOE Health and Mortality Studies

C. C. Lushbaugh, Spokesman, ORAU

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Encouraged by such groups as the AEC Advisory Committee for Biology and Medicine, UN Scientific Committee on Effects of Atomic Radiation, the Joint Congressional Committee on Atomic Energy and the Atomic Energy Labor-Management Advisory Committee, the AEC Division of Biology and Medicine began in 1963 to implement a staff recommendation (AEC Staff Paper 1136, June 27, 1963) to initiate a study to ascertain the feasibility of 1) recording, compiling and analyzing in a uniform systematic manner data of occupational radiation exposures and health experiences of AEC and AEC contractor employees, and 2) correlating lifetime health and mortality experience of ...employees with occupational radiation exposure..." (Ibid). Early in 1964 discussions with University of Pittsburgh staff resulted in establishing there a one-year feasibility study of correlating the lifetime health and mortality experience of AEC and AEC contractor employees. The University of Pittsburgh hired Dr. Thomas Mancuso, then a staff member of the State of Ohio Public Health Department, to be the principal investigator and study manager. Dr. Mancuso recruited Dr. Barkov Sanders, an actuarial statistician with the Social Security Administration, and Allen Brodsky, health physicist, to help with this study.

During the first year 19 AEC facilities were visited and data exploration begun at Hanford, Oak Ridge, several uranium feed mills of Manhattan Engineering District (MED), National Lead of Ohio and Mound Laboratory. The Oak Ridge facilities were considered to include "Y-12", "X-10", and "K-25" plants and the MED staffs of the University of Chicago, University of California (Berkeley), and Columbia University. Since it was considered feasible on the basis of the availability and quality of the records explored to carry out the proposed study, data collection began in 1965 (and in some cases merely reservation and

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storage) principally at Hanford, Oak Ridge, Monsanto (Mound), Mallinckrodt, and National Lead. All MED projects were estimated as having employed 421,000+ persons, but more recent audits of available or stored records sum to this number only if employees of post MED-AEC sites are included. During this year the Health and Safety Laboratory record system and that of Savannah River Plant stored in du Pont Hall of Records were evaluated for quality and completeness.

Although at the end of the first five years the recommendation was made that the study be authorized to include all sites, the feasibility of doing this was not established nor authorized. The goal of the AEC Health and Mortality Study at that time (about 1969) was restructured to prepare Hanford, Oak Ridge, and Mound Lab for analysis. However, as historic records of radiation exposures became available, it became increasingly apparent that quite low levels of radiation exposure had been achieved in AEC laboratories and plants. and the probability of demonstrating an association between such low exposures and such a late effect as death from cancer became questionable unless huge populations became available for analysis, but competing priorities for research funds have largely prevented an epidemiologic study expanded to include all sites.

By 1970 the feasibility of doing a restricted study was considered to have been "essentially established", and the potential duration of the study was estimated to extend well through the 1980's. During the late 1960's the interagency agreement was established between AEC and SSA to determine vital status of Hanford and Oak Ridge workers. A system for death certificate retrieval became the major focus of the University of Pittsburgh group that was set up in Oak Ridge. This group also worked closely with other data

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collection and collation groups established through field office contracts at Hanford and Oak Ridge with the Hanford Environmental Effects Foundation and the Computer Science and Health Physics Divisions of the UCC-Nuclear Division. Over the next six years 1400 high-density tapes containing all available employment data from these plants were created by the Oak Ridge UCC-ND staff. During this time, longevity analyses were undertaken largely as exploratory studies. Political urgencies and environment conflicts of the early 1970's, triggered later by the oil crisis and the rush to complete nuclear electrical generation plants, created urgencies for reevaluating radiation protection guides using human (occupational) experience. In 1975 under strong pressure from congressional overview committees and both intra- and extramural AEC review boards, the Division of Biology and Medicine, AEC, announced its intention to transfer the management of the Health and Mortality Study to Oak Ridge Associated Universities (ORAU). **This choice was made** because ORAU as a prime contractor of AEC and (shortly thereafter) ERDA operated a specialized laboratory dedicated to addressing programmatic problems of the agency as expeditiously as possible. Other major considerations were that ORAU had never been involved in any way in research and development of atomic weapons or nuclear energy technology and had excelled in studying human radiation effects and applying the findings to improving human radiation safety. In addition, although large amounts of historical employment data remained to be collected, vast amounts of data were stored in the computer banks of UCC-ND in Oak Ridge and the vaults of Oak Ridge Operations where they were protected from nonroutine use under the Federal Privacy Act. These data had up to that time not been scrutinized for omissions, errors and vali-

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dity except for the data of the Hanford facility which were identified in about 1972 as being most ready for epidemiologic analysis. The urgency for an answer as soon as possible to meet national and congressional needs suggested in 1976 that the Hanford population segment be separated from the rest of the H & M study. This program was ~~separated from the larger study and~~ assigned to Hanford Environmental Health Foundation (HEHF) and Battelle Pacific Northwest Laboratories (BNWL), where biostatistical and epidemiologic expertise was available on site to focus on this problem. During the terminal year of the University of Pittsburgh contract, analyses of the Hanford data were published by both the Hanford and Pittsburgh teams. The latter team strengthened by the recruitment of Drs. Alice Stewart and George Kneale produced results whose interpretations created intense national debate and did much to increase the public apprehensions about low-dose radiation exposures, even though numerous groups of experts as well as the Hanford study were highly critical of the Pittsburgh study. To date approximately 20 papers question that study's validity (B. L. Cohen, Science, 215, 1028-1029, 1982).

At about the same time (1975) that University of Pittsburgh was informed that FY 1977 was to be the terminal contract year during which an orderly transition was to result in ORAU continuing the H & M study in FY 1978 (July 1977), Los Alamos Scientific Laboratory (LASL, now LANL), Health Research Division, was directed to prepare a proposal to expand their epidemiologic studies of ²⁵⁰⁽²⁶⁺²²⁴⁾ plutonium-contaminated employees from ~~26 + 224~~ to include all plutonium workers at all DOE sites (see G. Voelz, et al, this workshop symposium). Shortly after the plutonium worker study was funded at LASL, the ≥ 5 -rem study was put in place at ORAU, initially as a registry of workers who, since 1947, had exceeded the 5-rem-per-annum constraint. ^{on occupational radiation exposure} The expansion of this study to

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determine the morbidity and mortality of such workers stemmed in part from a congressional hearing chaired by Representative Rogers who raised the question again of the safety of present radiation exposure constraints for atomic workers. Since this study and the LANL Plutonium Workers Study require ~~for control purposes~~ validated employment rosters and personnel records from the sites from which their special subpopulations originate (Table 1), a parallel effort was developed to obtain the employment rosters of all AEC facilities including those for which records were being stored for some future but presently unplanned study. In 1979 it was conceived that these rosters, when combined, would constitute a National Roster of Atomic Workers for possible use in future epidemiologic studies. Also in the FY 1979 period the infamous "study" of the Portsmouth, New Hampshire naval base by Dr. Najarian created ^athe furor of allegations that resulted in the establishment of an independent study by NIOSH of cancer mortality at Portsmouth and led to DOE/OHER putting in place a broader study of the work force at seven naval bases that involve the DOE Division of Naval Reactors program. This study (reported elsewhere in this symposium) under the direction of Dr. G. Matanowski, Johns Hopkins University (Table 1 and Figure 1), has provided approximately 1200 irradiated workers and 3600 controls to the approximately 1800 and 5500 controls collated from non-naval AEC-DOE facilities in the initial phase of establishing the ≥ 5 -rem-study roster. In a similar manner congressional concern was generated in FY 1978 largely by allegations of trade-union origin that serious late effects of occupational radiation and other exposures in atomic facilities have been hidden from public scrutiny. These concerns which were heightened rather than allayed by the negative findings of a study of the Savannah River Plant mortality experience by S. Pell

TABLE 1

DOE $\geq$ 5 REM STUDY

DOE/DOE CONTRACTOR
EMPLOYEES
N $\sim$ 600,000

CIVILIAN EMPLOYEES
DOE NAVAL
REACTOR PGM.
N $\sim$ 110,000

EMPLOYEES:
 $\geq$ 5 REMS/YR
REPORTED
N $\sim$ 3200

STILL
EMPLOYED
N $\sim$ 1120

TERMINATED,
RETIRED
N $\sim$ 2080

'UNKNOWN'S'
N $\sim$ 440

ALIVE
N $\sim$ 1300

DEAD
N $\sim$ 340

(HEALTH STATUS
FOLLOW-UP)

MORBIDITY
STUDY

N $\sim$ 3200

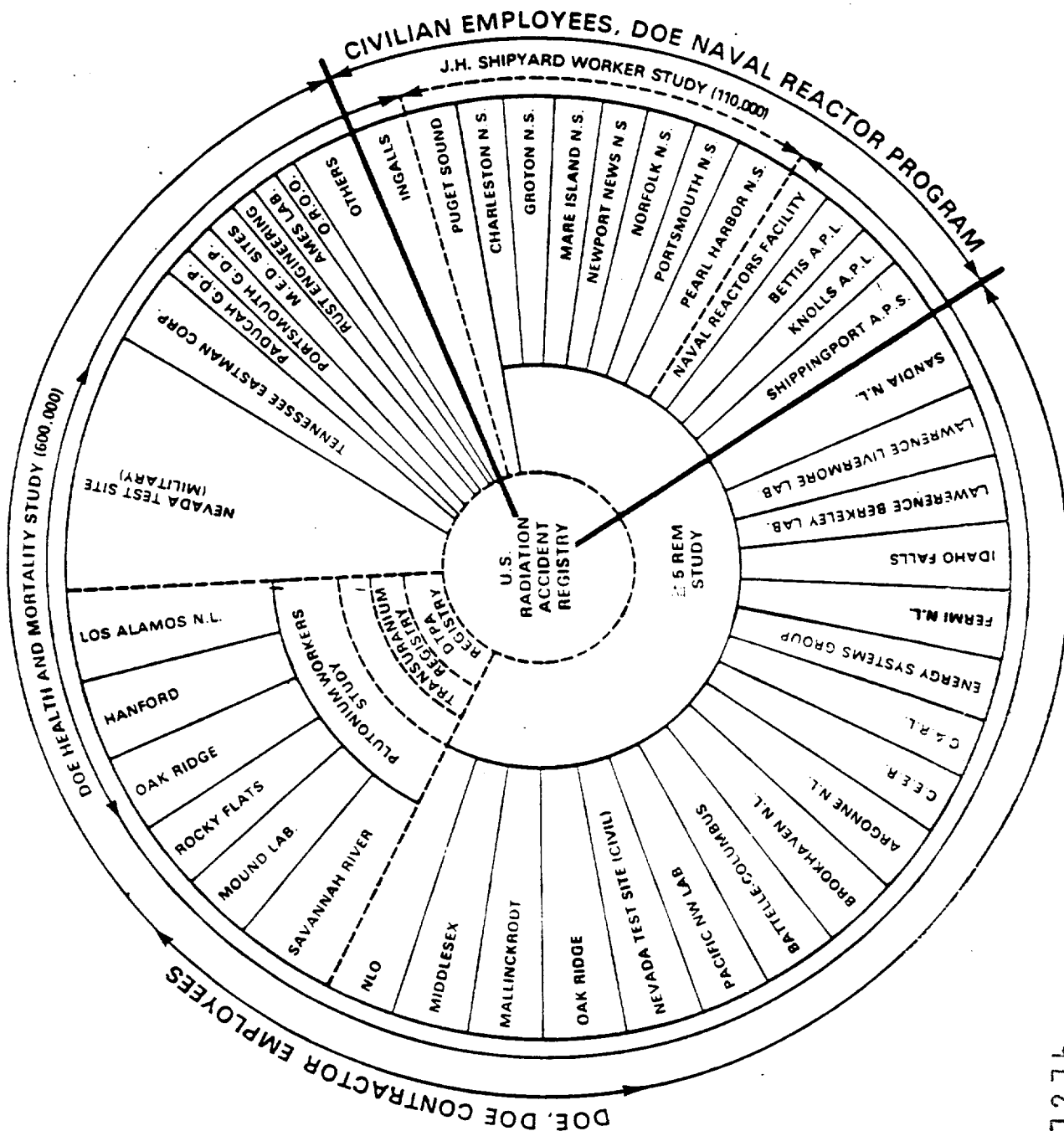
MORTALITY
STUDY

N $\sim$ 350

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Figure 1

DOE EPIDEMIOLOGIC STUDIES POPULATIONS



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of the du Pont Hall of Records, ignored the findings of Dr. Herbert Sauer, University of Missouri, who showed in three previous studies of the morbidity and mortality of the populus in SRP environs that cancer mortality was remarkably low. As a result, attention became focused on SRP and required that ongoing efforts to establish and validate SRP employment rosters, personnel and radiation exposure files ^{be} accelerated ^{to} and ^e include determination of standardized mortality rates for SRP as soon as possible.

Most recently (1981) the Health and Mortality Study Schema has been impacted by political urgency demanding scientific answers to questions generated in this case by the citizens and trade unions of Western New York State, and the New York State Legislature. Higher priority ^{as a result} ~~has now~~ been given to our retrieval of MED documents of uranium processing sites in the Buffalo region. The early phase of an epidemiologic study of that population is now under way with the collaboration of Union Carbide Corporation whose Linde Air Products Division in Tonawanda, NY (along with five other smaller plants) was the major site involved in World War II manufacture of uranium metal and gases. Active cooperation of the NY State Public Health Department (particularly vital statistics) and the Oil, Chemical and Atomic Workers Union is helping implement this study immensely. The Environmental Measurements Laboratory (EML) (former HASL) is also involved since they and the University of Rochester Radiation Project had the responsibility for the MED radiation exposure measurement and records system.

This historical description of the development and present overall configuration of the DOE Health and Mortality Study, its various segments, populations, subpopulations and operational responsibilities has proven

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to be confusing to program review committees and has not obtained complete agreement by everyone involved. Some of this confusion undoubtedly results from my perceptions, but some results from changing scientific and programmatic-pragmatic priorities of government, industry, workers and their families. These priorities ~~seem~~ have changed more rapidly than epidemiologic studies can be completed, particularly where, in studies like these, the art of handling the massive data bases involved has not yet reached the state where all the problems involved can be managed easily. The basic scientific question which this study addresses (in all of its subsets) ~~is, however, still un-~~
Then AEC
~~changed and~~ focuses 20 years after the inception of the ~~(now)~~ DOE Health and Mortality Study upon concerns for the safety of low-level radiation exposures in occupational settings. This question was once perceived as relatively simple if radiation exposures were sufficiently large and frequent to be effective. It is now known by the scientific community to be difficult because

The effects of radiation are
~~is~~ obscured by many factors such as other stressful or toxic exposures *such as tobacco smoking, industrial chemicals,* socioeconomics, geography, etc. The public community still perceives the intellectual debate as a cover-up and ~~the~~ industry needs to know whether *industrial* practices of the past harmed ~~the~~ workers, whether or not radiation exposure was involved. As a result, these studies today focus not only on radiation and its effects but upon the numerous other well-known nonradioactive sources of harmful effects in the atomic industrial work place--uranium dust, mercury, *and other toxic metals and fumes.* beryllium, cadmium, ~~etc.~~ The multiplicity of the studies are also confusing to reviewers but ~~are~~ *are* required for ~~interplant,~~ *making* geographic, socioeconomic, temporal and other comparisons.

The block diagram (Fig. 2) is an attempt ~~to~~ to obviate some of this confusion by illustrating the relationship of the three major Oak

Ridge studies actively under way at this time to other AEC/DOE facilities and DOE-supported segments of the larger study. The central large block shows the "Oak Ridge Segment" and the six major DOE facilities that now comprise it (total past and present population ~140,000); the Oak Ridge-only group of 4 sites, one of which (TEC, population 40,000) is defunct (80,000); the three gaseous diffusion plants where uranium, fluorine and nickel exposure are major threats (50,000 workers); and a block of special preliminary studies largely exploratory and hypothesis-generating focused on data subsets as data-base validation has permitted. The designation "UNC" acknowledges the collaborative efforts in these studies of the Departments of Epidemiology and Environmental Science of the School of Public Health of the University of North Carolina (Drs. Carl Shy, M. Ibrahim, J. Watson and staffs). The block to the left, labeled MED-Uranium shows the facilities involved in the so-called Niagara Frontier (3200 total populations of whom 2000 were Linde employees); and the other major early uranium processing sites--Mallinckrodt (MCW) (3700), National Lead of Ohio (6,600) and Middlesex (dotted lines indicating only an employment list at hand). The large narrow box extending across the diagram labeled ≥ 5 rem indicates the across-the-industry nature of this study while the arrows terminating in it indicate the sources of the study and control populations involved in this study. In the dotted-lined box to the right are listed the facilities where plutonium exposures were a major hazard and other sites where epidemiologic studies are the major concern of others (see text). Similarly the dotted-lined boxes are other DOE facilities classified as to their major focuses--weapons, research and development and reactors. Some of these sites are listed in other boxes and illustrate in part some of the areas of overlapping interests and concerns.

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The three studies comprising the major concern of the Oak Ridge-ORAU-Center for Epidemiologic Studies and its UNC collaborators are shown on this diagram within a single larger box in the interest of clarity.

Progress

The block diagram (Figure 3) depicts the various phases of the standard study process involved in ORAU/UNC protocols designed to produce publishable reports of a definitive, specific epidemiologic study of a DOE facility's health and mortality experience. The arrows show the directions of the progress and how the error correction, editing, and validation of the records occur simultaneously and repetitively as the various phases proceed in or out of phase with others, depending on record availability, completion of various steps by others such as Social Security Administration, Death Certificate Retrieval Office, State Departments of Vital Statistics, etc. Collection phases I and II when complete result in the necessary data for vital status determination to be carried out through SSA by our Death Certificate Retrieval Office. Completion of the identification of deaths and retrieval of their death certificates allow completion of a master roster file which can be explored analytically to see whether the data contains information basic for hypothesis generation, changing priorities or identifying problems needing immediate correction. As the master roster file data is being edited and validated, Phase III of collecting and organizing the personnel files, work history files and exposure files is accelerated. Completion of this set of files leads to formation of an inventory file which in its simplest use shows the commonality of the information for individual workers and allows frequency distribution analyses to be done so that design of the analytical

protocol can proceed. Completion of the experimental design provides guides for linking the data and providing a basic cross-linked analytical file from which data can be obtained for specific analyses to test hypotheses such as, for example, "four years of respiratory exposure to uranium dust does not result in an increased mortality from respiratory disease." Phase IV, obtaining and entering data from medical records, the most difficult of these tasks, is needed to control for such confounders as smoking, alcohol usage, intercurrent disease, genetic or familial abnormalities. When these data become available and the hazards assessments are complete, the data set is ready for epidemiologic study and final publication. The time scale at the top of the diagram shows the "lag" time to be 2 to 6 years between beginning and end. This long lag prevents studies of individual sites being done consecutively and forces these concurrent developments. Because delays cannot always be avoided, data from a facility of lesser programmatic interest can become ready for study before analytical file completion of high priority sites. These occurrences frequently lead review committees to question the wisdom of program management and to conclude that there is no direction and that fragmentation of the study is being encouraged. At the end of FY 1981 the various parts of the Oak Ridge studies were for these reasons at quite different stages of completion. In terms of the data collection and management phases shown in Fig. 3 and described briefly above, these statuses were (Table 2):

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Table 2

Present Phases of "Oak Ridge" Study Progress 1982

<u>Studies</u>	<u>Phases</u>
1. Niagara Frontier (6)	I & II*
Mallinckrodt	III + Presentation 1
National Lead of Ohio	IV + Presentation 1
2. <u>>5</u> rem	II & III
3. Oak Ridge Segment	
TEC	AF** Publication 1
Y-12	AF Presentation 2
X-10	AF Presentation 1
K-25	IF/AF + Special Studies
Portsmouth	III
Paducah	III

* I & II = master roster being formed

** AF = analytical file

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DOE HEALTH & MORTALITY STUDIES

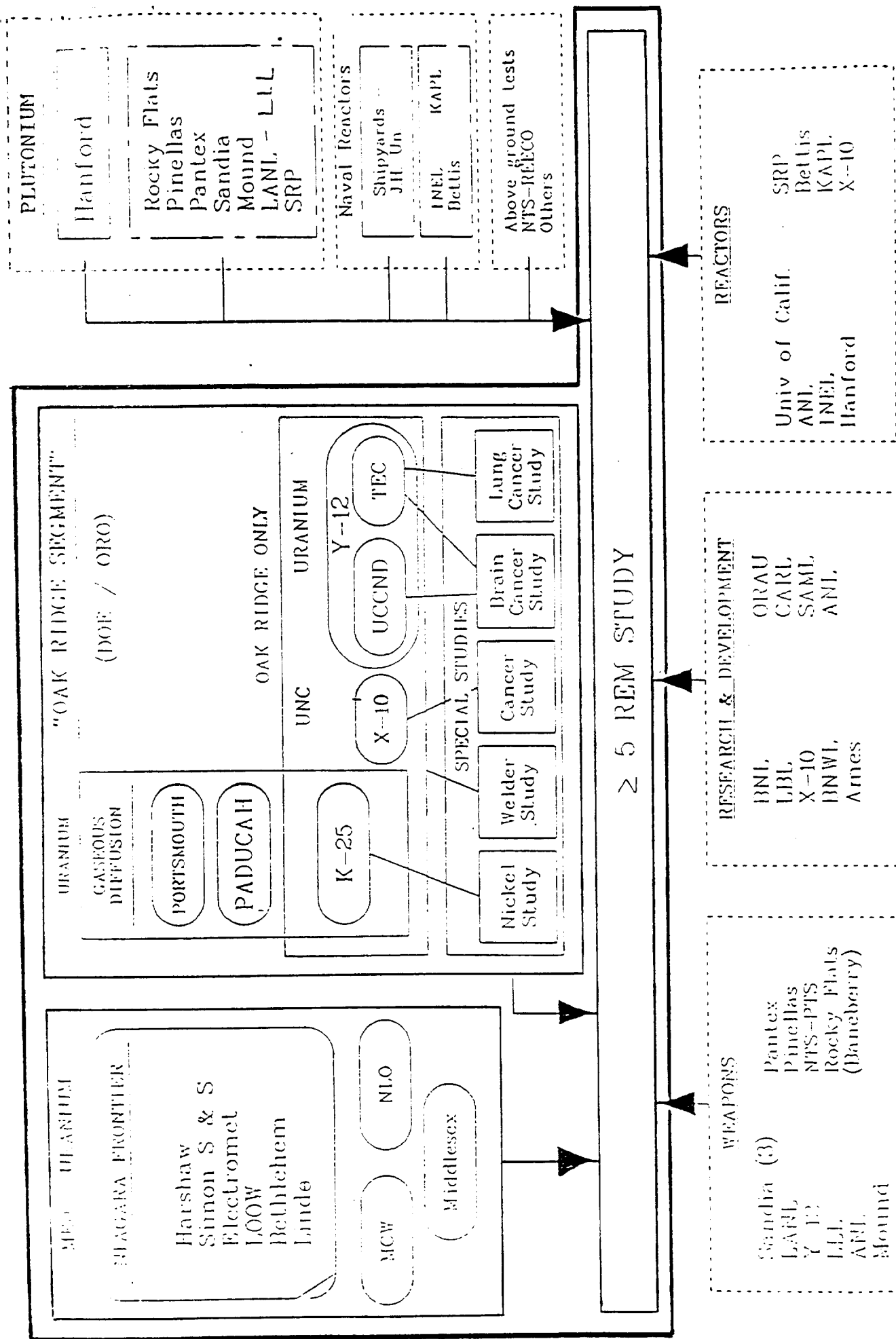
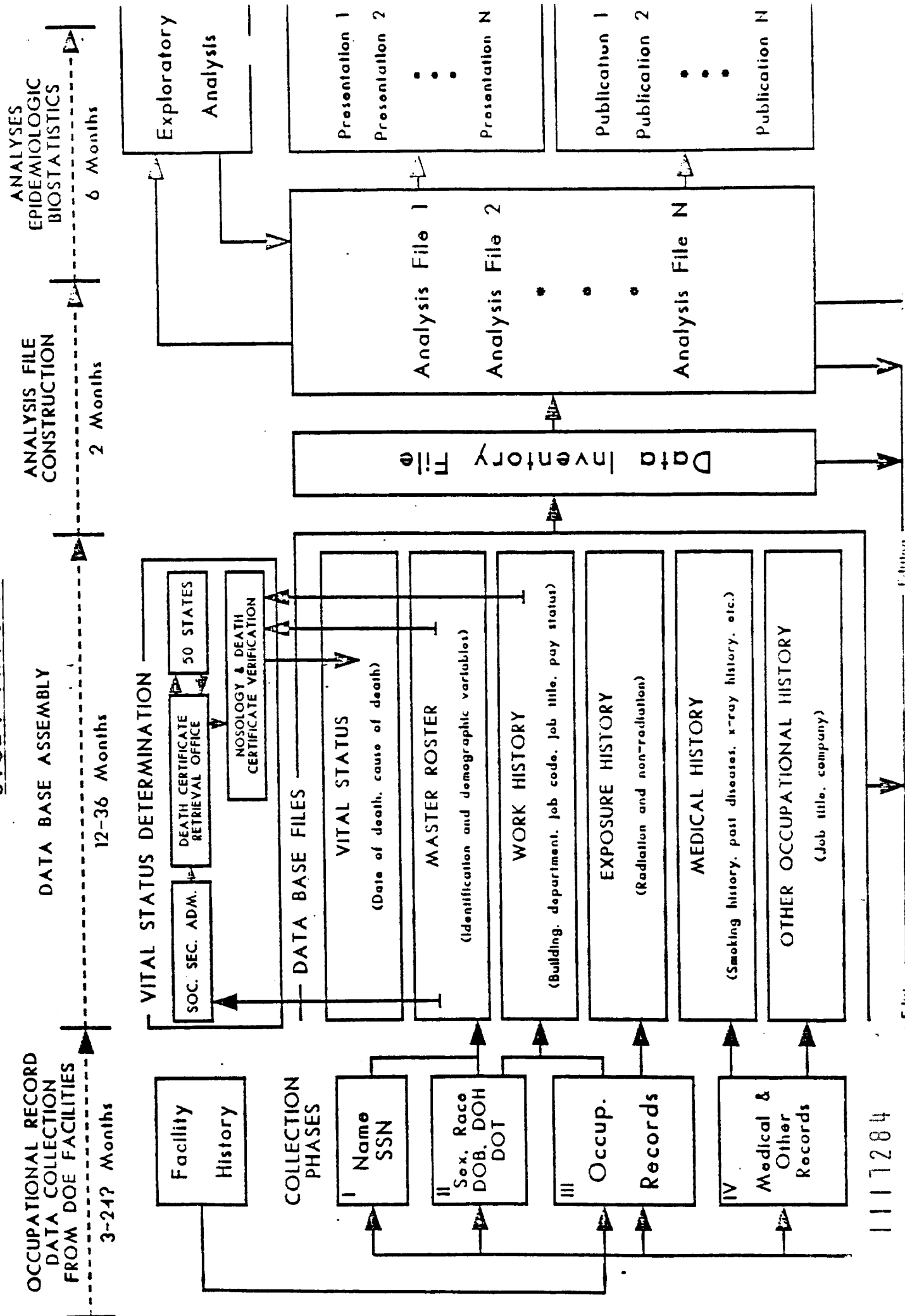


Figure 3

DEPARTMENT OF ENERGY HEALTH AND MORTALITY STUDIES

STUDY PROCESS



Summary of Research Progress FY 1982

A. Epidemiologic Studies

1. Y-12 Plant [Tennessee-Eastman Corporation (TEC), Oak Ridge]

Data collection and lung-dose calculations were completed for the lung cancer case-control study. A detailed evaluation of chemical exposures and their connection to work-history data was completed. An analysis file to include this information and to update mortality in the entire population through 1977 was created.

A case-control study of brain cancer deaths that occurred between 1948 and 1977 in the entire cohort was initiated. This study will investigate the effects of exposure to uranium dust and chemicals such as trichloroethylene, carbon tetrachloride and nitric acid.

The feasibility study for analysis of the large group of female workers (19,000) employed at Y-12 between 1943 and 1947 was completed. A preliminary proportional mortality ratio (PMR) analysis indicated an increase in respiratory diseases, particularly pneumonia, and a possible increase in lymphopoietic cancer, brain cancer, cancer in the uterus, cervix and skin. This PMR only contained deaths that occurred before the end of 1973. The data set has now been updated through 1977 and will be reexamined.

Even though the follow-up in the women is more difficult, and less complete than the follow-up in the men, methodologic research in this area indicated that case-control studies of the women will still yield valid results.

2. Y-12 Plant (UCC-ND, Oak Ridge)

A thorough exploratory analysis of the Y-12 preliminary file was performed in order to examine some of the effects of length of employment, age (i.e., pre- and post-retirement), and internal as well as external exposure. Since the

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"healthy worker effect" is always a concern, only employees who worked at least 6 months were included in the analysis in an attempt to remove any "transient worker" effects. The resulting cohort consisted of 6400 white males of whom 565 were identified as dead and 425 were of unknown vital status. Death certificates were retrieved and coded for underlying cause of death for 532 individuals.

Significant standardized mortality ratios (SMR) ($p < .05$) were observed for brain cancer individuals employed 5 to 10 years (SMR = 5.89, deaths = 6) and leukemia and aleukemia in individuals less than 40 years old (SMR = 10.37, deaths = 2). The SMR was close to significance for brain cancer in 40 to 65 year olds (SMR = 2.17, deaths = 8). A positive trend with age appears to occur in the SMR's for lung cancer and a negative trend appears for circulatory diseases. When looking at length of employment, the only consistent trends are negative for certain lymphatic tissue cancers and for respiratory diseases.

The major radiation hazard at the Y-12 plant is most likely internal exposure to the lungs. Comparing lung cancer SMR's between individuals monitored for internal exposure and those not monitored showed a possible positive trend (.89 vs 1.13) but no significant difference.

A Poisson rate analysis of the data resulted in an estimated relative risk for lung cancer in the monitored group of 1.34 with a 95% confidence interval of (.74, 2.46).

3. Oak Ridge National Laboratory (UCC-ND)

Two epidemiologic studies are being conducted on the X-10 cohort. The first is a retrospective cohort mortality study in which the mortality experience of X-10 workers will be contrasted with that in the general U. S. population for the years 1943-77. The second is a case-control study comparing the radiation

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and chemical exposure histories of cancer deaths and controls from the cohort.

A cohort of 8717 white males who worked for at least one month between 1/1/43 and 12/31/74 at X-10 has been identified for the first study. These are persons who did not work at any other DOE facility. Vital status follow-up on this cohort is being conducted. As of this writing, vital status has been determined for 88% of the cohort and death certificates have been obtained for roughly 95% of the known deaths. The data tapes containing external radiation dosimetry and work history information have been cleaned and prepared for analysis. The data tape containing internal radiation exposure information is still being cleaned.

Approximately 330 cancer cases and 660 controls have been selected from the cohort for the second study. The computer files containing work history, external radiation, and metal exposure data have been prepared.

4. Oak Ridge Gaseous Diffusion Plant (UCC-ND), K-25

The K-25 data inventory file was completed and contains records for approximately 43,900 individuals. Construction of the inventory file is a new step in our study process. This intermediate file contains one record per individual and provides information on the kinds of data available for each individual prior to analysis file construction. The file also furnished information on missing or incomplete data, and it is used as a tool for error detection and correction as well as for making informed decisions concerning the structure of future K-25 analysis files.

5. Oak Ridge Welders Study

Mortality and causes of death were studied for a cohort of 1302 white male welders employed at the nuclear facilities in Oak Ridge, TN between 1943 and 1977. Deaths reported as of mid-year 1979 were used in standardized mortality ratio

(SMR) analyses. For the entire cohort the SMR for all causes was 0.98 with a 95% confidence interval (c.i.) of (0.87, 1.11) and 1.26 ((5% c.i. = 0.80, 1.89) for lung cancer. The SMR for respiratory diseases (ICD 460-519) showed an increasing excess in mortality at 1.55 (95% c.i. = 0.97, 2.34) when compared to an earlier study where the SMR was 1.33 (95% c.i. = 0.71, 1.60). This excess appears to be due to emphysema with a significantly high SMR of 2.61 (95% c.i. = 1.25, 4.79). When looking at the subgroup of welders exposed to nickel oxides at the K-25 plant, no significant increases in mortality were seen due to any cause. The increase in respiratory diseases was seen in the non-K-25 welders, and when analyzed by facility, showed up in the welders who worked at the Tennessee Eastman Corporation (TEC) with an SMR of 2.56 (95% c.i. = 1.23, 4.72) based on ten observed deaths. In order to try to equalize follow-up time, welders hired before 1955 were analyzed by facility. This analysis showed very similar results to the full study with only TEC welders showing a significant excess mortality due to respiratory diseases.

6. Oak Ridge Facility Comparison Study (ORFCOM)

The Oak Ridge Facility Comparison Study (ORFCOM) file is envisioned as a bio-statistical resource for the DOE Health and Mortality Studies. ORFCOM will enable generation of death rates for the entire white male Oak Ridge worker population since 1943. These rates for the total white male Oak Ridge population are to provide a comparison standard for the K-25, X-10 and Y-12 studies. Use of this comparison group should eliminate the problems encountered in comparing groups of healthy workers with the overall U. S. or Tennessee populations which per force contain workers who terminated from all industries because of ill health. The health and mortality of Oak Ridge worker subpopulations of interest such as uranium-, phosgene- or nickel-exposed workers can be compared with that of

specific nonexposed segments of it. The internally generated rates of ORFCOM will also help to control for socioeconomic factors, diagnostic medical practices, and geographic disease differences that are difficult to evaluate when using U. S. or Tennessee vital statistics.

The ORFCOM study includes 72,814 white males who ever worked at any of the Oak Ridge plants (TEC, K-25, Y-12, X-10) through the end of 1977. An extensive analysis file was created that contains facility, date of first hire and last termination, vital status, date of birth, date of death, and cause of death (where appropriate). Four hundred sixty-five (465) individuals with erroneous and/or missing data were put into the error-correction system. A preliminary analysis was begun. Death certificates coded for the underlying cause of death were available for 88.5% of the 20,189 deaths identified by the Social Security Administration. Frequency distributions were generated for number of deaths by plant and cause of death in the overall population.

7. Mallinckrodt Chemical Works

Reentry of the employee film-badge data was completed. Efforts to increase the percentage of vital status determination were intensified. All white males whose vital status was unknown were sent to the Department of Motor Vehicles of Missouri and Illinois and were searched for on the Missouri death index. These efforts resolved the vital status for 32% of these status unknowns.

8. MED Sites

Rosters were developed and submitted to SSA for Linde, Harshaw, Lake Ontario Ordnance Works, Simonds Saw and Steel, and Electrometallurgical Laboratory. Film badge data, medical examinations, and serial blood and urinalyses were located for a number of the workers at these facilities. It was hoped that an exploratory analysis would be completed by mid-FY 82. However, we were unable to obtain death

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certificates from the state of New York for over 600 deaths in ~~Linde~~ ^{Durson} the largest population. ~~This problem has been corrected.~~

B. Data Management Systems

During FY 81, computer methodology and data management continued to be an important support function for all phases of the Health and Mortality Study. Expansion of both available hardware and in-house software resulted in greater usage of computer resources by nonprogrammers. Every aspect of the study now has computer applications. Six new CATHODE RAYTUBE (CRT) terminals, two new word-processing CRT's, and three new portable terminals give all personnel access to the computers. Also, the statistical multiplexor was upgraded from 16 to 32 ports, and an imager-printer was purchased as a fast, inexpensive hard-copy source. A color graphics system, including CRT, tape drive plotter, and imager, was purchased for use in the development of graphical representations of study results. The group was able to make use of the new mass storage unit at Computer Sciences Division (CSD) of Union Carbide Corporation to keep more data on-line and therefore more readily accessible.

The error detection and correction system was completely rewritten during FY 81. The entire system is now in place and has provided both a closed loop for error correction and a means of easy information retrieval by nonprogrammers. The procedure manual was rewritten to promote consistency and quality control.

New systems of files and software were developed for the ≥ 5 rem study, for hardcopy data inventory, for facility status reports, for alternate methods of vital status follow-up, and for data entry and verification using new screen-formatting software.

~~Niagara Frontier data were computerized from source documents. The K-25 data inventory file was completed and error correction was initiated for this~~

~~population.~~

C. Biostatistical Methods

Several computer programs for proportional hazards regression analysis were obtained and tested for use with fixed covariant occupational cohort data. Results were found to be consistent between programs and consistent with interpretations resulting from traditional epidemiologic analyses. Several published case-control data sets were also used for testing, and, again, the results obtained were uniform across programs.

The Poisson rate analysis program previously developed was further tested using time dependent data from the Y-12 preliminary study. Results were good and this analysis has now been incorporated into our routine methods. The GLIM software package was obtained and tested and will be incorporated into this rate analysis adding the capability of interactive model fitting.

D. Hazard Assessment

1. Radiation Hazards

A critical assessment of radiation data is required for a meaningful investigation of the relation of the risk of cancer morbidity or mortality to radiation dose. In order to determine the effect (or absence) of radiation exposure as a function of dose, the reliability of the dosimetry data must be known. The general objectives for assessing radiation dose data for workers at any site are: (1) to provide a well-defined body of data for use in the epidemiologic studies; (2) to provide dosimetry data that have been corrected for gross errors, checked for internal consistency, and assessed for overall veracity; and (3) to produce a permanent record (the Assessment Report) useful in documenting the dosimetric considerations employed in the performance of the project.

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Four major steps were identified for the dosimetry assessment procedure for a specific site: (1) feasibility study, (2) acquisition of data, (3) acquisition of supporting documentation, and (4) final assessment. The assessment procedure also defined the need for a general literature review and interviews with experts to document types of personnel monitoring devices used and their associated measurement errors.

Initial priority for dosimetry assessment was given to the "Oak Ridge Study" sites. The Oak Ridge National Laboratory assessment study is three-fourths complete for external radiation and approximately half complete for internal. The assessment of external monitoring shows that about 98% of the 509,108 data entries are usable and only about 2% require further investigation.

The Oak Ridge Y-12 plant was operated from 1943 to 1947 by the Tennessee Eastman Corporation (TEC). The primary function of the plant was to produce uranium enriched in the isotope U-235 for use in atomic weapons. The biological effects of and potential hazards from uranium exposures were not well understood in the mid-1940's, nor were there adequate monitoring methods for either external or internal radiation. The only monitoring information available is a limited amount of uranium air concentration data. Although these data are not specific to a given worker, a method has been developed for estimating crude lung doses from inhaled uranium.

The basic scheme is to determine the amount of inhaled uranium by connecting uranium air concentrations (air monitoring data) with individual workers via their department/job title. Using the rather good documentation on plant processes, the chemical forms and isotopic concentrations of the uranium can be determined. The biological transportability class can then be assigned. The fifty-year dose equivalent commitment to the lung is then calculated using the

dose equivalent per microcurie factors from the Nuclear Regulatory Commission's publication on internal dosimetry, NUREG/CR-0150. The individual's lung dose is then estimated by a "survival time" correction of the fifty-year value where survival time is defined as the interval between hire date and either death or the end of study follow-up, July 1, 1973.

2. Chemical Hazards

A valid study of health effects in nuclear industry workers must include an assessment of possible exposures to other toxic materials. In mid-1981 a chemical hazards assessment (CHA) section was established within the Hazards Assessment Group to direct concentrated effort toward recognition and evaluation of chemical exposures in study populations. A standard CHA procedure for records collection, data extraction, and assignment of hazard indices was developed and reviewed, and will be followed as closely as possible in each CHA study. At present the CHA study of the Y-12 (TEC) plant is completed through encoding, but requires verification and revisions. Information from this assessment is currently being used by members of other groups. The CHA studies of the Y-12 (UCC-ND) and X-10 (UCC-ND) plants have also been initiated and are both at the stage of records location and collection.

E. DOE ≥ 5 Rem Study Registry

The initial phase of data collection was completed in FY 81 for the present and former employees reported to have received ≥ 5 rems during at least one year of employment at 40 of the 76 surveyed sites of DOE, DOE contractors, or DOE's Naval Reactor Program. Inconsistencies, duplications, and omissions in the data were referred to the reporting sites for resolution; it was necessary for two facilities to revise and resubmit their entire rosters. The registry population now consists of 3146 individuals. Alternate methods have, thus far,

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been successful in determining the vital status of 418 of the 856 persons whose vital status was not determined by the Social Security Administration (SSA). These methods, that include follow-up by states' Motor Vehicle/ Drivers' License Departments, are being systematized by the Epidemiology Group, M&HSD, to facilitate the follow-up of larger numbers of "unknown" in the Health and Mortality Study populations. DCRO has obtained, verified, and coded (underlying cause of death, 8th Revision ICD) death certificates for 193 of the 338 individuals known to be dead. Data to aid in verification of an additional 88 certificates on-hand are being obtained from PSQ's stored locally or in Washington, DC. A very preliminary SMR analysis based on 55% death certificate ascertainment for 289 deaths among white males in the population, using the age adjusted mortality rates of the U.S. white male population for comparison, showed no excess mortality due to all causes ($SMR = 0.71$). SMR's ≥ 1.00 were obtained for mental disease (1.00), chronic nephritis (1.03) and cancers of the stomach ($1.05^{\sim}$), rectum (1.28), liver (1.49), larynx (1.55), and esophagus (1.54); none of the values was statistically significant. However, given the small number of cases in each of these categories and the incompleteness of the data at that time, no conclusions can or should be drawn from these results. The status of the study was presented in a poster session at the 1981 annual meeting of the Society for Epidemiologic Research. Work was begun to prepare a transitional file in which the data will be edited in preparation for the development of an analysis file.

In collaboration with the Epidemiology Groups at LANL and HERF, a basic, comprehensive, single-contact follow-up questionnaire has been developed that would serve the needs of the several on-going DOE Epidemiological studies at ORAU and Los Alamos, while avoiding multiple contacts of individuals who are

involved in more than one study.

The Hazards Evaluation Group developed a mail questionnaire program to gather data to document and assess radiation dosimetry methods used over time, the status of records systems and dosimetry data reported by the 40 sites reporting ≥ 5 rem exposures. The program is being tested currently at ten representative (by function) sites. Rosters of present and former employees at Brookhaven and Argonne and Sandia National Laboratories, and the National Accelerator Laboratory having been acquired as potential sources of internal comparison populations for cohort members exposed at those sites. Other ≥ 5 rem study facility employee rosters on hand are Oak Ridge (three facilities), NLO, Mound Laboratories, Comparative Animal Research Laboratory, Mallinckrodt Chemical Works, Bettis and Knolls Atomic Power Laboratories, and Lawrence Livermore Laboratory. Technically accessible rosters exist for employees at Hanford, Los Alamos National Laboratory, Savannah River Plant, and Rocky Flats and are in preparation (at Johns Hopkins University) for the shipyards with which DOE Naval Reactor Program facilities are associated. It is anticipated that these rosters will be available for selection of the comparison populations for the sites named.

Summary of Research Plan FY 1983

A. MED Sites

Death certificate retrieval will be completed to at least the 90% level for all sites. A preliminary "quick" mortality study will be initiated. Work will be done to resolve the vital status of those workers who are unknown to SSA. Work history files will be edited and the data base will be completed followed by analysis file construction.

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B. Oak Ridge Sites

1. Y-12 Plant [Tennessee Eastman Corporation (TEC), Oak Ridge]

The lung cancer case-control study will be completed during FY 82. Continued update of this cohort is planned with an ascertainment of new lung cancer deaths through 1979. This will add five years of follow-up to the TEC cohort and allow for a 30-year latency period in the cohort.

A second analysis of the mortality of the white male cohort using the new chemical exposure data and the 1979 SSA search mortality results will be completed. The phosgene study will also be updated in this manner. Surveillance will continue in the cohort of female workers and disease specific case-control studies will be planned. These studies will be based on the number of cases observed and whether there is a biologically plausible reason for a disease elevation (i.e., a reasonable hypothesis).

2. Y-12 Plant (UCC-ND, Oak Ridge)

An analysis of all white males employed for at least four months will be published. All individuals previously excluded because of erroneous data will be included and vital status follow-up through 1979 will be used. The SMR analysis will examine the mortality effect of length of employment, age, external radiation exposure level and internal exposure level (using a newly developed ordinal rank scale). Where appropriate, internal control groups will be used as the comparison population. Poisson rate analysis will be used to determine the relative risk due to both internal and external exposure levels. An upgraded study will be initiated in FY 83 incorporating the completed chemical hazards assessment.

3. Oak Ridge National Laboratory (UCC-ND)

When the follow-up of the X-10 white male cohort has been completed and the ambiguities in the work-history data have been resolved (department codes with no documentation), the mortality rate analyses will be carried out. Mortality rate comparisons will be made between the cohort and the general population and between subgroups of the cohort categorized according to radiation-dose levels and work-area assignments.

The case-control study of cancer deaths will also be completed during this time period. Other studies planned are: a retrospective cohort mortality study of all X-10 male employees, including those who worked at other DOE facilities, as part of an overall Oak Ridge study, and a mortality analysis of X-10 female workers.

4. Oak Ridge Gaseous Diffusion Plant (UCC-ND), K-25

The K-25 inventory file will be used to (1) generate hypotheses, (2) evaluate data available for study, and (3) determine data errors which are detectable by systematic editing checks. These errors will be sent to the archivist for correction and the corrections entered into all our files. The inventory file will be used to calculate disease rates over time in the K-25 population. These will be valuable when we later examine mortality in other gaseous diffusion plants such as Portsmouth and Paducah. A thorough exploratory analysis of mortality in K-25 workers from 1943 to 1979 will be conducted.

5. Oak Ridge Welders

The study done in FY 81 will be expanded to include (1) a comparison of the nickel welders at K-25 with the entire K-25 work force, and (2) a comparison of all welders with the entire Oak Ridge work force (from the ORFCOM file). The purpose of these comparisons is to fully examine the apparent increase in

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respiratory disease and to find out if it is specific to welders. These results will be published in FY 83.

6. Oak Ridge Facility Comparison Study (ORFCOM)

The ORFCOM file will be used to obtain smoothed estimates of the age-specific and cause-specific death rates for all white male Oak Ridge workers. These same estimates will be done for each plant separately. Age-birth year-cause specific death rates will be obtained from the file and used to compute expected death rates for the ≥ 5 rem study. The file will also be used to obtain an internal comparison of Oak Ridge workers by facility. Data errors identified during the ORFCOM analysis file construction will be corrected using source documents.

7. Mallinckrodt Chemical Works

The analysis file will be updated with the results of the 1982 SSA search, the results from DMV and the Missouri death index. The SMR analysis will be updated.

C. Data Management

During FY 82 and FY 83, development and implementation of a comprehensive security system for both DEC 10 and IBM disk files will continue. Increased efforts will be made to train all computer group personnel on all computer systems. The data-base file structures and associated software will be re-designed to accommodate the increasing volume of data required to maintain the study. In-house procedures for production of microfiche of state death indexes will be established. All UCC-ND population data (rosters, work history, exposure, etc.) will be updated through December 1980. An automated system to assist in death certificate verification will be completed. During FY 83, the

correction of errors detected during the building of the K-25 data inventory file will be completed and construction of an analysis file will begin. Computerization of systems for alternate methods of vital status follow-up will be expanded.

D. Biostatistical Methods

Testing of the appropriateness of the proportional hazards failure time model will continue. Cohort data with time dependent exposure variable from the Y-12 analysis and case-control data from the TEC lung cancer study will be used to see if results are consistent with other analytical methods. The ORFCOM file will be used to evaluate whether proportional hazards regression and/or Poisson rate analysis will prove appropriate for combining individuals from different facilities into one analysis. Other available methodology for combining results from individual studies will be reviewed and evaluated.

Graphics equipment has recently been acquired and a great deal of effort will be put toward developing its use as an analytical aide and alternative.

E. Hazard Assessment

1. Radiation Hazards

Assessment of dosimetry data for the ≥ 5 rem study will receive a high priority. A separate assessment plan is to be prepared for that study. Work on initial dose assessments projects identified the need for additional specificity for dosimetry assessment procedures. A Standard Assessment Procedure (SAP) is being developed by the ORAU/UNC Hazard Assessment Group. The SAP will be a recipe for ensuring that editing, characterization, validation and data set closure have been achieved. This procedure will be applied to dosimetry assessments for studies of individual sites as well as the ≥ 5 rem study.

2. Chemical Hazards

Records location and collection for the chemical hazard assessment (CHA) studies of the Y-12 (UCC-ND) and X-10 (UCC-ND) plants is in progress and should be completed in FY 82. Since data are extracted from the records continually as they are obtained, the CHA studies for these two facilities should be completed and available for use in analyses in FY 83. Preliminary work on CHA evaluations for the K-25 (UCC-ND) plant, Paducah, KY Gaseous Diffusion Plant, and Mallinckrodt Chemical Works will be initiated. This will include establishment of necessary communications with personnel at local plants and determination of existence and availability of records.

F. DOE ≥ 5 Rem Study Registry

Vital status of the study, ≥ 5 rem study population has been determined in the past two years in a series of submissions to the Social Security Administration as participants were identified and reported by surveyed facilities. Therefore, it is intended to resubmit the complete cohort to the SSA in Spring FY 83 in order to update vital status, to ensure uniformity of search for the cohort and to provide a consistent cut-off date for follow-up. Work will continue to ascertain, verify and code death certificates to assure maximum ascertainment. Work also will continue to resolve the vital status of "unknowns" using alternative sources of data that include searches of rosters of states' Motor Vehicles/Drivers' License Departments and of active and retired federal employees by the Office of Personnel management. Resolution of the status of terminated shipyard workers may be achieved in collaboration with investigators at the School of Public Health and Hygiene, Johns Hopkins University.

Data will be edited and validated in the transitional file; an analysis file will be developed by mid-82. Mortality in the cohort due to all and specific

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causes will be compared with the age adjusted mortality rates in the U. S. population. The feasibility will be investigated of using the mortality rates of more comparable populations such as workers in a nonradiation industry. A case-control study of the deaths in ≥ 5 rem study populations will be conducted when the necessary sources (i.e., complete remployee rosters) of data for selection of controls are available. Work will continue concurrently on the development of the morbidity phase of the study in which cancer, diseases of the respiratory and cardiovascular systems are outcomes of interest.

The comprehensive questionnaire will be finalized and submitted to OMB for approval. Pending that approval, work will begin on the selection of an internal comparison population of workers on a by-site basis beginning with a group of these sites for whom complete employee rosters are available at ORAU [i.e., Oak Ridge (three facilities), NLO, Mound, Hanford].

In an attempt to control for possible exposure to industrial hazards other than radiation (e.g., chemicals, asbestos, etc.), site-specific comparison groups will be matched initially by the department in which the cohort member was working at the time of his/her first ≥ 5 rem exposure. The technique of over-sampling will be used to provide a pool of potential controls from which to select a comparison group whose cumulative dose of that site is ≤ 1 rem; this method will reduce the number of individuals for whom detailed exposure data will be needed. The comparison group matched by site and by department will be further matched by sex, year of birth, age at hire, and length of employment equal to that of the cohort member or at least one calendar year. The X-10 ≥ 5 rem population will be used in a pilot study to test the feasibility of this method of selection of a comparison population. Previously described methods will be used to obtain morbidity data for a sample population comprised of samples

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of cohort and the comparison population members at the sites identified above.

Summary of Death Certificate Retrieval Office (DCRO)

Two submissions were made to SSA for vital status determination. These results totalled 107,711 persons and identified 3,992 deaths. The results of the second search (September 1981) were recently received and deaths identified in this search are not included in the 3,992 above.

Additional state death indexes were acquired from Connecticut, Massachusetts, Missouri, New Jersey, New Mexico, Virginia, Wisconsin and Wyoming. Our efforts to obtain additional indexes and to update the indexes on hand continue.

The problem of establishing an individual's vital status when it is unknown to SSA was addressed. Several alternative methods have been established and proven quite useful. They include: drivers' license registrations, newspaper obituaries, and the Railroad Retirement Board. An agreement has been made with Civil Service to utilize the Office of Personnel Management's Central Personnel Data File.

Efforts to reduce the inter-coder variation between the ORAU nosologist and the retired NCHS chief nosologist were so successful that the ORAU nosologist now has the sole responsibility for this job. All certificates are coded to the Eighth Revision of the ICD cause-of-death code. Certificates for deaths occurring on or after January 1, 1979 are additionally coded to the Ninth Revision by the new junior nosologist.

Summary statistics and population-specific status reports were added to the automated portion of the system. The production of these reports is handled by the computer group.

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Death Certificates on File in ORAU Data Bank FY 82

26,800 - Codes and computerized (in file NDEATH)

* - In nosology

* - In process of being verified, abstracted, entered on NDEATH

** 2,400 - Problems with verification

10,300 - 6,500 Hanford sibs and controls	{	No plans
2,000 OR sibs and controls		to
1,800 Rocky Flats, Mound, Los Alamos		computerize

7,300 - Hanford employees - plan to computerize

46,800 - Death certificates on hand

*New procedures since beginning use of in-house nosologist have eliminated the large numbers in these phases of the process. These numbers fluctuate but are less than 100 at any given time.

**Includes 986 Savannah River certificates which cannot be verified due to lack of demographic data for this population.

Death Certificate Collection Record

10,645 - Found by ORAU on or before February 5, 1981

4,823 - Found by ORAU from February 6, 1981 - February 5, 1982

31,355 - Found by the University of Pittsburgh team

46,823 - Death certificates on hand February 5, 1982

Death Certificates Under Current Search

3,253 - Declared dead - no DC - on DCROST

1,472 - Declared dead January 1981 submission - will be loaded to DCROST
for search March 1982

4,725 - Total declared dead

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AVAILABILITY OF STATE DEATH TAPES (OR MICROFICHE) TO HMS/DCRO

Obtained		Promised or	
State	Years	Possible	Denied
Alabama	1908-1980	Oklahoma	Arkansas
Arizona	1940-1977	South Dakota	Colorado
California	1960-1977	Utah	Idaho
Connecticut	1959-1977	Vermont	Illinois
Delaware	1939-1979		Indiana
Florida	1940-1978		Minnesota
Georgia	1919-1979		Nebraska
Kansas	1971-1979		New Hampshire
Kentucky	1963-1978		New York
Louisiana	1975-1978		Oregon
Maine	1960-1980		Pennsylvania
Massachusetts	1969-1978		South Carolina
Michigan	1969-1979		West Virginia
Mississippi	1958-1978		
Missouri	1943-1980		
Montana	1954-1977		
Nevada	1964-1978		
New Jersey	1957-1979		
New Mexico	1940-1980		
North Carolina	1975-1979		
North Dakota	1972-1977		
Ohio	1956-1977		
Tennessee	1949-1979		
Texas	1964-1980		
Virginia	1945-1980		
Wisconsin	1940-1958		
Wyoming	1940-1979		

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Persons needing follow-up to determine status of "UNKNOWNNS"

268 - Impossible SSN's

16,737 - Nonmatch on (SSN, SNAME) pair

32,072 - Status unknown

49,077 - Total needing follow-up by alternate means

Planned Progress in FY 83

The DCRO will continue to expand its efforts to establish worker vital status when it is unknown to SSA. The Civil Service Personnel Records system will be used regularly as an alternate source of vital status ascertainment pending the results from the first search. The National Death Index will also be used as a source of vital status ascertainment other than SSA. Other sources of vital status ascertainment that have proven to be helpful will continue in use. These sources include: state death indexes, newspaper obituaries, and State Departments of Motor Vehicles.

Computer programs will be completed to aid in the verification of death certificates so that the majority of this process may be carried out by the clerical staff. Certificates that are questionable or difficult to verify will be handled by the senior nosologist in conjunction with the archivist.

The established activities of the DCRO will continue. Communication with DCRO users will continue in an effort to make its services more responsive to their needs. Efforts will be made to acquire additional state death indexes and those already on hand will be updated. As needed, computer software will be revised and expanded to fit new and changing needs.



Oak Ridge
Associated
Universities

Memorandum

To File From Dr. Shirley Fry
Date June 7, 1985 Copies to W. Burr, D. Cragle, P. Kannan,
C.C. Lushbaugh, TEC file, ERF,
File
Subject PHONE CALL FROM DR. DOROTHY LEGARRETA

I was unavailable when Dr. Dorothy Legarreta (415-654-0100) called yesterday, two attempts to return her call were unsuccessful. She called again today. Dr. Legarreta said she was employed at the Crocker Lab in California during the MED era. She is now in Berkeley, California, where she works or consults for the Radiation Survivors Group; she is also an adjunct professor at the University of Nevada. She wanted a copy of the masters paper concerning the case control study of lymphatic cancer among TEC women. I referred this request to Craig Johnson at Rosewell Park Memorial Hospital. She also wanted to know how she could get a copy of the data set on the TEC women for a study of reproductive outcomes for which she already has funding! I told her these were DOE data and that she should make her inquiry to me in writing - she will.

SAF:fb

from Lyn Leenes
3903 hold 2/19
see this
over lunch

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PERSONNEL -1

FOIA

National Arch. 2919