ROCKETDYNE WORKER HEALTH STUDY

FINAL REPORT

EXECUTIVE SUMMARY & APPENDICES

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July 13, 2005

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13 July 2005

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*Because of copyright restrictions, four manuscripts submitted for publication cannot be posted on the website during the review processes. It is anticipated that they will be made available sometime in the foreseeable future.

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ROCKETDYNE WORKER HEALTH STUDY

INTERNATIONAL EPIDEMIOLOGY INSTITUTE

IEI EXECUTIVE SUMMARY

July 13, 2005

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STATEMENT OF WORK

The overall objectives outlined in the Statement of Work (12/14/00) were as follows:

> "A retrospective cohort mortality study will focus on individuals employed in either nuclear technology development or in rocket engine testing since 1950 at the following Boeing (Rocketdyne) facilities: Santa Susana Field Laboratory (SSFL) in the Simi Hills area of Ventura County, California, Canoga Park and De Soto Avenue. The study will determine whether mortality rates of cancer and other diseases are elevated among these workers, and whether mortality varies as a function of length of employment, place of employment (and or job title) or work with specific chemicals or radiation. Nested case-control studies shall be conducted for any type of cancer that appears to show an excess risk in the cohort (e.g. lung, leukemia or lymphoma)."

> "The published reports on Rocketdyne workers (UCLA studies) have recognized deficiencies, many acknowledged by the authors, and this extended study will incorporate a more comprehensive and rigorous approach. The observation period shall be extended, more appropriate comparison populations shall be sought, approaches to determining vital status shall be expanded, pre- and post-Rocketdyne radiation exposures shall be ascertained, internal radiation doses shall be determined in a comprehensive manner, and complete and detailed chemical exposure information shall be sought. Further, the seller will provide an experienced and highly credible research team committed to making this project their highest priority during the next five years."

The objectives in the Statement of Work (12/14/00) were addressed during the four years of study. Results are summarized in this Executive Summary, in nine booklets prepared for the seven meetings of the Scientific Committee, and in four manuscripts prepared for publication. The Executive Summary begins with an Overall Summary and then continues with brief summaries of specific study activities and issues including Institutional Reviews, Population Identification, Population Tracing, External and Internal Radiation Dosimetry, Chemical Exposure Assessment, Study Findings, Auxiliary Analyses, Comparisons with the Previous UCLA Study, and Final Comments. The PowerPoint presentation for the worker meetings 6-8 April 2005 is included at the end of the Executive Summary.

OVERALL SUMMARY. A retrospective cohort mortality study was conducted of 46,970 Rocketdyne workers employed for at least 6 months in either nuclear technology development or in rocket engine testing since 1948 at the Santa Susana Field Laboratory (SSFL) and at nearby facilities, including Canoga Park and De Soto Avenue in California. The Rocketdyne workers were grouped into three populations: those monitored for radiation (Radiation Cohort), those who worked at SSFL (Chemical Cohort) and those who worked at all other facilities (Comparison Cohort). The Radiation Cohort consisted of 5,801 workers monitored for radiation of whom 2,232 were also monitored for internal radionuclide uptake. The Chemical Cohort consisted of 8,372 workers at SSFL of whom 1,651 were test stand mechanics assumed to have the greatest potential for exposure to chemicals such as hydrazines and trichloroethylene (TCE). The Comparison Cohort consisted of 32,979 workers employed at the other Rocketdyne facilities. There were 182 workers who during their career at Rocketdyne had been monitored for radiation and also had worked as test stand mechanics. These workers, 30 of whom were found to have died, are included in both the Radiation and the Chemical Cohorts.

Methods. The Rocketdyne population was identified from Kardex work history cards, electronic personnel files and radiation dosimetry records. Other personnel records evaluated included worker transfer lists, medical record index cards, medical records, and personnel lists (phone directories). Workers were classified by work location, job title, pay type (hourly or salary), and whether they were monitored for radiation or held an administrative/scientific position. Lifetime occupational radiation doses were derived from company records of external and internal exposures and record linkages with national dosimetry datasets. Bioassay data were evaluated using current International Commission of Radiation Protection (ICRP) biokinetic models to estimate annual radiation doses for 16 organs or tissues. The estimation of internal radiation doses accounted for the type of radionuclides taken into the body and their likely chemical forms, time of exposure, and excretion patterns. The mortality experience of all workers through 1999 was determined by examination of national, state and company records. Observed numbers of deaths were compared with the number expected in the general population of California adjusting for age, gender, race and calendar year. Internal cohort dose-response analyses using Cox proportional hazards models were conducted to evaluate trends over categories of cumulative radiation dose and over years of potential exposure to chemicals. For the Radiation Cohort the comparison group for the internal cohort dose-response analyses was in most cases Rocketdyne workers who were not monitored for radiation. For the Chemical Cohort the comparison group for the internal cohort dose-response analyses was in most cases Rocketdyne workers who did not work at SSFL and who were not monitored for radiation. However, various other referent groups were used in the analyses and any differences were noted.

Overall Results. Overall, the 46,970 Rocketdyne workers (including both radiation and chemical cohorts together) accrued 1.3 million person-years of observation (average 27.6 years). Vital status was determined for 99.2% of the workers: 11,118 (23.7%) had died and only 368 (0.8%) were lost to follow-up. Cause of death was determined for all but 280 (2.5%) of those who had died. The overall mortality experience among all Rocketdyne workers was lower than that of the general population of California, i.e., the ratio of observed to expected numbers of deaths (the Standardized Mortality Ratio, or SMR) was less than 1.0 (SMR 0.87; 95% CI 0.85-0.88). Low overall mortality was seen among radiation workers (SMR 0.79; 95% CI 0.75-0.83; n=1,468 deaths), SSFL workers (SMR 0.83; 95% CI 0.80-0.86; n=2,251 deaths) and among the other

Rocketdyne workers (SMR 0.90; 95% CI 0.88-0.92; n=7,429). The observed numbers of cancer deaths also were slightly below population expectation for all workers (SMR 0.93; 95% CI 0.89-0.96; n=3,189 deaths), radiation workers (SMR 0.90; 95% CI 0.82-0.99; n=456 deaths), SSFL workers (SMR 0.89; 95% CI 0.82-0.96; n=655) and the other Rocketdyne workers (SMR 0.94; 95% CI 0.90-0.98). The ratios of observed to expected deaths (SMRs) computed using United States rates were lower than those computed using California rates, whereas county rates (combined Los Angeles and Ventura Counties) were similar to those computed using California rates. No cause of death was significantly elevated. There were no notable increases in cancer deaths over time since first hire, or by duration of employment at SSFL or at the other Rocketdyne facilities.

Overall Radiation Results. Among the 5,801 radiation workers, the mean dose from external radiation was 13.6 mSv (maximum 1,000 mSv); the mean lung dose from external and internal radiation combined was 19.1 mSv (maximum 3,600 mSv). Only 69 workers had career doses from external radiation greater than 200 mSv, and only 111 workers had lung doses greater than 200 mSv when internal doses were considered. Deaths from all cancers taken together (SMR 0.90; 95% CI 0.82-0.99 , n = 456), all leukemia excluding chronic lymphocytic leukemia (CLL) (SMR 1.16; 95% CI 0.69-1.84; n = 18), and lung cancer (SMR = 0.89; 95% CI 0.76-1.05; n = 151) were not significantly elevated. Internal cohort dose-response analyses revealed no significant trends over categories of increasing radiation dose for all cancers taken together, leukemia, lung cancer or any other cancer. There were no significant associations found among the 2,232 workers who were monitored for internal radionuclide intakes. For all cancers excluding leukemia, the RR at 100 mSv was estimated as 1.04 (95% CI 0.86 - 1.26) and for all leukemia excluding CLL it was 1.32 (95% CI 0.71 - 2.45).

Overall Chemical Results. Overall, 1,651 test stand mechanics were identified and assumed to have the greatest potential exposure to chemicals associated with the testing of rocket engines. Compared with the general population of California, test stand mechanics had a lower risk of dying overall (SMR 0.90; 95% CI 0.82-0.98) and a similar risk of dying from cancer (SMR 1.03; 95% CI 0.88-1.20). The mortality experience of the other male hourly workers at SSFL was similar to that of the test stand mechanics for all causes (SMR 0.97; 95% CI 0.91-1.03), all cancers (SMR 0.93; 95% CI 0.82-1.06), and all specific cancers. No cancer of *a priori* interest among test stand mechanics was significantly increased: lung (SMR 1.07; 95% CI 0.8-1.4), esophagus (SMR 1.03; 95% CI 0.3-2.4), kidney (SMR 1.78; 95% CI 0.8-3.5), bladder (SMR 0.98; 95% CI 0.3-2.5), liver (SMR 0.97; 95% CI 0.3-2.5), and non-Hodgkin's lymphoma (SMR 0.80; 95% CI 0.3-1.9). Among the 315 male test stand mechanics with likely exposure to hydrazines, there were no significant increases for any cancer and, based on internal cohort analyses, no evidence of a dose response over years of potential exposure for all causes of death (SMR 0.89, n=101), all cancers taken together (SMR 1.09, n= 33), lung cancer mortality (SMR 1.45, n=15), or any specific cancer. Among the 1,114 workers potentially exposed to TCE, there were no significant increases for all causes of death (SMR 0.87; 95% CI 0.78-0.96), all cancers taken together (SMR 1.00; 95% CI 0.83-1.19) or any specific cancer. Based on internal cohort analyses, there was no significant dose response over years of potential exposure to TCE for all cancers combined, lung cancer or any other cancer. Cancer of the kidney was elevated based on 7 deaths (SMR 2.22; 95% CI 0.89-4.57) and there was a suggestion of a dose response over years of potential TCE exposure, although the trend was not significant. For the three malignancies most frequently found to be elevated in studies of TCE exposure (i.e., cancers of the kidney and liver and non-Hodgkins lymphoma), the combined SMR based on 12 deaths was not significantly increased (SMR 1.09; 95% CI 0.56, 1.90).

Questionnaire Survey. A questionnaire survey of 139 workers indicated that hourly workers (n=66) were significantly more likely than salaried workers (n=71) to have smoked cigarettes (61% vs 41%; p=0.02). The smoking prevalences of hourly workers who responded to this survey were also greater than smoking prevalences in the general population of California, and indicate the need for caution when interpreting comparisons with the general population for these subgroups because of the likely differences in tobacco use. All test stand mechanics were hourly workers. National surveys also indicate that blue collar workers smoke cigarettes to a greater extent than both white collar workers and people in the general population (Lee et al. 2004; Howard 2004; CDC 2004a, 2004b).

Overall Conclusions. The Rocketdyne workforce overall, including those monitored for radiation, those employed at SSFL and test stand mechanics potentially exposed to hydrazines or TCE, did not experience a statistically significant increased mortality for any cancer, including lung cancer, that could be linked to radiation dose, years of employment at SSFL, years of employment as a test stand mechanic, or years of potential exposure to hydrazines or TCE. No statistically significant internal cohort dose-response relationship was seen for leukemia, lymphoma, or cancers of the esophagus, liver, bladder, kidney or any other cancer over categories of radiation dose or years of potential chemical exposure. We conclude that radiation exposure has not caused a detectable increase in cancer deaths in this population and that work at the SSFL rocket engine test facility or as a test stand mechanic is not associated with a statistically significant increase in cancer mortality overall or for any specific cancer. A slight non-significant increase in leukemia (excluding CLL) was seen among radiation workers, although a similar non-significant increase in CLL (a malignancy not associated with radiation) was also observed. A slight non-significant increase in kidney cancer and a slight non-significant decrease in bladder cancer was also seen among radiation workers. Additional follow-up would be needed to clarify the inconsistent finding with regard to radiation and kidney cancer (a cancer not generally found increased in radiation exposed populations) as well as the non-significant association observed for kidney cancer and potential TCE exposure. Additional follow-up might also clarify the non-significant elevated risk of lung cancer among workers potentially exposed to hydrazines when compared with the general population.

SPECIFIC STUDY APPROACHES AND ISSUES

The following sections provide summary details of study approaches, methods and issues, including those raised by the Science Committee during the conduct of the study.

1. Institutional Review Board (IRB) and other Approvals. To conduct a study involving human subjects it was necessary to receive approval from a number of IRBs and other Human Subjects Review committees. Applications were prepared and approvals were received from the Boeing Company, Vanderbilt University, Oak Ridge National Laboratory, National Center for Health Statistics (National Death Index), Social Security Administration, Health Care Financing Administration (now Centers for Medicare & Medicaid Services), University of Southern

California (Cancer Surveillance Program), Nuclear Regulatory Commission, Department of Energy, and U.S. Air Force.

2. Identification of the Worker Population. Sources to identify workers and obtain exposure information included Kardex job history cards, an electronic personnel file, Radiation Safety folders, personnel listings (phone directories), medical index cards, medical records, and transfer lists. Excluded from study were those who had worked less than 6 months (6,601) and those who were not Rocketdyne employees or who had insufficient identifying information for tracing (813). A cohort of 46,970 eligible workers was developed (Figure 1). There were 5,801 workers monitored for radiation, 8,372 workers at SSFL (including 1,651 test stand mechanics of whom 182 were also monitored for radiation) and 32,979 workers at other Rocketdyne facilities.

3. Population Tracing. Vital status was determined for 99.2% of the worker population. Mortality information was received from the Social Security Administration, California Surveillance Program, Health Care Financing Administration (CMS), Compserv Inc., PBI, Rocketdyne records, state vital statistics departments, and the National Death Index. Individuals were confirmed alive (35,458, 76%) from Rocketdyne personnel and retirement records, the Social Security Administration and the Health Care Financing Administration (CMS) databases. There were 11,144 (23.9%) study subjects who were found to have died. Only 368 workers were lost to follow-up, i.e., 0.8% of all workers (Figure 1).

4. Cause of Death Determination. Cause of death was sought for all 11,118 workers who were found to have died in the United States and all but 265 (2.4%) were obtained. Sources of cause of death information included death certificates available from the Rocketdyne personnel files, the California Death Tape, the California Surveillance Program, the National Death Index and death certificates obtained from individual state departments of vital statistics.

5. Radiation Dosimetry (Figure 2, Figure 3, Figure 4). Organ-specific doses from lifetime occupational exposure to external radiation and radionuclide intakes were estimated for the 5,801 Rocketdyne/Atomics International workers monitored for radiation and employed for more than 6 months between 1948-1999. Radiation-related activities included the operation of ten nuclear reactors and seven criticality test facilities, nuclear fuel fabrication, reactor disassembly, spent nuclear fuel decladding, laboratory work and storage of nuclear material. The radiation workforce was identified from the over 14,000 radiation record folders in the Radiation Safety (Health Physics) offices. Information in the radiation folders was scanned into machine-readable images and sent to a central location for abstraction and dose assessment. To obtain prior and subsequent occupational exposure information, the roster of all workers, including those not known to be radiation workers, was matched against nationwide dosimetry files after permissions were received from the Department of Energy, the Nuclear Regulatory Commission, the Landauer Dosimetry Company, the U.S. Army, and the U.S. Air Force. Requests were also made to investigators of other worker studies to match their dosimetry files against our roster of Rocketdyne workers. Computation of organ doses from radionuclide intakes was complicated by the diversity of bioassay data collected over a 40 year period (urine and fecal samples, lung counts, whole-body counts, nasal smears, and wound and incident reports) and the variety of radionuclides with documented intake including isotopes of uranium, plutonium, americium, calcium, cesium, cerium, zirconium, thorium, polonium, promethium, iodine, zinc, strontium,

and hydrogen (tritium). Over 30,000 individual bioassay measurements, recorded on 11 different bioassay forms, were abstracted. The bioassay data were evaluated using current ICRP biokinetic models to estimate annual doses for 16 organs or tissues taking into account time of exposure, type of radionuclide, and excretion patterns. A modification of the ICRP respiratory model for relatively insoluble material was applied to uranium aluminide, and proposed ICRP models were used for promethium and cerium. Detailed internal exposure scenarios were developed and annual internal doses were derived on a case-by-case basis for workers with committed equivalent doses indicated by screening criteria to be greater than 10 mSv to the organ with the highest internal dose.

The mean cumulative external dose based only on exposures received while employed by Rocketdyne was 10.0 mSv and the dose distribution was highly skewed (maximum 500 mSv) (Figure 2). Only 45 workers received greater than 200 mSv while employed at Rocketdyne. However, 1,833 (or 32%) of the Rocketdyne radiation workers had been monitored for radiation at other nuclear facilities and incorporation of these doses increased the mean dose to 13.6 mSv (maximum 1,005 mSv) and the number of workers with >200 mSv to 69 (Figure 4). For a small number of workers (n=292), lung doses from internal radionuclide intakes were relatively high (mean 106 mSv; maximum 3,560 mSv), and increased the overall population mean dose to lung from 13.6 mSv to 19.1 mSv and the number of workers with lung dose >200 mSv to 111. Nearly 10% of the radiation workers (587) were monitored for neutron exposures (mean 1.2 mSv) at Rocketdyne and another 2% were monitored for neutron exposures elsewhere. These cumulative neutron dose levels were small in comparison with other external and internal radiation doses. Without considering all sources of occupational exposure, however, an incorrect characterization of worker exposure would have occurred with the potential to bias results. For 604 (10%) of the Rocketdyne workers, the doses received at other facilities both prior to and after employment at Rocketdyne were greater than the doses received at Rocketdyne. Similarly, a small number of workers monitored for internal radionuclides contributed disproportionately to the number of workers with high lung doses. A manuscript describing the dosimetry approach has been submitted for publication. Another manuscript describing the unique aspects of internal exposure to uranium aluminide has also been submitted for publication.

6. Chemical Exposure Assessment (Figure 5). The potential for chemical exposures at SSFL from 1948 until 1999 was estimated from job history records and work at specific test stands. The workforce, particularly the test stand mechanics, were potentially exposed to a wide range of rocket fuels, oxidizers, exhaust gases, solvents and other chemicals. This potential exposure to a mixture of substances at rocket engine test areas was evaluated in terms of years of employment at a test stand. Several patterns of potential exposure to specific chemicals were identified based on the quantity used and the number of workers exposed. These patterns included hydrazines used as a fuel in some rocket engines, trichloroethylene (TCE) used to clean (“flush”) engines and TCE as a utility solvent to clean small metal parts. Since these patterns of exposure existed only at certain test stands during certain rocket engine tests, individual test stand mechanics had to be placed at specific test stands during specific calendar years to estimate their potential for exposure. Because the work history information available on Kardex cards was not specific enough to do this, historical personnel listings (phone books) were relied upon to make this placement. Confirmation of these assignments was based on information gleaned from walkthrough surveys at operating and closed test stands with knowledgeable personnel who

were involved with specific engine tests over the years, discussions with over 100 long-term employees (both retired and active), and existing medical records which often listed the specific test stands and specific chemicals that the employees worked with.

Overall, 1,651 test stand mechanics were identified within the SSFL workforce of 8,372 (Figure 5). There were 315 test stand mechanics with likely exposure to hydrazines and 205 with possible exposure to hydrazines. The terms "likely" and "possible but unlikely" were used to distinguish two levels of potential exposures to hydrazines: "likely" meant we were able to assign an individual to a test area where hydrazines were used throughout the year whereas "possible but unlikely" meant that hydrazines were used only in one of several areas within a large test area and we were unable to distinguish which test stand mechanics worked in those areas where hydrazines were used from those who worked in areas where hydrazines were not used. We estimate that less than about 10% of the 205 workers classified as "possible but unlikely" actually worked with hydrazine and had potential for exposure. There were 1,114 workers with potential exposure to TCE. There were 182 test stand mechanics who also had been monitored for radiation. The approach to chemical exposure assessment is included in the draft manuscript on the mortality experience of Rocketdyne workers who tested rocket engines.

7. Study Findings.

The entire workforce of 46,970 workers had a lower risk of death from all causes compared to the general population of California (SMR 0.87; 95% CI 0.85-0.88) (Figure 6).

a. Radiation Cohort (Figures 3, 4, 6-8). Overall, 5,801 workers were monitored for radiation, including 2,232 monitored for radionuclide intakes (Figure 3). The mean dose from external radiation was 13.6 mSv (maximum 1,000 mSv); the mean lung dose from external and internal radiation combined was 19.1 mSv (maximum 3,600 mSv). Only 69 workers had career doses from external radiation greater than 200 mSv and only 111 workers had lung doses greater than 200 mSv when external uptakes were considered. Vital status was known for 97.6% of the workers of whom 25.3% (n = 1,473) had died. The average period of observation was 27.6 years. Radiation workers had a lower risk of death form all causes (SMR 0.79) than the general population of California (Figure 7). All cancers taken together (SMR 0.90, n = 456) and all leukemia excluding chronic lymphocytic leukemia (CLL) (SMR 1.16, n = 18) were not significantly elevated. The most frequent cancer deaths were of the lung (SMR = 0.89, n = 151), colon (SMR = 1.17, n = 47) and prostate (SMR = 0.93, n = 37). Internal cohort dose-response analyses revealed no significant trends for all cancers taken together (Figure 8), leukemia (Figure 9), lung cancer or any other cancer over categories of increasing radiation dose. Slight positive dose-response trends were seen for kidney cancer and slight negative trends were seen for bladder cancer and for cirrhosis of the liver based on the internal dose-response analyses. For all cancers excluding leukemia, the RR at 100 mSv was estimated as 1.04 (95% CI 0.86 - 1.26) and for all leukemia excluding CLL it was 1.32 (95% CI 0.71 - 2.45). There were no significant modifications in the estimates of radiation risk over categories of attained age, age at exposure, or time since exposure.

b. Chemical Cohort (Figures 5, 10-20). The Chemical Cohort consisted of 8,372 workers at SSFL of whom 1,651 were test stand mechanics with the greatest potential for chemical exposures, including 182 test stand mechanics who also were monitored for radiation (Figure 5). The all cause mortality among SSFL workers (SMR 0.83; 95% CI 0.80-0.86; n=2,251 deaths) and among the other Rocketdyne workers (SMR 0.90; 95% CI 0.88-0.92; n=7,429) were lower than the general population (Figure 10, Figure 11). The all cancer mortality SMRs were similar among SSFL workers (SMR 0.89; 95% CI 0.82-0.96) and the other Rocketdyne workers (SMR 0.94; 95% CI 0.90-0.98). No cause of death was significantly elevated. There were no notable increases over time since first hire or duration of employment at SSFL. Test stand mechanics had a lower risk of dying overall (SMR 0.88; 95% CI 0.81-0.95) and a similar risk of dying from cancer (SMR 1.00; 95% CI 0.86-1.16) compared with the general population (Figure 12). No cancer was significantly increased (Figure 13, Figure 14). The SMRs for cancers of *a priori* interest among test stand mechanics were: lung (SMR 1.07; 95% CI 0.8-1.4), esophagus (SMR 1.03; 95% CI 0.3-2.4), kidney (SMR 1.78; 95% CI 0.8-3.5), bladder (SMR 1.14; 95% CI 0.4-2.7), liver (SMR 0.89; 95% CI 0.2-2.3), and non-Hodgkin's lymphoma (SMR 0.89; 95% CI 0.3-1.9). There were no significant increases for any cancer among the 474 male test stand mechanics who worked more than 5 years on a test stand. Among the 315 male test stand mechanics with likely exposure to hydrazines, there were no significant increases for any cancer and no evidence of a dose response over years of potential exposure for all causes of death (SMR 0.89, n=101), all cancers taken together (SMR 1.09, n= 33), lung cancer mortality (SMR 1.45, n=15) or any specific cancer (Figures 15-17). For those who worked less than or more than 1.5 years with likely hydrazine exposure, the RRs of lung cancer were 0.74 and 0.70, respectively (Figure 18). It is noted that the RR of lung cancer for test stand mechanics not exposed to hydrazines was lower than for those with potential hydrazines exposure, although the difference is not statistically significant. Among the 1,114 workers potentially exposed to TCE, there were no significant increases for any cause of death (overall SMR 0.87; 95% CI 0.78-0.96) or for all cancers taken together (SMR 1.00; 95% CI 0.83-1.19) (Figure 19). There was no significant dose response over years of potential exposure to TCE for all cancers taken together, lung cancer or any other cancer (Figure 20, Figure 21). Cancer of the kidney was elevated based on 7 deaths (SMR 2.22; 95% CI 0.89-4.57), although the increase was not statistically significant. Non-Hodgkins lymphoma and cancers of the kidney and liver, combined, were not elevated based on 12 deaths (SMR 1.09; 95% CI 0.56-1.90), and there was no evidence of a dose-response (Figure 22). These three cancers are those most frequently found to be elevated in studies of TCE-exposed populations.

8. Other Analyses and Evaluation.

Additional analyses and evaluations were conducted and are summarized below.

a. White Males. Analyses limited only to white males were conducted for all Rocketdyne workers, the radiation workers and the chemical (SSFL) workers. The observed to expected ratios for all 43 causes of death evaluated did not differ from those computed for the entire population, including women and non-white races. White males constitute the majority (nearly 75%) of all Rocketdyne workers.

b. External Comparison Populations. Although internal cohort dose-response analyses based on radiation dose or based on years worked with potential exposure to chemicals was the primary focus of the evaluation of health risks among Rocketdyne employees, external comparisons with the general population were also made to evaluate patterns of risk over time and by duration of employment. There were three general populations that could be used for comparison purposes: the population of California (which we used), the population of the United States (which was used by the previous investigators from UCLA) and the population of persons residing in Los Angeles and Ventura Counties. Many Rocketdyne workers had been born in states other than California and moved to Los Angeles or Ventura County for employment. Many Rocketdyne workers also left California for employment elsewhere (e.g., Washington State, Missouri, Idaho) or for retirement (e.g., Florida). Approximately 25% of deaths occurred outside of California, 50% in Los Angeles or Ventura Counties and 25% in other California counties. It is not known where the majority of workers are currently residing or whether or when they left California. The observed to expected ratios of deaths (i.e., the SMRs), were similar when comparisons were made with the general populations of California or with Los Angeles and Ventura Counties. The SMRs were consistently lower when comparisons were made with the general population of the United States. None of the external populations is ideal and there are unknown factors such as differences between workers and the general population in health, occupational exposures and confounding factors (e.g., tobacco use) that cannot be accounted for in the analyses. However, patterns of risk over time and by duration of employment can be informative with regard to revealing the presence of any occupational risks. The most comparable general population to the Rocketdyne Workforce probably lies midway between the California and United States populations. However, internal comparisons, described below, are more appropriate when making inferences about workplace exposures and effects.

c. Internal Comparison Populations. Internal cohort dose-response analyses did not rely upon an external population but rather compared various groups of Rocketdyne workers over categories of radiation dose or over categories of years worked with potential exposure to chemicals. All analyses included adjustments for gender, race, age, pay type (hourly or salary), and most analyses included an adjustment for duration of employment. These internal cohort analyses are preferred for causal inferences. There were no internal cohort analyses for which the test for trend in increasing risks over the categories of exposure were statistically significant, i.e., no trend p-value was <0.05. For most internal cohort dose-response analyses, all Rocketdyne workers not monitored for radiation were used as the referent category, but other groups were used as well. For example, dose-response analyses for the Radiation Cohort used monitored workers with no measured dose as the referent; none of these analyses produced a significant trend, although slightly lower relative risks at the highest dose categories were seen. Similarly for the Chemical Cohort, the different referent groups evaluated included all Rocketdyne workers not monitored for radiation, and all SSFL workers not monitored for radiation. For test stand mechanics potentially exposed to hydrazines (or TCE), test stand workers with no known potential exposure to the chemical being evaluated were also used as referent. None of these analyses produced a significant trend. Using either the Rocketdyne or SSFL groups as referent produced essentially the same relative risks at the highest dose categories of years worked with potential exposure to the chemical/s of interest. Using as referent the relatively small number of test stand mechanics with no years of exposure to the chemical/s of interest produced no statistically significant trends and all the confidence limits about the relative risk estimates became wider. The lung cancer risk among the 205 workers with “possibly but unlikely” exposure to hydrazine was greater than the lung cancer risk among the 315 workers with “likely” exposure potential.

d. Healthy Worker Effect. The healthy worker effect usually refers to a type of bias that results from using a general population for comparison with an occupational group. The general population differs from a working population in ways that are likely to affect the risk of dying. The bias is related to selection processes that are in force when a worker enters the workforce and to the health characteristics that enable a worker to continue on the job for many years. Workers in general are healthier than the general population and as such are less likely to die at a young age. These selection factors, however, usually diminish over time, especially for deaths due to cancer. Analyses were conducted excluding the first 10 years of follow-up after a worker was hired and, while the SMRs rose in general, none was statistically significant and no different patterns of risk were seen. Similarly, internal cohort dose-response analyses were conducted excluding the first 10 years of follow-up and no significant trends were seen over categories of exposure for any cancer or groups of cancers. To learn whether short-term workers had different patterns of risk over time than workers of longer duration, SMR analyses were conducted. There were no material differences in the patterns of risk over time whether a worker had been employed at Rocketdyne for less than 5 years or whether he had been employed for more than 10 years.

e. Radiation Dose Lagging. There is a certain period of time before damaged cells can develop and be diagnosed as a leukemia or as a cancer. This minimum latency period is usually taken as 2 years for leukemia and 10 years for solid cancer, i.e., cancers occurring shortly after radiation exposure are not likely related to the radiation exposure but to other causes. Analyses were conducted lagging the dose for two years for leukemia and 10 years for solid cancers, i.e., any exposures occurring in these time periods before the diagnosis of cancer or end of follow-up are excluded. Because most of the high doses occurred in the 1950s and 1960s, lagging doses in the analyses had little effect on the computations of risk over categories of radiation organ dose or on the significance of the trend tests.

f. Workers Monitored for Radiation Only at Rocketdyne. To evaluate whether radiation received while employed at Rocketdyne resulted in any adverse health effects, analyses were restricted to the 3,968 workers who were monitored for radiation only at Rocketdyne and at no other place of employment. There were no significant elevations in cancer risk or significant dose-response relations found. The previous investigation did not exclude workers who where monitored for radiation elsewhere but did exclude the doses received elsewhere. Not including the relatively large contribution to radiation dose received by the 1,776 (31%) workers who were monitored for radiation other than at Rocketdyne could be misleading, as 604 (10%) had received greater doses elsewhere than at Rocketdyne (Figure 4).

g. Smoking Evaluation. To learn more about the smoking habits of hourly and salaried workers, a brief questionnaire survey was conducted in 2004. A sample of living workers was selected and approximately half of those mailed a questionnaire responded (68 hourly and 71 salaried workers). Compared to salaried workers, hourly workers were significantly more likely to have smoked cigarettes (61% vs 41%), to be current smokers (9% vs 0%), to have started smoking at a younger age, to have quit at an older age, to smoke for more years (31.4 yr vs 21.1 yr) and to have smoked more cigarettes during their lifetime as measured in terms of “pack-years”. The number of cigarettes smoked each day and the use of other tobacco products, such as cigars, did not differ significantly between the two groups. The value of the survey is limited because only survivors are included and the response rate was only 50%. Distinctions between SSFL workers and the workers at other facilities by pay type were not informative because of the small numbers, e.g., there were only 29 salaried workers overall who had smoked cigarettes. Nonetheless, these distributions are consistent with information obtained from a sample of over 120 medical records of test stand workers; smoking information was available for over 60 who had completed questionnaires in the 1960s which included queries on cigarette smoking habits, i.e., just over 60% of the hourly workers were current or former smokers. National surveys of smoking habits among hourly (blue collar) and salaried (white collar) workers also indicate a significantly higher prevalence of tobacco use among hourly workers compared to salaried workers and hourly workers compared to the general population. These evaluations indicate that caution should be exercised when interpreting comparisons in cancer risk between hourly workers and salaried workers and between hourly workers and the general population because of the differences in smoking habits. This is seen in the SMR analyses in that hourly workers in general had higher rates of death from lung cancer and other smoking related causes of death such as heart disease and non-malignant respiratory diseases such as emphysema. It has been suggested that smoking prevention programs should be considered for blue collar workers (Howard 2004). While patterns of risk in the observed and expected ratios can be informative, the internal cohort dose-response analyses comparing hourly workers to hourly workers and salaried workers to salaried workers over categories of exposure are the most informative with regard to investigating causal associations.

h. Hourly and Salary Workers. The risk of death is usually found to be different between hourly and salaried workers in occupational studies. As such, all internal dose-response analyses included an adjustment for pay type, except for those analyses where only specific pay types were evaluated. Comparisons with the general population were made for hourly workers and SMRs were generally higher than 1.0 for smoking-related causes of death in comparison with the general population of California, whereas there were few elevations when comparisons were made with the general population of the United States. Salaried workers on the other hand generally had low SMRs for most causes of death. As indicated above in (g), these differences may be related to differences in the use of tobacco products, although there may be other reasons. Because the general population differs in many ways from a worker population, use of internal comparisons is the more appropriate way to evaluate the exposures of interest. There was no evidence in these analyses that the risk of death from all cancers taken together or for any specific cancer among hourly workers (or salaried workers) increased with increasing numbers of years worked at SSFL, or with increasing level of radiation dose, or with increasing numbers of years with potential exposure to hydrazines, TCE or work as a rocket engine test stand mechanic.

i. Radiation Dose Response by Pay Type. Several analyses were conducted with regard to possible radiation associations and pay type classification. One internal cohort dose-response analysis evaluated the effect of not controlling for pay type and another evaluated the dose-response over hourly and salaried workers separately. Similar to the overall analyses, not adjusting for pay type did not change the pattern of cancer risk over categories of radiation dose and there were no discernible differences in the internal cohort dose-response analyses that were restricted to either hourly or salaried workers.

j. Chemical Cohort Tables Excluding Radiation Workers. To be consistent with the previous investigation conducted by UCLA, analyses for the chemical cohort were conducted excluding the workers who were monitored for radiation. No material difference was seen, in large part because the number excluded, only 182, was small.

k. Time and Duration Analyses for SSFL and the Other Rocketdyne Workers. SMR analyses using California rates as referent were conducted for three durations of employment (<5 years, 5-9 years and > 10 years) by three intervals of follow-up after first hire (< 10 years, 10-29 years, and > 30 years) for selected causes of death. For the SSFL hourly male workers, there were no noticeable patterns. For the other Rocketdyne hourly male workers, there also were no apparent patterns although lung cancer and non-respiratory lung disease were significantly elevated in several subgroups and heart disease was generally elevated. When U.S. rates were used for comparison, there were no significant elevations for any cause of death within any subgroup. As discussed previously, caution in interpreting the SMR analyses is warranted when hourly workers, who apparently smoke more than the general population, are evaluated. The more valid comparisons are the internal cohort evaluations. Internal cohort dose-response analyses based on years worked at SSFL or years worked at the other Rocketdyne facilities did not indicate any increasing trends over categories of years worked.

l. Figures. Graphical representations of many of the internal cohort dose-response analyses for radiation and chemical exposure are presented in addition to the tabular data found throughout the study documents. These figures provide a visual representation of the number of cases involved in the analyses as well as variations in the estimates of relative risk. Several of these figures have been added to this Executive Summary as were the figures presented at the 6-8 April 2005 worker meetings.

m. Test Stand Workers. Although test stand mechanics were assumed to have the greatest potential for exposure to chemicals during the testing of rocket engines, there were other workers at test stands who had some, but much lower, potential for exposure. These included inspectors, engineers, and instrument mechanics. Analyses were conducted to see whether elevated cancer rates were apparent among all test stand workers and among test stand workers excluding the test stand mechanics. There were no discernible differences and no significant findings. While all test stand mechanics were hourly workers, many of the other test stand "workers" were salaried workers. Further, it seems likely that the chemical exposures received outdoors at a test stand were lower than for indoor circumstances because of the dilution and dispersion that occurs in the open air.

n. Special Groupings of Cancer Sites. For the radiation analyses, groupings of cancer sites were made to be similar to the previous UCLA investigation, i.e., aerodigestive sites and all leukemia and lymphomas combined. These groupings, however, are not typical based on etiologic considerations, i.e., the causes of leukemia differ from the causes of lymphoma. The National Cancer Institute SEER (Surveillance Epidemiology and End Results) cancer registries also do not use such categories. A recent exchange of letters on the issue of lumping leukemias and lymphomas together appeared in the January 2005 issue of the American Journal of Epidemiology (Poole et al. 2005; Lee et al. 2005). Regardless, there were no associations with radiation dose based on internal cohort dose-response analyses for any of these groupings.

o. Asbestos. There was no evidence of significant/heavy excessive exposure to asbestos for any of the worker cohorts. Observed numbers of mesothelioma deaths and deaths due to cancer of the pleura and peritoneum did not differ from the expected numbers of deaths in these categories.

p. Beryllium. There was no evidence of excessive exposure to beryllium for any of the worker cohorts. Only one death certificate had mention of berylliosis.

q. Trend Tests. Trend tests for all internal cohort radiation dose-response analyses were conducted by entering the individual cumulative radiation dose as a continuous measure into a Cox proportional hazards model along with the exact same set of covariates used in the corresponding categorical dose analysis. This continuous measure of dose was the actual radiation dose value received by each individual worker. From the Cox model, a single estimate of risk was calculated for this continuous measure and the p-value from a Wald chi-square test was presented in the tables as the 'p for linear trend.' Thus, the individual dose values and not group values are used to calculate the trend test. Trend tests were conducted in similar manner described above for the internal cohort dose-response analyses with years worked taken as the continuous variable of exposure. However, there was one exception. For the tables with hydrazines exposure broken down by "potential" and "possible but unlikely", ordinal values were used for the independent variable. The ordering was based on a logical ranking of the potential for hydrazine exposure among workers in each category. Linear trend tests are used in most of the evaluations and point and interval estimates are also presented for each category in each interval dose-response table. Use of a linear trend test in radiation studies is standard procedure, especially in studies of low dose exposures.

9. <u>Comparisons with UCLA Study.</u>

a. Radiation Cohort. Our radiation cohort differs in several ways from the earlier UCLA study (Ritz et al. 1999b, 2000; Morgenstern and Ritz, 2001). We included all workers (men and women) who were hired up to 1999 and followed through December 31, 1999; the previous cohort accrual stopped December 31, 1993 and follow-up was through December 31, 1994. The current study included workers employed for at least six months at Rocketdyne whereas the previous investigation included anyone monitored for radiation, including short-term workers. We excluded workers not employed at Rocketdyne, i.e., contract workers and visitors. For 617 workers with only a radiation folder and not a Kardex or electronic job history, we were able to include 332 workers who had both a Rocketdyne serial number and sufficient identifying information for tracing. Additional data sources that we used to confirm and obtain employment histories included over 50,000 medical index cards, detailed dosimetry files, worker transfer lists and employment personnel listings (telephone directories). The previous investigation excluded workers without a personnel work history or identifying information. These differences resulted in our radiation cohort being larger by 1,194 (25.9%) workers than the previous study, i.e., 5,801 workers compared to 4,607 workers (Morgenstern and Ritz 2001).

Our study expanded and extended the previous UCLA investigation by five years and did not find significant associations with radiation dose for lung cancer hemato- and lymphopoietic cancers or aerodigestive cancers (Morgenstern and Ritz 2001; Ritz et al. 1999b, 2000). The previous investigators recognized the small size of the population studied and the low occupational doses received and concluded that their findings would have to be confirmed by other studies and/or further follow-up of the Rocketdyne workforce (Morgenstern and Ritz 2001; ATSDR 1999). The differences in findings between the two studies are likely related to the additional years of follow-up, coupled with differences in study design and the approach to dose assessment. The number of workers monitored for internal radiation (2,232 vs. 2,297) was similar but the number of externally monitored workers (5,743 vs 4,563) was appreciably larger in our investigation. The expanded numbers and longer follow-up (161,605 person-years vs about 119,100 person-years) resulted in an additional 593 deaths from all causes (a 67.8% increase) and an additional 198 deaths from all cancers (a 76.7% increase). Another difference was that the previous investigation was not able to include the occupational doses accumulated by 1,776 (31%) of the workers at places of employment other than at Rocketdyne. The dose received elsewhere by 604 (10.4%) workers was greater than the dose received at Rocketdyne. Further, we were able to compute radiation doses from the intake of radionuclides for specific organs and did not use lung dose as a surrogate for dose to all organs. Finally, different analytical methods were used in that the previous analyses used logistic regression whereas we used Cox proportional hazards methods (Callas et al. 1999).

b. Chemical Cohort. Our SSFL cohort also differs in several ways from the one previously reported (Ritz et al. 1999a; Morgenstern and Ritz, 2001). We included all workers (men and women) who were hired up to 1999, whereas the previous cohort included only men and accrual stopped in 1980. We included test stand workers who worked on the Peacekeeper missile system from 1979 to about 1999 and who had potential exposure to hydrazines as well as other chemicals. We included 182 test stand workers who were also monitored for radiation whereas they were excluded in the previous investigation. We identified additional workers for study from transfer lists, personnel listings (phone books) and medical record index cards, and then sought their Kardex work histories. The current study included workers employed for at least six months at SSFL whereas the previous investigation required that a worker spend at least two years at any Rocketdyne/Rockwell division with apparently no minimum time restriction for work at SSFL. These differences resulted in our cohort of SSFL workers being 37.1% larger than the previous cohort, i.e., 8,372 workers compared with 6,107. In addition, the previous study did not estimate potential exposure to TCE and assumed all test stand mechanics were potentially exposed to hydrazines. We were able to make more refined estimates of exposure potential to both TCE and hydrazines. We determined that the percentage of test stand mechanics with potential exposure to hydrazines was between 19-33%, depending on how we classified the workers with regard to likely or “possible not unlikely” exposure potential. Over 65% of the test stand mechanics were unlikely to have been exposed to hydrazines to any appreciable degree.

Our study, expanded with a larger population and 5-year increase in follow-up, did not find a significant association between lung cancer and exposure to hydrazines as previously reported (Morgenstern and Ritz 2001; Ritz et al. 1999a). The previous investigators recognized the small size of the hydrazine-exposed population studied and concluded that their findings would have to be confirmed by other studies and/or further follow-up of the Rocketdyne workforce (Morgenstern and Ritz 2001; ATSDR 1999). Our larger numbers of workers and longer follow-up (248,849 person-years vs about 171,100 person-years) resulted in an additional

830 deaths from all causes (a 59.6% increase), an additional 243 cancer deaths (a 60.1% increase), and an additional 66 deaths from lung cancer (a 45.2 % increase) among SSFL workers. We found little evidence that work as a test stand mechanic during the 1960s was related to an increased risk of lung cancer. Finally, we did not limit our investigation only to workers at SSFL, but included the 32,979 workers employed at nearby Rocketdyne facilities as an additional comparison or referent group, enhancing the statistical power of the internal dose-response analyses.

The previous investigation also reported an association between hydrazines and all lymphatic and hematopoietic malignancies taken together (including CLL) based on 41 deaths which was not seen in our extended follow-up with 67 deaths. Such an aggregated category, as discussed above in (n), is not generally examined because the component malignancies, i.e., Hodgkin's disease, non-Hodgkin's lymphoma, multiple myeloma, and myelogenous leukemia, have such different etiologies (Poole et al. 2005; Lee et al. 2005).

10. <u>Final Comments.</u>

Every epidemiologic study has strengths and weaknesses and the Rocketdyne Health Study is not an exception. The limitations of the study include the relatively low exposures to radiation and chemicals which limits the ability to detect increased risks. The number of cancer deaths can determine whether a study has the ability to detect a statistically significant increase. Studies involving small numbers are not as powerful as studies with large numbers. Small numbers result in estimates of risk that are very imprecise which means that chance often cannot be ruled out as an explanation for the findings. This does not mean that there was no increase in risk, just that the ability of the study to detect the risk was limited. Mortality and not incidence or illness was evaluated. Chemical exposure could be evaluated only as "potential" since few measurements were made in the early years. Lifestyle factors such as diet and tobacco use were also not known.

On the other hand the study has several strengths. Multiple data sources were used to identify the worker population of whom 99.2% were located. Radiation exposure assessment was comprehensive and included obtaining doses before and after Rocketdyne tenure. The assessment of organ doses from internal intakes of radionuclides used state-of-the-art methodologies. Chemical exposure assessment was facilitated by knowledge of test stand assignment and chemical use which enabled a more accurate assessment of hydrazines and TCE. Auxiliary analyses were conducted to augment and support the main analyses, including comparisons with other workers at Canoga Park and other local Rocketdyne facilities.

The radiation dose distribution for workers is relatively low and much lower than in other studies where effects are clearly evident. The numbers exposed to "high" doses of radiation are small, as are the numbers of workers "potentially" exposed to hazardous test stand chemicals. The exposure assessment problem for the chemicals is recognized, which necessitates having to use "years worked" as a surrogate for actual exposure. Further, chemical exposures at a test stand occurred outdoors where concentrations were likely diluted. Attempts to improve the exposure assessment to radiation or to chemicals are unlikely to yield an appreciable improvement. Additional investigation of potential confounding influences, such as tobacco use, would likely be unproductive because of the absence of any significant increases over categories of radiation dose to lung or over categories of years worked as a test stand mechanic. Further, obtaining accurate and valid smoking information would be difficult for those who have died, where surrogate responses from spouses or children many years after the fact would have to be obtained. Finally, the number of cancers for some sites of potential interest, such as kidney, are small and generally less than 10 and not amenable for meaningful case-control evaluation. Thus, the small numbers of workers in the study, the relatively low exposures to radiation and test stand chemicals, and the absence of any significant or consistent excesses argues at this time against the need for a nested case-control investigation.

The Rocketdyne workers are an aging population with the median age in 1999 being just over 60 years overall and nearly 70 years for test stand mechanics. Through 1999, 23.7% (11,118) of the Rocketdyne workforce had died. Based on age and current mortality patterns, an additional 5,000 workers would be expected to die by the end of 2005, including approximately 700 radiation workers and 1,000 SSFL workers. An additional mortality follow-up through 2005 would result in a much more powerful evaluation of the potential risk from work in nuclear technology development and work at rocket engine test facilities. Any inconsistencies in the current data could be resolved with further follow-up and suggestive patterns could be clarified, such as the non-significant increase in leukemia among radiation workers, the non-significant increase in lung cancer among hydrazine-exposed workers, and the non-significant increase in kidney cancer among TCE-exposed workers. Because there were no significant increases seen in the cohort internal dose-response evaluations, however, there seems little justification to consider nested case-control studies at this time.

11. <u>Manuscripts.</u>

Dosimetry Paper

Boice JD Jr, Leggett RW, Dupree BE, Wallace P, Mumma M, Cohen SS, Brill AB, Chadda B, Boecker B, Yoder RC, Eckerman KF. A comprehensive dose reconstruction methodology for former radiation workers. <u>Health Phys</u> (Submitted)

Uranium Aluminide Paper

Leggett RW, Eckerman KF, Boice JD Jr. A respiratory model for uranium aluminide based on occupational data. <u>J Radiol Prot</u> (Submitted)

Radiation Epidemiology Paper

Boice JD Jr, Cohen SS, Mumma MT, Dupree Ellis E, Eckerman KF, Leggett RW, Boecker BB, Brill AB, Henderson B. Mortality among Rocketdyne/Atomics International workers monitored for radiation 1948-1999. (In Draft)

SSFL / Chemical Epidemiology Paper

Boice JD Jr, Marano D, Cohen SS, Mumma MT, Blot WJ, Brill AB, McLaughlin JK, Henderson B. Mortality among Rocketdyne workers who tested rocket engines, 1948-1999. (In Draft)

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13. Summary Charts and Figures

Figure 1. Vital Status of Rocketdyne Workers
Figure 2. External Radiation Dose Distribution
Figure 3. Radiation Cohort
Figure 4. Comparing Radiation Dose Received Only at Rocketdyne with Total Dose Received at All Facilities

Figure 5. SSFL (Chemical) Cohort
Figure 6. Entire Rocketdyne Workforce Compared to General Population of California
Figure 7. Radiation Workers Compared to General Population of California
Figure 8. Radiation Dose Response for All Cancer Excluding Leukemia
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Figure 10. SSFL Workers (Chemical Cohort) Compared to the General22 Population of California
Figure 11. Dose Response for All Cancers Combined by Years Worked at SSFL
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Figure 13. Dose Response for All Cancers Combined by Years Worked as a Test Stand Mechanic
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Figure 20. Dose Response for All Cancers Combined for Test Stand Mechanics with Potential Exposure to Trichloroethylene (TCE)
Figure 21. Dose Response for Lung Cancer for Test Stand Mechanics with Potential Exposure to TCE
Figure 22. Dose Response for TCE Suspected Cancers* for Test Stand Mechanics with Potential Exposure to TCE

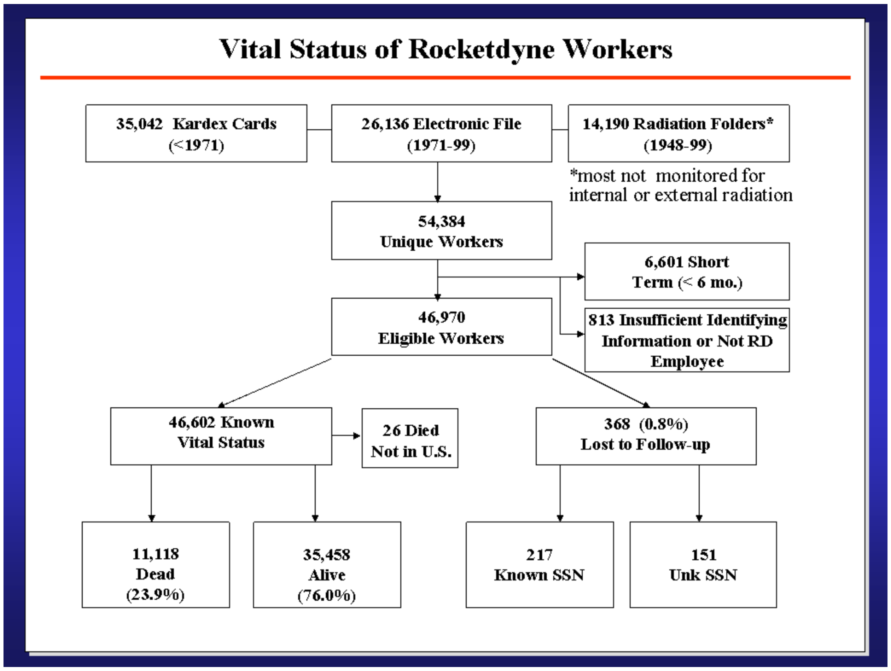


Figure 1

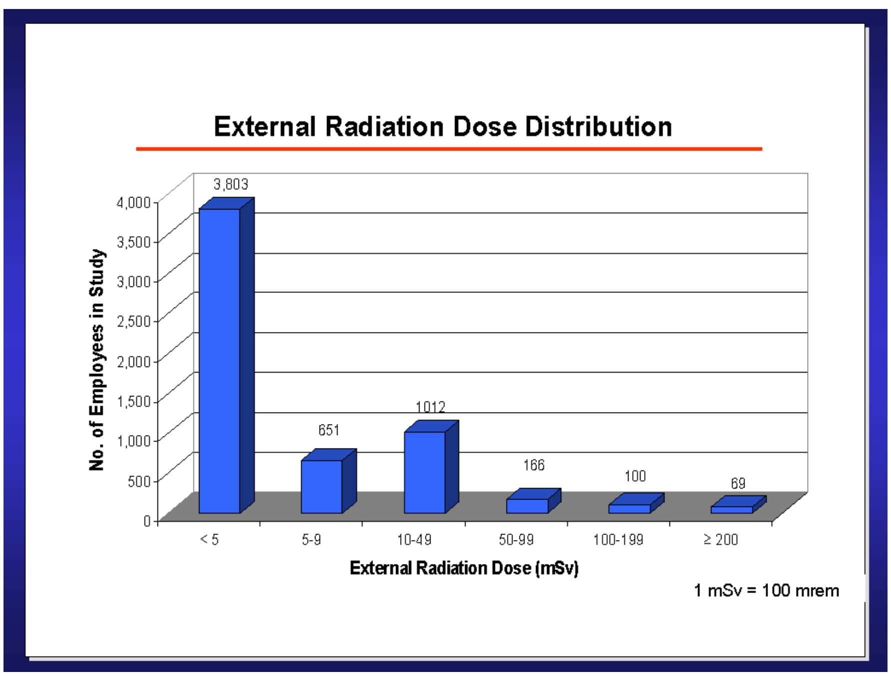
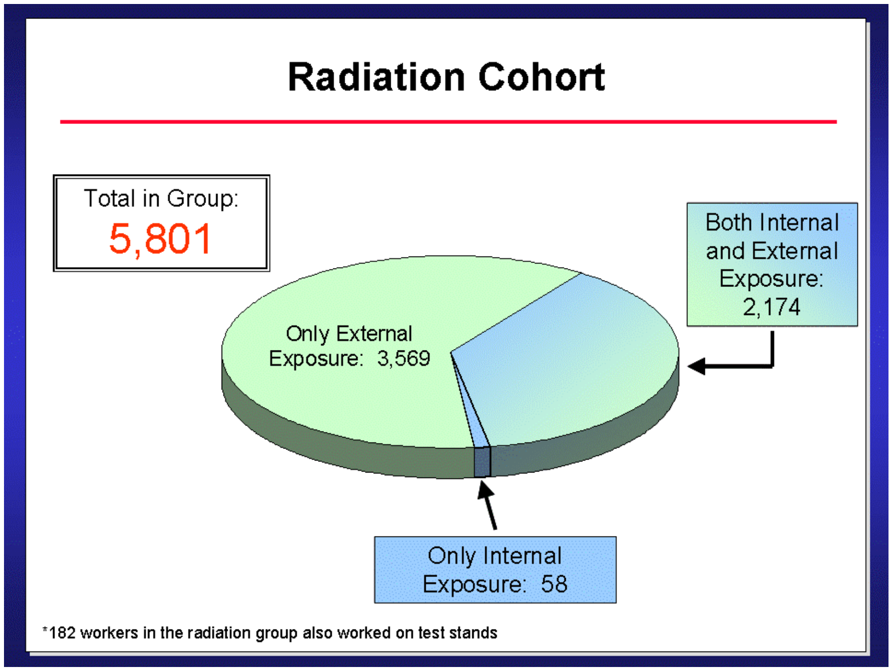


Figure 2



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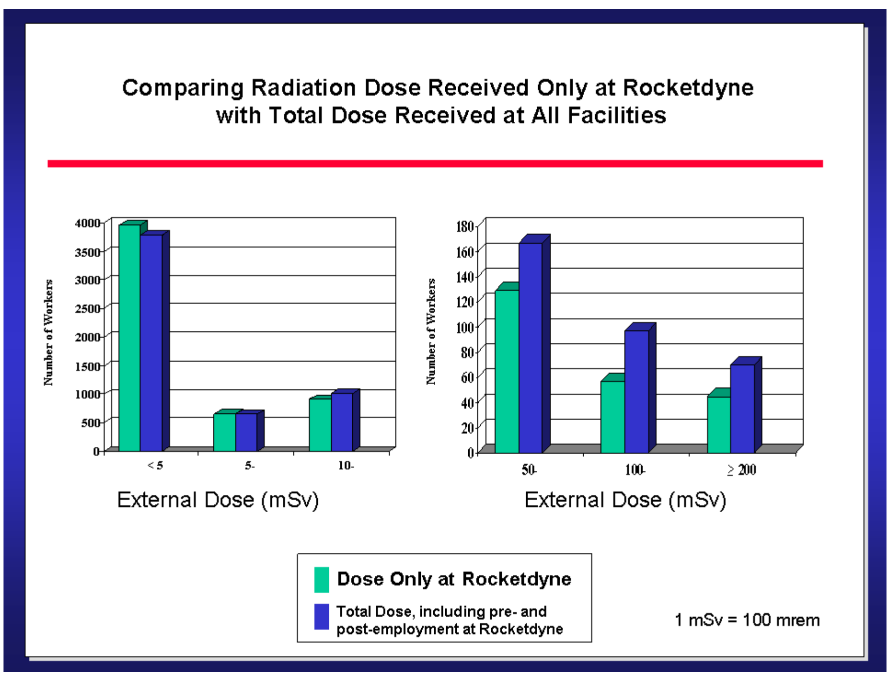

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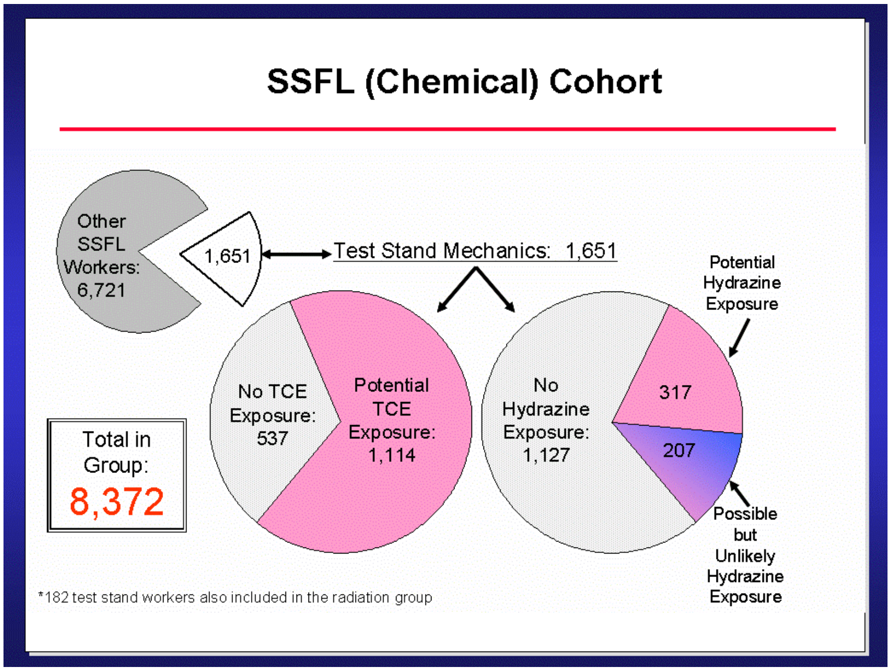

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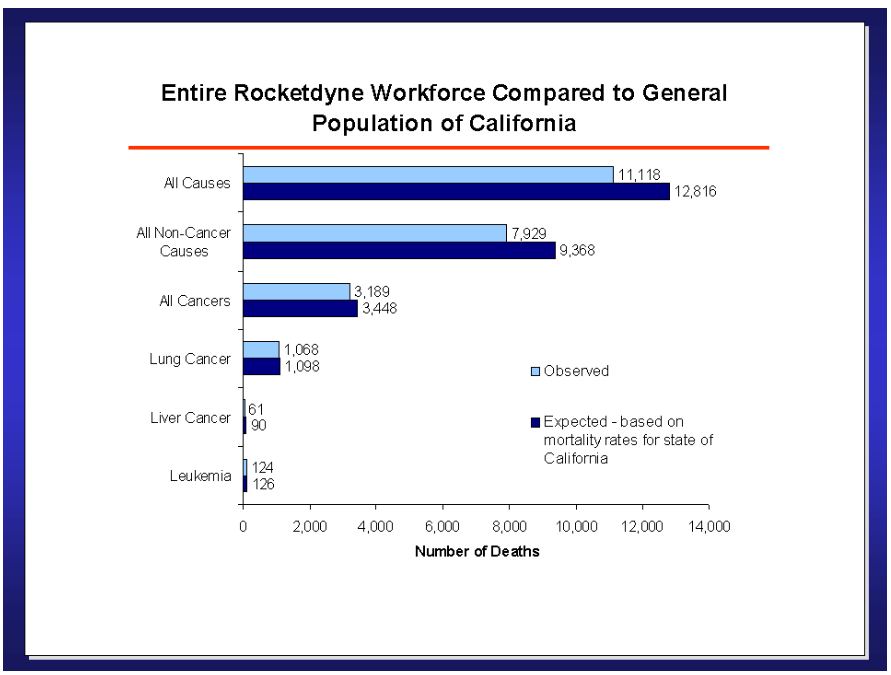

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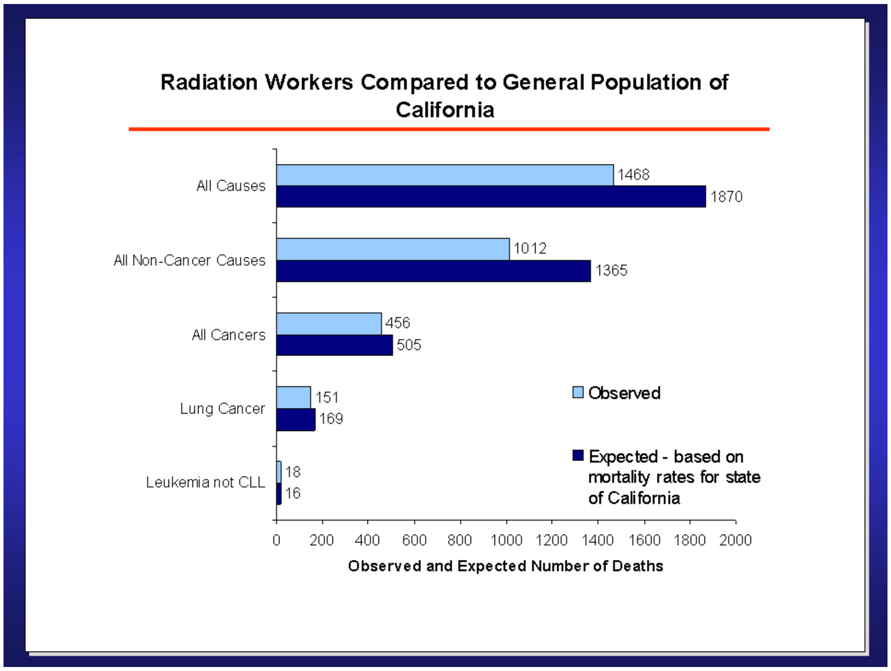

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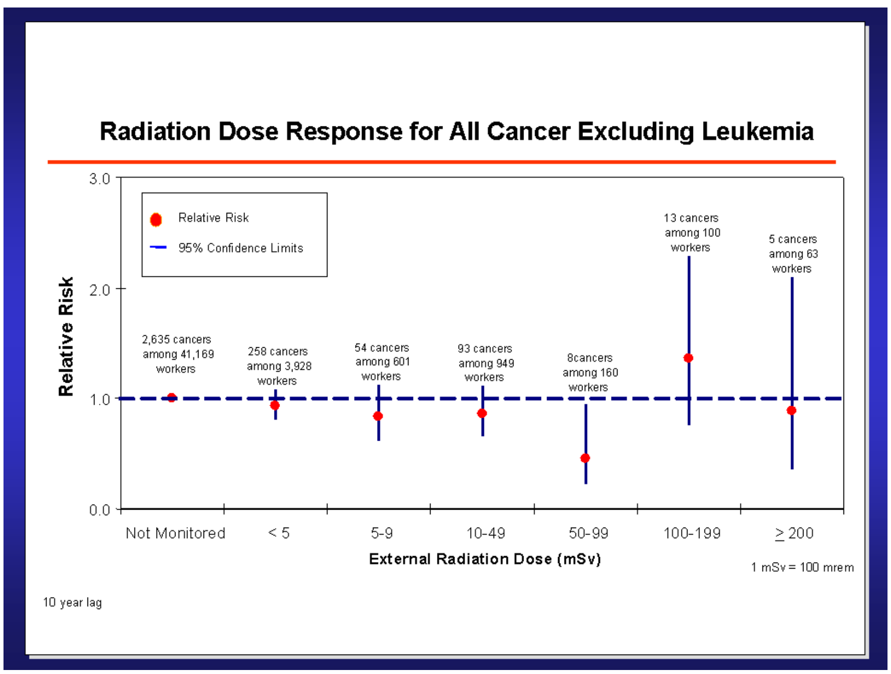

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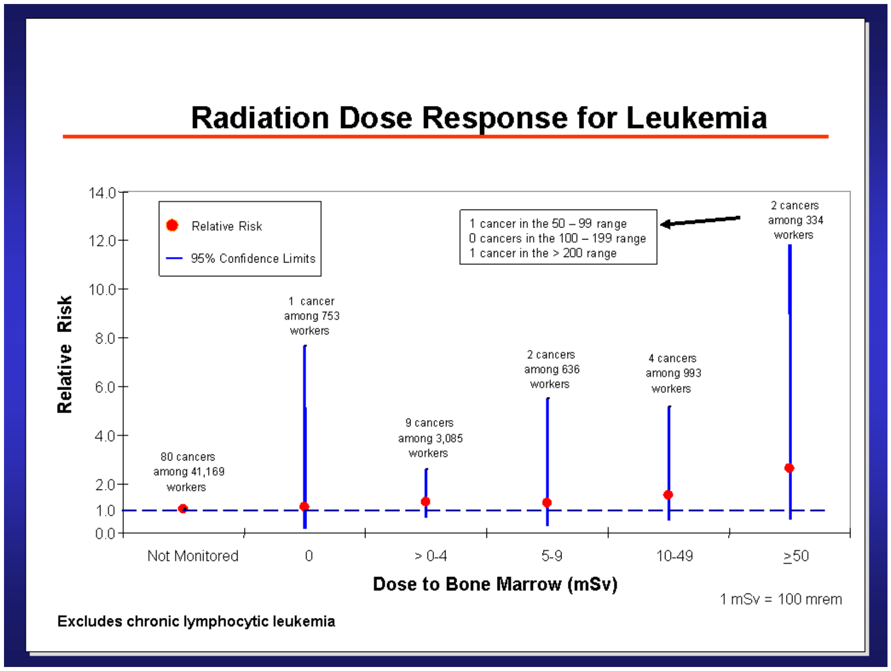

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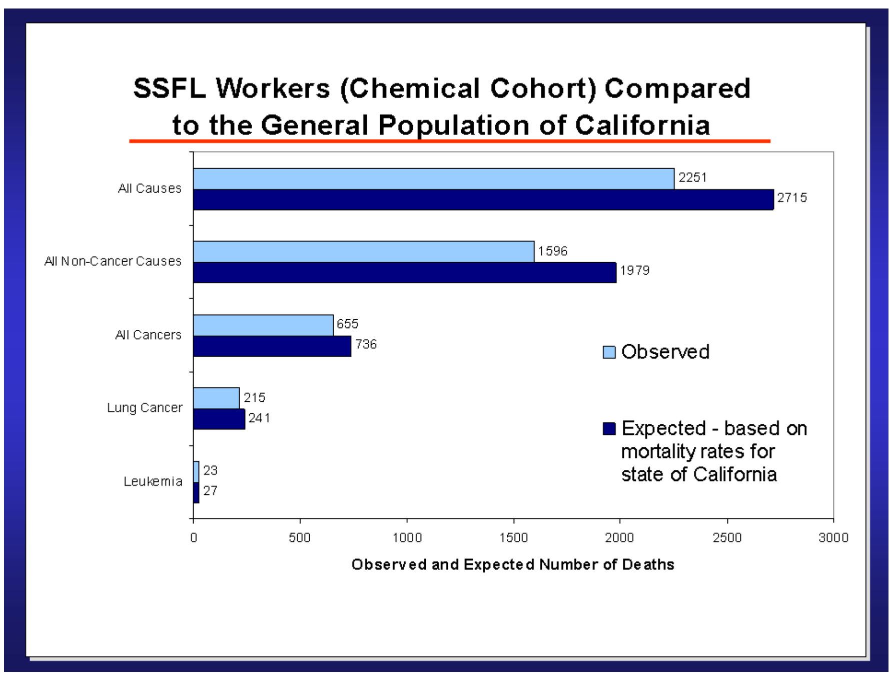

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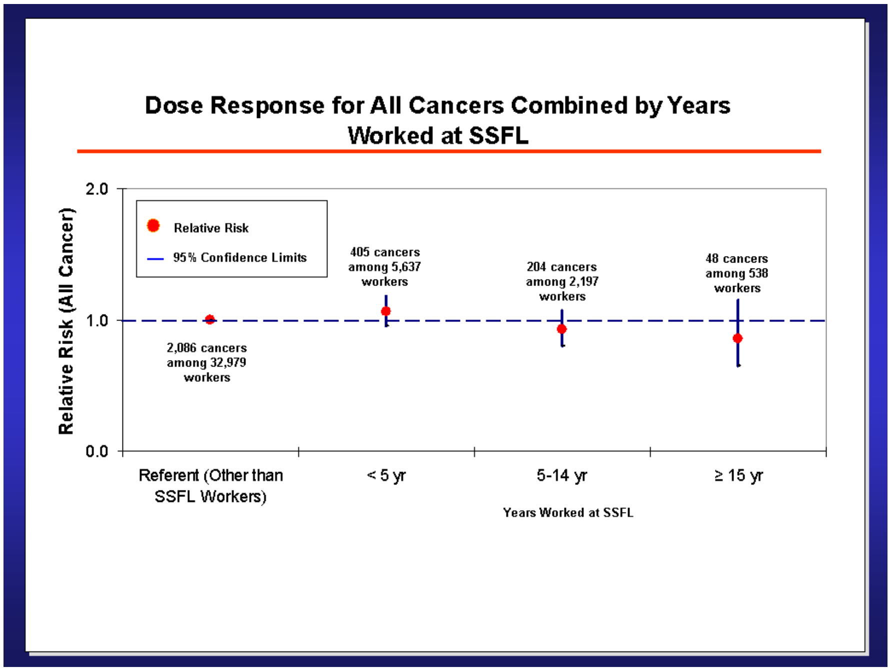

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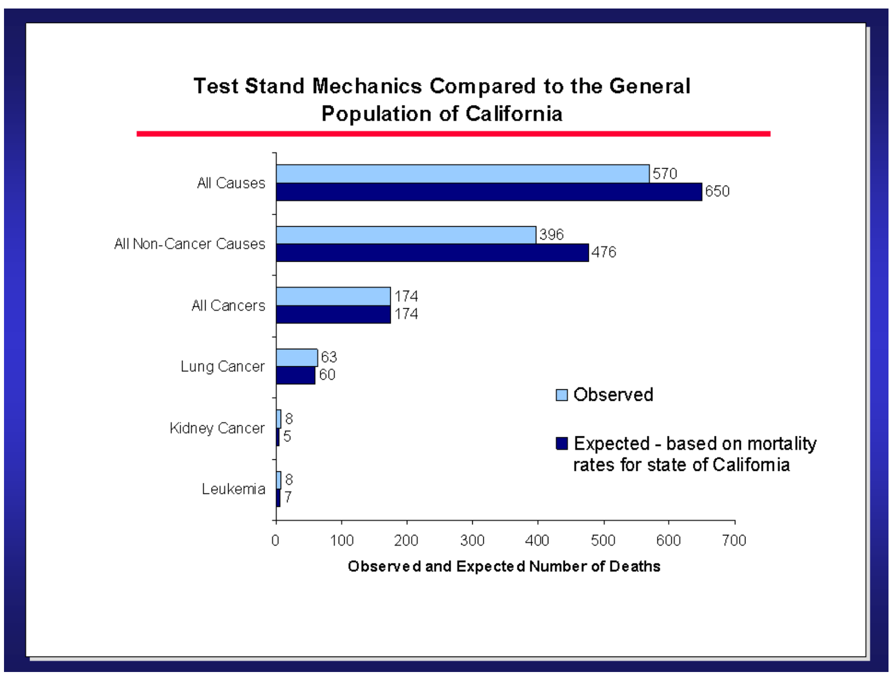

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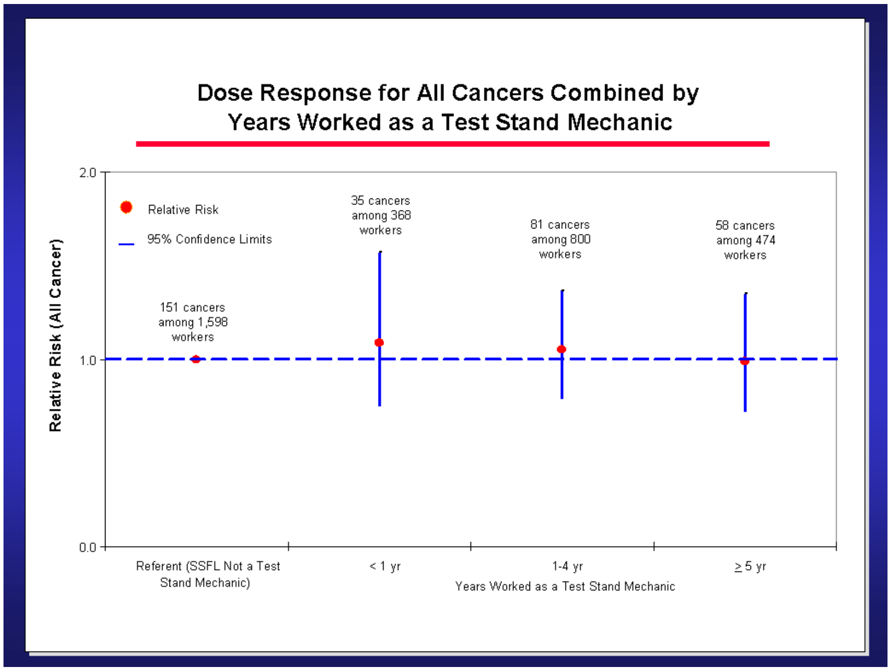

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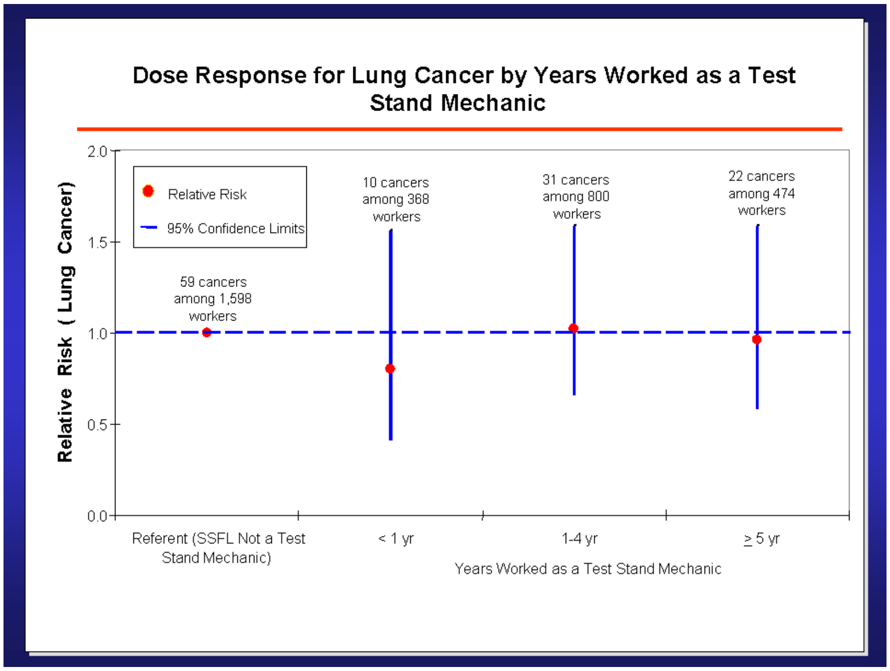

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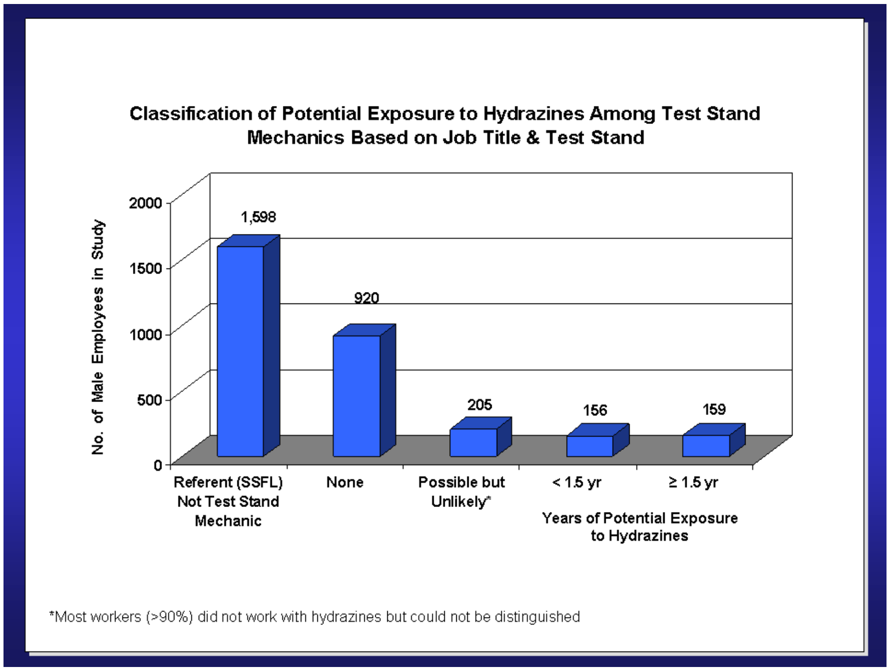

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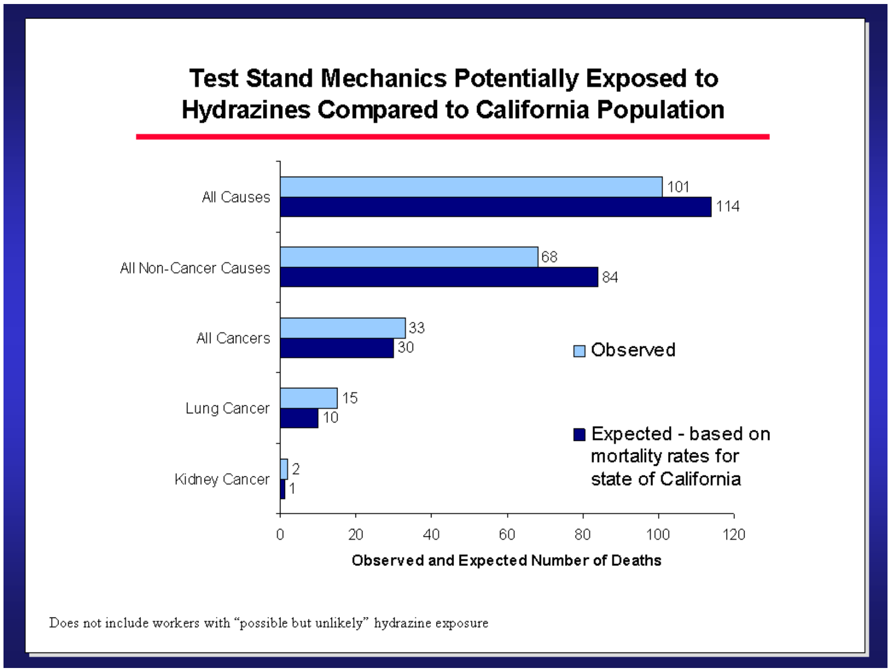

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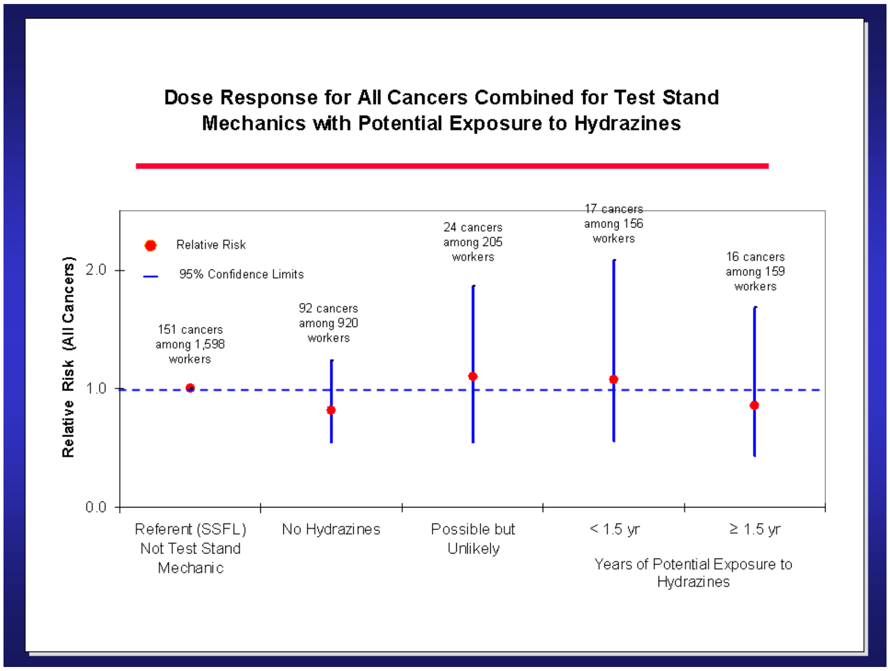

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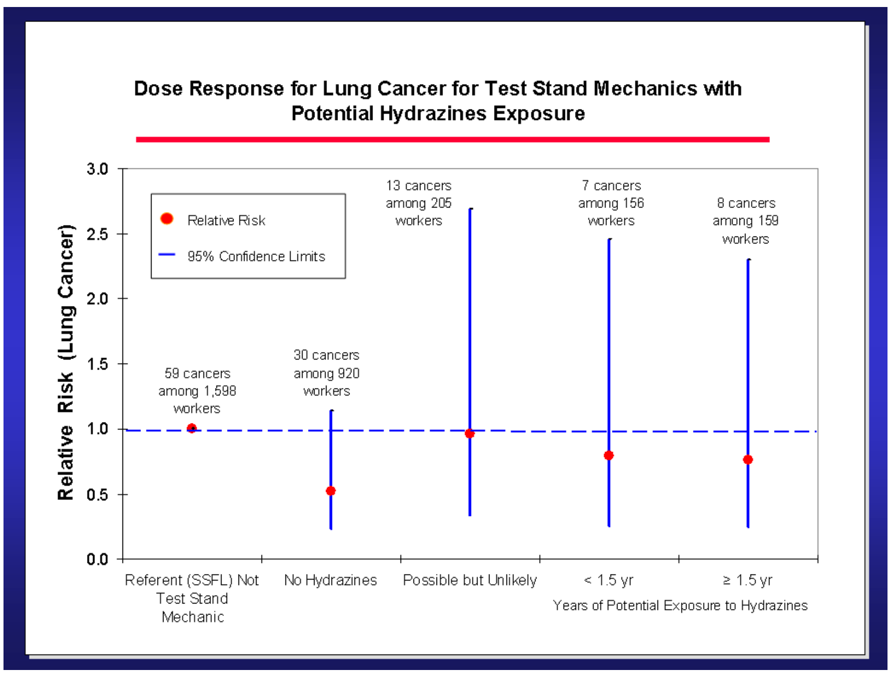

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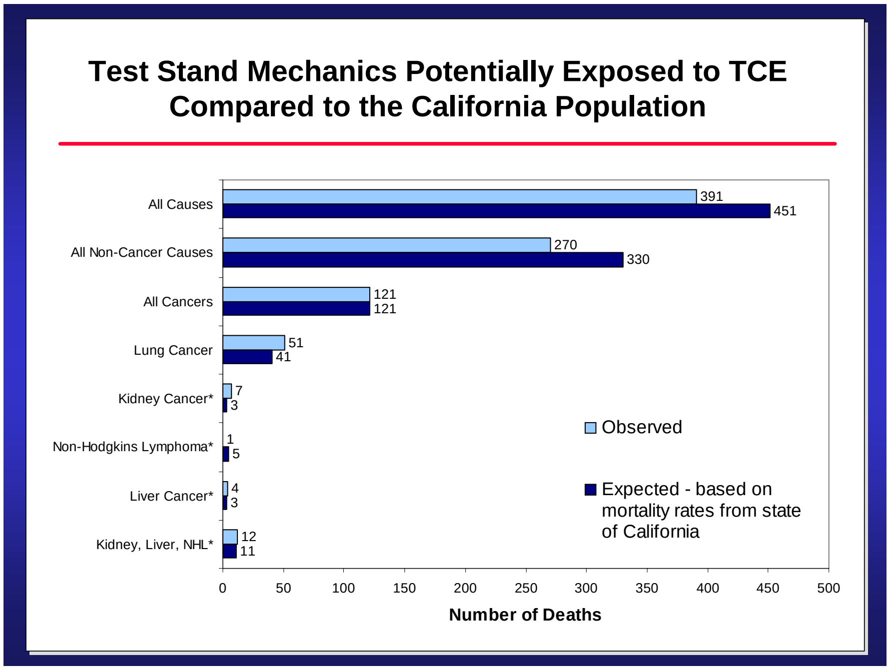

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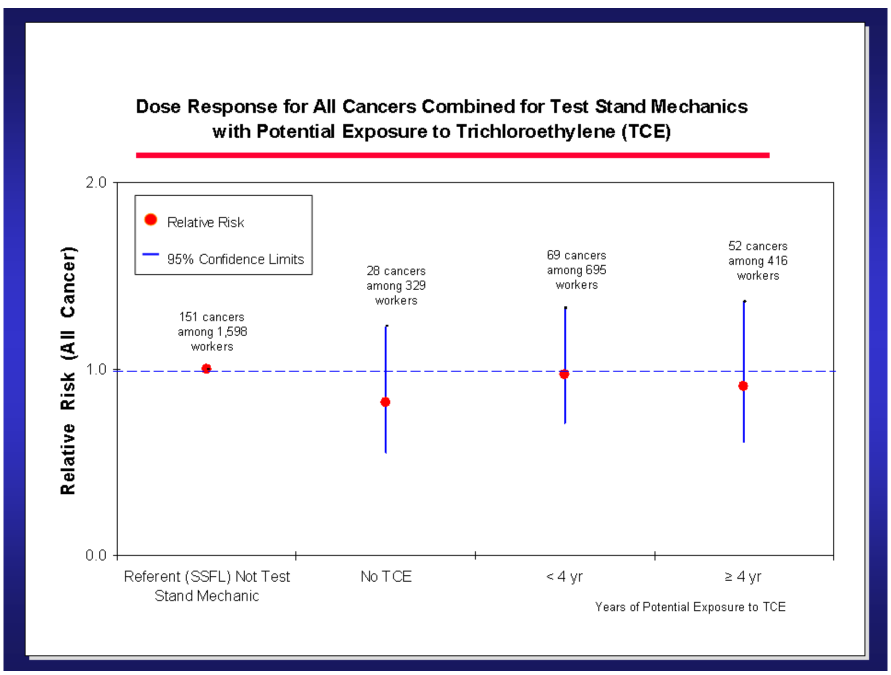

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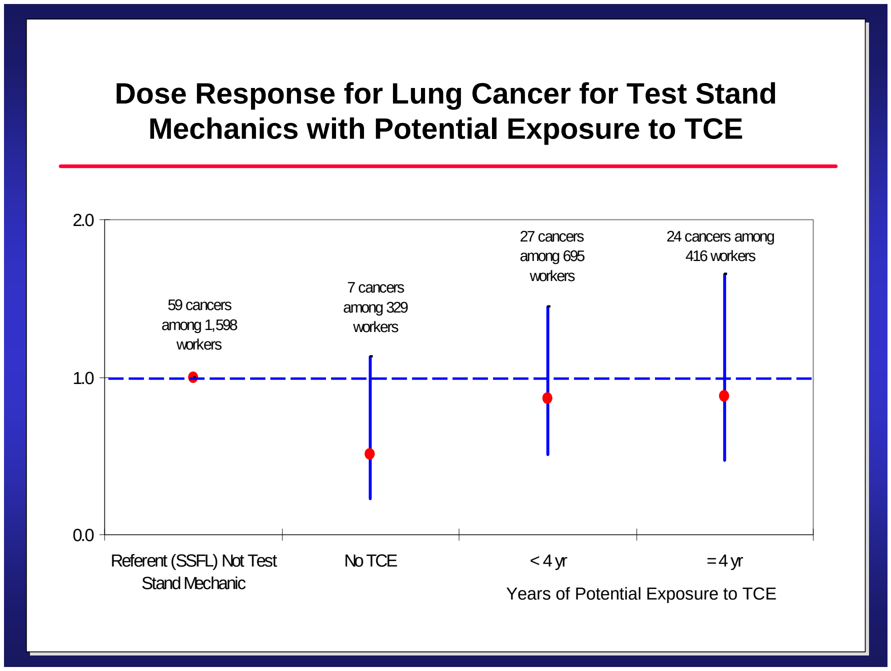

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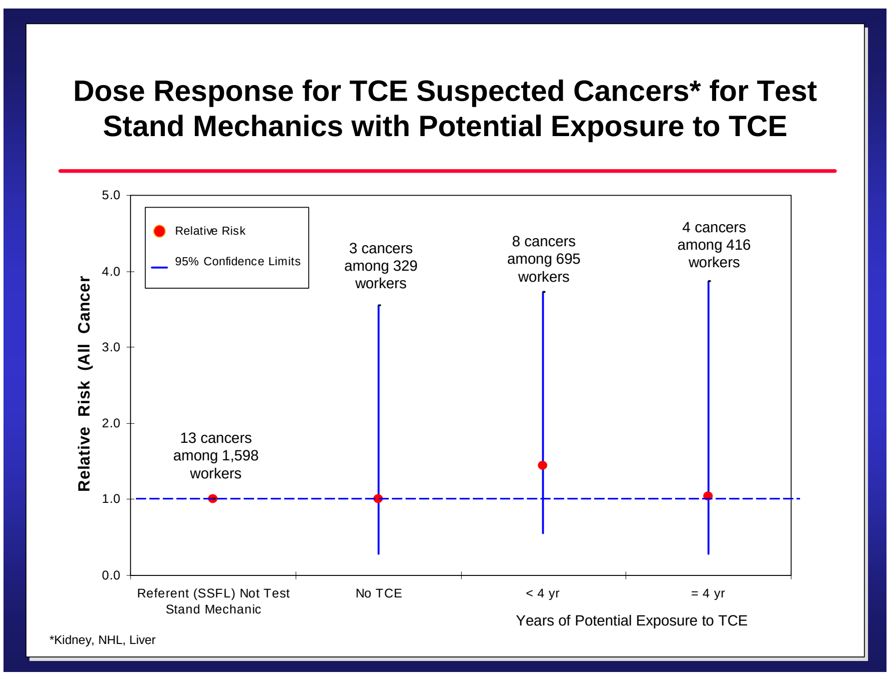

Figure 22

14. PowerPoint Presentation 6-8 April 2005

Figure 1pp. Overview
Figure 2pp. Who was in the study?
Figure 3pp. What were the two types of radiation exposure?
Figure 4pp. How many people were in the radiation group?
Figure 5pp. Potential chemical exposure characterized by years worked
Figure 6pp. Nine discussion sessions
Figure 7pp. How many SSFL workers were potentially exposed to chemicals as test stand mechanics?
Figure 8pp. Worker Groups
Figure 9pp. Rocketdyne workers had a lower risk of death than the general population of California
Figure 10pp. Rocketdyne radiation workers had a lower risk of death than the general population of California
Figure 11pp. Most radiation workers received very low exposures
Figure 12pp. What was the effect of including pre- and post-Rocketdyne radiation dose?
Figure 13pp. Interpreting Dose Response Graphs
Figure 14pp. No evidence that radiation increased the risk of dying from cancer (excluding leukemia)
Figure 15pp. No evidence that radiation increased the risk of dying from lung cancer
Figure 16pp. Suggestive, although not statistically significant, evidence that radiation increased the risk of dying from leukemia
Figure 17pp. Radiation Summary Findings
Figure 18pp. SSFL workers (Chemical Group) had a lower risk of death than the general population of California
Figure 19pp. No evidence that working at SSFL increased the risk of dying from all cancers combined
Figure 20pp. Test stand mechanics had a lower risk of death than the general population of California
Figure 21pp. No evidence that working as a test stand mechanic increased the risk of dying from all cancers combined
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Figure 23pp. Classification of potential exposure to hydrazines among test stand mechanics based on job title and test stand
Figure 24pp. Test stand mechanics potentially exposed to hydrazines had a lower risk of death overall but slight increased risk of dying from cancer compared to the general population of California
Figure 25pp. No evidence that test stand mechanics with potential exposure to hydrazines had an increased risk of dying from all cancers combined
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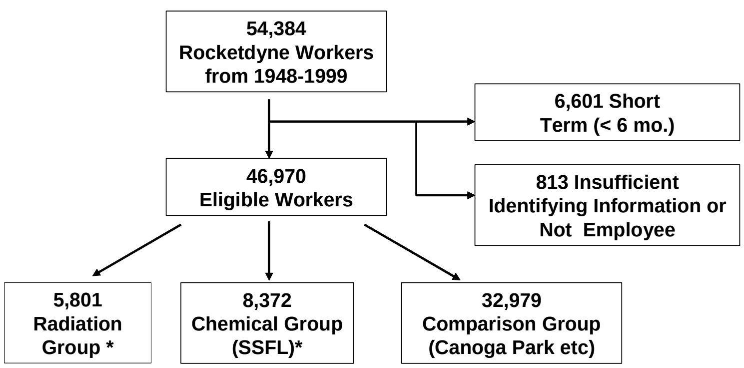
Figure 27pp. Classification of potential exposure to trichloroethylene (TCE)* among test stand mechanics based on job title and test stand

Figure 28pp. Test stand mechanics potentially exposed to TCE had a lower risk of death overall but similar risk of dying from cancer compared to the general population of California
Figure 29pp. No evidence that test stand mechanics with potential exposure to TCE had an increased risk of dying from all cancers
Figure 30pp. Chemical Summary Findings
Figure 31pp. Limitations
Figure 32pp. Strengths
Figure 33pp. Conclusion

Rocketdyne Follow-On Health Study
6-8 April 2005
Overview

Figure 1pp

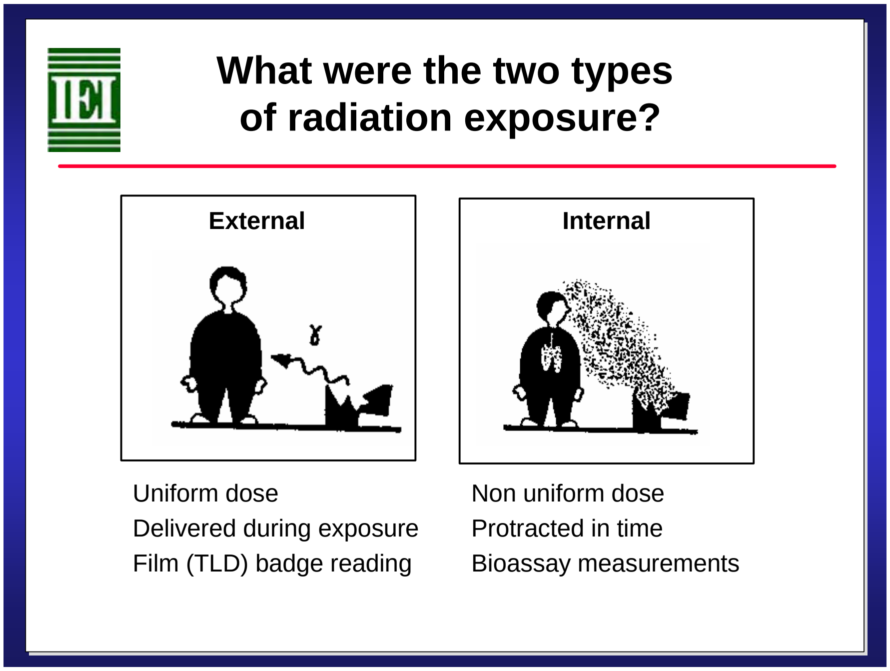
Who was in the study?



99.2% of eligible workers as of 12/31/99 were traced

*182 workers included in both groups

Figure 2pp



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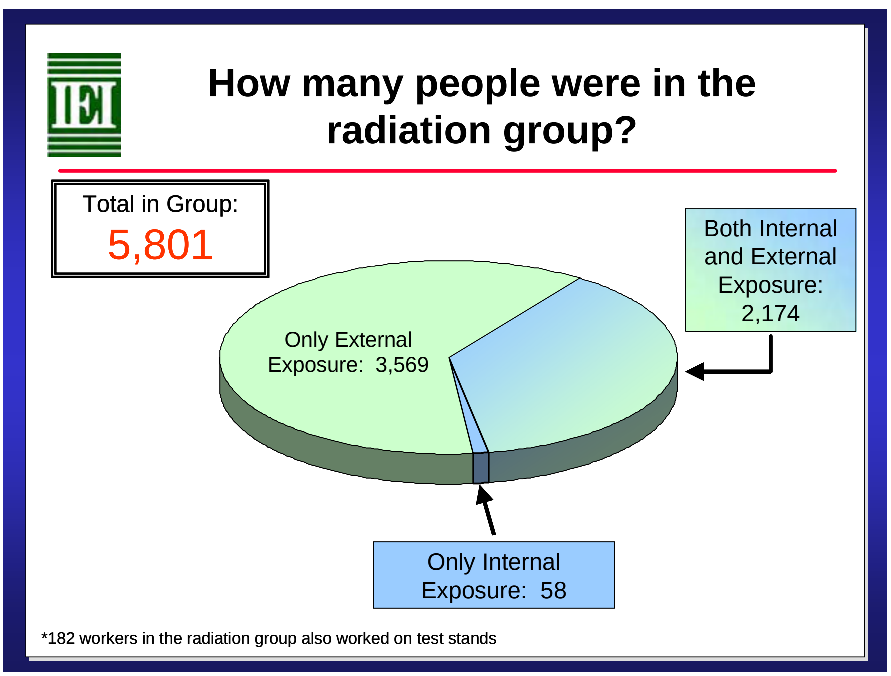


Figure 4pp

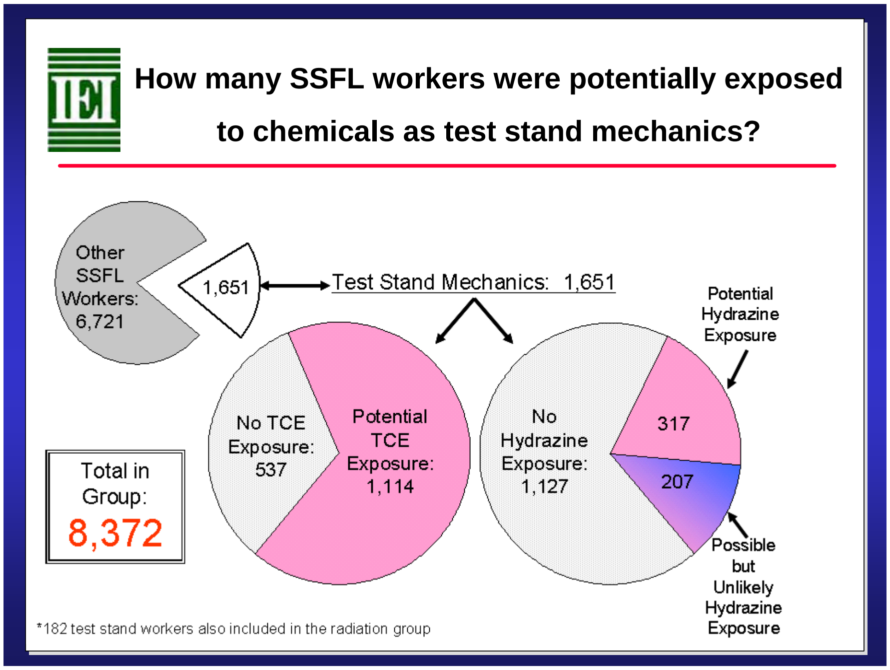
Potential Chemical Exposure Characterized by Years Worked

- Work at SSFL
- Work as Test Stand Mechanic
  - Exposure to “Test Stand Environment”, including chemical mixture of fuels, oxidizers, exhaust gasses, solvents and other chemicals
  - Hydrazines
  - TCE as a “Utility Solvent”
  - TCE as a “Flush Solvent”

Figure 5pp

Nine Discussion Sessions

Figure 6pp



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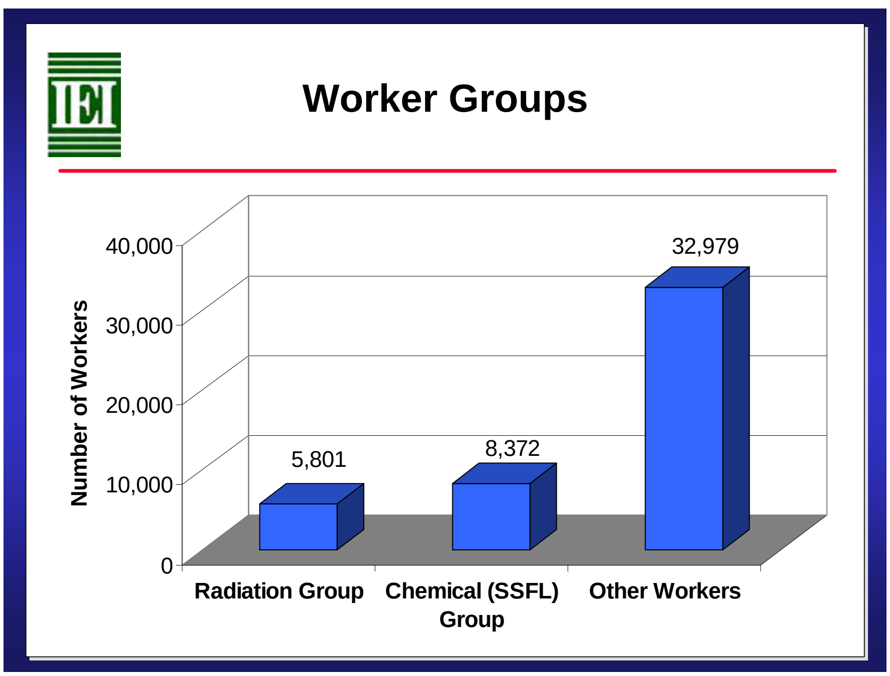

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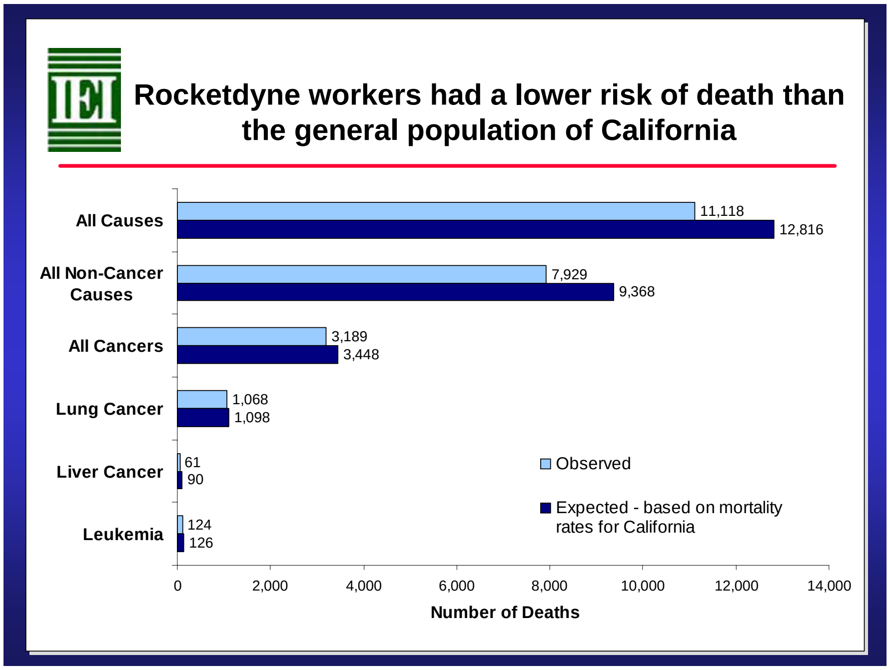

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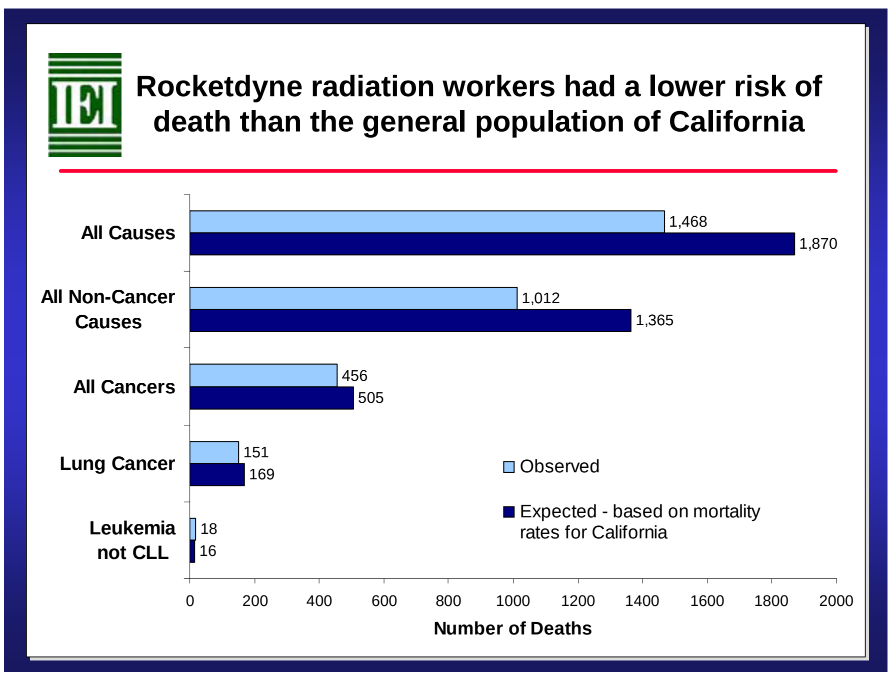

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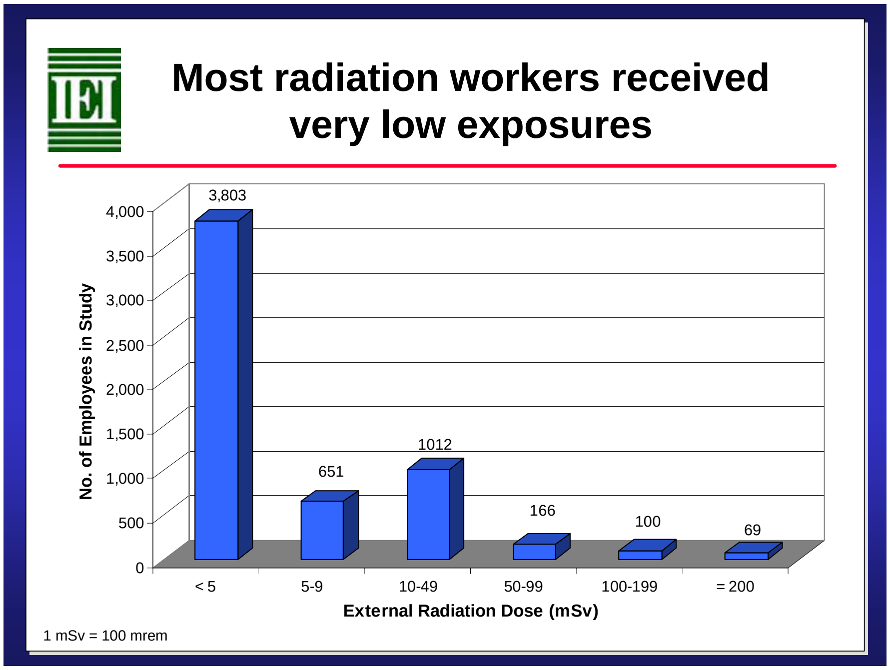

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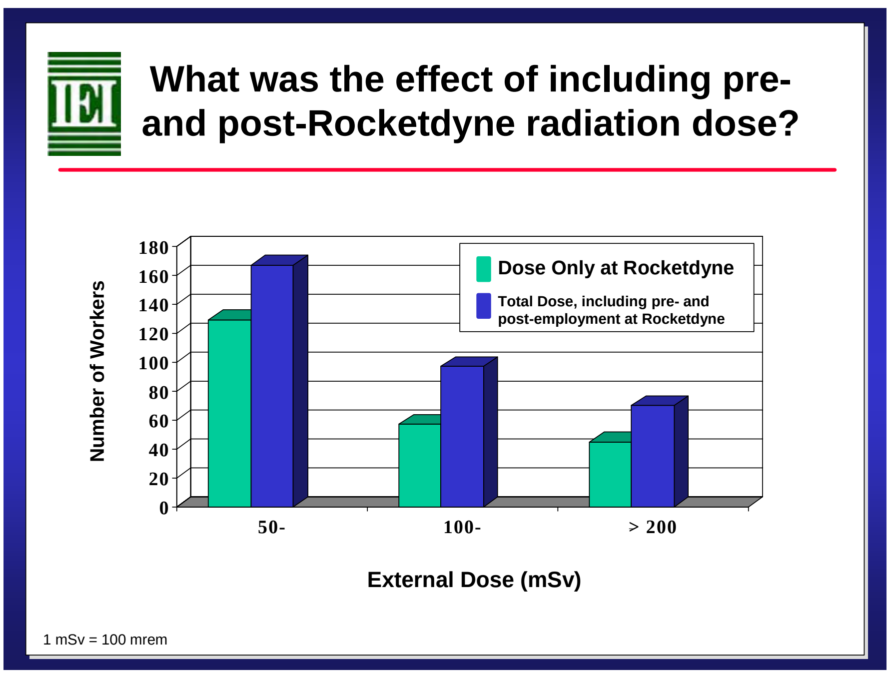

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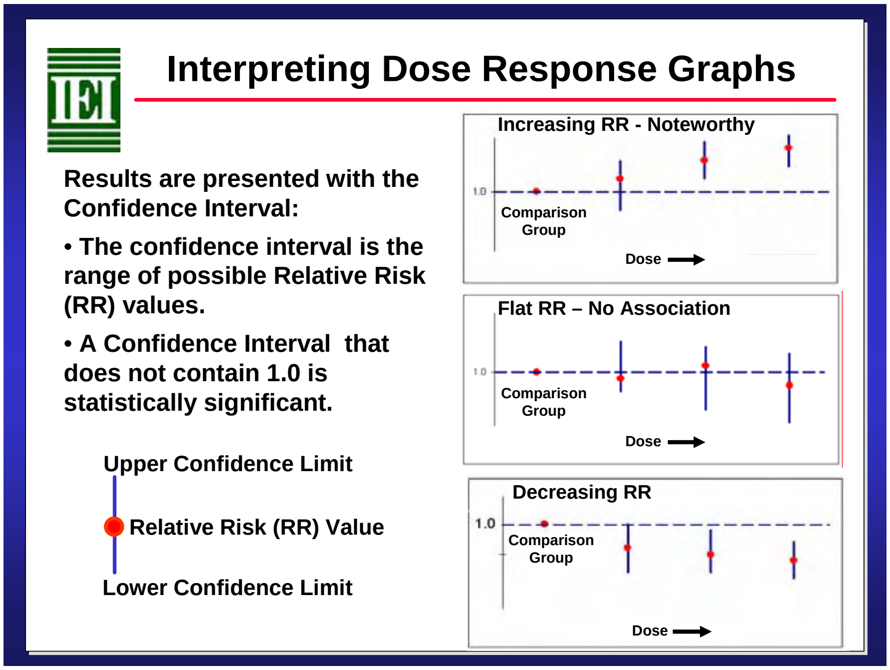

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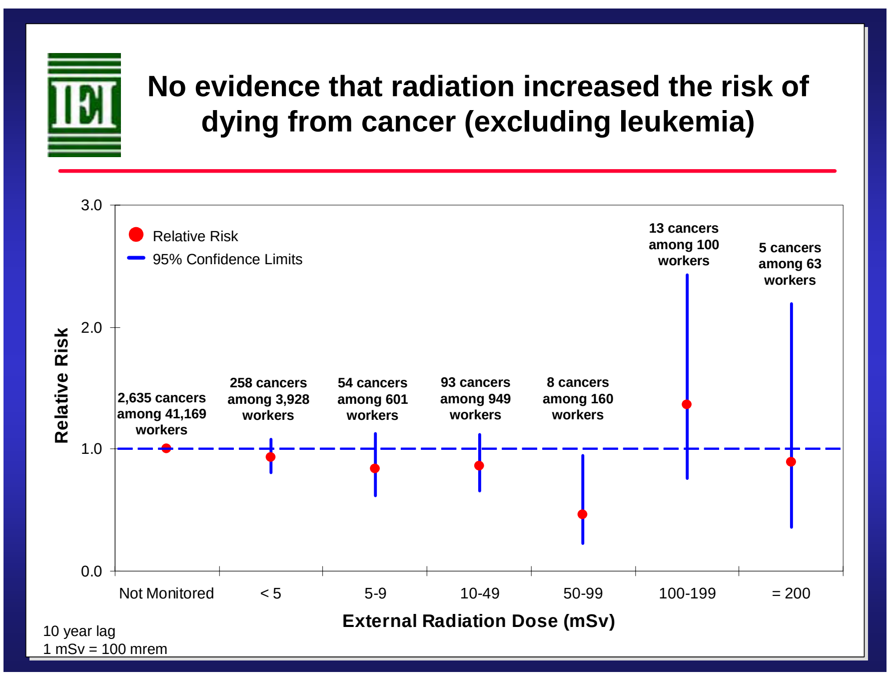

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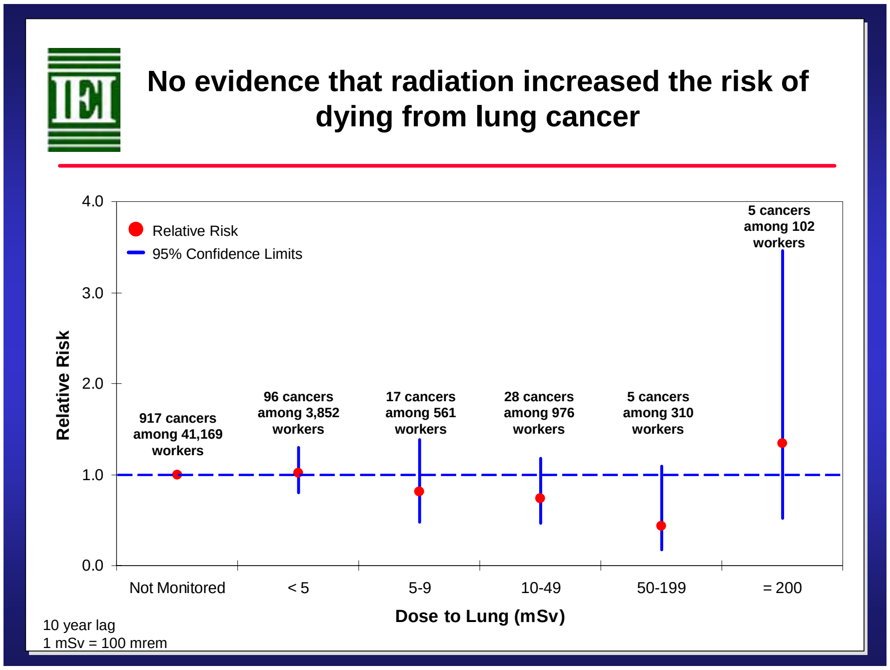

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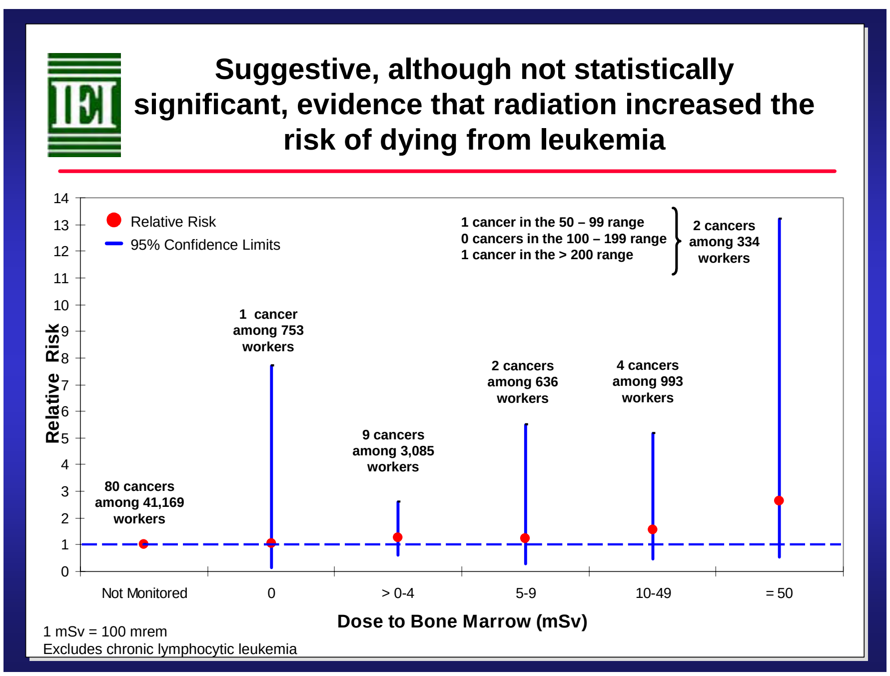


Figure 16pp

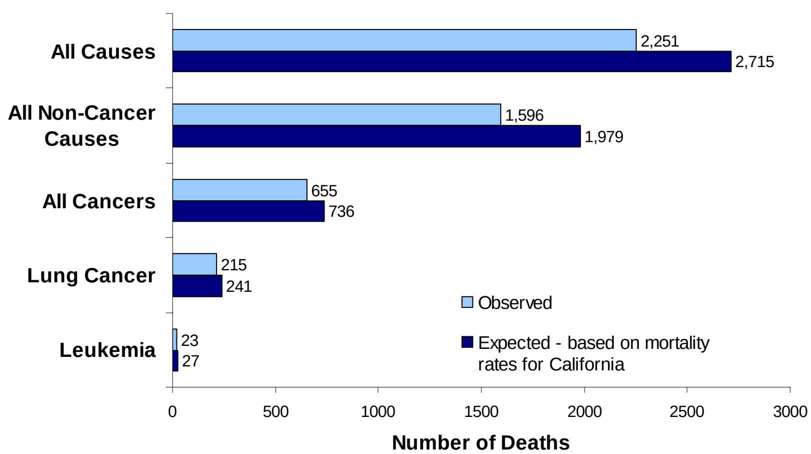
Radiation Summary Findings

Radiation exposure has not caused a detectable increase in cancer deaths among Rocketdyne workers

- Mean dose was low
- There were no significant trends between radiation dose and any cancer, including lung cancer
- Suggestive trend for leukemia was based on small numbers (18 observed v 15.5 expected) and trend was not statistically significant

Figure 17pp

SSFL workers (Chemical Group) had a lower risk of death than the general population of California



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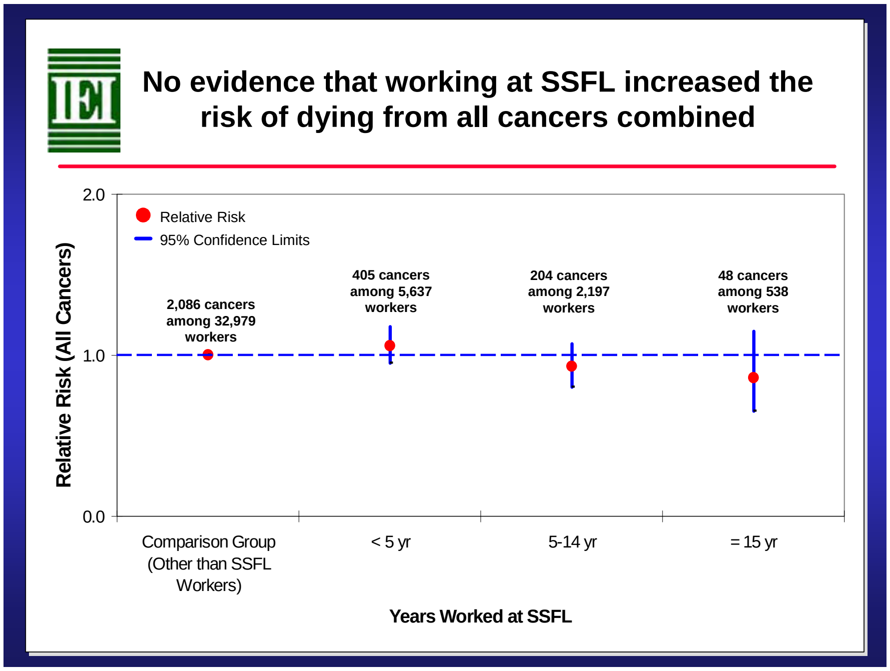

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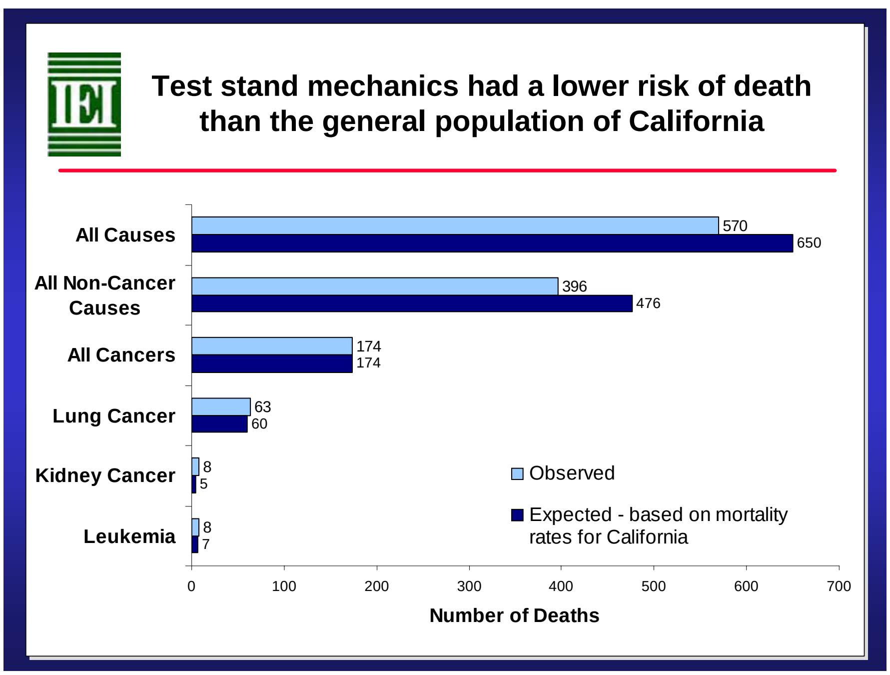

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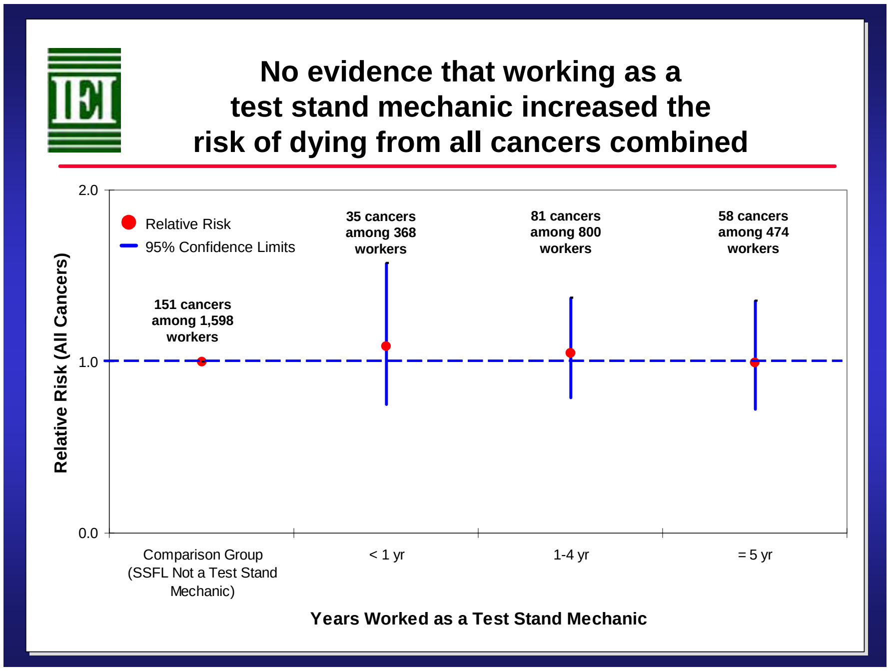

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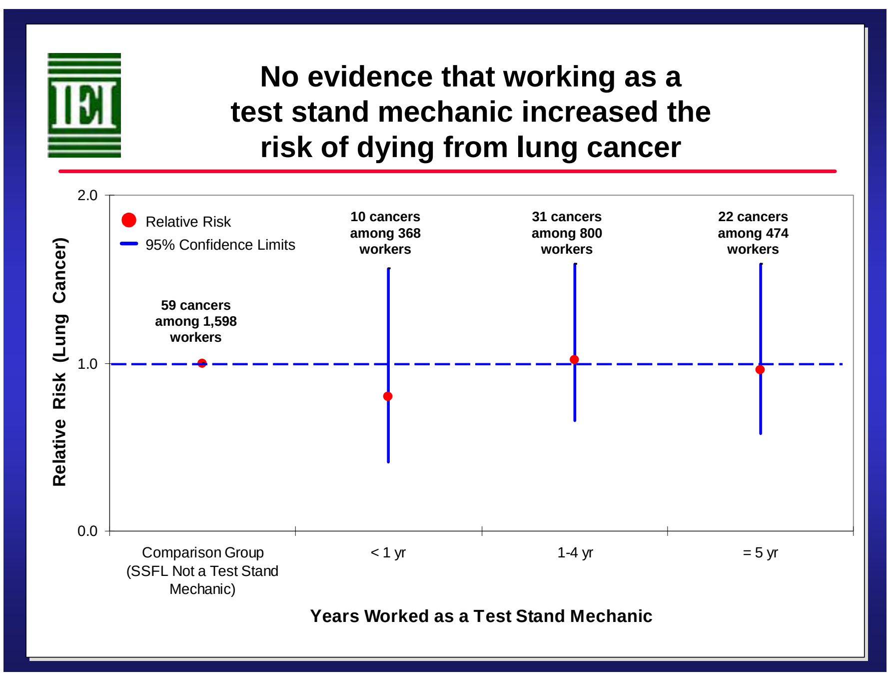

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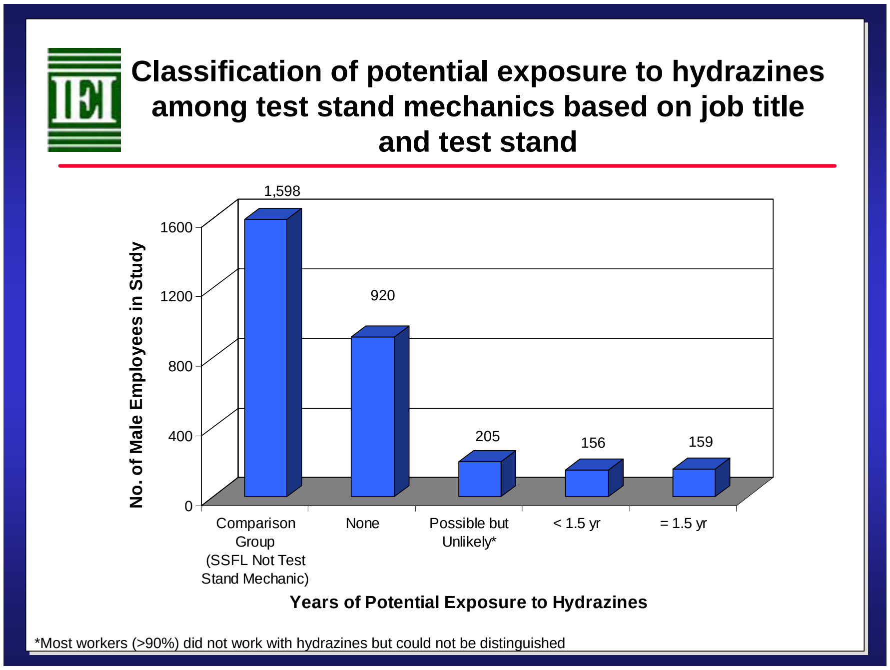

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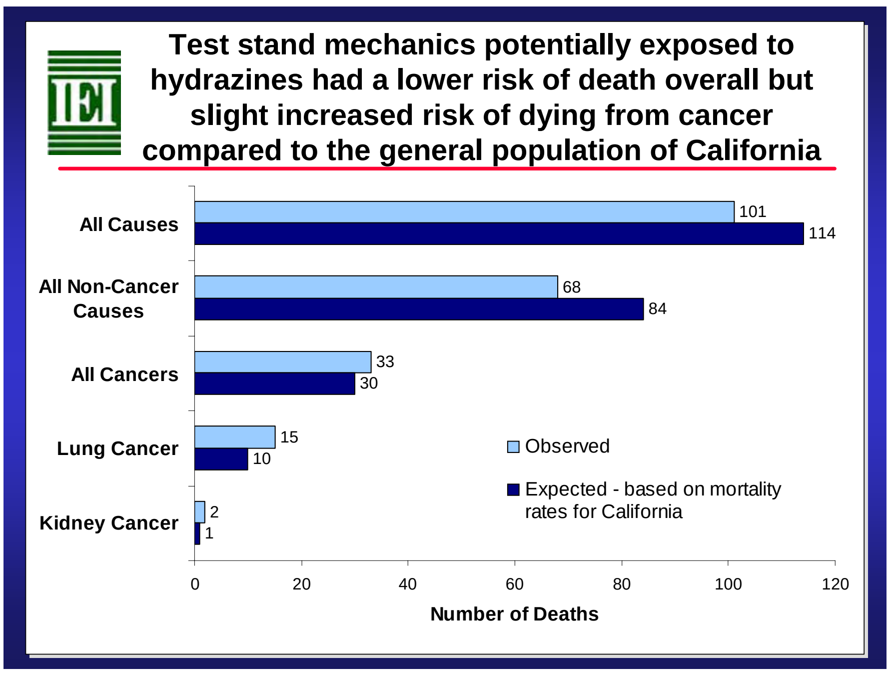

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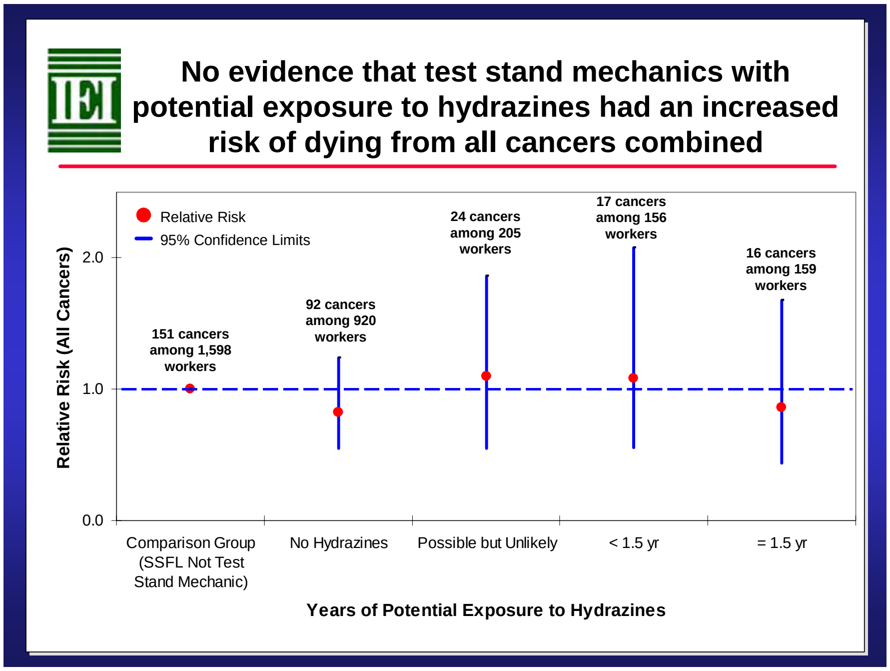

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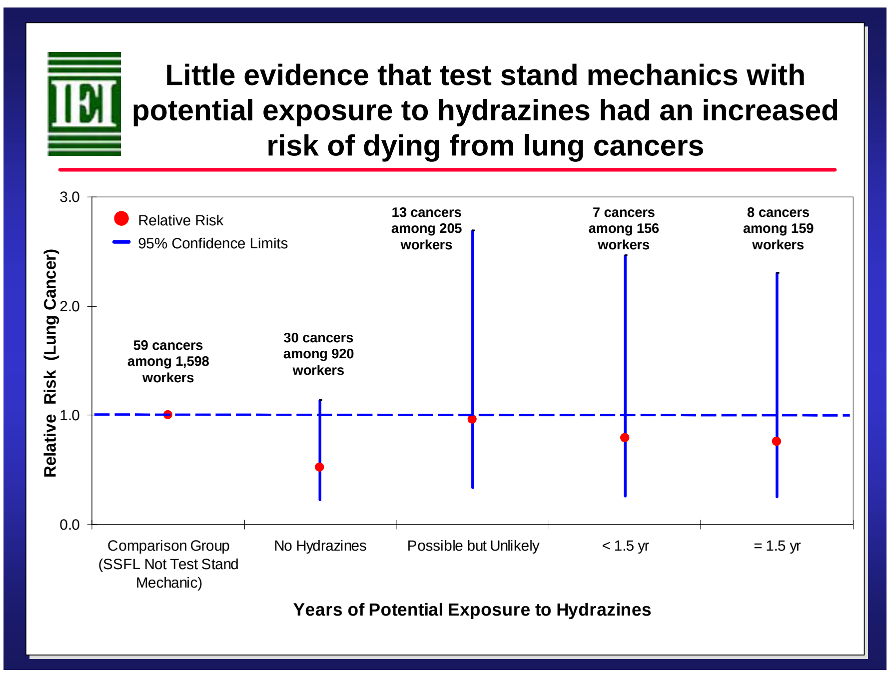

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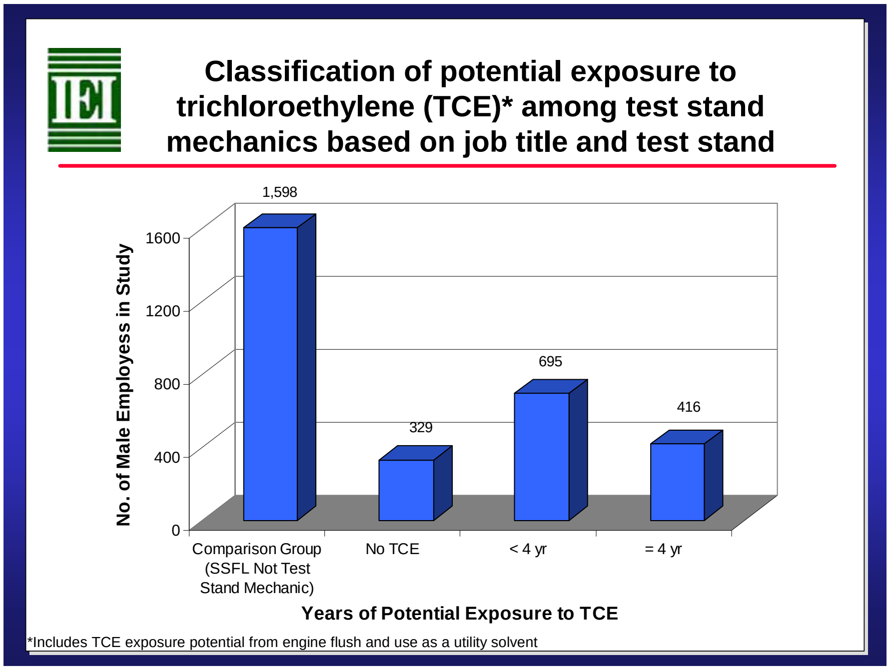

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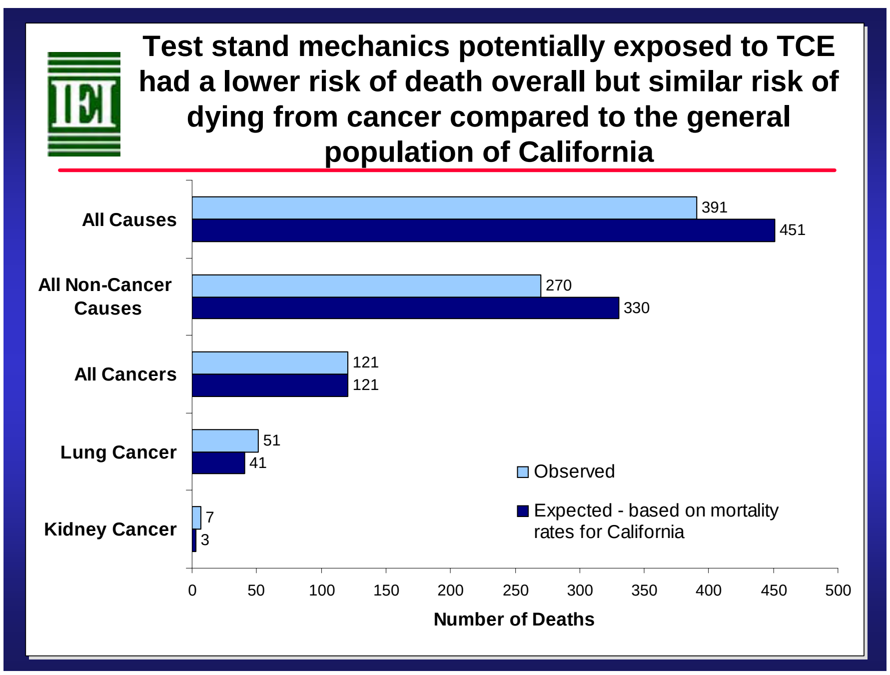


Figure 28pp

No evidence that test stand mechanics with potential exposure to TCE had an increased risk of dying from all cancers

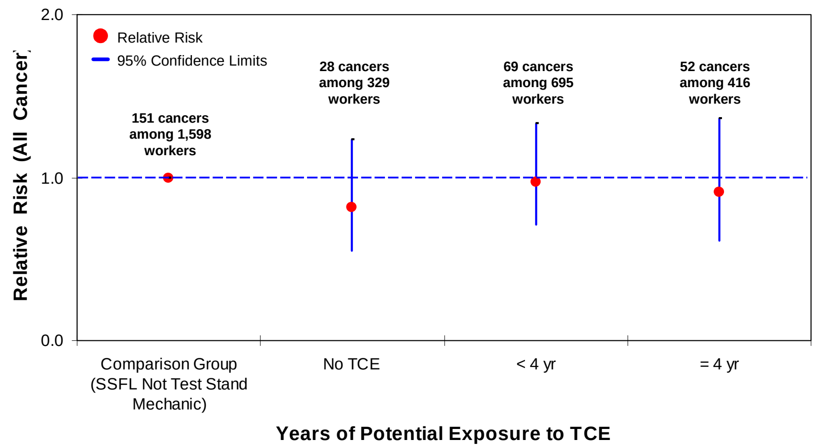


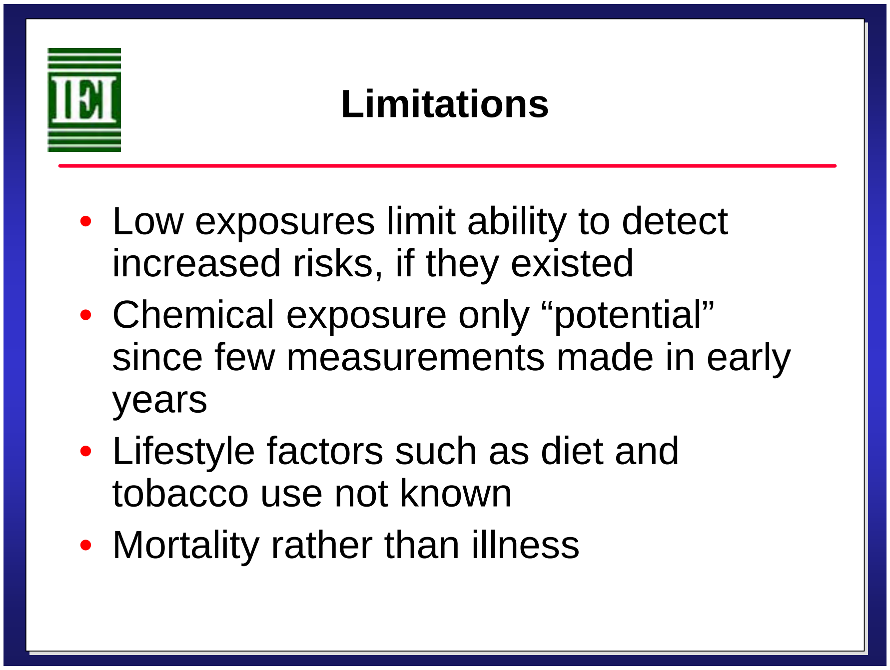
Figure 29pp

Chemical Summary Findings

Work at SSFL, as a test stand mechanic or with specific chemicals, has not caused a detectable increase in cancer deaths among Rocketdyne workers

- There were no significant trends or any significant excesses of cancer among workers at SSFL, or among test stand mechanics
- Hydrazines were not linked to significant increased risk of cancer, although lung cancer elevated compared to general population
- TCE was not linked to any significant increased risks of cancer

Figure 30pp



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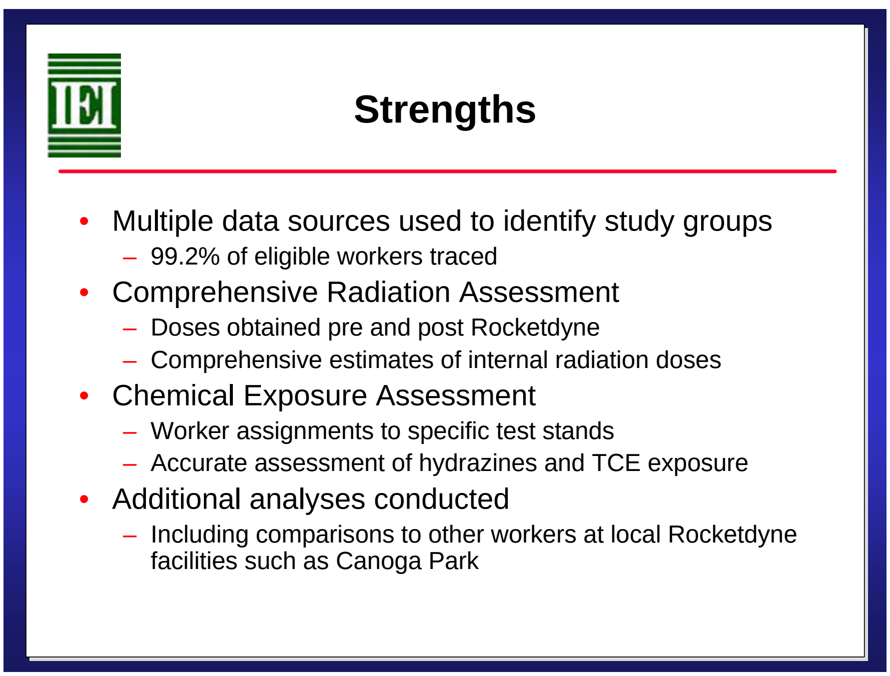

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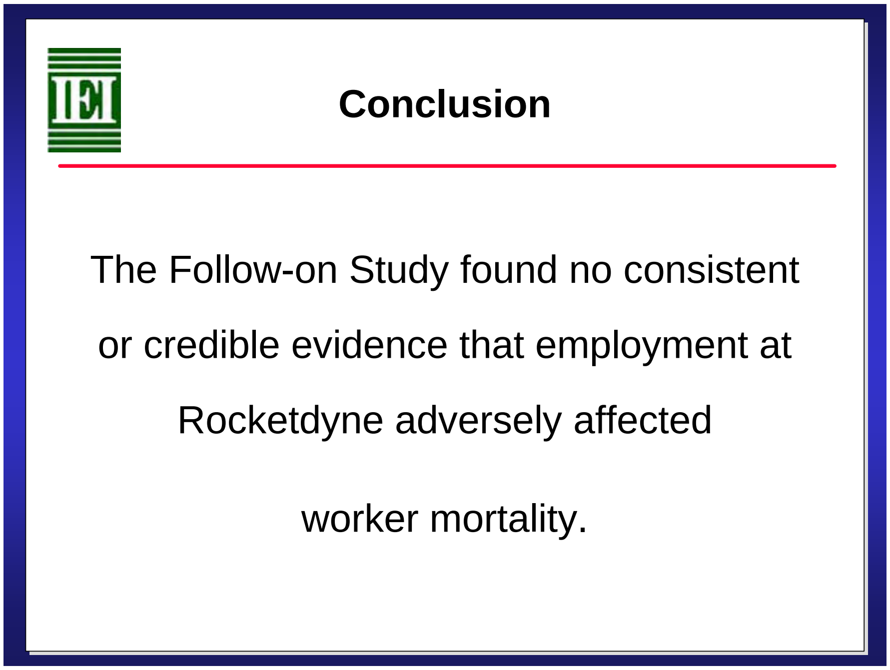
Conclusion
The Follow-on Study found no consistent or credible evidence that employment at Rocketdyne adversely affected worker mortality.

Figure 33pp

ROCKETDYNE WORKER HEALTH STUDY

Appendix A

INTERNATIONAL EPIDEMIOLOGY INSTITUTE

Combined Rocketdyne Worker Analyses

July 13, 2005

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Appendix A. Combined Rocketdyne Worker Analyses

Appendix A provides summary totals of all Rocketdyne Workers including the Radiation Workers, SSFL Workers, and the Other Rocketdyne Workers (mainly Canoga Park and De Sota Avenue facilities). The Radiation Paper provides the analytical data on Radiation Workers and the Chemical Paper on SSFL and Other Workers. These tabulations are for all workers combined and for white males. In addition comparisons are made with respect to the influence on the SMR values of choosing different general populations to compute the expected values for comparison.

A1. Demographic and Occupational Characteristics of All Rocketdyne Workers Employed for At Least Six Months Between 1948-1999 by Demographic and Occupational Characteristics

A2. Observed and Expected Numbers of Deaths, Standardized Mortality Ratios (SMR), for Rocketdyne Workers Employed for At Least Six Months 1948-1999 and Followed Through 1999 by Worker Subpopulations

A3. Observed and Expected Numbers of Deaths, Standardized Mortality Ratios (SMR), for Rocketdyne Workers Employed for At Least Six Months 1948-1999 by Worker Subpopulations (White Males Only)

A4. Comparison of Expected Number of Deaths and SMRs Using Three Different Sets of Mortality Rates for 46,970 Rocketdyne Workers Employed At Least 6 Months, 1948-1999 (Gender and Race Combined). 46,970 Total Rocketdyne Workers and 1.3 Million Years of Follow-up

A5. Place of death for Rocketdyne Workers

A6. Distribution of Race of the Non-White Rocketdyne Workers by Year of Hire and Whether Employed in an Administrative Job. Over the Years, Black Employees Were the Most Prevalent Racial Group Until the 1980s When They Were Surpassed by Asian Employees.

Appendix Table A1. Demographic and Occupational Characteristics of All Rocketdyne workers employed for at least six months between 1948-1999 by demographic and occupational characteristics

Characteristic	Radiation No.	Radiation %	SSFL Workers[1] No.	SSFL Workers[1] %	Other Rocketdyne[2] No.	Other Rocketdyne[2] %	Total Rocketdyne No.	Total Rocketdyne %
Gender								
Male	5,335	92.0	7,083	84.6	24,775	75.1	37,012	78.8
Female	466	8.0	1,289	15.4	8,204	24.9	9,958	21.2
Race								
White	4,695	80.9	6,629	79.2	24,643	74.7	35,808	76.2
Non-white								
Asian	89	1.5	142	1.7	1,178	3.6	1,407	3.0
Black	199	3.4	189	2.3	1,560	4.7	1,944	4.1
American Indian	18	0.3	10	0.1	96	0.3	121	0.3
Other/Missing	800	13.8	1,402	16.7	5,502	16.7	7,690	16.4
Pay type								
Hourly	3,285	56.6	5,241	62.6	21,076	63.9	29,420	62.6
Salary	2,516	43.4	3,131	37.4	11,903	36.1	17,550	37.4
Year of Birth								
<1920	937	16.2	1,419	16.9	4,847	14.7	7,184	15.3
1920-1929	1,670	28.8	2,155	25.7	6,064	18.4	9,849	21.0
1930-1939	1,701	29.3	2,663	31.8	7,326	22.2	11,643	24.8
1940-1949	769	13.3	1,170	14.0	6,743	20.4	8,652	18.4
1950-1959	534	9.2	680	8.1	4,876	14.8	6,055	12.9
≥1960	190	3.3	285	3.4	3,123	9.5	3,587	7.6
Year of Hire								
<1948	98	1.7	204	2.4	831	2.5	1,127	2.4
1948-1959	2,471	42.6	4,048	48.4	7,990	24.2	14,432	30.7
1960-1969	1,963	33.8	2,501	29.9	11,383	34.5	15,817	33.7
1970-1979	607	10.5	685	8.2	3,530	10.7	4,778	10.2
1980-1989	595	10.3	797	9.5	7,614	23.1	8,981	19.1
≥1990	67	1.2	137	1.6	1,631	4.9	1,835	3.9
Year of Termination								
<1960	319	5.5	16	0.2	35	0.1	365	0.8
1960-1969	2,370	40.9	4,425	52.9	14,269	43.3	21,018	44.7
1970-1979	924	15.9	1,167	13.9	3,859	11.7	5,940	12.6
1980-1989	844	14.5	1,100	13.1	5,003	15.2	6,916	14.7
1990-1999	817	14.1	1,051	12.6	5,697	17.3	7,538	16.0

Characteristic	Radiation No.	Radiation %	SSFL Workers[1] No.	SSFL Workers[1] %	Other Rocketdyne[2] No.	Other Rocketdyne[2] %	Total Rocketdyne No.	Total Rocketdyne %
Active (12/31/1999)	527	9.1	613	7.3	4,116	12.5	5,193	11.1
Duration of employment								
0.5-0.9	215	3.7	366	4.4	2,202	6.7	2,780	5.9
1-4	1,730	29.8	2,821	33.7	13,143	39.9	17,658	37.6
5-9	1,205	20.8	1,587	19.0	6,212	18.8	8,985	19.1
10-14	939	16.2	1,367	16.3	4,626	14.0	6,900	14.7
15-19	579	10.0	690	8.2	2,808	8.5	4,056	8.6
≥20	748	12.9	1,481	17.7	3,832	11.6	5,993	12.8
Missing	385	6.6	60	0.7	156	0.5	598	1.3
Years of follow-up								
<1	95	1.6	46	0.5	357	1.1	498	1.1
1-4	191	3.3	264	3.2	1,091	3.3	1,543	3.3
5-9	349	6.0	344	4.1	1,501	4.6	2,192	4.7
10-19	886	15.3	1,335	15.9	8,831	26.8	11,019	23.5
20-29	1,075	18.5	1,302	15.6	5,061	15.3	7,387	15.7
30-39	2,360	40.7	2,872	34.3	11,089	33.6	16,288	34.7
40-49	837	14.4	2,177	26.0	5,049	15.3	8,003	17.0
≥50	8	0.1	32	0.4	0	0.0	40	0.1
Age at end of follow-up								
<40	356	6.1	392	4.7	3,561	10.8	4,296	9.1
40-49	647	11.2	850	10.2	5,426	16.5	6,884	14.7
50-59	981	16.9	1,510	18.0	7,704	23.4	10,163	21.6
60-69	1,902	32.8	2,958	35.3	8,294	25.1	13,104	27.9
70-79	1,482	25.5	2,033	24.3	5,799	17.6	9,275	19.7
80-89	409	7.1	587	7.0	2,051	6.2	3,038	6.5
≥90	24	0.4	42	0.5	144	0.4	210	0.4
Vital Status as of 12/31/1999								
Alive	4,191	72.2	6,076	72.6	25,367	76.9	35,484	75.5
Dead	1,468	25.3	2,251	26.9	7,429	22.5	11,118	23.7
Lost to follow-up	142	2.4	45	0.5	183	0.6	368	0.8
Total	**5,801**		**8,372**		**32,979**		**46,970**	

[1] 182 SSFL workers who were monitored for radiation have been included

[2] 'Other Rocketdyne' comprised of not monitored for radiation workers at non-SSFL facilities such as De Soto Avenue and Canoga Park

Appendix Table A2. Observed and Expected Numbers of Deaths, Standardized Mortality Ratios (SMR), for Rocketdyne Workers Employed for at least Six Months 1948-1999 and Followed through 1999 by Worker Subpopulations.

Worker Population	**Monitored for Radiation**				**SSFL[1]**				**Other Rocketdyne[2]**				**Total Rocketdyne**			
No. of Workers	**5,801**				**8,372**				**32,979**				**46,970**			
Person-years of Observation	**161,605**				**254,198**				**884,412**				**1,297,821**			
Cause of Death (ICD9)	**Obs**	**Exp**	**SMR**	**95% CI**	**Obs**	**Exp**	**SMR**	**95% CI**	**Obs**	**Exp**	**SMR**	**95% CI**	**Obs**	**Exp**	**SMR**	**95% CI**
All Causes of Death (001-999)	1,468	1,870.3	0.79	0.75-0.83	2,251	2,714.5	0.83	0.80-0.86	7,429	8,270.1	0.90	0.88-0.92	11,118	12,816.9	0.87	0.85-0.88
All Malignant Neoplasms (140-208)	456	504.9	0.90	0.82-0.99	655	735.9	0.89	0.82-0.96	2,086	2,218.8	0.94	0.90-0.98	3,189	3,448.9	0.93	0.89-0.96
Buccal Cavity & Pharynx (140-149)	8	13.0	0.62	0.27-1.22	11	18.6	0.59	0.30-1.06	45	54.6	0.82	0.60-1.10	64	85.9	0.75	0.57-0.95
Esophagus (150)	12	14.0	0.86	0.44-1.50	21	19.4	1.08	0.67-1.65	40	54.4	0.74	0.53-1.00	73	87.5	0.83	0.65-1.05
Stomach (151)	21	17.9	1.17	0.73-1.79	23	25.6	0.90	0.57-1.35	66	76.4	0.86	0.67-1.10	109	119.6	0.91	0.75-1.10
Colorectal (153-154)	56	49.9	1.12	0.85-1.46	70	72.6	0.97	0.75-1.22	177	218.3	0.81	0.70-0.94	303	339.8	0.89	0.79-1.00
Biliary Passages & Liver (155,156)	5	13.5	0.37	0.12-0.86	11	19.2	0.57	0.29-1.03	45	58.3	0.77	0.56-1.03	61	90.7	0.67	0.51-0.86
Pancreas (157)	21	26.3	0.80	0.49-1.22	36	38.2	0.94	0.66-1.31	112	113.8	0.98	0.81-1.18	169	177.8	0.95	0.81-1.11
Larynx (161)	9	5.5	1.63	0.74-3.09	11	7.8	1.41	0.71-2.53	23	21.6	1.06	0.67-1.59	42	34.8	1.21	0.87-1.63
Bronchus, Trachea, & Lung (162)	151	168.8	0.89	0.76-1.05	215	241.2	0.89	0.78-1.02	705	692.4	1.02	0.94-1.10	1,068	1,098.7	0.97	0.92-1.03
Breast (174, 175)	5	5.7	0.88	0.29-2.05	15	16.5	0.91	0.51-1.50	88	97.4	0.90	0.73-1.11	108	119.6	0.90	0.74-1.09
All Uterine (Females only) (179-182)	0	1.2	--	0.00-2.99	4	3.8	1.06	0.29-2.72	15	23.4	0.64	0.36-1.06	19	28.4	0.67	0.40-1.04
Cervix Uteri (180)	0	0.6	--	0.00-5.78	2	1.9	1.07	0.13-3.85	5	12.0	0.42	0.14-0.97	7	14.5	0.48	0.19-0.99
Other Female Genital Organs (183-184)	0	1.7	--	0.00-2.20	4	5.2	0.76	0.21-1.96	27	31.5	0.86	0.57-1.25	31	38.4	0.81	0.55-1.15
Prostate (Males only) (185)	37	39.7	0.93	0.66-1.29	50	53.2	0.94	0.70-1.24	143	145.0	0.99	0.83-1.16	229	237.0	0.97	0.85-1.10
Testes & Other Male Genital Organs (186, 187)	1	1.5	0.69	0.02-3.82	2	2.3	0.88	0.11-3.19	3	6.2	0.48	0.10-1.41	6	9.9	0.60	0.22-1.31
Kidney (189.0-189.2)	12	12.8	0.94	0.49-1.64	21	18.3	1.15	0.71-1.76	53	51.5	1.03	0.77-1.35	86	82.3	1.05	0.84-1.29
Bladder & Other Urinary (188, 189.3-189.9)	8	12.2	0.65	0.28-1.29	16	17.2	0.93	0.53-1.51	42	48.9	0.86	0.62-1.16	65	78.1	0.83	0.64-1.06
Melanoma of Skin (172)	8	9.8	0.82	0.35-1.62	13	14.2	0.92	0.49-1.57	34	40.4	0.84	0.58-1.18	55	64.1	0.86	0.65-1.12
Brain & CNS (191-192)	17	14.8	1.15	0.67-1.83	20	22.0	0.91	0.56-1.41	65	65.0	1.00	0.77-1.28	102	101.5	1.01	0.82-1.22
Thyroid & Other Endocrine Glands (193-194)	0	1.6	--	0.00-2.29	2	2.4	0.82	0.10-2.97	11	7.5	1.47	0.73-2.62	13	11.5	1.13	0.60-1.93
Bone (170)	0	1.0	--	0.00-3.52	1	1.6	0.63	0.02-3.53	10	4.9	2.03	0.97-3.73	11	7.5	1.46	0.73-2.61
All Lymphatic, Haematopoietic Tissue (200-208)	51	49.7	1.03	0.76-1.35	68	72.5	0.94	0.73-1.19	196	215.4	0.91	0.79-1.05	314	336.5	0.93	0.83-1.04
Hodgkins Disease (201)	5	2.5	1.99	0.65-4.63	29	28.3	1.02	0.69-1.47	13	12.1	1.07	0.57-1.84	23	18.6	1.24	0.79-1.86
Non-Hodgkins Lymphoma (200, 202)	19	19.5	0.98	0.59-1.52	5	4.0	1.26	0.41-2.94	75	84.1	0.89	0.70-1.12	122	131.5	0.93	0.77-1.11
Leukemia & Aleukemia (204-208)	25	18.8	1.33	0.86-1.97	23	27.3	0.84	0.53-1.26	76	81.0	0.94	0.74-1.18	124	126.6	0.98	0.81-1.17

Worker Population	Monitored for Radiation				SSFL[1]				Other Rocketdyne[2]				Total Rocketdyne			
No. of Workers	5,801				8,372				32,979				46,970			
Person-years of Observation	161,605				254,198				884,412				1,297,821			
Cause of Death (ICD9)	**Obs**	**Exp**	**SMR**	**95% CI**	**Obs**	**Exp**	**SMR**	**95% CI**	**Obs**	**Exp**	**SMR**	**95% CI**	**Obs**	**Exp**	**SMR**	**95% CI**
Chronic Lymphocytic Leukemia (204.1)	7	3.4	2.04	0.82-4.21	3	4.9	0.61	0.13-1.79	15	13.9	1.08	0.60-1.78	25	22.1	1.13	0.73-1.67
Leukemia other than CLL	18	15.5	1.16	0.69-1.84	20	22.6	0.89	0.54-1.37	61	67.6	0.90	0.69-1.16	99	105.4	0.94	0.76-1.14
Multiple Myeloma	2	8.4	0.24	0.03-0.86	11	12.1	0.91	0.46-1.63	29	35.8	0.81	0.54-1.16	42	56.1	0.75	0.54-1.01
Mesothelioma, MN of pleura/peritoneum[3]	1	1.0	1.01	0.03-5.61	0	1.4	0.00	0.00-2.63	7	4.0	1.77	0.71-3.65	8	6.3	1.27	0.55-2.49
Smoking-related cancers	221	252.6	0.87	0.76-1.00	331	360.8	0.92	0.82-1.02	1,020	1,037.2	0.98	0.92-1.05	1,567	1,645.1	0.95	0.91-1.00
AIDS (042-044, 795.8)	1	16.9	0.06	0.00-0.33	5	22.7	0.22	0.07-0.51	33	97.9	0.34	0.23-0.47	39	137.0	0.29	0.20-0.39
Diabetes (250)	18	32.0	0.56	0.33-0.89	30	46.6	0.64	0.43-0.92	127	143.1	0.89	0.74-1.06	175	221.0	0.79	0.68-0.92
Cerebrovascular Disease (430-438)	67	94.0	0.71	0.55-0.91	102	138.2	0.74	0.60-0.90	386	445.3	0.87	0.78-0.96	553	675.7	0.82	0.75-0.89
All Heart Disease (390-398, 404, 410-429)	499	642.8	0.78	0.71-0.85	793	924.1	0.86	0.80-0.92	2,557	2,720.5	0.94	0.90-0.98	3,838	4,274.4	0.90	0.87-0.93
Non-malignant respiratory disease excluding pneumonia and influenza	68	102.2	0.67	0.52-0.84	153	147.3	1.04	0.88-1.22	419	442.1	0.95	0.86-1.04	639	689.3	0.93	0.86-1.00
Emphysema (492)	17	22.8	0.75	0.43-1.19	32	33.3	0.96	0.66-1.36	89	100.2	0.89	0.71-1.09	138	155.8	0.89	0.74-1.05
Cirrhosis of Liver (571)	38	71.5	0.53	0.38-0.73	48	104.3	0.46	0.34-0.61	186	306.6	0.61	0.52-0.70	272	481.1	0.57	0.50-0.64
Nephritis & Nephrosis (580-589)	12	10.2	1.18	0.61-2.06	13	14.7	0.88	0.47-1.51	45	46.0	0.98	0.71-1.31	70	70.7	0.99	0.77-1.25
All External Causes of Death (800-999)	106	159.2	0.67	0.55-0.81	160	237.5	0.67	0.57-0.79	516	773.1	0.67	0.61-0.73	777	1,167.3	0.67	0.62-0.71
Accidents (850-949)	60	92.6	0.65	0.49-0.83	99	138.8	0.71	0.58-0.87	302	447.2	0.68	0.60-0.76	459	677.2	0.68	0.62-0.74
Suicides (950-959)	31	46.5	0.67	0.45-0.95	52	69.1	0.75	0.56-0.99	166	214.0	0.78	0.66-0.90	246	328.8	0.75	0.66-0.85
Unknown Causes of Death	25				50				205				280			

[1] 182 test stand mechanics who were monitored for radiation have been included

[2] 'Other Rocketdyne' comprised of not monitored for radiation workers at non-SSFL facilities such as De Soto Avenue and Canoga Park

[3] Mesothelioma was not a codeable cause of death until 1999: ICD10 (C45). Before 1999, cancer of the pleura and peritoneum (ICD9 158.8, 158.9, 163) have been used as crude approximations of mesothelioma mortality.

Appendix Table A3. Observed and Expected Numbers of Deaths, Standardized Mortality Ratios (SMR), for Rocketdyne Workers Employed for at Least Six Months 1948-1999 and Followed through 1999 by Worker Subpopulations (White Males Only).

Worker Population	Monitored for Radiation				SSFL[1]				Other Rocketdyne[2]				Total Rocketdyne[3]			
No. of Workers	4,855				6,579				21,304				32,587			
Person-years of Observation	138,836				206,261				577,412				920,261			
Cause of Death (ICD9)	**Obs**	**Exp**	**SMR**	**95% CI**	**Obs**	**Exp**	**SMR**	**95% CI**	**Obs**	**Exp**	**SMR**	**95% CI**	**Obs**	**Exp**	**SMR**	**95% CI**
All Causes of Death (001-999)	1,342	1,724.1	0.78	0.74-0.82	1,973	2,405.4	0.82	0.78-0.86	5,825	6,442.0	0.90	0.88-0.93	9,109	10,533.7	0.87	0.85-0.88
All Malignant Neoplasms (140-208)	417	462.1	0.90	0.82-0.99	560	640.4	0.87	0.80-0.95	1,563	1,655.3	0.94	0.90-0.99	2,530	2,747.1	0.92	0.89-0.96
Buccal Cavity & Pharynx (140-149)	8	11.9	0.66	0.24-1.22	11	16.7	0.66	0.33-1.18	33	43.2	0.76	0.51-1.05	51	71.4	0.72	0.53-0.94
Esophagus (150)	10	13.0	0.73	0.32-1.32	20	17.9	1.12	0.68-1.73	34	45.4	0.76	0.52-1.05	64	75.9	0.84	0.64-1.06
Stomach (151)	18	16.3	1.09	0.61-1.67	21	22.8	0.92	0.54-1.35	52	60.1	0.86	0.63-1.12	89	98.9	0.90	0.72-1.11
Colorectal (153-154)	51	46.0	1.11	0.83-1.46	63	63.9	0.98	0.74-1.25	142	166.9	0.85	0.72-1.00	254	275.7	0.92	0.81-1.04
Biliary Passages & Liver (155,156)	5	11.9	0.41	0.09-0.86	11	16.3	0.67	0.34-1.21	33	41.8	0.80	0.54-1.11	49	69.7	0.71	0.52-0.93
Pancreas (157)	21	24.2	0.86	0.50-1.28	29	33.6	0.86	0.55-1.21	86	86.8	0.99	0.78-1.21	135	144.0	0.94	0.79-1.11
Larynx (161)	9	5.2	1.71	0.67-3.03	9	7.3	1.24	0.57-2.36	20	18.6	1.07	0.66-1.66	37	31.0	1.19	0.81-1.61
Bronchus, Trachea, & Lung (162)	140	157.0	0.89	0.75-1.05	186	216.8	0.86	0.74-0.99	562	552.0	1.02	0.94-1.11	884	922.2	0.96	0.90-1.03
Breast (174, 175)	0	0.5	--	0.00-6.72	0	0.8	0.00	0.00-4.81	2	2.0	1.00	0.12-3.63	2	3.3	0.61	0.07-2.19
Prostate (Males only) (185)	35	38.3	0.91	0.64-1.27	48	52.1	0.92	0.68-1.22	133	138.4	0.96	0.80-1.14	215	227.8	0.94	0.82-1.08
Testes & Other Male Genital Organs (186, 187)	1	1.4	0.70	0.02-3.92	2	2.2	0.90	0.11-3.26	3	6.0	0.50	0.10-1.47	6	9.6	0.62	0.17-1.22
Kidney (189.0-189.2)	12	12.1	0.99	0.51-1.73	18	16.8	1.06	0.59-1.62	46	42.9	1.07	0.77-1.40	75	71.6	1.05	0.82-1.31
Bladder & Other Urinary (188, 189.3-189.9)	7	11.8	0.60	0.24-1.23	16	16.3	0.98	0.56-1.60	37	43.2	0.85	0.58-1.16	59	70.9	0.83	0.62-1.06
Melanoma of Skin (172)	8	9.4	0.85	0.37-1.68	13	13.2	0.98	0.47-1.59	27	34.2	0.78	0.50-1.11	47	56.5	0.84	0.61-1.11
Brain & CNS (191-192)	16	13.9	1.14	0.60-1.78	17	19.7	0.86	0.47-1.32	50	51.1	0.99	0.73-1.29	83	84.3	0.98	0.78-1.22
Thyroid & Other Endocrine Glands (193-194)	0	1.5	--	0.00-2.52	2	2.1	0.96	0.12-3.48	10	5.3	1.85	0.77-3.19	12	8.9	1.34	0.62-2.22
Bone (170)	0	1.0	--	0.00-3.81	1	1.4	0.71	0.02-3.96	7	3.8	1.80	0.57-3.40	8	6.2	1.27	0.45-2.33
All Lymphatic, Haematopoietic Tissue (200-208)	47	46.2	1.01	0.73-1.33	59	64.5	0.92	0.70-1.18	154	168.1	0.92	0.78-1.08	259	277.7	0.93	0.82-1.05
Hodgkins Disease (201)	3	2.3	1.29	0.27-3.76	23	25.2	0.91	0.58-1.37	10	9.5	1.05	0.50-1.93	18	15.4	1.16	0.64-1.77
Non-Hodgkins Lymphoma (200, 202)	18	18.1	0.99	0.55-1.50	5	3.6	1.40	0.46-3.27	57	65.5	0.87	0.65-1.11	97	108.4	0.89	0.72-1.08
Leukemia & Aleukemia (204-208)	25	17.5	1.42	0.88-2.04	22	24.4	0.90	0.56-1.36	67	64.0	1.04	0.80-1.31	113	105.5	1.07	0.89-1.29
Chronic Lymphocytic Leukemia (204.1)	7	3.3	2.12	0.68-4.01	3	4.5	0.67	0.14-1.95	14	11.7	1.19	0.59-1.91	24	19.3	1.23	0.75-1.78
Leukemia other than CLL	18	14.4	1.25	0.74-1.98	19	20.1	0.94	0.57-1.47	53	52.8	1.00	0.74-1.29	90	87.0	1.03	0.82-1.26
Multiple Myeloma	1	7.7	0.13	0.00-0.72	9	10.6	0.85	0.39-1.61	19	27.2	0.70	0.39-1.05	29	45.3	0.64	0.41-0.89
Mesothelioma, MN of pleura/peritoneum[4]	1	0.9	1.06	0.03-5.89	0	1.3	0.00	0.00-2.87	6	3.3	1.81	0.50-3.58	7	5.5	1.26	0.40-2.39
Smoking-related cancers	207	235.2	0.88	0.76-1.01	289	325.3	0.89	0.79-1.00	818	832.1	0.98	0.92-1.05	1,305	1,387.0	0.94	0.89-0.99

Worker Population	Monitored for Radiation				SSFL[1]				Other Rocketdyne[2]				Total Rocketdyne[3]			
No. of Workers	4,855				6,579				21,304				32,587			
Person-years of Observation	138,836				206,261				577,412				920,261			
Cause of Death (ICD9)	**Obs**	**Exp**	**SMR**	**95% CI**	**Obs**	**Exp**	**SMR**	**95% CI**	**Obs**	**Exp**	**SMR**	**95% CI**	**Obs**	**Exp**	**SMR**	**95% CI**
AIDS (042-044, 795.8)	1	15.4	0.07	0.00-0.36	5	20.8	0.24	0.08-0.56	28	84.7	0.33	0.22-0.48	34	120.5	0.29	0.20-0.39
Diabetes (250)	16	28.8	0.56	0.32-0.90	28	39.6	0.70	0.45-0.99	89	102.4	0.87	0.69-1.06	133	170.1	0.78	0.65-0.92
Cerebrovascular Disease (430-438)	58	84.4	0.69	0.51-0.88	86	117.5	0.73	0.58-0.90	279	322.7	0.87	0.77-0.97	421	522.8	0.81	0.73-0.89
All Heart Disease (390-398, 404, 410-429)	471	602.7	0.78	0.71-0.86	713	842.1	0.85	0.79-0.91	2,132	2,241.6	0.95	0.91-0.99	3,304	3,673.3	0.90	0.87-0.93
Non-malignant Respiratory Disease excluding Pneumonia and Influenza	62	95.2	0.65	0.50-0.83	134	130.7	1.03	0.86-1.21	327	344.7	0.95	0.85-1.06	522	568.3	0.92	0.84-1.00
Emphysema (492)	16	21.5	0.74	0.43-1.21	29	30.2	0.96	0.64-1.38	76	81.9	0.93	0.73-1.16	121	133.2	0.91	0.76-1.09
Cirrhosis of Liver (571)	32	66.2	0.48	0.32-0.66	40	94.1	0.43	0.30-0.58	149	244.9	0.61	0.52-0.72	221	403.9	0.55	0.48-0.63
Nephritis & Nephrosis (580-589)	11	9.1	1.21	0.60-2.16	9	12.7	0.71	0.33-1.35	32	33.8	0.94	0.62-1.30	52	55.4	0.93	0.69-1.21
All External Causes of Death (800-999)	91	144.1	0.63	0.51-0.78	148	210.0	0.70	0.59-0.83	407	603.6	0.68	0.61-0.74	641	955.3	0.67	0.62-0.73
Accidents (850-949)	55	84.7	0.65	0.48-0.83	91	124.1	0.73	0.59-0.90	241	357.0	0.68	0.59-0.77	384	564.4	0.68	0.62-0.75
Suicides (950-959)	27	43.7	0.62	0.39-0.87	49	63.3	0.77	0.56-1.01	136	176.7	0.77	0.65-0.91	209	283.0	0.74	0.64-0.84
Unknown Causes of Death	24				43				153				221			

[1] 182 test stand mechanics who were monitored for radiation have been included

[2] Other Rocketdyne' comprised of not monitored for radiation workers at non-SSFL facilities such as De Soto Avenue and Canoga Park

[3] Because of race-weighting in SMR calculations, subpopulation sums do not match total exactly. Also 182 workers monitored for radiation are also included in the SSFL population.

[4] Mesothelioma was not a codeable cause of death until 1999: ICD10 (C45). Before 1999, cancer of the pleura and peritoneum (ICD9 158.8, 158.9, 163) have been used as crude approximations of mesothelioma mortality.

Appendix Table A4. Comparison of expected number of deaths and SMRs using three different sets of mortality rates for 46,970 Rocketdyne workers employed at least 6 months, 1948-1999 (gender and race combined). 46,970 total Rocketdyne workers and 1.3 million years of follow-up.

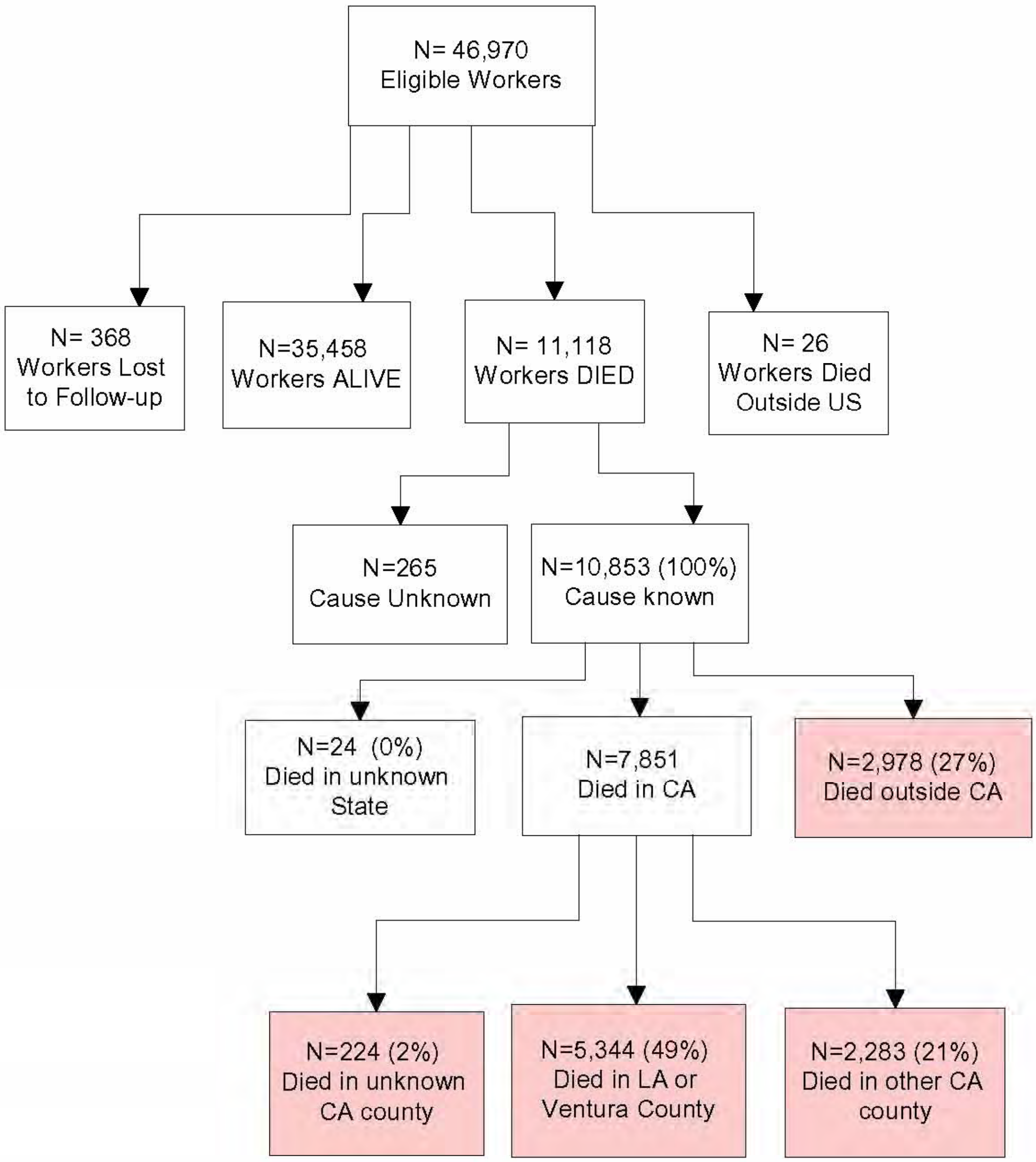
Population Rates		United States			California			Los Angeles/Ventura County		
Cause of Death (ICD9)	**Obs**	**Exp**	**SMR**	**95% CI**	**Exp**	**SMR**	**95% CI**	**Exp**	**SMR**	**95% CI**
All Causes of Death (001-999)	11,118	13,873.6	0.80	0.79-0.82	12,816.9	0.87	0.85-0.88	12,943.9	0.86	0.84-0.88
All Malignant Neoplasms (140-208)	3,189	3,727.9	0.86	0.83-0.89	3,448.9	0.93	0.89-0.96	3,388.4	0.94	0.91-0.97
Buccal Cavity & Pharynx (140-149)	64	86.6	0.74	0.57-0.94	85.9	0.75	0.57-0.95	89.4	0.72	0.55-0.91
Esophagus (150)	73	98.0	0.75	0.58-0.94	87.5	0.83	0.65-1.05	84.5	0.86	0.68-1.09
Stomach (151)	109	113.4	0.96	0.79-1.16	119.6	0.91	0.75-1.10	129.6	0.84	0.69-1.02
Colorectal (153-154)	303	382.1	0.79	0.71-0.89	339.8	0.89	0.79-1.00	343.7	0.88	0.79-0.99
Biliary Passages & Liver (155,156)	61	86.2	0.71	0.54-0.91	90.7	0.67	0.51-0.86	100.8	0.61	0.46-0.78
Pancreas (157)	169	182.0	0.93	0.79-1.08	177.8	0.95	0.81-1.11	176.3	0.96	0.82-1.11
Larynx (161)	42	43.3	0.97	0.70-1.31	34.8	1.21	0.87-1.63	38.1	1.10	0.79-1.49
Bronchus, Trachea, & Lung (162)	1,068	1,269.3	0.84	0.79-0.89	1,098.7	0.97	0.92-1.03	1,028.5	1.04	0.98-1.10
Breast (174, 175)	108	118.5	0.91	0.75-1.10	119.6	0.90	0.74-1.09	123.3	0.88	0.72-1.06
All Uterine (Females only) (179-182)	19	29.6	0.64	0.39-1.00	28.4	0.67	0.40-1.04	30.8	0.62	0.37-0.96
Cervix Uteri (180)	7	15.7	0.45	0.18-0.92	14.5	0.48	0.19-0.99	15.9	0.44	0.18-0.91
Other Female Genital Organs (183-184)	31	37.4	0.83	0.56-1.18	38.4	0.81	0.55-1.15	39.6	0.78	0.53-1.11
Prostate (Males only) (185)	229	246.0	0.93	0.81-1.06	237.0	0.97	0.85-1.10	226.0	1.01	0.89-1.15
Testes & Other Male Genital Organs (186, 187)	6	9.8	0.61	0.22-1.33	9.9	0.60	0.22-1.31	10.1	0.59	0.22-1.29
Kidney (189.0-189.2)	86	89.2	0.96	0.77-1.19	82.3	1.05	0.84-1.29	79.5	1.08	0.87-1.34
Bladder & Other Urinary (188, 189.3-189.9)	65	81.9	0.79	0.61-1.01	78.1	0.83	0.64-1.06	79.6	0.82	0.63-1.04
Melanoma of Skin (172)	55	57.2	0.96	0.72-1.25	64.1	0.86	0.65-1.12	61.0	0.90	0.68-1.17
Brain & CNS (191-192)	102	100.6	1.01	0.83-1.23	101.5	1.01	0.82-1.22	104.4	0.98	0.80-1.19
Thyroid & Other Endocrine Glands (193-194)	13	11.2	1.16	0.62-1.99	11.5	1.13	0.60-1.93	12.0	1.08	0.58-1.85
Bone (170)	11	8.8	1.24	0.62-2.23	7.5	1.46	0.73-2.61	8.2	1.35	0.67-2.41
All Lymphatic, Haematopoietic Tissue (200-208)	314	347.9	0.90	0.81-1.01	336.5	0.93	0.83-1.04	342.8	0.92	0.82-1.02
Hodgkins Disease (201)	23	21.1	1.09	0.69-1.63	18.6	1.24	0.79-1.86	19.9	1.15	0.73-1.73
Non-Hodgkins Lymphoma (200, 202)	122	133.3	0.92	0.76-1.09	131.5	0.93	0.77-1.11	133.8	0.91	0.76-1.09
Leukemia & Aleukemia (204-208)	124	130.9	0.95	0.79-1.13	126.6	0.98	0.81-1.17	128.8	0.96	0.80-1.15
Chronic Lymphocytic Leukemia (204.1)	25	25.7	0.97	0.63-1.44	22.1	1.13	0.73-1.67	21.6	1.16	0.75-1.71
Leukemia other than CLL	99	106.1	0.93	0.76-1.14	105.4	0.94	0.76-1.14	107.8	0.92	0.75-1.12
Multiple Myeloma (203)	N/A	N/A	N/A	N/A	56.1	0.75	0.54-1.01	56.6	0.74	0.54-1.00
Mesothelioma, MN of pleura/peritoneum	8	7.0	1.14	0.49-2.25	6.3	1.27	0.55-2.49	5.4	1.47	0.64-2.90
Smoking-related cancers[1]	1,567	1,850.3	0.85	0.81-0.89	1,645.1	0.95	0.91-1.00	1,575.9	0.99	0.95-1.04
AIDS (042-044, 795.8)	39	86.2	0.45	0.32-0.62	137.0	0.29	0.20-0.39	173.6	0.23	0.16-0.31
Diabetes (250)	175	279.3	0.63	0.54-0.73	221.0	0.79	0.68-0.92	248.2	0.71	0.61-0.82
Cerebrovascular Disease (430-438)	553	713.1	0.78	0.71-0.84	675.7	0.82	0.75-0.89	673.6	0.82	0.75-0.89
All Heart Disease (390-398, 404, 410-429)	3,838	4,853.0	0.79	0.77-0.82	4,274.4	0.90	0.87-0.93	4,628.9	0.83	0.80-0.86
Non-malignant respiratory disease excluding pneumonia and influenza	639	734.6	0.87	0.80-0.94	689.3	0.93	0.86-1.00	584.3	1.09	1.01-1.18
Emphysema (492)	138	141.0	0.98	0.82-1.16	155.8	0.89	0.74-1.05	138.7	1.00	0.84-1.18
Cirrhosis of Liver (571)	272	332.7	0.82	0.72-0.92	481.1	0.57	0.50-0.64	528.6	0.52	0.46-0.58
Nephritis & Nephrosis (580-589)	70	111.0	0.63	0.49-0.80	70.7	0.99	0.77-1.25	73.4	0.95	0.74-1.20

Population Rates		United States			California			Los Angeles/Ventura County		
Cause of Death (ICD9)	**Obs**	**Exp**	**SMR**	**95% CI**	**Exp**	**SMR**	**95% CI**	**Exp**	**SMR**	**95% CI**
All External Causes of Death (800-999)	777	1,133.3	0.69	0.64-0.74	1,167.3	0.67	0.62-0.71	1,133.0	0.69	0.64-0.74
Accidents (850-949)	459	690.2	0.67	0.61-0.73	677.2	0.68	0.62-0.74	597.3	0.77	0.70-0.84
Suicides (950-959)	246	269.9	0.91	0.80-1.03	328.8	0.75	0.66-0.85	329.1	0.75	0.66-0.85
Unknown Causes of Death	280									

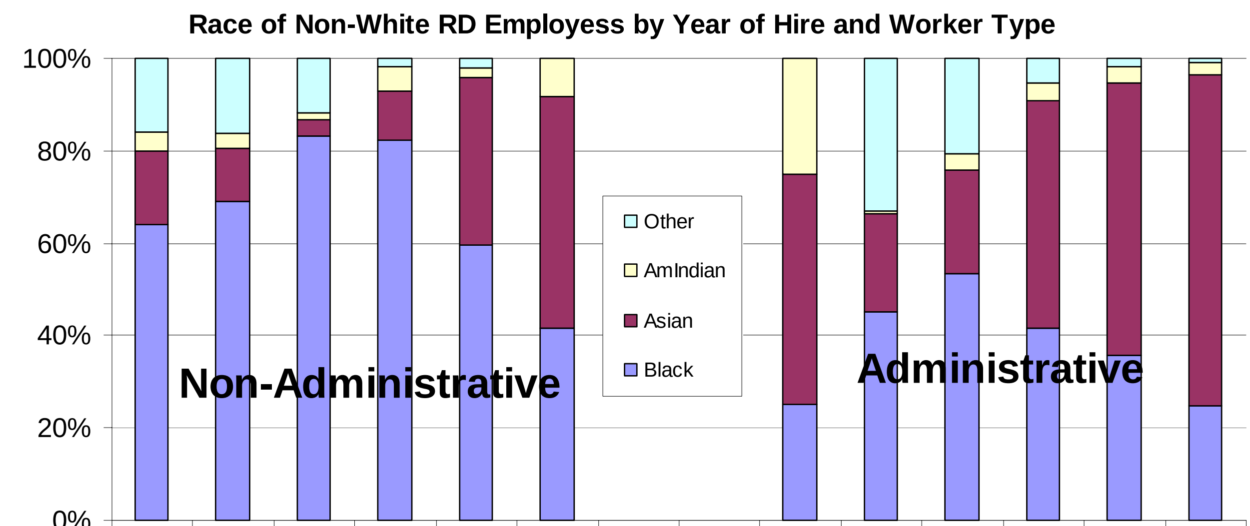
[1] Mesothelioma was not a codeable cause of death until 1999: ICD10 (C45). Before 1999, cancer of the pleura and peritoneum (ICD9 158.8, 158.9, 163) have been used as crude approximations of mesothelioma mortality.

Appendix A5. Place of Death for Rocketdyne Workers

December 1, 2004



Appendix A6.



	1928-50	1950-59	1960-69	1970-79	1980-89	1990-99			1928-50	1950-59	1960-69	1970-79	1980-89	1990-99
Other	4	41	38	4	10	0			0	52	52	28	16	3
AmIndian	1	8	5	12	10	1			1	1	9	20	31	8
Asian	4	29	12	24	172	6			2	33	56	261	526	217
Black	16	175	271	185	283	5			1	71	134	221	317	75

Distribution of Race of the Non-White Rocketdyne Workers by Year of Hire and Whether Employed in an Administrative Job. Over the year, Black employees were the most prevalent racial group until the 1980s when they were surpassed by Asian employees.

ROCKETDYNE WORKER HEALTH STUDY

Appendix B

INTERNATIONAL EPIDEMIOLOGY INSTITUTE

Study Topics

July 13, 2005

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Appendix B. Study Topics

Appendix B covers a group of diverse topics that were addressed during the conduct of the study.

B1. Asbestos

B2. Beryllium

B3. Value of the Phone Books (personal listings) in Identifying Test Stand Mechanics

B4. Value of Medical Index Cards in Identifying Workers and Transfer Workers

B5. Value of Medical Records in Confirming Chemical Assignments

B6. Quality Control Procedures

B7. Distinguishing workers by pay type (hourly, salary) and administrative and non-administrative jobs

B8. Overall Vital Status Tracing and Cause of Death Determination Flowchart

Appendix B1. Asbestos

Asbestos. Asbestos was used in thermal system insulation materials in several locations at Atomics International, including the sodium pit of Building 143 and in the sodium loops in Building 6. Small amounts of asbestos also could be found at test stands in some miscellaneous materials such as gaskets and wiring insulation, but it was not extensively used in thermal system insulation. To evaluate whether asbestos exposure might have resulted in an increased cancer risk in this population, an attempt was made to identify workers who developed or died from mesothelioma. All Rocketdyne workers, including the 5,801 radiation workers, were included in this evaluation.

Identifying workers who died from mesothelioma was not straightforward because it was only in 1999 that mesothelioma *per se* was classified as a cause of death in ICD10 (C45). Prior to 1999, mesothelioma deaths had to be identified or estimated from surrogates such as cancer of the pleura or cancer of the peritoneum in ICD9 (163, 158.8, 158.9). For deaths back to 1950 there is no generally accepted range of ICD codes that might indicate death due to mesothelioma. For example, if the cause of death was listed as mesothelioma without mention of site, an "other cancer" code (ICD8, 199.1) most often would be assigned. Attempts to obtain a comprehensive listings of possible ICD codes included contacting CDC and NCHS, Harvard University, the SEER registries, IARC, NRPB and investigators such as Julian Peto in the United Kingdom (Peto et al., 1981). An article by the Wisconsin Division of Health, the lead agency for the EPA's School Asbestos Programs since 1979, was also informative (Anderson et al., 1991). The "likely" and possible codes for which death certificates were searched for mention of mesothelioma included the following:

ICD (years)	Likely Codes	Possible codes
10th (1999+)	C45	
9th (1979-98)	163, 158.8, 158.9	199.1, 199.9, 212.4, 229.9
8th (1968-78)	163.0	158.8, 158.9, 199.1, 212.3, 212.4, 228
7th (1958-67)	162.2	158, 197.9, 211, 212, 227
6th (1950-57)	162.2	158, 197.9, 211, 212, 227

Death information from the NDI also included contributing causes of death and these were also sought for possible mesothelioma involvement. To date, there were 11 deaths with "likely codes" of which 8 were found to have mention of mesothelioma on the death certificate. The other 3 deaths were found to be lung cancer cases dying in 1968 for which cause of death had been incorrectly coded using the ICD7 for lung cancer (which was the same code as cancer of the pleura in ICD8). UCLA reported 4 mesotheliomas in their cohort (CHEM FINAL REPT 1999), and 3 of our 7 mesothelioma deaths occurred after 1994 when the UCLA follow up ended. An evaluation of the work histories revealed nothing remarkable about the job held at Rocketdyne/Atomics International. No mesothelioma deaths occurred among SSFL workers, 1 occurred among radiation workers and 7 among the other Rocketdyne workers.

It should be noted that we did not exclude in any of the SMR analyses the 3 lung cancers that were mis-coded as pleural cancers. In 1967 lung cancer was coded as 163 (ICD7), but in 1968 cancers of the pleura was coded as 163 (ICD8). Occasionally the wrong code was used during these transitional years. Because the CA rates used to compute expected values used these incorrect values we did not change the observed numbers since we had no way of correcting the expected numbers.

In additional to the mortality evaluation, linkage with the California Surveillance Program for cancer incidence in Los Angeles county was performed. Workers with mesothelioma histology codes (M-9500, M-9501, M-9502, M-9503 and M-9055) were identified and their job histories and death certificates were being evaluated. Two incident cases overlapped with the 7 deaths due to mesothelioma mentioned above. One worker had a “deferred” cause of death on his certificate and thus was not identified from the mortality searches. Several had mention of “mesothelioma” on their death certificates, but were not coded to any of our possible categories above, e.g., causes of death included suicide, hypertension and melanoma. One worker was diagnosed with mesothelioma in 1990 and is still alive. Additional workers who developed mesothelioma were identified from Rocketdyne files, e.g., compensation claims and Human Resource evaluations. One worker did not have a Kardex work history. Another had worked in the U.S. Navy. Searching over 2,000 death reports from the NDI for contributing causes of death did not identify any additional mesotheliomas. Nor did searches of the available 4,000 death certificates from the Boeing Company.

For the causes of death due to mesothelioma in ICD10 and surrogate “likely” causes in the other ICDs, we computed observed to expected ratios to learn whether their might be an observable increase in comparison with the general population of California (OBS = 8, EXP = 6.3; SMR = 1.27; 95% CI = 0.55-2.49). However, it should be noted that 3 of these deaths were lung cancers mis-coded as mesothelioma.

For the totality of workers who developed or died of mesothelioma, we looked at their work histories to learn whether any clusters of occupations in time and place have occurred that might suggest a common exposure to asbestos. Most workers were employed at Canoga Park or DeSota Avenue and few workers (2) were employed at SSFL, few were radiation workers (5), several were short-term workers, several had asbestos exposure prior to Rocketdyne employment (e.g., one worker was a financial planner at Rocketdyne who’s asbestos exposure had occurred 40 years previously). Workers identified appeared to be an eclectic group with no discernible similarities. Job titles included research engineer, lathe machinist, physician, buyer, estimator, truck driver, stock room clerk, propulsion test technician, mechanic AER, rocket assembler, and sheet metal. The sources of identifying the 22 mesothelioma diagnoses are also eclectic.

Job Category	**No.**	**%**
SSFL-Non-Administrative	1	4.6
Test Stand Engineer	1	4.6
Non-SSFL Non-Administrative	11	50.0
Non-SSFL Administrative	4	18.2
Radiation Monitored	5	22.7
Total	22	100.0

There was little suggestion of an asbestos problem based on mortality evaluations (8 observed vs 6.3 expected) and the "total" 22 cases identified from cancer registry linkage, available death searches, multiple cause of death evaluations and company records is about what would be roughly expected (i.e., cases about 3 times deaths).

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Peto J, Henderson BE, Pike MC, et al. Trends in mesothelioma incidence in the United States and the forecast epidemic due to asbestos exposure during World War II. In Peto R, Schneiderman M (eds) Quantitation of Occupational Cancer. Banbury Report 9. Cold Spring Harbor Laboratory, 1981, pp 51-85.

Appendix B2. Beryllium

Beryllium. Beryllium powder was mixed with oxidizers for use in experimental rocket propellants in some research areas and thrust chambers of the Mars Orbiter Engine (RS 21) was made of beryllium metal. A beryllium neutron reflector was used in the development of the SNAP rocket. The number of workers exposed to beryllium appeared small but a mortality analysis was conducted to learn the extent of any potential problem.

An evaluation of the death certificates for all causes of death with a potential for beryllium contribution was conducted. All Rocketdyne workers, including the 5,801 radiation workers were included in this evaluation. Over 10,000 deaths were evaluated covering the years 1950 through 1999, with 4 different ICD classifications. Codes for each of these ICD classifications were selected that corresponded to acute berylliosis, chronic beryllium disease, other chronic interstitial pneumonia, other pneumoconioses and related diseases, or pulmonary fibrosis. Only 1 of 28 matches had a specific beryllium code (ICD8 - 516.0). 25 matches were “pulmonary fibrosis” and 2 were “other” interstitial lung disease. Only the one beryllium code had mention of beryllium on the death certificate.

This analysis was extended later to include all multiple causes of death (available from NDI). No new cases of beryllium disease were found.

All ICD codes with specific mention of beryllium *(ICD10 - J63.2 ; ICD9 - 503; ICD8 - 516.0; ICD7 - 524)* were included as were the less specific diagnoses that might indicate possible beryllium involvement. The codes evaluated were:

ICD10 (1999+)

Definite:	J63.2	**Berylliosis** (lung). Pneumoconiosis due to inhalation of **beryllium**.
Definite:	J84.9	Interstitial pneumonia

ICD9 (1979-98)

Likely:	503	Pneumoconiososis due to other inorganic dust (including **Berylliosis**)
Possible:	508.9	Respiratory conditions due to unspecified external agent
Possible:	515	Postinflammatory pulmonary fibrosis

ICD8 (1968-78)

Likely:	516.0	Other pneumoconioses and related disease, due to inhalation of other inorganic dust (including **Berylliosis**)
Possible:	517	Other chronic interstititial pneumonia

ICD7/6 (1950-67)

Likely:	524	Other specified pneumoconiosis and pulmonary fibrosis of occupational origin
Possible:	523.3	Pneumoconiosis NOS

The causes of death also were evaluated in a group of over 95 workers who were identified as having potential for exposure to beryllium from company records such as the HSIS air sampling database. Thirteen of these workers had died but none had any of the “beryllium” diseases or possible diseases listed above.

Summary. The mortality data provided little indication of excessive exposure to beryllium. However, multiple causes of death could be evaluated only after 1978 from the NDI linkages. California death tapes do not include multiple causes of deaths. The NDI data were supplemented with evaluation of the over 4,000 death certificates available from the Boeing Company and from the various state departments of vital statistics.

Appendix B3. Personnel Listings

Rocketdyne Personnel Assignment Listings (Phone books). We located and computerized the Rocketdyne phone books for the period from 1956 to 1994, with the exception of 1967-1969 and 1971-1972 which could not be found. The phone books listed the specific test stand where a person worked. Complete rosters were available for the period 1956-1966, which covered both the highest employment period at SSFL and the greatest amount of chemical usage. Although phone books prior to 1956 where not available, this was of little consequence since it is likely that neither TCE nor hydrazine were used extensively before 1956.

The phone books proved to be valuable in two ways. First, they allow us to place test mechanics at specific test stands during specific years. This ability, coupled with the knowledge of where and when specific chemicals were used, allowed a better estimate of exposure to specific chemicals. Second, the phone books identified a large number of additional test stand mechanics not in our Kardex database or in the previous study cohort. To obtain work history information on these workers, however, it was necessary to identify the specific facility or division within Rockwell/Rocketdyne where the workers transferred taking their Kardex cards with them. This transfer information often was found on nearly 55,000 medical index cards that we had scanned into an accessible database. Armed with employee name and transfer division, Boeing personnel were able to locate the "missing" Kardex cards for most of these test stand mechanics who had been employed in the 1950s and 1960s.

Appendix B4. Medical Index Cards

Medical Index Cards. Over 55,000 medical index cards were available in the Boeing medical offices. They often included personal information such as name, social security number, serial number, date of birth, date of hire, date of transfer, date of termination. As above (B3), they were extremely helpful in directing our efforts to obtain missing Kardex cards for test stand mechanics identified from the personnel listings (phone books). They were also used in quality control measures to confirm spellings of names, important dates, social security numbers and whether a worker was actually employed at Rocketdyne (i.e., whether a serial number was present).

Appendix B5. Medical Records

Medical Records. As discussed fully in the Chemical paper, a conscientious medial assistant interviewed workers who were undergoing special physical examination because of working with toxic substances. Often recorded was the test stand and actual chemicals worked with. These records were used to validate our chemical exposure assignments. Unfortunately, in the late 1960s it appears that records for all workers who had terminated employment were destroyed so the early years were not complete.

Use of medical records. There are two sources of medical information, 55,000 medical index cards and 28,000 medical history folders. The medical index cards were useful in locating workers who transferred and in confirming or supplying identifying information such as social security number, serial number, date of birth and date of hire. The actual medical records, available for over half the work force, was used to confirm the fact of chemical exposure and in some instances actually provide exposure information for those workers not found in the phone book listings. From a sample of over 120 medical history folders, we found specific information on chemical exposures, on the specific test stand where the employee worked, and on smoking history. The medical records also indicated, and later confirmed by interviews with employees and with medical personnel who worked 1967-95, that not all test stand mechanics received medical examinations. It appears that test stand mechanics who worked with hydrazines or other toxic chemicals received routine or specialized medical exams, whereas, most mechanics working at the large test stands did not. Prior to the late 1960s, medical records were kept only for about 5 to 7 years after a worker terminated employ and so are not complete for some of the earliest workers.

Appendix B6
Quality Control Procedures

Data Entry Errors

Work histories of Rocketdyne employees prior to 1972 were recorded on Kardex brand work history forms. Pertinent personal identifier, demographic variables, and work history from these records was keyed into a Microsoft Access database. As with any large-scale data entry operation, some degree of keying error will occur. In order to minimize these errors, a number of quality controls mechanisms were implemented.

In addition to the hard-copies of the Kardex records, Rocketdyne also provided an image-based database (Alchemy) containing some personal identifiers (name and SSN) for most of the Kardex records. Data from extracted from the Alchemy database and was pre-loaded into the Access data entry system. During the keying operation, if the keyed values for name, date of birth, and Social Security number (SSN) were identical to the value extracted from the Alchemy system, the keyed value was accepted. If the keyed value was different from the Alchemy value or the Alchemy value was missing, the data entry system warned the data entry operator, and required the value to be typed again. In addition, at the conclusion of data entry, any discrepancies between the keyed values and the Alchemy systems in key personal identifiers were manually reviewed and corrected in the Access system.

Missing /Incorrect Personal Identifiers and Duplicate Records

Because of the complexity of this study, it was necessary to utilize a large number of datasets from various sources, such as Rocketdyne electronic human resources records, keyed Kardex Access database, Rocketdyne provided radiation folders, Rocketdyne provided radiation dosimetry records, radiation monitoring agencies, Rocketdyne medical history folders, and from vital status files agencies such as Social Security administration, HCFA, PBI, and others. Every dataset was converted into a SAS dataset, and then underwent a series of procedures in order to fill in missing or reconcile discrepant key personal identifiers such as SSN, name, and date of birth. The methods to do these comparisons typically consisted of 1) identifying discrepant or missing names and/or date of birth once the datasets were merged by SSN; and 2) performing ‘soft’ merges based on name and/or date of birth and identifying missing or incorrect SSNs. If the dataset was supposed to have a unique record for each person, another set of procedures were run in order to identify duplicate records, again by SSN and/or name.

These procedures where often tedious and required an extensive amount of manual review in order to either confirm a correct soft match, or to determine the correct personal identifier or records once a discrepancy or duplicate was discovered. Corrections were made to a modified version to the original dataset (when possible), or hard-coded into the SAS programs that created the file from its original format into SAS. After each dataset underwent these QC procedures, they were then incorporated into a single master relational database.

Job History Categorization

For analytical purposes, it is necessary to categorize persons into discrete categories, such as “Test Stand Mechanic”, “hourly” versus “salary”, or “administrative” versus “non-administrative”, and “Santa Susana” versus “non-Santa Susana” based on a potentially complex work history. For example, a person could have started their career as an non-non-administrative worker, then worked at Santa Susana as a test stand mechanic, and finished their career as a salaried engineer. A hierarchical priority based on ever having a particular job type was developed in order to categorize persons into 10 discrete job type categories. Hourly/salaried status was determined based the time spent in hourly jobs as a percentage of their total career time. Administrative/non-administrative status was determined based on the final job category placement. Santa Susana status was based on ever having worked at a Santa Susana facility. A number of procedures were performed to test the accuracy of these algorithms.

First, a listing of all job titles within four mutually exclusive categories (hourly and administrative, hourly and non-administrative, salaried and non-administrative, and salaried and non-administrative) of worker types was created. An industrial hygienist then reviewed the job titles within each of the four categories. For the most common job titles that did not appear in the appropriate category, the complete work histories of a sample of workers with that particular job title were reviewed by an industrial hygienist.

Also, a random sample of 25 hourly and 25 salaried Santa Susana workers, and 15 hourly and 15 salaried radiation workers was drawn, and underwent a thorough review to determine if the ‘hourly’/’salary’ designation was accurate. All Santa Susana workers were determined to have been assigned correctly. Within the radiation workers, one worker had insufficient work history to accurately determine final hourly/salaried status.

During data entry into the Access database, for efficiency, persons with work histories with no positions at the Santa Susana facility had only the first job keyed. Therefore, if this person terminated prior to 1972, the hourly/salary designation of this job type would be the only electronic record available to calculate time spent within either hourly or salaried jobs. In order to test if this method was accurate to properly classify persons as either hourly or salaried, a random sample of 25 hourly and 25 salaried Santa Susana workers with job history records from Kardex records only were sampled. A manual review of the entire Kardex work history was conducted, and time spent within each job pay type was calculated. One person out of the sample was classified as salaried (based on their first job), although they spent over 20% of their total career time as hourly. Therefore the method used to assign pay type to non-Santa Susana workers who terminated prior to 1972 was measured to be 98% accurate.

Industrial Hygiene Chemical Exposure

In order to test the accuracy of the chemical exposure assessment, we selected six test stand mechanics from each of the six chemical exposures (total time as a test stand mechanic, TCE Flush time, Number of TCE Flushes per year per mechanic, TCE Utility time, likely hydrazine and possible hydrazine exposure time) including mechanics with no exposure. An industrial hygienist performed a thorough review of these work histories directly from the raw Kardex or human resources provided electronic file, with special emphasis on test stand location, chemical used at that test stand location during that time period, job type, and time within each position. The independent results were then compared with the calculated results generated from the computer programs. For all selected persons, the value derived from manual review matched the computed generated value.

Radiation Dosimetry

A number of radiation dosimetry data sources where obtained to reconstruct the entire dose history for Rocketdyne workers. In addition to the personal identifier check outlines above, a number of quality control procedures where performed on the dose histories in order to check the accuracy and completeness of the individual sources. One procedure consisted of calculating a worker’s career dose at a specific date in two or more radiation data sources, and comparing the values. Doing so would determine the relative completeness of the individual data sources. If discrepancies were found, a manual review of each of the dose histories could then identify chronological gaps in dose history within one of the data sources, or inaccurate, misclassified, or miskeyed dose readings. More details on the approach to radiation dosimetry can be found in the Dosimetry Paper and Uranium Aluminide Paper.

Appendix B7: Distinguishing Pay Type and Administrative/Non-Administrative Jobs

Determining Hourly/Salaried Status

Position records from both the Kardex and human resources electronic file were appended together into a complete Rocketdyne workforce work history database. Positions with zero days (i.e. records for an administrative change only) were deleted from the entire work history database. Every position had a start date, an end date, (from which the number of days worked at the position was calculated), a numeric *job code*, and a numeric *pay code*. Rocketdyne Human Resources personnel provided a list that linked pay type (i.e. hourly or salaried) to the majority of numeric pay codes. This list was used to assign a pay-type of either 'Hourly', or 'Salaried', to each *position* based on the pay-code. However, for about 14% of the positions, the pay code was either missing, or was not on the list provided by Rocketdyne.

In order to assign an Hourly/Salaried designation to the missing pay code positions, we used the frequency of the pay type among each specific *job code*. That is, all positions were subset into 3 datasets: those with an 1) 'Hourly', 2) 'Salaried', or 3) ‘Unknown’ pay-type. Among the hourly and salaried positions datasets, the number of times the pay-type occurred within each unique job code was calculated. These two datasets were merged together by job-code, to produce the following:

JobCode	JobTitle	HourlyCount	SalaryCount
111	Mechanic	90	10
222	Engineer	10	90
333	Expeditor	40	60

The percentage of salaried pay-type was then calculated for each *job code* (SalaryPercent = SalaryCount/(HourlyCount + SalaryCount) * 100). If a particular job-code had a salary percentage GREATER OR EQUAL TO 80%, THEN THAT JOB CODE WAS CONSIDERED A SALARIED JOBCODE. Otherwise, it was considered to be an hourly job code.

Once pay-type was determined for all job codes, the assigned pay-type was merged onto unknown pay-type positions dataset by job code. This allowed a known pay-type to be assigned for over 97% of the 238,000 positions in the RD workforce work history database.

In order to assign a *pay-type to a person*, the sum of the days a particular person spent in each of the 3 pay-type categories (hourly, salaried, or unknown) was calculated. The percentage of time spent in positions with a salaried pay-type (among positions with a KNOWN pay-type) was then calculated for each person as (SalaryPercent = SalaryDays/(SalaryDays + HourlyDays) * 100). A person was considered salaried IF THEY SPENT GREATER THAN OR EQUAL TO 80% OF THEIR WORK HISTORY IN SALARIED POSITIONS. If a person did not have at least one position in their work history with a known pay type, they were categorized as an 'Unknown' pay-type. Otherwise, persons were able to be categorized as either a 'salary' or 'hourly' worker. This allowed for the categorization of 92% of all RD employees as either hourly or salaried based on the keyed work history.

For efficiency, entire work histories were not originally keyed for radiation workers who did not hold positions at the Santa Susanna facility for greater than six months. Because pay type was an important confounder in our statistical analyses, a manual review of the work histories of these approximately 1,900 radiation workers was performed. to classify each worker as either 'Salaried' or 'Hourly'. Administrative/Non-Administrative status was also determined for these workers (see Administrative section). Incorporating these radiation workers increased categorization to 95% of all Rocketdyne employees as either hourly or salaried, and 99% of eligible workers.

Determining Worker Category

Each employee was categorized into a person-level category based on their entire work history such that it best reflected their potential exposure to chemicals in the work place environment. Unlike the pay-type designation, which used the percentage of time within each pay-type, the worker category designation used an ever/never approach giving higher priority to jobs with the greatest potential for chemical exposure. That is, if an employee ever worked as a test stand mechanic, they were categorized as a test stand mechanic, even if they spent the majority of their career in other job categories. The priority ordering used for categorizing workers was:

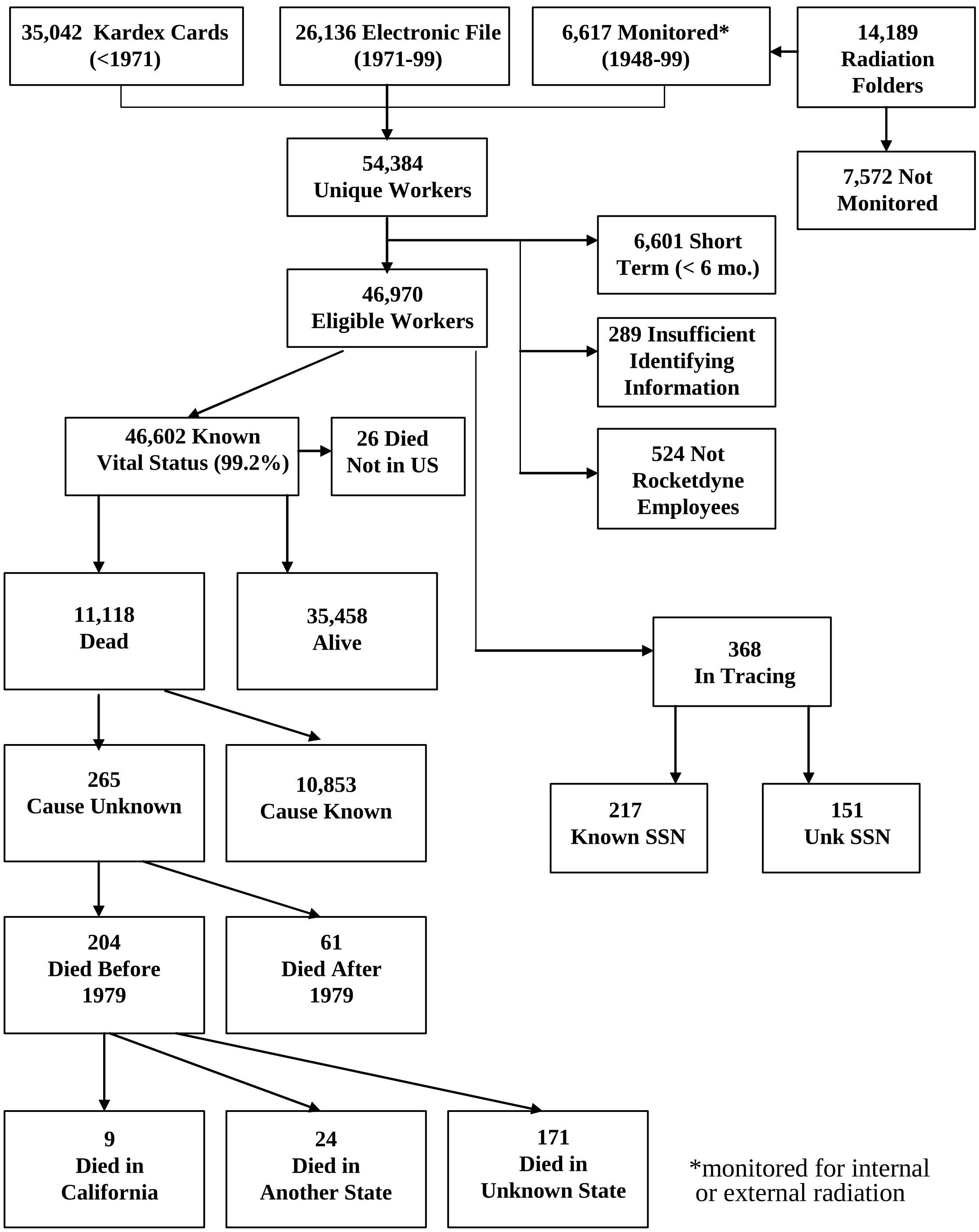
1) Test Stand Mechanic
2) Research Mechanic
3) Research Engineer
4) Test Stand Engineer
5) Instrument Mechanics
6) Inspectors
7) SSFL - Non-administrative
8) SSFL - Administrative
9) NonSSFL - Non-administrative
10) NonSSFL - Administrative

Administrative/Non-Administrative Status

The designation of administrative versus non-administrative was based upon the final person-level category in which a worker was placed. Administrative status was given to research engineers, test stand engineers, and SSFL and Non-SSFL Administrative workers. Non-administrative status was assigned to test stand mechanics, research mechanics, instrument mechanics, inspectors, and SSFL and Non-SSFL non-administrative workers. Thorough checking procedures were performed in order to verify the accuracy of these designations (see Quality Control section, B6).

Appendix B8 Vital Status Tracing and Cause of Death Determination Flowchart

Figure 1. Vital Status of Total Rocketdyne Workforce



Appendix B9. Additional Cancer Incidence Discussion

Cancer Incidence

- The study was designed as a mortality investigation to extend the previous mortality study conducted by UCLA an additional 5 years. This extension, coupled with a larger study size and more comprehensive assessment of exposures, would provide an adequate test to the hypotheses raised in the previous study regarding possible increases in cancer deaths due to radiation and hydrazines.
- Cancer incidence analyses were not vigorously pursued for several reasons. First, the coverage would be incomplete. Although the United States has a national death registry which began in 1979, we do not have a national cancer registry. California has a cancer registry, but it began in 1988 and thus would miss cancers that occurred in the prior 40 years of study follow-up (which began in 1948) and it would miss all cancers that were diagnosed in other states. Los Angeles County has a cancer registry which began in 1973, but would miss cancers that were diagnosed in the prior 25 years of study follow-up and those diagnosed among residents of other counties in California (such as Ventura) as well as cancers that occurred in other states.
- Second, it would not be feasible to obtain information on cancer incidence for workers diagnosed with cancer in California and not covered by the existing cancer registries or for workers who left the state. The mortality investigation indicated that at least 25% of workers had moved out of the state for other employment opportunities or for retirement. Workers had moved to each of the 50 states. Current or last addresses are not available for most of the workers and they are not easily obtained. For those who died, the next of kin would have to be located and permissions received to access medical records. Not only would the cost be prohibitively high, but the difficulties in obtaining complete and accurate data would render results difficult to interpret.
- Third, it was felt that for the cancers of primary interest (i.e., lung cancer and leukemia), that mortality was a good indicator of incidence because the case fatality rate was so high, especially during the lengthy period of follow-up for the investigation (1948-99).
- Finally, a comprehensive mortality coverage of all workers for all years of the study was believed to be a sounder methodologic approach than an incomplete cancer incidence evaluation of an unknown number of workers who remained in the state of California. One limitation in conducting a cancer incidence study in California is that although the number of cancers occurring in and after 1988 among residents could be determined (the numerator), rates could not be accurately estimated because it is not known how many workers are living in California during the period of cancer registration (i.e., the denominator is not known). Given the mobile nature of the worker population and their age, the number of non-California residents might be substantial, and accurate estimates of "person-years" of observation while in cachement areas covered by the cancer registries would be problematic.
- This is not to say that cancer incidence was not looked at. We had matched our

entire worker file with the Los Angeles cancer registry (1973-1999). The matches were used in our evaluation of mesothelioma occurrence as described in Appendix B1. We also note that 36% of the cancers diagnosed in LA county occurred prior to 1988, indicating a minimum percentage of cancers that would be missed if the California registry were relied upon.

- The LA Registry was also used to evaluate the accuracy of the cause of death registrations for workers whose cancers had been diagnosed in LA county.
- We also evaluated the correspondence between cancer incidence and cancer death with regard to the primary cancers of interest. For the combined Radiation and Chemical Cohorts, 172 lung cancers were diagnosed over the years 1973-1999 of whom 156 workers had died (90.7%). For all cancers combined, there were 1,101 diagnoses of cancer of whom 694 (63%) had died. These evaluations indicate that a comprehensive mortality evaluation of all workers, including those who moved throughout the United States, would be a methodologically sound and statistically powerful approach to evaluate possible workplace hazards, in contrast to a cancer incidence study with incomplete calendar years of coverage for an unspecified underlying population (at least at the current time).

ROCKETDYNE WORKER HEALTH STUDY

Appendix C

INTERNATIONAL
EPIDEMIOLOGY
INSTITUTE

Tobacco Use, Smoking Survey

July 13, 2005

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Appendix C. Tobacco Use, Smoking Survey

Appendix C presents analyses of a 2004 survey on smoking habits.

Smoking Evaluation

C1. Health Status

C2. Smoking History

- 2a. Age Started Smoking
- 2b. Current Smokers
- 2c. Age Quite Smoking
- 2d. Cigarettes Per Day
- 2e. Other Tobacco Use
- 2f. Years Smoked
- 2g. Cumulative Amount (Pack-Years)

C3. Exercise

C4. Response Rate

C5. Age at Response

C4. Response Rate

Appendix C.

Smoking Evaluation. To learn more about the smoking habits of hourly and salaried workers, a brief questionnaire survey was conducted in 2004. A sample of living workers was selected and approximately half of those mailed a questionnaire responded (68 hourly and 71 salaried workers). Compared to salaried workers, hourly workers were significantly more likely to have smoked cigarettes (61% vs 41%), to be current smokers (9% vs 0%), to have started smoking at a younger age, to have quit at an older age, to smoke for more years (31.4 yr vs 21.1 yr) and to have consumed more cigarettes during their lifetime as measured in terms of "pack-years". The number of cigarettes smoked each day and the use of other tobacco products, such as cigars, did not differ significantly between the two groups. The survey is limited because only survivors are included and the response rate was low, only 50%. In addition, addresses could only be found for about 50% of those originally selected. Distinctions between SSFL workers and the workers at other facilities by pay type were not informative because of the small numbers, e.g., there were only 29 salaried workers overall who had smoked cigarettes. Nonetheless, these distributions are consistent with information obtained from a sample of over 120 medical records of test stand workers of whom smoking information was available on over 60 who had completed questionnaires in the 1960s which included queries on cigarette smoking habits, i.e., just over 60% of the hourly workers were current or former smokers. National surveys of smoking habits among hourly (blue collar) and salary (white collar) workers also indicate a significantly higher prevalence of smoking among hourly workers compared to salaried workers and hourly workers compared to the general population. These evaluations indicate that caution must be exercised when interpreting comparisons in cancer risk between hourly workers and salaried workers and between hourly workers and the general population because there is strong evidence that there are significant differences in smoking habits. This is seen in the SMR analyses in that hourly workers in general have higher rates of lung cancer and other smoking related causes of death such as heart disease and non-malignant respiratory diseases such as emphysema. It has been suggested that smoking preventive programs should be considered for blue collar workers (Howard 2004). While patterns of risk in the observed and expected ratios can be informative, the internal dose-response analyses comparing hourly workers to hourly workers and salaried workers to salaried workers over categories of exposure are the most informative with regard to investigating causal associations.

Additional discussion and references can be found in the Discussion section of the Chemical Paper. "The previous UCLA investigation had abstracted medical records of over 1000 workers to learn whether smoking information might be available and whether smoking status might vary over categories of estimated hydrazine exposure (essentially, among test stand workers). There was little evidence that smoking was a confounder, since smoking prevalences were quite similar among the test stand workers and other workers (Morgenstern and Ritz 2001). It might be noted, however, that the available medical records were limited, in that practically all medical records for workers who terminated employment prior to about 1970 (i.e., for over 66% of the test stand workers) had been destroyed, and were thus not available for review in the 1990s. In addition, most of the questionnaires available in existing medical records had been administered in the 1960s and changes in smoking habits over the years could not be evaluated. To obtain additional information on smoking histories and the possible association with pay code, a brief smoking survey was conducted of a random sample of 200 living workers who fell into one of four categories: hourly and salaried workers at SSFL and hourly and salaried workers at the other Rocketdyne facilities where radiation work was performed. Just over 64% of the hourly workers reported being a current or former smokers, whereas the proportion among salaried workers was 40%, indicating the importance of controlling for pay code in the analyses as a surrogate measure of smoking. Even though survey methods differed, the prevalences of current smokers, in our survey are generally similar to recent national and California population estimates (CDC 2004a, CDC 2004b). We found 9 % of hourly workers reporting current smoking, and none of the salaried workers in our sample with a median age of 71 years. The national prevalence of smoking in 2002 (the latest year for which estimates are available) were 10% at ages 65+, and smoking prevalences in California were 24% lower than the national level. The smoking prevalence of California males over the age of 70 years is estimated to be below 7%. Thus our small survey was consistent with previous large-scale investigations indicating that hourly workers smoke more than salaried workers and more than the general population. Nonetheless, the study is limited in not having information on the smoking habits of the workers studied."

Centers for Disease Control and Prevention (CDC). Cigarette smoking among adults – United States, 2002. MMWR Morb Mortal Wkly Rep 53:427-431, 2004a.

Centers for Disease Control and Prevention (CDC). State - specific prevalence of current cigarette smoking among adults – United States, 2002. MMWR Morb Mortal Wkly Rep 52:1277-1280, 2004b.

Howard J. Smoking is an occupational hazard. Am J Ind Med 46:161 169, 2004.

C1. Smoking Survey (2004) – Health Status

How would you describe your health?

Health Status	Hourly	(%)	Salary	(%)	Total	(%)
Excellent	7	(10)	16	(23)	23	(17)
Very Good	22	(32)	31	(44)	53	(38)
Good	16	(24)	12	(17)	28	(20)
Fair	12	(18)	8	(11)	20	(14)
Poor	9	(13)	3	(4)	12	(9)
Deceased	2	(3)	1	(1)	3	(2)
Total	68		71		139	
p-value from χ^2 test for association:				0.08		

C2. Smoking Survey (2004) - Ever Smoked

Have you smoked at least 100 cigarettes in your entire life?

Ever Smoked	Hourly	(%)	Salary	(%)	Total	(%)
Yes	40	(61)	29	(41)	69	(50)
No	26	(39)	42	(59)	68	(50)
Total	66		71		137	
p-value from χ^2 test for association:				0.02		

Note: Tabulations include (136) workers who returned a survey and (1) deceased worker whose survey was completed by next-of-kin.

C2a. **Smoking Survey (2004) - Age Started Smoking**

About how old were you when you first started smoking cigarettes regularly?

Age Started (yr)	Hourly (%)		Salary (%)		Total (%)	
< 15	5	(13)	2	(7)	7	(10)
15-19	22	(56)	18	(62)	40	(59)
20-24	11	(28)	5	(17)	16	(24)
≥25	1	(3)	4	(14)	5	(7)
Total	39		29		68	
Mean (Std dev) age	16.6 (3.1)		17.9 (3.7)			
p-value from t-test for equality of means:			0.05			

Note: (1) smoker did not answer this question

C2b. Smoking Survey (2004) - Current Smoker

If you answered 'Yes' to the question 'Have you smoked at least 100 cigarettes in your entire life," do you smoke cigarettes now?

Current Smoker	Hourly (%)		Salary (%)		Total (%)	
Yes	6	(15)	0	(0)	6	(9)
No	34	(85)	29	(100)	63	(91)
Total	40		29		69	
p-value from Fisher's exact test[1] for association:			0.04			

[1]Because of small cell counts, Fisher's exact test was used instead of χ^2 test.

C2c. **Smoking Survey (2004) - Age Quit Smoking**

At what age did you quit?

Age Quit (yr)	Hourly (%)		Salary (%)		Total (%)	
<30	2	(6)	7	(24)	9	(15)
30-39	11	(35)	8	(28)	19	(32)
40-49	4	(13)	6	(21)	10	(17)
≥50	14	(45)	8	(28)	22	(37)
Total	31		29		60	
Mean (Std dev) age	46.3 (14.7)		40.0 (14.4)			
p-value from t-test for equality of means:			0.09			

Note: (3) former smokers did not answer this question

C2d. Smoking Survey (2004) – Intensity (Cigarettes per Day)

On average how many cigarettes a day did you smoke?

Cigarettes/Day	Hourly (%)		Salary (%)		Total (%)	
<10	9	(23)	4	(14)	13	(19)
10-19	6	(15)	9	(31)	15	(22)
20-29	19	(48)	9	(31)	28	(41)
≥30	6	(15)	7	(24)	13	(19)
Total	40		29		69	
Mean (Std dev)	17.8 (9.7)		21.5 (17.3)			
p-value from t-test for equality of means:			0.25			

C2f. Smoking Survey (2004) - Other Tobacco Use

Have you ever used any of the tobacco products listed below?

Tobacco Product	Hourly (%)		Salary (%)		Total (%)	
Chewing Tobacco						
Yes	3	(7)	1	(3)	4	(5)
No	41	(93)	32	(97)	73	(95)
p-value from Fisher's exact[1] test:				0.63		
Snuff Tobacco						
Yes	2	(5)	2	(6)	4	(5)
No	42	(95)	31	(94)	73	(95)
p-value from Fisher's exact[1] test:				0.99		
Pipes						
Yes	14	(32)	15	(45)	29	(38)
No	30	(68)	18	(55)	48	(62)
p-value from Fisher's exact[1] test:				0.24		
Cigars						
Yes	9	(20)	11	(32)	20	(26)
No	35	(80)	23	(68)	58	(74)
p-value from Fisher's exact[1] test:				0.30		

[1]Because of small cell counts, Fisher's exact test was used instead of χ^2 test.

C2g. Smoking Survey (2004) – Duration of Smoking

Duration of smoking (derived as age quit minus age start or, if current smoker, current age minus age start)?

Duration (yr)	**Hourly (%)**		**Salary (%)**		**Total (%)**	
<10	2	(6)	4	(14)	6	(9)
10-19	9	(25)	10	(34)	19	(29)
20-29	7	(19)	6	(21)	13	(20)
30-39	7	(19)	6	(21)	13	(20)
≥40	11	(31)	3	(10)	14	(22)
Total	36		29		65	
Mean (Std dev)	31.4 (16.8)		21.1 (12.8)			
p-value from t-test for equality of means:			0.01			

Note: (4) of the 69 former and current smokers were missing information necessary to calculate this value.

C2h. Smoking Survey (2004) - Cumulative Amount of Tobacco Use

Cumulative amount (derived as the product of the average number of cigarettes per day times the duration of smoking in years divided by 20 (the number of cigarettes in a pack).

Pack-years	Hourly (%)		Salary (%)		Total (%)	
<5	5	(14)	5	(17)	10	(15)
5-9	2	(6)	4	(14)	6	(9)
10-19	7	(19)	7	(24)	14	(22)
20-29	6	(17)	3	(10)	9	(14)
30-39	5	(14)	5	(17)	10	(15)
40-59	7	(19)	3	(10)	10	(15)
≥60	4	(11)	2	(7)	6	(9)
Total	36		29		65	
Mean (Std dev)	30.3 (23.4)		26.2 (29.6)			
p-value from t-test for equality of means:			0.54			

Note: (4) of the 69 former and current smokers were missing information necessary to calculate this value.

C3. Smoking Survey (2004) - Exercise

On how many of the past 7 days did you exercise or do sports for at least 20 minutes that made you sweat or breathe hard (e.g., dancing, jogging, basketball, etc.)?

Days Exercised Past Week	**Hourly (%)**		**Salary (%)**		**Total (%)**	
0	26	(40)	18	(26)	44	(33)
1	6	(9)	8	(11)	14	(10)
2	8	(12)	12	(17)	20	(15)
3	11	(17)	12	(17)	23	(17)
4	0	(0)	7	(10)	7	(5)
5	9	(14)	7	(10)	16	(12)
6	2	(3)	0	(0)	2	(1)
7	3	(5)	6	(9)	9	(7)
Total	65		70		135	
p-value from Fisher's exact test[1] for association:				0.07		

Note: (3) deceased workers not included in tabulation. (1) worker did not answer this question

[1]Because of small cell counts, Fisher's exact test was used instead of χ^2 test.

C4. Smoking Survey (2004) – Response Rate

Response Rate[1]	Hourly (%)	Salary (%)	Total (%)
Number Selected	300 (100)	300 (100)	600 (100)
Number Mailed Questionnaire	145 (46)	147 (46)	292 (49)
Number Responded	68 (23)	71 (24)	139 (23)

[1] 300 hourly and 300 salaried workers known to be alive 31 December 1999 were randomly selected. Current mailing addresses were sought and (292) were found. (292) questionnaires were mailed and tabulations are made as of 17 December 2004. (6) workers were found to have died. (3) surveys were returned by next-of-kin for deceased workers.

C5. Smoking Survey (2004) – Age distribution

Current age of respondents (as of date questionnaire was received):

Current Age	Hourly (%)		Salary (%)		Total (%)	
< 50	10	(15)	12	(17)	22	(16)
50 – 59	8	(12)	12	(17)	20	(14)
60 – 69	15	(22)	12	(17)	27	(19)
70 – 79	24	(35)	27	(38)	51	(37)
≥ 80	11	(16)	8	(11)	19	(14)
Total	68		71		139	
Mean age (std dev)	67.8	(12.6)	67.0	(12.8)	67.4	(12.7)
Median age (range)	71.1	(37.7-84.8)	69.8	(41.6-94.0)	70.0	(37.7-94.0)

Note: Tabulations include (136) workers who returned a survey and (3) deceased workers whose surveys were completed by next-of-kin.

ROCKETDYNE WORKER HEALTH STUDY

Appendix D

INTERNATIONAL EPIDEMIOLOGY INSTITUTE

Comparisons with Previous Investigation by UCLA

July 13, 2005

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Appendix D. Comparisons With Previous Investigation by UCLA

Appendix D compares the summary data from the previous investigation by UCLA (Morgenstern and Ritz 2001) with those from the current investigation.

Table D1. Descriptions of the Radiation and Chemical Cohorts of Rocketdyne/AI Workers Comparing the Previous Investigation (UCLA) with the Current Investigation (IEI)

Table D2a. Distribution of Total Cumulative Doses (mSv) of External and Internal Radiation and Hydrazine Exposure in the Radiation and Chemical Cohorts of Rocketdyne/AI Workers, 1950-1993 (Morgenstern and Ritz, 2001, Table 2)

Table D2b. Distribution of Total Cumulative Doses (mSv) of External and Internal Radiation and Hydrazine Exposure in the Radiation and Chemical Cohorts of Rocketdyne/AI Workers, 1948-1999 (Current IEI Study)

Table D3. External Comparisons of Rocketdyne/AI Workers in Radiation and Chemical Cohort with General Population: Estimated SMRs and 95% CIs for Selected Causes of Death, 1950-1994 (UCLA Morgenstern and Ritz, 2001, Table 3) and 1948-1999 (IEI)

Table D4a Estimated RR for the Effect of Cumulative External Radiation Dose on Cancer Mortality Among Externally Monitored Workers, by Cancer Type and Dose Category (UCLA)

Table D4b Estimated RR for the Effect of Cumulative Radiation Dose on Cancer Mortality by Cancer Type and Dose Category (IEI)

Table D5a Estimated RR for the Effect of Hydrazine Exposure on Lung Cancer Mortality Among Workers in the Chemical Cohort by Exposure Category (UCLA) (Table 8, Morgenstern and Ritz , 2001)

Table D5b Estimated RR for the Effect of Years Worked as a Test Stand Mechanic on Lung Cancer Among Male Test Stand Mechanics with Hourly SSFL Workers as Referent (IEI)

Table D5c Estimated RR for the Effect of Cumulative Potential Exposure to Hydrazines (Likely and Possible) on Lung Cancer Among Test Stand Mechanics with Hourly SSFL Workers as Referent (IEI)

Table D1. Descriptions of the Radiation and Chemical Cohorts of Rocketdyne/AI Workers Comparing the Previous Investigation (UCLA) with the Current Investigation (IEI)

	Externally Monitored		Internally Monitored		Chemical	
	UCLA	**IEI**	**UCLA**	**IEI**	**UCLA**	**IEI**
Number of subjects	4,563	5,743	2,297	2,232	6,107	8,372
Percent male	94.0	92.0	96.6	96.3	100	84.6
Mean follow-up time (yrs)	26.1	27.9	25.4	30.4	29.0	30.4
Number of total deaths	875	1,449	441	599	1,391	2,251
Total mortality rate (per 10^5/yr)	737	906	755	883	786	886
Number of cancer deaths	258	447	134	203	404	655
Cancer mortality rate (per 10^5/yr)	217	279	229	300	228	258
Pay type (% of total)						
Hourly/union	50.7	56.5	56.2	62.6	11.3	62.6

Table from Morgenstern and Ritz (Table 1, 2001) with follow-up through 1950-1993. The IEI numbers are from the current investigation (1948-1999).

COMMENT.
The current IEI investigation is larger and the follow-up longer than the previous UCLA study. Accordingly there were more deaths to evaluate. Another notable difference is the apparent low percentage of hourly workers in the UCLA Chemical Cohort (11.3%) compared to our 62.6 %.

Table D2a. Distribution of Total Cumulative Doses (mSv) of External and Internal Radiation and Hydrazine Exposure in the Radiation and Chemical Cohorts of Rocketdyne/AI Workers, 1950-1993 (Morgenstern and Ritz, 2001, Table 2)

External Radiation			Internal Radiation			Hydrazine Exposure		
mSv	**No.**	**%**	**mSv**	**No.**	**%**	**Category**	**No.**	**%**
<10	3,391	74.3	0	1,333	58.0	None	4,368	71.5
10 - < 20	589	12.9	> 0 - < 5	691	30.1	Low	32	0.5
10 - < 200	549	12.0	5 - < 30	256	11.2	Medium	654	10.7
≥ 200	34	0.7	≥ 30	17	0.7	High	1,053	17.2
Mean = 11.9 mSv			Mean = 2.1 mSv					

Table D2b. Distribution of Total Cumulative Doses (mSv) of External and Internal Radiation and Hydrazine Exposure in the Radiation and Chemical Cohorts of Rocketdyne/AI Workers, 1948-1999 (Current IEI Study)

External Radiation			Internal Radiation (Lung Dose)[1]			Hydrazine Exposure[2]		
mSv	**No.**	**%**	**mSv**	**No.**	**%**	**Category**	**No.**	**%**
<10	4,454	76.8	<10	150	6.7	Referent (SSFL)	1,598	52.6
10 - < 50	1,012	17.4	10 - < 50	1,726	77.3	None	920	30.3
50 - < 200	266	4.6	50 - < 200	253	11.3	Possible	205	6.7
≥ 200	69	1.2	≥ 200	103	4.6	> 0 – 1.4 yr	156	5.1
Mean = 13.6 mSv			Mean = 19.1 mSv			≥ 1.5 yr	159	5.2

[1] Includes external lung dose also.

[2] Male hourly workers other than test stand mechanics at SSFL used as referent. “Possible” hydrazine exposure reflects the uncertainty of actually working at a test stand where hydrazine was used. “Likely” years of potential exposure to hydrazines is presented. In total, there were 315 test stand mechanics with likely exposure to hydrazine and 205 with possible exposure.

COMMENT.

Compared with the earlier UCLA investigation, the current IEI study included more workers exposed to external radiation, had about the same number of workers monitored for internal radiation, and had fewer workers exposed to hydrazines. The mean dose of workers monitored for external radiation was 14% greater in the IEI investigation. The dose distribution for the workers monitored for internal radiation includes much higher categories in the current investigation because, in part, the external lung doses were also added to the internal dose for each individual. In addition, different and more current biokinetic models of dose computation were used. The current study was also able to assign test stand mechanics to test areas where hydrazines were used and determine the number of years worked with the potential for exposure to hydrazines. The previous UCLA investigation apparently assumed that all test stand mechanics were potentially exposed to hydrazines whereas we estimate that less than 30% of test stand mechanics were potentially exposed to hydrazines.

Table D3. External Comparisons of Rocketdyne/AI Workers in Radiation and Chemical Cohort with General Population: Estimated SMRs and 95% CIs for Selected Causes of Death, 1950-1994 (UCLA Morgenstern and Ritz, 2001, Table 3) and 1948-1999 (IEI)

	Externally Monitored		**Internally Monitored**		**Chemical Cohort**	
Cause of Death (IDCA-8)	**No. Deaths**	**SMR (95% CI)**	**No. Deaths**	**SMR (95% CI)**	**No. Deaths**	**SMR (95% CI)**
All causes (001-998)						
UCLA (compared to U.S. population)	844	0.68 (0.64-0.73)	433	0.72 (0.66-0.80)	1,391	0.66 (0.62-0.69)
IEI (compared to California population)	1,449	0.78 (0.74-0.82)	599	0.81 (0.75-0.88)	2,251	0.83 (0.80-0.86)
All cancers (140-229)						
UCLA	248	0.79 (0.69-0.89)	133	0.87 (0.73-1.03)	404	0.79 (0.68-0.83)
IEI	447	0.89 (0.81-0.98)	203	1.04 (0.90-1.19)	655	0.89 (0.82-0.96)
Lung cancer (162)						
UCLA	87	0.75 (0.60-0.92)	46	0.81 (0.59-1.08)	146	0.74 (0.62-0.86)
IEI	148	0.88 (0.75-1.04)	69	1.05 (0.81-1.32)	215	0.89 (0.78-1.02)
Leukemia (204-207)						
UCLA	18	1.60 (0.95-2.52)	8	1.46 (0.63-2.88)	10	0.52 (0.25-0.96)
IEI	25	1.34 (0.87-1.98)	10	1.35 (0.65-2.49)	20	0.89 (0.54-1.37)
Lymphopoietic cancers (200-208)						
UCLA	30	1.01 (0.68-1.44)	12	0.83 (0.43-1.45)	41	0.81 (0.58-1.11)
IEI	51	1.03 (0.77-1.36)	21	1.07 (0.66-1.64)	29	1.02 (0.69-1.47)

COMMENT.
The current investigation has larger numbers and somewhat greater SMR values than the UCLA investigation. UCLA compared the study cohorts with the U.S. general population whereas we used the California general population for comparison. Also, the table for UCLA is restricted to white males whereas we included women and all races. Regardless, there were no statistically significant increases in either study.

Table D4a Estimated RR for the Effect of Cumulative External Radiation Dose on Cancer Mortality Among Externally Monitored Workers, by Cancer Type and Dose Category (UCLA) (Table 4, Morgenstern and Ritz, 2001)

Cancer Type (ICD-9)	Dose (mSv)	No. Deaths	RR	95% CI	Trend *P*
All sites (140-239)	<10	177	1	--	0.036
	10 - < 20	41	1.07	(0.75-1.52)	
	20 - < 200	36	1.13	(0.78-1.65)	
	≥ 200	4	3.10	(1.13-8.48)	
Lymphopoietic (200-208, excluding 204.1)	<10	15	1	--	0.003
	10 - < 20	7	1.74	(0.68-4.45	
	20 - < 200	4	1.00	(0.31-3.21)	
	≥ 200	2	15.7	(3.33-73.5)	
Lung (162)	<10	65	1	--	0.045
	10 - < 20	8	0.63	(0.30-1.33)	
	20 - < 200	12	1.18	(0.61-2.28)	
	≥ 200	2	4.70	(1.05-21.0)	

Table D4b Estimated RR for the Effect of Cumulative Radiation Dose on Cancer Mortality by Cancer Type and Dose Category (IEI)

Cancer Type (ICD-9)	Dose (mSv)	No. Deaths	RR	95% CI	Trend *P*
All sites (140-239)	Not monitored	2,733	1.00	Ref	0.25
	0	44	1.22	(0.90-1.66)	
	> 0-	214	0.89	(0.76-1.02)	
	5-	60	0.93	(0.70-1.24)	
	10-	105	0.99	(0.77-1.27)	
	50-	12	0.69	(0.39-1.25)	
	100-	14	1.53	(0.87-2.67)	
	≥ 200	7	1.25	(0.58-2.71)	
Lymphopoietic (200-208, excluding 204.1)	Not monitored	245	1.00	Ref	0.18
	0	3	1.03	(0.33-3.26)	
	> 0-	19	0.88	(0.54-1.44)	
	5-	11	2.10	(1.04-4.22)	
	10-	8	0.93	(0.41-2.14)	
	≥ 50-	3	1.14	(0.32-3.97)	
Lung (162)	Not monitored	917	1.00	Ref	0.49
	0	17	1.37	(0.84-2.26)	
	> 0-	74	0.93	(0.72-1.21)	
	5-	21	1.03	(0.63-1.67)	
	10-	27	0.75	(0.47-1.19)	
	50-	7	0.63	(0.28-1.40)	
	≥ 200	5	1.39	(0.54-3.60)	

COMMENT.
The current study has more cancer deaths to evaluated and more workers who received relatively high doses. This is in part because we had included all occupational exposures received both at Rocketdyne and elsewhere. The UCLA study reported statistically significant radiation risks among workers who received greater than 200 mSv and statistically significant dose-response trends. The current investigation revealed no statistically significant findings at any dose level and none of the dose-response trends approached statistical significance. P-values for the current study are 1-sided.

Table D5a Estimated RR for the Effect of Hydrazine Exposure on Lung Cancer Mortality Among Workers in the Chemical Cohort by Exposure Category (UCLA) (Table 8, Morgenstern and Ritz , 2001)

Exposure Category	No. Deaths Lung Cancer	RR	95% CI
None	97	1	--
Medium	5	0.41	(0.17-1.02)
High	44	1.68	(1.12-2.52)

Table D5b Estimated RR for the Effect of Years Worked as a Test Stand Mechanic on Lung Cancer Among Male Test Stand Mechanics with Hourly SSFL Workers as Referent (IEI)

Exposure Category	No. Deaths Lung Cancer	RR	95% CI
Referent (SSFL workers)	59	1.00	--
< 1 year	10	0.80	(0.41-1.56)
1 – 4 years	31	1.02	(0.66-1.59)
≥ 5 years	22	0.96	(0.58-1.59)

Table D5c Estimated RR for the Effect of Cumulative Potential Exposure to Hydrazines (Likely and Possible) on Lung Cancer Among Test Stand Mechanics with Hourly SSFL Workers as Referent (IEI)

Exposure Category	No. Deaths Lung Cancer	RR	95% CI
Referent (SSFL workers)	59	1.00	--
No Hydrazine exposure	30	0.52	(0.23-1.14)
Possible (not likely) Hydrazine exposure	13	0.96	(0.34-2.69)
Likely Hydrazine exposure >0 – 1.4 years	7	0.79	(0.26-2.46)
Likely Hydrazine exposure ≥ 1.5 years	8	0.76	(0.25-2.30)

COMMENT.
The previous study by UCLA assumed all test stand mechanics were exposed to hydrazines. These workers represent the "High" exposure category in their table D5a. For comparison, we present our analyses of lung cancer among test stand mechanics over categories of years worked as a test stand mechanic (D5b) and our analyses with respect to years worked with "likely" or "possible" exposure to hydrazines (D5c). We observed no association between hydrazines potential exposure and risk of lung cancer.

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Appendix E

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Databases Used

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Appendix E. Databases Used

Name	*Format*	*Record Level(s)*	*Source*	*Description*
Personnel Related Data				
Boeing Human Resources Electronic database	ASCII text	Person and Job	Rocketdyne	Contains detailed demographic data on 26,000 persons and 257,000 work history records
Alchemy Kardex Image Database	Alchemy	Kardex Image	Rocketdyne	Image scans of Kardex job history cards for over 35,000 Rocketdyne workers prior to 1972. Also include supplemental, and previously missing Kardex databases
Rocketdyne Phonebooks	Hard Copy	Job-location-timeperiod	Rocketdyne	Received physical phone books from Rocketdyne. Keyed approx. 15,000 names, dates and location entries
Rocketdyne Transfer Lists	MS Excel	Person	Rocketdyne	Names, SSN, and serial number of 5300 workers who transferred to other Boeing divisions, along with the transfer division and date of transfer.
Rocketdyne Medical Cards	Alchemy	Person	Rocketdyne	Image scans of 53,000 worker's 3x5 medical index cards - contained SSN, serial number, often division transferred to
Boeing Contractors Lists	dBase files	Person	Rocketdyne	List of 4,675 known contractors names, SSN (if known), employer, and contrator badge number
Boeing Medical Records Database	MS Excel	Person	Rocketdyne	List of 24,013 medical records folders, along with worker name, SSN, serial and Iron Mountain archive code
Radiation Related Data				
Radiation Records Image Database	Alchemy	Radiation Record Image	Rocketdyne	Image scans of Radiation Safety folders for over 14,000 workers
Garcia Radiation Dosimetery Database - Historical	dBase file	Person	Rocketdyne	Names, some SSNs, birthdates, and total dose for Rocketdyne employment period for 6434 individuals
Dosimetery Personel History Files	dBase file	Person - Time Period	Rocketdyne	3,927 radiation badge readings for 406 radiation workers
Rocketdyne Dosimetery System (1990)	dBase file	Person-Year Dose	Rocketdyne	3,828 yearly dose summaries of 1605 radiation workers from 1990-2000
Landauer Dosimetery Database	ASCII text	Person-Account-Annual Dose	Landauer	21,949 annual external doses for 3,297 Landauer accounts (2,144 Rocketdyne employees)
Radiographer dose scans database	Alchemy	Badge dosimetery report	Rocketdyne	Image scans of Gardray (1966-1968) and Landauer (1969-1985) badge readings for radiographers
Radiation Exposure Monitoring System (REMS)	ASCII text	Person-Facility-Year Dose	US Dept. of Energy	Contains 4,120 annual doses among 884 workers
DOE Historical Radiation Database	ASCII text	Person-Facility-Year Dose	US Dept. of Energy	Contains 7,881 annual doses among 1,515 workers
DOE Termination Radiation Database	ASCII text	Dose	US Dept. of Energy	Contains 1,066 cumulative termination doses among 398 workers
US Air Force Radiation Database	MS Access	Type - Dose Type	US Air Force	workers
US Army Radiation Database	MS Access	Person-Year Dose	US Army	Contains 366 annual doses among 171 workers
System (REIRS)	MS Excel	Person-Time Period Dose	Comm.	Contains 1,328 doses among 1071 workers
Vital Status Related Data				
Rocketdyne Death Certificates	Alchemy	Person	Rocketdyne	Images scans of all death certificates on file at Rocketdyne
Rocketdyne Death List	MS Excel	Person	Rocketdyne	Name, SSN, date of death, and uncoded cause of death for 166 Rocketdyne workers
Atomics International Reunion List	MS Word	Person	Rocketdye	Names of ~340 Atomics International employees who attended a reunion event post 12/31/1999

Social Security Administration Master File	ASCII Text	Person	SSA	Vital status of all workers: 53,403 (first submission) and 2,205 (second submission) workers. Resulted in identifying approx 11,000 deaths
HCFA (now CMS) Vital Status Matches	ASCII Text	Person-Match	US Health Care Financing Administration	Vital status of 31,000 workers (age > 60 submitted). Resulted in identifying approx 7,400 deaths
National Death Index Vital Status Matches	ASCII Text	Person-Match	National Death Index	Coded causes of death for 2,684 workers known to have died (probable deaths submitted)
California Surveillance Program Vital Status Matches	ASCII Text	Person-Match	CA Surveillance Program	Coded causes of death for 9,169 workers who died in California (entire workforce submitted)
PBI Vital Status Matches	ASCII Text	Person-Match	Pension Benefits International	Vital status of all workers. Resulted in identifying approx 12,224 deaths
California Death Statistical Master File	ASCII Text	Person	CA Dept. Vital Statistics	Name, birth date, and death date for deaths in CA, 1960-2002. Found additional 88 deaths
California Death Index	ASCII Text	Person	CA Dept. Vital Statistics	Name, birth date, and death date for deaths in CA, 1940-1965. Found additional 24 deaths
ComServ Vital Status Matches	ASCII Text	Person	ComServ, Inc.	Matches of 1,281 workers with unknow vital status 45 confirmed dead, 957 confirmed alive
UCLA Data (provided by Boeing)				
UCLA All Radiation database	MS Excel	Person	Rocketdyne	Name, SSN, birth date, hire date, termination date and summed external dose of 14,054 radiation workers - used only as QC to check our independent evaluation
UCLA Annual external doses database	MS Excel	Person-Year	Rocketdyne	8,984 annual external doses for 6,259 workers (name/ssn), including location of dose - used only as QC to check our independent evaluation
UCLA Internal Dose Database	MS Access	Person	Rocketdyne	Summed Internal doses for 2,297 workers (name/ssn/dob) - used only as QC to check our independent evaluation
UCLA Radiation Cohort Database	MS Excel	Person	Rocketdyne	List of 4,607 workers in UCLA radiation cohort, including Name, SSN, birth date, start and end years of radiation monitoring, and duration of employment at Rocketdyne - used only as QC to check our independent evaluation
UCLA CEDR radiation database	ASCII text	Person	CEDR	UCLA radiation cohort - detailed information on external and internal dose, asbestos exposure, etc. - used only as QC to check our independent evaluation
UCLA Chemical Cohort Database	MS Excel	Person	Rocketdyne	UCLA chemical cohort of 6108 workers. Worksheets designate vital status and exposure level. - used only as QC to check our independent evaluation
Miscellaneous				
IEI Medical Record Abstractions	MS Access	Person-Medical Report	Rocketdyne/IEI	Abstraction of 1,209 medical reports (1950-1999) among 123 workers, abstracting chemical exposure and test stand
Rocketdyne Retiree List	MS Access	Person	Rocketdyne	List of 309 Rocketdyne retirees
Rocketdyne HSIS database	MS Excel	Exposure Measurements	Rocketdyne	Industrial Hygiene exposure measurements

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Appendix F

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Glossary of Terms

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Appendix F. Glossary of Terms

This glossary contains brief explanations for terms or concepts that are used throughout the Final Report and in the radiation and chemical papers.

Alpha particles. Alpha particles are the largest and slowest moving type of radiation. They are helium nuclei consisting of 2 neutrons and 2 protons. Alpha particles can move through the air only for a few inches before being stopped by air molecules, and would, for example, be stopped easily by a sheet of paper or the skin. The biological hazard is greatest when alpha particle emitters are ingested or inhaled.

Atomics International. Atomics International was dedicated to the research and development of nuclear energy and operated ten nuclear reactors and seven criticality facilities over the years. Nine of the ten reactors operated at power levels below one megawatt. Other radiation-related activities included fabricating nuclear fuel, dissembling and decontaminating reactor facilities, decladding spent nuclear fuel, and storing nuclear material. The radiation work at the Rocketdyne facilities did not involve any nuclear weapons activities or the production or testing of nuclear weapons components. During the years 1958 through 1983, enriched uranium and plutonium fuels were fabricated for research, space and power reactors. Rocketdyne, a rocket engine test facility, merged with Atomics International in the 1950s. The company was owned and operated by various companies including North American Aviation, Rockwell International and now the Boeing Company. Currently, the SSFL is operated by the Rocketdyne Propulsion and Power Division of Boeing and is jointly owned by Boeing and the National Aeronautical and Space Administration. Throughout these reports, "Rocketdyne" is used to represent all corporate names under which radiation work was conducted over the past 50 years.

Beta particles. Beta particles are much smaller and faster moving than alpha particles. They are electrons that are emitted from the nucleus. Beta particles pass through paper and can travel in the air for about 10 feet. However, they can be stopped by thin shielding such as a sheet of aluminum foil and would not penetrate much beyond the skin.

Hydrazine. Hydrazine is a white or colorless liquid with an ammonia-like odor that is used in rocket fuels, chemical manufacturing and as an oxygen scavenger in the treatment of boiler water.

Committed Effective Dose. Following an intake of a radioactive material, there is a period of time during which the radioactive substance remains in the body and exposes specific tissues at varying rates. For the purpose of radiation protection and to limit the intake of future radioactive materials when a prior intake remains in the body, the effective dose received over a 50 year period for adults is computed and called the committed effective dose; committed because much of the dose is received in the future while the radioactive substance remains in the body. For individual risk assessment the committed effective dose is an inappropriate unit. The proper unit would be the radiation absorbed dose or equivalent dose to the tissue of interest received during an appropriate time period, and should not include the future dose estimated to be received beyond the current date an individual developed cancer.

Cox Proportional Hazards Modeling. One of three multiplicative models commonly employed in the analysis of occupational cohort studies, the other two techniques being logistic regression and Poisson regression. Cox proposed the proportional hazards model for analysis of continuous survival time data. The model relates the hazard rate $\lambda(t)$ to the covariate vector x as $\lambda(t,x)=\lambda_o(t)exp\ (\beta x)$. Analysis focuses on the risk set of all subjects in the cohort at risk at the time (age) each event occurred, using the covariate values at that particular point in time. In this way, the proportional hazards model accounts for changes over time in subjects at risk and in covariates.

Effective Dose. Effective dose is a quantity used in radiation protection and is also expressed in units of sievert (see also *Equivalent dose*). Effective dose allows one to compare risks of partial body exposures either from external or internal radiations to any site with those from whole body exposure by applying tissue weighting factors (ICRP 1991). This unit is not appropriate for individual risk assessment because it does not relate directly to tissue dose. For example, equivalent dose each year to the lung from inhaled radon can be computed to be about 1,000 mrem (10 mSv). Applying the tissue weighting factor of 0.12 for the lung results in an effective dose of 120 mrem. This effective dose is helpful when estimating the total consequences or detriment from different types of radiation exposures to an individual.

Epidemiology. Epidemiology can be defined as the study of the distribution and causes of disease in human populations. More simply, epidemiology is the study of what causes illness in people. The radiation and chemical studies are cohort studies where workers are identified, classified with regard to exposure, and then followed forward in time to record subsequent deaths.

Equivalent dose. Not all types of radiation are similar in their ability to produce a specific effect. The relative biological effectiveness (RBE) of radiation characterizes its ability to produce a specific disorder compared to a standard, usually x-rays. The international unit of biological equivalent dose is the sievert (Sv). The sievert represents the absorbed dose in gray multiplied by an appropriate radiation weighting factor. For x-rays, gamma rays, beta particles and electrons this weighting factor is 1, whereas for alpha particles the weighting factor is 20. The previous unit of equivalent dose was the rem with 1 Sv = 100 rem = 100,000 mrem. For x-rays, gamma rays and beta particles 1 Sv = 100 rem = 100 rad.

External Radiation. Penetrating radiation from sources of radiation outside the body, such as gamma rays and x-rays.

Gamma rays. Gamma rays travel at the speed of light and penetrate matter more easily than either alpha or beta particles. They are very high frequency electromagnetic rays. It takes a thick shield of steel, lead, or concrete to stop gamma rays. X-rays and gamma rays are identical except for their source of origin. Gamma rays originate from the nucleus of decaying radionuclides and x-rays originate from outside the nucleus, such as when speeding electrons are slowed within x-ray tubes (*i.e.*, an x-ray machine).

Health Worker Effect. The healthy worker effect usually refers to the potential bias in using a general population for comparison with an occupational group. The general population differs from a working populations in ways that are likely to affect the risk of dying. The bias is related to selection processes that are in force when a worker enters the workforce and to the health characteristics that enable a worker to continue on the job for many years. Workers in general are healthier than the general population and as such are less likely to die at a young age. These selection factors, however, usually diminish over time, especially for causes of death due to cancer. Analyses are often conducted excluding the first 10 years of follow-up after a worker to remove some of the influence of the healthy worker effect. More importantly, though, internal cohort dose-response analyses are conducted comparing workers to workers at the same facility and thus eliminate the possible bias when comparing to an external general population.

Internal Radiation. Radioactive substances (radionuclides) can be ingested or inhaled into the body and the release of radioactive energy in tissue is termed internal radiation.

Lagging. A concept used in the analysis of radiation cohort data for which the exposure occurring prior to the outcome of interest is excluded. For leukemia data, the exposure received 2 years prior to the date of death from leukemia is often excluded. For solid cancer data, the exposure received 10 years prior to the date of death from cancer is usually excluded from the analyses. The concept of lagging is that it takes some time before an exposure can damage a cell/s that would eventually be diagnosed as a malignancy. Exposure the day before the diagnosis of a cancer, for example, could not be linked etiologically to the cancer.

Monitoring for Radiation. Workers in an area with potential exposure to ionizing radiation would be monitored for the amount of radiation received so as to be in compliance with occupational standards. If the potential exposure were from external (penetrating) sources of radiation such as gamma rays or x-rays, the worker would wear a monitoring device such a a film badge or TLD (thermoluminescence dosimeter). If the potential exposure were to radioactive material that could be ingested or inhaled, the worker would be monitored with bioassays such as urine samples. The radioactivity in collected samples of urine would be measured and the amount of radioactive material intake estimated.

mSv. mSv (milliSievert) is the international unit of radiation equivalent dose (and also radiation effective dose). 1 mSv is equal to 10 mrem.

Non-SSFL. Rocketdyne facilities other than SSFL, i.e., mainly those at Canoga Park and De Soto Avenue.

Radiation absorbed dose. Biological effects are related to the amount of radiation energy absorbed by specific tissues. Radiation dose is the amount of energy absorbed in tissue and is measured in gray (Gy). The unit for dose used to be the rad, but the conversion is simple 1 Gy = 100 rad.

Radionuclides. Radionuclides are unstable elements that will eventually transform into another element by changing the number of protons in the nucleus. This change causes the atom to release either beta particles (electrons) or alpha particles (helium nuclei) and possibly energy in the form of gamma rays. Beta particles, alpha particles, and gamma rays emitted from changing atoms are different forms of ionizing radiation.

Rocketdyne. In 1948, North American Aviation established the Santa Susana Field Laboratory (SSFL) at the boundary of Los Angeles and Ventura counties as a rocket engine testing facility. During the next 50 years, 11 major rocket engine and component test areas were developed at SSFL. North American Rockwell (1967-1973), Rockwell International (1973-1996), and now the Boeing Company (1996+) have been the corporate owners of the test facilities. The Rocketdyne Propulsion Division was created in 1955 and “Rocketdyne” is used throughout the reports to include all Rocketdyne workers at SSFL and nearby facilities regardless of corporate affiliation.

SMR. Standardized Mortality Ratio. The ratio of the observed number of deaths divided by the expected number of deaths computed from external rates of disease available in the general population. Occasionally the ratio of observed to expected deaths is multiplied by 100 in presentations.

SSFL. Santa Suzana Field Laboratory.

Test Stand Mechanic. Hourly workers who had the greatest potential for exposure to chemicals in the course of rocket engine testing.

Test Stand Worker. Although Test Stand Mechanics had hands on experience during the testing of rocket engines and thus the greatest potential exposure to chemicals (fuels and solvents), there were other Test Stand Workers who had much lower potential for such chemical exposure. These were the Research Engineer, Test Stand Engineer, Instrument Mechanic, and Inspector. All of these workers can be generally classified as Test Stand Workers, but it was mainly the Test Stand Mechanic who received special physical examination because of his or her potential exposure to toxic chemicals.

Trichloroethylene (TCE). TCE is a colorless and sweet smelling liquid that was widely used after World War II as a solvent to remove grease from metal parts.

ROCKETDYNE WORKER HEALTH STUDY

Appendix G

INTERNATIONAL EPIDEMIOLOGY INSTITUTE

Rocketdyne Follow-On Worker Health Study

Study Brochure
October 2001

July 13, 2005

BOEING

Rocketdyne Propulsion & Power

ROCKETDYNE
Follow-on Worker Health Study

October 2001

The Boeing Company, in partnership with the United Aerospace Workers (UAW), is conducting a follow-on to the Rocketdyne Worker Health Study.

BACKGROUND

The Rocketdyne Worker Health Study was initiated in 1991 at the request of state legislators responding to community concerns about using radioactive and toxic substances at the Santa Susana Field Laboratory (SSFL). Conducted by University of California at Los Angeles (UCLA) researchers, overseen by the California Department of Health Services (DHS) and funded by the US Department of Energy, the two-phase study focused on employee exposure to radiation, chemicals and asbestos. Throughout the process, Rocketdyne and the UAW worked with the DHS and UCLA to facilitate the study.

OVERSIGHT PANEL FORMED

The DHS convened an oversight panel consisting of outside experts, community members, and UAW, DHS, and National Institute for Occupational Safety and Health (NIOSH) technical staff to select the investigator, oversee the conduct of the study and evaluate the results. The DHS Oversight Panel was confident in the principal findings of the UCLA study, although the study was limited by shortages of detailed exposure data.

RADIATION PHASE RESULTS

The Rocketdyne Worker Health Study radiation phase was released in September 1997. The purpose of the radiation phase was to determine if exposure to radiation increased the risk of dying from cancer among 4,607 Rocketdyne/Atomics International (AI) employees. The UCLA researchers concluded that:

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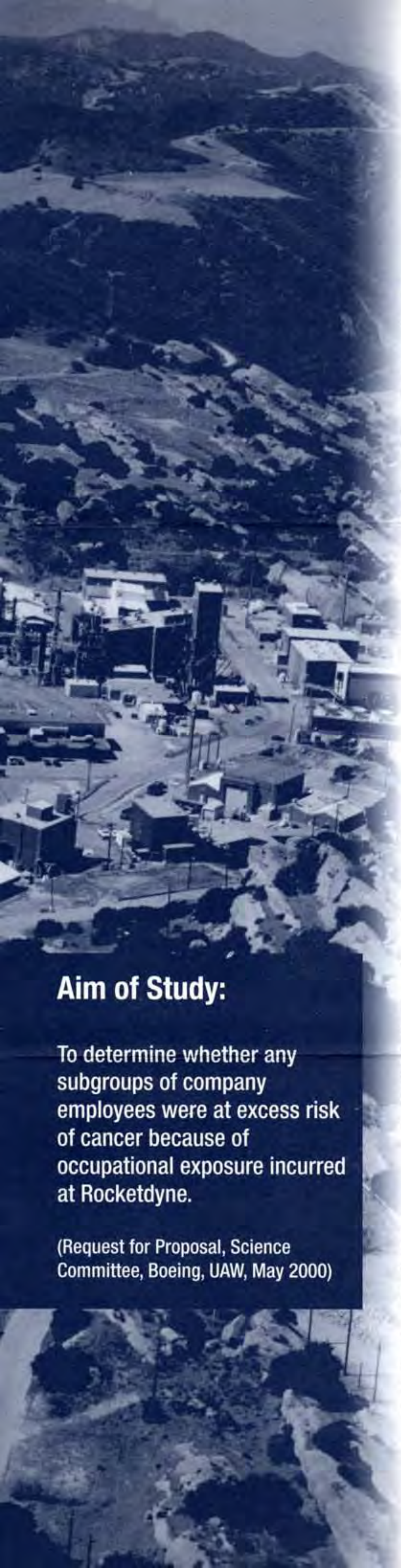
We take the issue of employee health very seriously. We are committed to this further study in order to get the best evaluation of the data that is possible. Because the health and safety of our employees is a top priority, we will conduct a detailed study of activities and exposures of Rocketdyne workers to continue answering your questions.

We plan to produce the most meaningful study possible by assembling the wealth of employee and retiree information and insight that comes from first-hand experience in our operations that required the use of hazardous materials. These individuals are in the best position to enrich our understanding of what actually took place over the past five decades. If you have information that would add value to this effort and would like to participate in the process, please call us at 800/808-1160.

At Rocketdyne, nearly 80 professionals in Safety, Health and Environmental Affairs are dedicated to ensuring a safe, clean and healthy workplace and environment. This commitment not only means protecting you on the job today, but also helping you better understand what past activities might have meant for your health.

Byron Wood
Vice President & General Manager
Rocketdyne Propulsion & Power

Ron Gettelfinger
Vice President, National Aerospace Dept.
International Union, UAW



Aim of Study:

To determine whether any subgroups of company employees were at excess risk of cancer because of occupational exposure incurred at Rocketdyne.

(Request for Proposal, Science Committee, Boeing, UAW, May 2000)

- An increased risk existed for leukemia/lymphoma and lung cancer. The 34 individuals in the high exposure group represented less than 1% of the 4607 people who were studied by UCLA for radiation exposure at Rocketdyne.
- Overall, Rocketdyne workers had a lower incidence of death from "all causes" and "all cancers" when compared to both the US population and other worker groups.

Chemical Phase Results

The Rocketdyne Worker Health Study chemical phase was released in April 1999. In this phase, UCLA researchers examined the risk of dying from lung and other types of cancer among 6,107 Rocketdyne/AI employees presumed to have had the highest exposure to hydrazines, and 4,563 Rocketdyne/AI employees presumed to have had the highest exposure to asbestos. These groups were then compared to those workers presumed to have had lower exposure to the two selected chemicals. The chemical phase did not look at actual measured doses to individual workers, but instead, grouped workers in exposure classifications based on job titles. The UCLA researchers concluded that:

- A greater risk existed of dying from lung cancer among the group of workers with the presumed highest exposure to hydrazines.
- A potential increased risk existed of dying from cancers of the blood and lymph system, bladder and kidney among the group of workers with the presumed highest exposure to hydrazines.
- No association existed between asbestos exposure and lung cancer.

Expert Peer Review Process

Distinguished outside experts, or peer reviewers, in the fields of epidemiology, biostatistics, oncology, toxicology, public health and occupational health were employed by Rocketdyne to provide a technical review for each phase of the study to aid in our understanding the results. The focus of their review was to evaluate the methodology, results, strengths and limitations of the study. Rocketdyne asked each peer reviewer to focus on certain aspects of the study based on his or her areas of expertise.

Rocketdyne's outside peer reviewers played an invaluable role in evaluating the study to help our employees understand the health implications. The Rocketdyne review panel stated that the UCLA study was not conclusive but that it did raise questions about potential worker health issues that needed further study. Therefore, the panel recommended that Rocketdyne immediately begin a follow-on study to aid in providing those needed answers.

Moving Forward

In support of our commitment to answer questions raised by the UCLA study and on the recommendations of our expert review team, Rocketdyne, in partnership with the UAW, initiated a process two years ago to conduct a Rocketdyne Worker Health Follow-on Study.

The first step in this effort was completed in 1999. We assembled a new group of outside experts to oversee the Follow-on Study. Jointly selected by Rocketdyne and the UAW, the Rocketdyne Worker Health Science Committee is comprised of the following specialists in their specific areas of expertise and affiliations:

Scott Davis, PhD	Epidemiology/Radiation	University of Washington/ Fred Hutchinson Cancer Research Center
John Dement, PhD, CIH	Industrial Hygiene/Epidemiology	Duke University
Karl Kelsey, MD	Cancer/Toxicology	Harvard School of Public Health/ Brigham and Women's Hospital
John Peters, MD	Environmental Medicine	USC School of Medicine
Jack Siemiatycki, PhD	Epidemiology/ Biostatistics	University of Quebec/ Armand Frappier Institute
Laura Welch, MD	Occupational Medicine/ Radiation Epidemiology	George Washington University/ The Washington Hospital Center

The Science Committee was tasked with determining what the Follow-on Study would address and selecting a contractor to perform the work.

Project Scope

Boeing and the UAW jointly developed the process to select a contractor for the Follow-on Study, which was based on a process the UAW uses at other sites to study workers. The Science Committee reviewed the UCLA studies, visited SSFL and developed a project scope of work. The scope of work specifies the study of workers exposed to radiation during nuclear research or cleanup and/or potentially exposed to chemicals during rocket engine testing. These groups will include the same two worker groups studied by UCLA. The Follow-on Study will be more comprehensive by including a workers' total radiation dose from their entire work history and by evaluating all of the chemical usage associated with rocket engine testing. This study will include all appropriate exposure groups and will follow the workers an additional seven years since 1993, which was the ending date of records examined in the UCLA study.

A Request for Proposal was sent to more than 100 potential bidders, including universities, schools of public health and private consultants. Potential candidates submitted preliminary qualifications to aid the Science Committee in narrowing the selection to four qualified bidders. The four bidders submitted detailed proposals that were reviewed by the Science Committee. The UCLA study team did not submit preliminary qualifications.

Contractor Selection

In December 2000, the Science Committee selected the International Epidemiology Institute (IEI), a leading epidemiology research organization that works in conjunction with Vanderbilt University. This selection was solely the responsibility of the Science Committee—neither Rocketdyne nor the UAW voted. The Science Committee concluded that IEI/Vanderbilt brought the most qualified team of experts in the radiation exposure area and had the most comprehensive approach to the chemical exposure assessment. The contract was signed and put into place effective January 2001.

The principal investigator is Dr. John Boice, Scientific Director at IEI, Professor of Medicine at Vanderbilt University and former head of the Radiation Epidemiology Branch of the National Cancer Institute. He brings over 25 years of experience in conducting studies of groups exposed to ionizing radiation, is currently advisor to the United Nations on radiation effects and is on the Main Commission of the International Commission on Radiation Protection and Measurement. The IEI team includes a wide-range of internationally known scientists from Oak Ridge National Laboratory, Oak Ridge Associated Universities and Vanderbilt University. IEI also has many years of experience in conducting studies of workers exposed to chemicals in manufacturing, assembly and maintenance in the aerospace industry.

Study Improvements :

The Study will be more comprehensive by including a workers' total radiation dose from their entire work history and by evaluating all of the chemical usage associated with rocket engine testing.

ENSURING CONFIDENTIALITY

Whenever humans are the subject of a research study, even an epidemiology study of potential health outcomes, the study protocol is reviewed to ensure that correct procedures are being used and employee records will be kept confidential. These reviews are conducted by Institutional Review Boards (IRB).

For the Follow-on Study, the IRB study protocol review covered areas such as how workers are to be contacted, the types of questions to be asked, and what measures IEI/Vanderbilt will employ to ensure that all data is handled confidentially. For this study, these measures will include the following:

- Files with personal identifiers (such as name, address, phone number) will be stored in locked cabinets in a secure location with access available only to study personnel.
- Personal identifiers will not be entered into the data analysis files.
- Computers will be password protected.
- All personal identifiers will be removed before the study becomes public.

Boeing required that two IRB reviews be completed and the study protocol approved before any employee or company information would be provided to the contractor. The first IRB review was performed by Boeing, with participation from the UAW, and the second was completed by Vanderbilt University. In both cases, the study protocol was approved.

WHAT'S NEXT?

With oversight from the Science Committee, IEI/Vanderbilt will move forward with this Follow-on Study over the next three years. Some ways in which IEI/Vanderbilt will be gathering information include conducting employee and retiree interviews, reviewing historical company documents and searching records from the Social Security Administration and other federal and state departments of vital statistics.

Periodic updates will be made available to current and former employees during the Follow-on Study.

If you have questions or would like more information about the details contained in this communiqué, please call Rocketdyne at 800/808-1160 or the UAW Health & Safety Department at 313/926-5563.

October 2001 (Rev)

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CP7521/01

ROCKETDYNE WORKER HEALTH STUDY

Appendix H

Responses to Issues Raised by Science Committee (2001-2005)

July 13, 2005

RESPONSES TO SCIENCE COMMITTEE COMMENTS RECEIVED FEBRUARY 10, 2005 ON FINAL REPORT*

ROCKETDYNE WORKER HEALTH STUDY

INTERNATIONAL EPIDEMIOLOGY INSTITUTE

March 10, 2005

* Because of copyright restrictions, detailed tables of the study findings cannot at this time be posted on the website during the journal review process of four manuscripts submitted for publication. It is envisioned, however, that they will be made available sometime in the forseeable future.

Each of the 14 comments from the Science Committee is reproduced in bold and then followed by an IEI response. The additional tables requested are found in the attached Appendix.

1. **The SC continues to be impressed with the quantity and quality of work carried out in such a short time. The following comments are intended to improve on an already excellent product.**

    Response: Thank you.

2. **The SC appreciates the responsiveness of IEI to the various requests that we formulated over the past few months.**

    Response: Thank you. We will continue in our attempt to be responsive to the issues raised by the Science Committee.

3. **We recognize that IEI has added a large number of tables to these reports and that integrating them quickly with the text was not easy. Some of the tables are mentioned in the text and others are not. IEI might want to review the text and tables to see if there are any more tables that should be commented on, even if briefly. For example, Chem 2.2, 3.0, 6.2, 6.4 are not mentioned in the text but appear as part of the tables attached to the paper. One editorial comment from the SC is that the ordering of tables could be reversed, to respect the principle of going from the general to the particular. As an example, in the Radiation results paper, Table 3.2 would precede Table 3.1.**

    Response: Comments for the Tables mentioned above are included below. We will provide comments also for other Tables with missing comments as recommended. We will also integrate these comments into the appropriate manuscripts and documents. We will reorder the tables as recommended. Below we list the titles for the above mentioned tables followed by comments.

    Chem Table 2.2 Observed and Expected Numbers of Deaths and Standardized Mortality Ratios (SMR) for Rocketdyne Workers in the Chemical Cohort by Work Location (SSFL, Other Rocketdyne Facilities, Total) White Males Only. General Population of California Used to Compute Expected Numbers.

    Comment: Analyses were conducted for white male workers separately. Because white male workers make up the large majority of workers in the study population, there were no noticeable differences in the SMRs compared to analyses including all races and all genders. For example, for white male workers at SSFL, the SMR for all cancers was 0.87 (95% CI 0.89-0.95) based on 560 deaths (Table 2.2). For all SSFL workers, both men and women and both white and non-white workers, the SMR for all cancers was 0.89 (95% CI 0.82-0.96) based on 655 deaths (Table 2.1).

    Chem Table 3.0 Observed and Expected Numbers of Deaths and Standardized Mortality Ratios (SMR) for SSFL Workers by Time Since First Hire (Latency). General Population of California Used to Compute Expected Numbers.

Comment: Duration and latency SMR analyses were also conducted for 3 latency intervals and 3 duration of employment categories for 12 selected causes of death [Table 2.2; Appendix Table 2.2]. No cause of death, including lung cancer, was significantly elevated in any latency category. Risk for all cancers and lung cancer were higher among workers in the years 10 or more after first hire than in the first 10 years after hire, as typically seen in occupational studies where the low risk immediately after hire is attributed to factors that select healthy persons into the workforce. Such initial selection often decreases with increasing follow-up and there were no differences seen in years 10 to 29 (SMR all cancer 0.90) and in years 30+ (SMR all cancer 0.92). No cause of death, including lung cancer, was significantly elevated in any duration category and no clear patterns emerged, e.g., for duration of employment categories of < 5 yr, 5-9 yr, and 10+ yr the SMRs for lung cancer were 1.14, 1.25, and 1.03, respectively (Appendix Table 2.2).

Chem Table 6.2 Observed and Expected Numbers of Deaths and Standardized Mortality Ratios (SMR) for Male Hourly Test Stand Mechanics by Duration of Employment as a Test Stand Mechanic. General Population of the United States Used for Comparison.

Comment: Table 6.2 presents the SMRs for test stand mechanics by duration of employment using the general population of the United States for comparison. These SMR values are generally lower than those computed using the population of California for comparison (Table 6.1). Neither the US general population nor the California general population are ideal comparison groups because of differences between workers and the general population in potential confounding factors, and because of the selection factors of health associated with employment. As such, the internal cohort analyses are preferred in making inferences as to the possible effect of workplace employment on health (e.g., Tables 6.3 and 6.4 discussed below). Even the choice of California versus the United States for comparison is not entirely straightforward because at least 25% of the workers had left California after employment at Rocketdyne (based on information found on the death certificates for place of death). The use of the US population for comparison is often used in occupational studies because of availability of rates and because of the mobility of the workforce. The SMRs were lower when comparisons were made with the US population than the California general population. Thus the more accurate SMR values for this mobile population likely lies somewhere between those computed using US rates and those computed using California rates. Comparisons with the general population are useful for assessing patterns of risk that might be further analyzed within the cohort.

Chem Table 6.4 Internal Cohort Dose-Response and Relative Risk (RR) Computations for All Cancer Combined, Lung Cancer and Kidney Cancer for Test Stand Mechanics Over Categories of Years Worked as a Test Stand Mechanic. Other SSFL Workers Used as Referent.

Comment: Table 6.4 is similar to Table 6.3 except that only SSFL workers are used as the referent category whereas all Rocketdyne workers not monitored for radiation were used in Table 6.3. The distributions of risk over categories of years worked as a test stand mechanic were nearly identical as were the p-values for trend. For all cancers and lung cancer there was no evidence of increasing risk with increasing years worked as a test stand mechanic; and the RRs among the 474 mechanics who worked more than 5 years on a test stand were 0.99 (95% CI 0.72-1.35) and 0.96 (95% CI 0.58-1.59), respectively. There was a tendency for kidney cancer to be increased with increasing years worked but numbers were small and trend not significant (p=0.8).

4. **Trend tests play a large role in IEI's interpretation of findings. The methods used are sometimes ambiguous. For instance in a table like Rad 6.2, it is not stated whether the values tested are the individual values or group values. In a table like Chem 8.1, it is not clear what values were used for the independent variable. Nor is it clear whether a linear trend test is the best test of an association in a situation where there may be measurement error and non-linearity of effects. We believe the trend tests are informative, but so are point and interval estimates, especially in the face of exposure misclassification, which is inevitable in any retrospective investigation.**

Response: We will be more explicit with regard to the methods used in conducting the tests for trend. Trend tests for all internal cohort radiation dose-response analyses were conducted by entering the individual cumulative radiation dose as a continuous measure into a Cox proportional hazards model along with the exact same set of covariates used in the corresponding categorical dose analysis. This continuous measure of dose was the actual radiation dose value received by each individual worker (in units of rem). From the Cox model, a single estimate of risk was calculated for this continuous measure and the p-value from a Wald chi-square test was presented in the tables as the 'p for trend.' Thus, for Rad Table 6.2 the individual dose values and not group values are used to calculate the trend test.

Trend tests were conducted in similar manner described above for the internal cohort dose-response analyses with years worked taken as the continuous variable of exposure. However, there was one exception. For Chem Table 8.1 ordinal values were used for the independent variable, and we have now added a footnote to the table in this regard. The ordering was based on a logical ranking of the potential for hydrazine exposure among workers in each category.

We have used linear trend tests in most of the evaluations and agree that point and interval estimates are also important to present. Thus, we have presented point and interval estimates for each category in each interval dose-response table. In some of the tables we have also evaluated heterogeneity in the point estimates without any underlying assumption as to a monotonic increase in risk with measures of exposure (Rad Table 10). We also note that using a linear trend test in radiation studies is standard procedure, especially in studies of low dose exposures. We agree that measurement error and misclassification are important limitations in such studies as the one conducted and discuss this limitation in two paragraphs in the Discussion section of the chemical paper.

5. **There are some tables where sparse numbers mean that there is very little power to detect effects in subgroup analyses. In that case we would like an analysis that collapses subgroups. For Rad Tables 6.1 and 6.2 the SC requests estimates of RR with some collapsing of subgroups, for Dose > 5 (combined) and Dose > 10 combined, in addition to those already shown. The other table where we request an analysis collapsing categories is Chem Table 8.3, presenting data with all hydrazine combined compared to test stand mechanics without potential for hydrazine exposure.**

   Response: As requested, we have collapsed the dose data in Rad Table 6.1 and 6.2. Also, we combined the data in Chem Table 8.3 as requested. These new tables can be found in the appendices at the end of this response document. However, we do not believe the combination of hydrazine categories is appropriate. We perhaps have not been clear on the difference between the two categories. The "potential but unlikely" category meant that workers were employed at a large testing area where hydrazines had not been used except at a small sub-area which involved a few workers who we could not identify. For the majority of workers, potential exposure to hydrazine was not an issue because they worked on large engines where hydrazines were not used. However, because we could not distinguish the small number of workers potentially exposed to hydrazines from the larger number not potentially exposed, we created a category of "possible but unlikely" exposure potential. Chem Table 8.3 (also included in the Appendices) was recommended previously by the Scientific Committee and we believe is the scientifically appropriate one. This table separates the potential but unlikely exposure group from the potential exposure group. Nonetheless, the requested Table is found in the Appendix and there was no evidence of trend in years worked combining potential with unlikely exposure to hydrazines. The radiation re-categorization also had little effect on the observed patterns or on the point estimate for the high dose category. It is noted that the point estimates (RRs) for CLL tended to be larger than the point estimates for the non-CLL leukemias which is counter to expectation since CLL is not considered inducible by radiation.

6. **The SC needs to see Rad Table 3.1 broken down by hourly/salary.**

   Response: We provide Rad Table 3.1 broken down by hourly/salary in the attached Appendix. This in an external comparison with rates from the general population of California. We believe the internal cohort comparisons are the most appropriate ones (e.g., Rad Appendix Tables 1.3R and 1.4R also attached) where hourly workers are compared to hourly workers and salaried workers are compared to salaried workers; which minimizes the potential problem of differing characteristics such as smoking habits between the hourly and salaried worker population and the general population. See response to comments (3) and (9). Splitting the data (Table 3.1, included) into an additional two groups also increases the number of comparisons made (35 to 70) which could lead to statistically significant results due to chance rather than a real effect. There also is no reason to believe that hourly workers would respond differently to radiation than salaried workers. Further, Rad Table 3.1 involves only external exposure and not the internal dose contribution which hinders interpretation. Again, the internal cohort dose-response analyses are optimum for making inferences because the full range of doses are included, comparisons with the general population are avoided, and pay type can be adjusted for in the analyses. Such internal cohort analyses for major cancer sites and combinations are found in Rad Tables 5.1, 5.2, 5.3, 6.1, 6.2, 6.3, 7.0, 8.1, 8.2 and Rad Appendix Tables 1.3R, 1.4R, 2.2R, 2.3R, 3.1R, 3.2R, 4.1R, 4.2R, 5.1R, 5.2R.

Other comparisons with the general population for hourly and salaried workers can be found in Rad Appendix Tables 1.1R and 1.2R and Chem Tables 5.1, 5.2 and 6.1 as requested previously. It can be noted that there were few significant elevations in SMRs for hourly workers based on comparisons with California rates and no significant elevations when US rates are used. As described in (3), the more accurate SMR values must be between those computed from US rates and California rates for this mobile population.

7. **Initially, IEI intended to carry out some analyses using the Lockheed workers as a comparison population. Has this been done but not reported?**

Response: Initially, we had thought that it would be possible to make direct comparisons between the Lockheed Martin Worker Study and the Rocketdyne Worker Study, but we decided that the Canoga Park and De Soto Avenue workers would be an even more appropriate comparison group which could be followed for the same number of calendar years. The mortality follow-up of the Rocketdyne workers was up to the year 2000, whereas the Lockheed Martin Cohort stopped in 1996. The Canoga Park and De Soto workers also were similar in selection factor for employment, health care and local residence as SSFL workers.

8. **For many of the contrasts examined, statistical power to detect an effect was low and confidence intervals were wide. Such findings may be consistent with the null hypothesis but they don't prove it. The SC thinks the limitations of the data in detecting hazards (which were inherent in the study and not the fault of the investigators) need to be clearly stated alongside the interpretation of the results.**

Response: We agree. More can be added with regard to explicit statements about the limitations of the data to detect hazards. In the Discussion sections we will enhance this point regarding the ability to detect presumed risks in this worker population. We have also drafted a "text-box" to the lay summary (see below) and look forward to the SC comments on how best to portray these issues to workers and the retirees.

"Making causal inferences based on small numbers of cases. The number of cancer deaths can determine whether a study has the ability to detect a statistically significant increase. Studies involving small numbers are not as powerful as studies with large numbers. Small numbers result in estimates of risk that are very imprecise which means that chance often cannot be ruled out as an explanation for the findings. This does not mean that there was no increase in risk, just that the ability of the study to detect the risk was limited. Similarly, there were also tendencies for risk to decrease with increasing amounts of radiation such as for lung cancer and liver cancer. Again, the decrease was not statistically significant and chance could not be excluded as a possible explanation. Non-statistically significant decreasing trends or tendencies do not mean that radiation reduced the risk of cancer any more than non-statistically significant increases mean that radiation caused the increase. The study just wasn't large enough to provide clear results."

9. **The interpretation of lung cancer results is critical. The SC is concerned that the sentence included in the title of the several tables ("Caution in Interpretation… General Population") is an inappropriate flag. It is unorthodox to include such a disclaimer in a title and it might lead to inference that the results are uninformative. The SC does not necessarily disagree with the spirit of this statement but we feel that it would be preferable to deal with this particular issue in the text as with any other issue that affects the interpretation of results.**

   Response: We have now removed the phrase in the table titles regarding concern over differences in smoking habits between hourly and salaried workers that might be responsible for some of the patterns observed. These issues had been discussed fully in the text, as well as in the sub-study recommended by the Science Committee regarding smoking habits between salaried and hourly workers.

10. **IEI states that their results "fail to confirm" the UCLA findings. The reader could interpret this in different ways. It may mean that the results differ or it may mean that IEI interprets the same results in a different way. It may be worthwhile to spell out what is meant by "fail to confirm", as noted above under (8).**

   Response: At the request of the SC we had attempted to spell out differences between the UCLA study and the IEI study. An entire section had been added to the Final Report Appendix presenting the differences in the exposure categories and in the findings. We tried to match our categories to those presented by UCLA. Our general statement regarding "fail to confirm" was meant to imply that the statistically significant findings reported by UCLA and the patterns reported were not borne out with our additional follow-up. We will, however, try to use more explicit language in the Executive Summary, and papers, so as not to be misleading. We agree, also, that issues of statistical power are also important and will discuss more fully as done in our response to (8).

11. **The SC notes that there has not been an explicit discussion of the possibility of conducting nested case-control studies. IEI appears to think this would not be fruitful. The SC thinks it is important that IEI makes it clear what their recommendation is in this regard, and state explicitly why they have reached this conclusion.**

   Response: In the Executive Summary, section 10 on Recommendations we state "Because there were no significant increases seen in the cohort internal dose-response evaluations, there seems little justification to consider nested case-control studies at this time. The additional number of cancer deaths that would accrue in a further follow-up, however, would be informative with regard to the health evaluation of Rocketdyne Workers."

Our conclusion is based upon several observations, including the absence of any significant or consistent excesses. As the SC mentions in (5) and (8) the study in general has limited statistical power to detect effects (whether using a cohort approach or a case-control approach). The radiation dose distribution is very low and much lower than in other studies were effects are clearly evident. The numbers exposed to "high" doses of radiation are small, as are the numbers of workers "potentially" exposed to hazardous chemicals. The exposure assessment problem for the chemicals is recognized by the SC as above, which includes having to use "years worked" as a surrogate for actual exposure and to the fact that the exposures occur outdoors and not in enclosed spaces where concentrations are necessarily diluted. Attempts to improve the exposure assessment to radiation or to chemicals are unlikely to yield an appreciable improvement. Additional investigation of potential confounding influences, such as tobacco use, would not be recommended because of the absence of any significant increases over categories of radiation dose to lung or over categories of years worked as a test stand mechanic. Obtaining accurate and valid smoking information would be difficult, also, for those who have died, where surrogate responses from spouses or children many years after the fact would have to be obtained. Finally, the number of cancers for some sites of potential interest, such as kidney, are small and generally less than 10 and not amenable for meaningful case-control evaluation.

Thus, the small numbers of workers in the study, the relatively low exposures to radiation and chemicals, and the absence of any significant or consistent excesses argues at this time against the need for a nested case-control investigation.

12. **In judging the results of this study, one has to break it down by outcome. Is there an excess risk of lung cancer? Is there an excess risk of leukemia? Is there an excess risk of kidney cancer? At present it is quite difficult to form a clear opinion because the results for a given outcome (e.g. lung cancer) are spread over scores of tables. It would help the SC and other readers if all the findings on the three cancers of concern (lung, leukemia, and kidney) are retrieved and presented in a single (long) table. Such a table should include information on the exposure group, the comparison population, whether external or internal, the table of origin, and other critical variables that define the contrast.**

Response: The Science Committee is asking for a table that summarizes the findings on lung cancer, leukemia and kidney cancer. It is requesting that all exposure groups and comparison populations and analyses be put together in one long format. We have made an attempt and include 5 tables in the Appendix summarizing the internal cohort analyses for lung cancer, kidney cancer and leukemia for the radiation cohort and the chemical cohort. We have not had the time to do a similar tabulation for the SMR analyses but note that the information is available in the tables in the Final Report. The SMR analyses are also more limited than the internal cohort dose-response analyses presented, as discussed in (6), for making inferences.

13. **IEI has done an excellent job. Because of various administrative and logistical exigencies, it is necessary to produce a report quickly on this study. Nevertheless the**

database remains one which could potentially be further analyzed and exploited to elucidate possible health risks among the workers at Boeing. This could take the form of new analyses with the data available, or nested case-control studies, or tracing in incidence tumor registries, or additional mortality follow-up. Boeing and UAW must establish guidelines for the storage and maintenance of the data that were collected in this enterprise, and develop a system for allowing access to the data so that useful analyses can be conducted in the future by others.

> Response: Boeing has already agreed that the edited datasets (without personal identifiers) are to be placed on the DoE website (CEDR, Comprehensive Epidemiologic Data Resource). This will be done as soon as manuscripts and other contract work are complete. Other issues regarding the database are to be decided by Boeing and UAW.

14. **The documents presented represent the work and opinions of IEI. The SC intends to produce its own brief document summarizing its interpretations of the results. This should be done in March 2005.**

> Response: IEI looks forward to receiving a copy of your document summarizing interpretation of the results. I'm confident that we can converge on a single summary that would be helpful to Boeing and UAW when describing the study results to workers and retirees.

INTERNATIONAL
EPIDEMIOLOGY
INSTITUTE, LTD.

January 14, 2005

To: Steve Lafflam, Division Director, Safety, Health and Environmental Affairs
From: John Boice, Scientific Director, IEI
Subject: Final Report for Rocketdyne Worker Health Study

Enclosed is the revised Final Report taking into account the recommendations made during the 6 December 2004 meeting of the Science Committee. The components are:

- Executive Summary
  - Index of Radiation Tables and Figures
  - Index of Chemical Tables and Figures
  - Index of Tables and Items in the Detailed Appendices
- Radiation Study
  - Radiation Tables and Figures
- Chemical Study
  - Chemical Tables and Figures
  - Index and Tables of Chemical Cohort Excluding Radiation Workers
- Radiation Dosimetry Paper
- Uranium Aluminide Paper
- Detailed Appendices

A detailed summary of recent work as well as a summary of the revisions made in response to the recommendations received during the December meetings also are attached.

We are working on a draft "Lay Summary" and should be able to send to you shortly.

Enclosures (as above)

cc: Scientific Advisors for Rocketdyne Worker Health Study
Frank Mirer

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Responses to the Recommendations Made During the December 2004 Meetings
January 15, 2005

New Items and General Comments:

1. *Figures.* Figures have now been added to the Radiation and Chemical Sections for selected internal cohort dose-response analyses.

2. *Multiple Comparison Groups.* For many of the analyses, different comparison groups are now presented. For SMR analyses, comparisons are made with California and with the U.S. general populations and occasionally with the Los Angeles + Ventura county populations.

For internal cohort analyses for the Chemical Cohort (test stand mechanics for example), comparisons are presented with Rocketdyne workers, SSFL workers, and with "zero exposed" test stand mechanics (for hydrazines and TCE analyses) as referent.

3. *White Males.* Analyses restricted only to white males are presented.

4. *Early Years after Hire.* Tables are presented which exclude the first 10 years of follow-up after hire.

5. *Latency and Duration.* Several tables are presented by latency intervals (time since hire) within categories of duration of employment.

6. *Lagging.* Radiation tables are presented with a 2-year lag for leukemia analyses and a 10-year lag for analyses of solid cancers.

7. *UCLA Comparisons.* Detailed comparisons with the previous investigation by UCLA are now presented in the Appendices, Section D. The key summary tables from the UCLA investigation are reproduced and then the data corresponding to the current investigation are presented for comparisons.

8. *Smoking.* The results of the Smoking Survey have been tabulated and are presented in the Appendices, Section C.

9. *Dosimetry Paper.* Was submitted to Health Physics and received a favorable review (tentative acceptance).

10. *Reformatting and Restructuring Tables*. As recommended, detailed listings of tables and detailed titles have been prepared. Further, all tables pertaining to the Radiation Study now follow the Radiation Paper in the format of detailed index (listing), text tables, appendices tables and figures. All tables pertaining to the Chemical Study follow the Chemical Paper in format: index, text tables, appendices tables, figures. The appendices radiation and chemical tables mainly are those "auxiliary" tables that support statements made throughout the texts.

11. *Appendices.* As before, the appendices include an eclectic group of items pertaining to (A) a few additional analyses and summary tables that include "all" (radiation and chemical) Rocketdyne workers studied, (B) study topics such as asbestos, (C) detailed smoking survey results, (D) tabular comparisons with UCLA study, (E) databases used during the study, (F) glossary of terms, (G) study documents (essentially volume 7A distributed 6 December 2004 which included IRB approvals, quarterly reports, etc).

12. *Executive Summary.* This provides an overview of the study conduct and results. Brief paragraphs then follow summarizing the (1) IRB approvals, (2) identification of study population, (3) tracing of population, (4) cause of death determination, (5) assessment of radiation doses, (6) chemical exposure assessment, (7) study findings, (8) auxiliary analyses, (9) comparisons with the UCLA study, (10) recommendations for future study, (11) manuscript drafts.

Responses to each of the 20 items distributed after the 6 December meeting of the Science Committee are made below in *italics*.

1. Revise table titles to be more specific. Longer titles as needed.

   All table titles have now been revised to be as explicit as possible with regard to content. Footnotes also have been added to aid understanding.

2. Provide a list of all tables.

   Two detailed listings of the tables and figures have been provided, one for the Radiation Study and the other for the Chemical Study. These index listings are found after the Executive Summary and also reproduced after the respective Radiation and Chemical papers.

3. Conduct analyses that include the radiation exposed workers who were test stand mechanics in the SSFL cohort.

   The 182 test stand mechanics, who also had been monitored for radiation, have now been included in all Chemical tables. We have kept the previous tables that do not include the radiation workers as an additional appendix in the Radiation Section with each title including the letters NR for "no radiation". UCLA did not include the workers monitored for radiation.

4. Place Appendices Analyses after the Appropriate Paper and not in separate Appendices.

   All the chemical-specific and radiation-specific analyses and tables have now been placed after the appropriate paper. The are referred to as "radiation appendix tables" or "chemical appendix tables". The only analytical tables that remain in the Appendices are a few overview tables that include all Rocketdyne workers studied, i.e., combining the radiation and chemical cohorts.

5. Be more consistent in description of results. Use "statistical significance" as appropriate. More uniformity and care in describing risks that are not "statistically significant" risks.

   We have attempted to be more uniform in describing results, but some inconsistencies may remain. We will continue to review and revise for consistency and clarity.

6. Radiation paper. Latency analysis, Table 3a. 2-year latency for leukemia and perhaps 10-year latency for solid cancer. Conduct dose response with internal referent with lags also.

   Analyses have now been conducted and tables presented with 2-year latency periods for leukemia and 10-year latency periods for solid cancers. Internal cohort dose-response analyses have also been conducted with 2-year lags for leukemia and 10-year lags for solid cancers. [see Radiation Tables 2.3, 3.1, 4.1, 5.1, 5.3, 6.1, 6.3, 8.1, Appendix Tables 1.3R, 1.4R, 2.2R, 3.1R, 4.1R, 5.1R; Chemical Tables 2.3, Appendix Tables 2.2C, 3.0C] Analyses without latency considerations and lags are also presented.

7. More evaluation of Hydrazine. Analyses using "no hydrazine exposure as the referent". Little is known about hydrazine, but exposure is outdoors (Simi = windy) and not in confined environment. Anomalies in SMR analyses. But be careful in reading too much in the SMRs since hydrazine workers all hourly, non-administrative and general population contains salaried workers and not optimum comparison. More confidence in the radiation findings since doses low, and little excess expected and little seen, and body of literature to support finding. Not so for hydrazine. Little human literature. But number exposed also low.

   Internal cohort dose-response analyses for hydrazine (and TCE) have now been conducted using three different comparison groups: All Rocketdyne workers, SSFL workers, and test stand mechanics with no years of work with hydrazine (or, correspondingly, with TCE). [See Tables 8.1-8.3 and 9.1-9.3].

8. Non-SSFL hourly workers have significant excess risk compared with some general population

comparisons. Hourly, non-administrative workers likely select on smoking but could be chemical/other worker environment. Conduct internal analyses by years worked at non-SSFL facilities. Conduct duration and latency analyses also. Perhaps force of mortality is in the long latency but short duration group. Perhaps health related termination.

Internal dose-response analyses have been conducted for the non-SSFL workers over years worked for all cancers taken together, lung cancer and kidney cancer using two different referent cateogies: SSFL workers who were not test stand mechanics and non-SSFL who had worked less than 2 years [Chemical Appendix Tables 4.1, 4.2]. No trends or subcategories were statistically significant.

Duration and latency SMR analyses were also conducted for 3 latency intervals and 3 duration of employment categories for 12 selected causes of death [Appendix Table 3.0]. As stressed throughout the report, hourly workers are know to use tobacco to a greater extent than salaried workers and the general populations and care is necessary when evaluating SMR analyses. Lung cancer was significantly elevated in several categories but no clear patterns emerged, e.g., for duration of employment categories of < 5 yr, 5-9 yr, and 10+ yr the SMRs were 1.25, 1.15, and 1.15 respectively.

9. Conduct similar latency (years since first hire), duration analyses for SSFL workers also as above.

Duration and latency SMR analyses were also conducted for 3 latency intervals and 3 duration of employment categories for 12 selected causes of death [Appendix Table 2.2]. No cause of death, including lung cancer, was significantly elevated in any categories and no clear patterns emerged, e.g., for duration of employment categories of < 5 yr, 5-9 yr, and 10+ yr the SMRs for lung cancer were 1.14, 1.25, and 1.03, respectively.

10. Consider moderate upgrade of conclusion of the Chemical paper regarding findings for TCE.

The conclusion has been slightly modified. *The discussion of the association between TCE and kidney cancer is as follows. "Arguments favoring a causal interpretation in our series include the magnitude of the increase risk, over two-fold, the suggestion of a dose response and the consistency with animal evidence. Arguments against a causal interpretation include the small numbers of observed cases, i.e., no association was statistically significant, the absence of any increased risk for the other cancers, such as lymphomas, thought to be inducible by TCE, the role of chance due to multiple comparisons, and exposure assessment inaccuracies. Nonetheless, the finding should be evaluated further in any additional follow-up of the Rocketdyne population.*

11. Dose response analyses separate for hourly and salary workers.

Radiation internal cohort dose-response analyses have been conducted separately for hourly and salaried workers for all cancer taken together, all cancers excluding leukemia, and lung cancer [Appendix Tables 1.3R, 1.4R]. Analyses with and without 10-year lagging of dose are presented.

Internal cohort dose-response analyses have been conducted separately for hourly and salaried workers for all cancers and lung cancer for workers in the Chemical cohort over years of employment at SSFL [Chemical Table 10.2]

12. Stomach cancer data missing in Appendix Table C6.

The stomach cancer data have now been included. It was missing in previous Appendix Table C2, not C6. This table has been modified and is now Chemical Table 10.1.

13. Consider preparing a Lexicon or Glossary of terms/definitions used throughout. Monitored, hourly, salaried, administrative, etc.

A five page glossary of terms used throughout the report has now been included as Section F in the Appendices.

14. Revisions to be made by IEI by January 15, 2005.

    Revisions complete on January 14, 2005 and placed in Federal Express envelops for next business day delivery.

15. Advisory Committee to have Conference Call, January 26, 2005, 11 am EST.

    We understand that the conference call has been changed to January 31, 2005. It has been set up by Nina Mattera and is scheduled for 10 a.m. (Pacific Time). The phone line is scheduled for 2 hours in the event extra time is needed. (866) 350-0777 then Pass Code - 83605#

16. Don't wait to send all revisions at once. Send radiation first. Send the lay summary for radiation at that time also (with the general information that pertains to both rad and chemical).

    We decided not to send the Radiation pieces first but to send everything 2 weeks in advance of the January 31st telephone conference call.

17. Smoking Survey. Complete details as survey questionnaires come in. Add write up of the abstraction done of medical records. Include national survey data and add California data if it exists.

    Detailed results of the Smoking Survey are now presented in Section C of the Appendices. A discussion of the Smoking Survey results, abstraction of medical records and comparisons with national and California data can be found in the Appendices Section C as well as in the Discussion Section of the Chemical Paper. The conclusions are that hourly workers use tobacco products to a greater extent than salaried workers, and that hourly workers have used tobacco products to a greater extent than the general population, including the general population of California which has lower prevalences of smoking than practically all other states. [See also: Centers for Disease Control and Prevention (CDC). Cigarette smoking among adults – United States, 2002. MMWR Morb Mortal Wkly Rep 53:427-431, 2004a. And Centers for Disease Control and Prevention (CDC). State - specific prevalence of current cigarette smoking among adults – United States, 2002. MMWR Morb Mortal Wkly Rep 52:1277-1280, 2004b.]

18. Roll Out, communication plan tentative for April 6-8. April 6 for travel and perhaps practice. April 7 and April 8 for 2 presentations to workers and one presentation to retirees. Be ready for press inquiries but don't make press release. Be able to respond to public questions.

    A lay summary is being drafted for distribution for review shortly. Presentations will be made as discussed.

19. Provide specific exposure information for workers who are still alive and may wish to know their Rocketdyne radiation dose.

    Specific radiation exposure information will be provided for workers still alive regarding their exposure while working at Rocketdyne.

20. Steve Lafflam asks that these "rough" notes be sent to him, Frank Mirer and the Advisory Committee.

    The notes were sent as requested around 7 p.m. after the meeting had concluded on 6 December 2004.

ROCKETDYNE WORKER STUDY (11 MAY 01)

Responses to Requests of the Scientific Advisory Committee at 1 Feb 2001 Meeting

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I. **Provide a more specific approach to the study conduct based on new knowledge gained from visits and data evaluation.**

The numbers in the various figures will change somewhat as the study progresses. Best estimates are presented.

A. Population Identification

1. Radiation Workforce (see Figure 1).

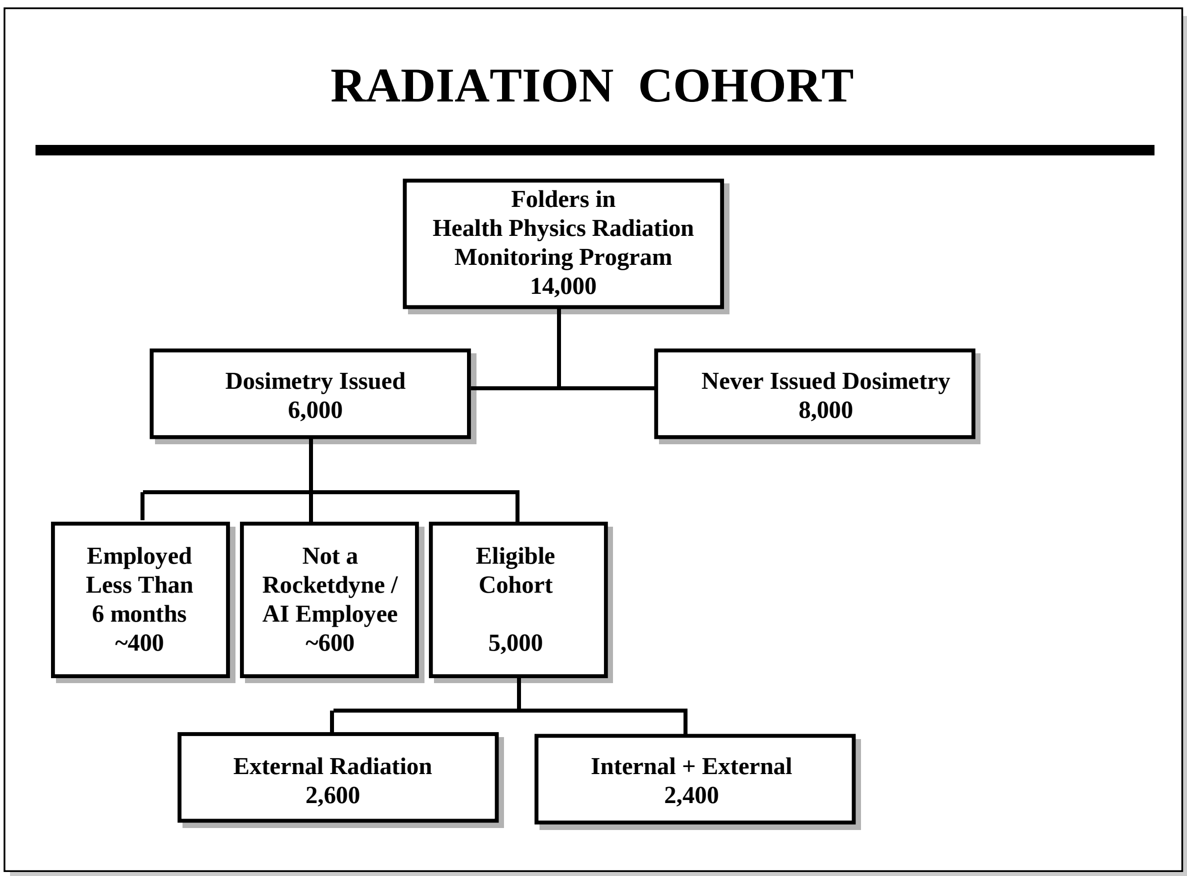

Figure 1 - Radiation Cohort, numbers are approximate

The radiation workforce will be identified from the 14,000 personnel folders within the Health Physics Radiation Monitoring Program (HPRMP). All records will be imaged and evaluated for eligibility, i.e., the workers must have been issued dosimetry, worked for at least 6 months at Rocketdyne/Atomics International (AI), and been an employee at

Rocketdyne/AI. Radiographers employed prior to 1984 will be included. Workers will be classified as to whether they were exposed to external sources of radiation (gamma rays, x-rays, neutrons) or had the potential for inhalation or ingestion of radionuclides such as uranium, plutonium, strontium, cesium, tritium or others. Over 8,000 of the 14,000 folders in the HPRMP belonged to individuals who were never issued dosimetry badges because they never worked in a radiation area. Also the folders included visitors and contractors and others who were not employed at Rocketdyne/AI. Thus, the radiation worker population will consist of about 5,000 workers exposed to external and/or internal radiation sources. All 14,000 records are being scanned, each file will be evaluated for eligibility, and then the radiation measurements will be computerized. Thus, numbers are still approximate. Approximately 1,600 of the radiation workers apparently worked at facilities other than SSFL (Figure 2).

2. SSFL Chemical Workers - Test Stand Workers (see Figure 2)

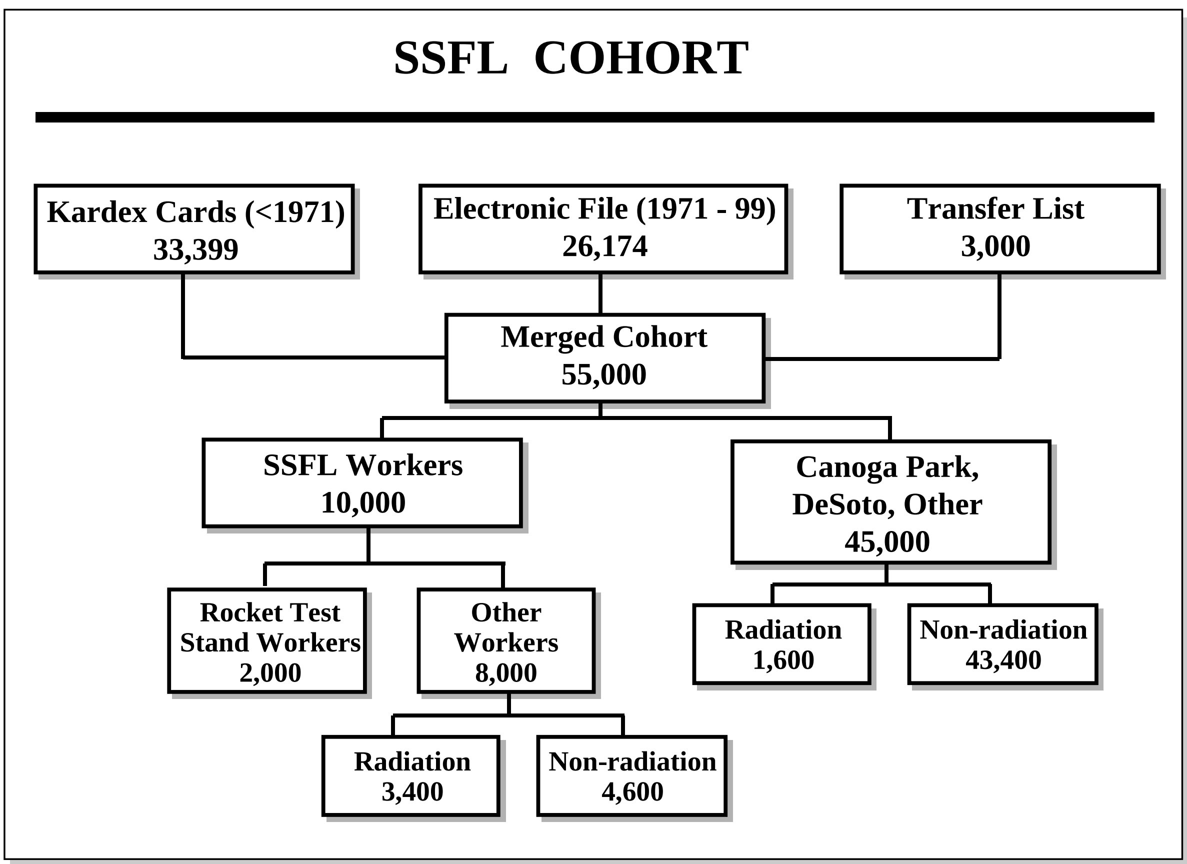

Figure 2 - SSFL Cohort, numbers are approximate

The SSFL workforce will be identified from the scanned Kardex cards, the electronic personnel files and the transfer list. Based on single, double or triple letter location codes, the SSFL workforce will be identified. Eligible workers must have worked at least 6 months at SSFL. The key group potentially exposed to chemicals will be the rocket test stand workers who will be identified from job titles and interviews (discussed below). Currently it is estimated that about 2,000 were involved with rocket engine testing with potential for exposure to fuels, solvents and other chemicals. Approximately 4,600 other SSFL workers will also be evaluated for exposure to chemicals used in the course of laboratory or other work.

3. Comparison Workers

There will be two potential sources of non-exposed or minimally exposed workers, those at SSFL and those at other facilities such as Canoga Park. It is estimated that approximately 48,000 Rocketdyne workers will be available for comparison purposes with the radiation and chemical workers. They will be followed for mortality and basic job histories will be determined. Comparison workers must have been employed by Rocketdyne/AI for at least 6 months.

B. Radiation Exposure Assessment

1. Radiation Records

The radiation exposure data will be extracted from the scanned dosimetry files of the HPRMP (Figure 1). Although there are over 14,000 folders in the HPRMP, fewer than 6,000 workers were issued dosimetry badges and thus eligible for study and data abstraction.

10. PERIOD OF EXPOSURE FROM MO (23)	DAY	YR (27)	TO MO (28)	DAY	YR (32)	11 X OR GAMMA DOSE FOR THE PERIOD (rem) DECIMAL (33–38)	12. BETA DOSE FOR THE PERIOD (rem) DECIMAL (39–44)	13. NEUTRON DOSE FOR THE PERIOD (rem) DECIMAL (45–50)	TOTAL DOSE FOR THE PERIOD (rem) DECIMAL
1	01	4	3	31	4	030			030
4	01	4	6	30	4	050			050
7	01	4	9	30	4	060			060
10	01	4	12	31	4	050			050

Figure 3 – Example of External Radiation Record (1964)

Information abstracted for external exposures (for example, Figure 3) will include:

Name
Social Security Number
Year of radiation record
Period of Exposure
Penetrating dose such as X or Gamma (Units)
Non-penetrating dose such as Beta (Units)
Beta Dose
Neutron Dose
Number of Badges Reported

The abstracted dose will be checked against the computerized files of the Landauer dosimetry company which provided dosimetry services during most of the calendar years of study.

DATE	TYPE	ANALYSIS	METHOD	RESULTS	REFERENCE
18 Sept 67	Urine	UR	ID	78 d/m/	U.S. Testing
25 Sept 67	Urine	UR	ID	90	U.S. Testing
2 Oct 67	Urine	UR	ID	78	"
9 Oct. 67	Urine	UR	ID	116	"
16 Oct 67	Urine	UR	ID	175	"
23 Oct 67	Urine	UR	ID	40	"
28 Oct. 67	Fecal	UR UF	ID IA	58 d/m/485 9.29 μg/485	U.S. Testing
30 Oct. 67	Urine	UR	ID	60	U.S. Testing
6 Nov 67	Urine	UR	ID	66	U.S. Testing
17 Nov 67	TBC	U235 for U234		0.0089 μCi U234	UCLA
24 Nov 67	TBC	"		0.0087 μCi U234	ORNL
20 Nov 67	Urine	UR	ID	47	US Testing
21 Nov 67	TBC	U235 for U234		0.0086 μCi U234	UCLA
27 Nov 67	Urine	UR	ID	54	US Testing

MFP | Gβ | H3 | Po | Pu | Th | Gα | ISO | Hg | Pb | Be

Figure 4 – Example of Bioassay Data (1967)

Information abstracted from bioassay data are more complex (Figure 4) and will require individual assessments. Important information to capture will include, in addition to the personal identifiers, specific radionuclides, urine, fecal, and whole body radionuclide count results. Information on acute versus chronic uptakes, solubility and particle size will be captured to the extent available. Air sampling information will be evaluated as available.

2. Lifetime doses

Lifetime occupational exposure to radiation will be captured to the extent available. Sources will include:

Rocketdyne/AI records as above
Rocketdyne/AI records of pre-Rocketdyne dose
Linkages with the following data sets for post-Rocketdyne dose:
- REIRS, Nuclear Regulatory Commission
- REMS, Department of Energy (DOE)
- CEDR, Comprehensive Epidemiological Data Resource, DOE
- Landauer Dosimetry Company Files

3. Bioassay and external dose determination as discussed in the original proposal (Figure 5).

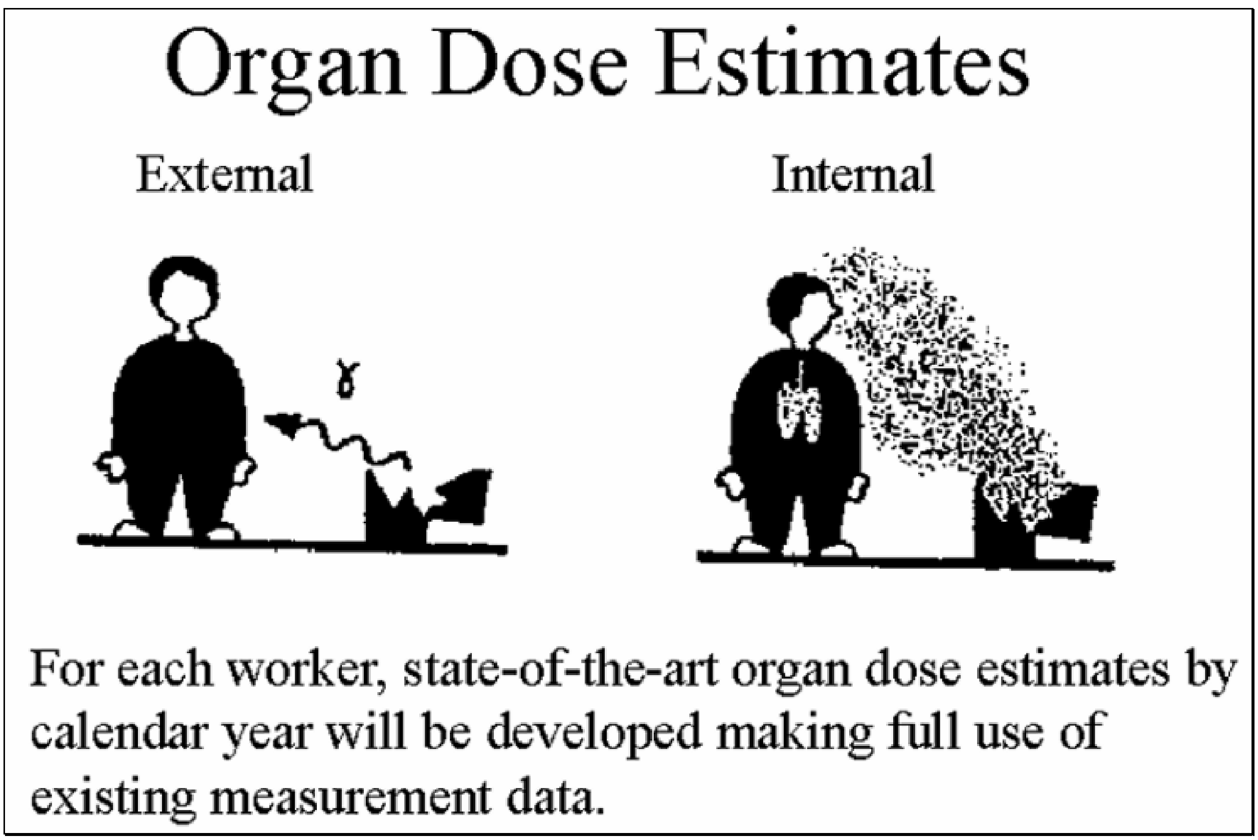

Figure 5 - Organ Dose Estimation

We reviewed the folders for 22 current or former Rocketdyne workers with potential internal exposures to radionuclides. Some of these workers were chosen at random, and some were chosen because bioassay records indicated elevated intakes for at least short periods. The review had two main purposes: (1) to familiarize ourselves with the type of exposure information available in the files, so that we could begin to modify our computer codes to address the types of exposures received at Rocketdyne, and (2) to help determine the type of information that could be computerized by ORAU to facilitate our calculation of internal dose for the large number of cases to be addressed. It appears from these records that exposures often were acute, but in some cases elevated exposures may have continued for several months. The assignment of exposure scenarios is complicated by indications that inhaled material may have been insoluble in some cases and either soluble or a mixture of soluble and insoluble in other cases. It appears that reasonably good estimates of organ doses can be made in most cases.

We recently received scans of the radiation dosimetry records for 100 workers with elevated bioassay measurements and have begun to examine those records in a continued effort to develop a suitable methodology for back-calculating organ doses from the Rocketdyne data. Although generic bioassay models and codes are already available, it is necessary to adapt these to the specific types of information available for the Rocketdyne workers.

C. Chemical Exposure Assessment

Workers will be evaluated for their potential for chemical exposure using a variety of means. Job histories will be important for identifying specific job titles that will require further evaluation. Interviews with workers will be selected based on job titles. Personnel assignment lists, purchasing records, test stand operation records and other records will be incorporated into the exposure assessment scheme.

1. Job Histories (see Figure 6)

Date	Job Title	Location / Plant
1-08-58	MEC ENG PRO T	S
5-17-59	MEC–PROP TST	SH
1-23-61	MEC-PROP TST L/O REINST	SL
3-18-62	MEC-TST S	SL
4-21-63	TEC ENG TST	SL
.	.	.
.	.	.
.	.	.
3-13-66	TEC ENG TST	SH
8-27-67	MEC-TST S	SL
1-02-69	MEC-TST S	SE
12-27-70	MEC-TST S	SL
7-27-75	TEC-ENG TST	TBD

Figure 6 – Example of Job History from Kardex Personnel Cards

For SSFL workers, job histories will be abstracted from the Kardex images or obtained from the electronic personnel files. Jobs with potential for chemical exposure will be identified from job titles, such as engine test mechanics and certain laboratory personnel and equipment handlers. Detailed job histories for radiation workers with chemical exposures will also be abstracted.

2. Test Stand Historical Database

A test stand historical database will be developed (Figure 7). Program, engine, fuels, oxidizers and other chemicals will be enumerated. This database will help in assessing the potential for chemical exposures over calendar years and test sites for specific workers.

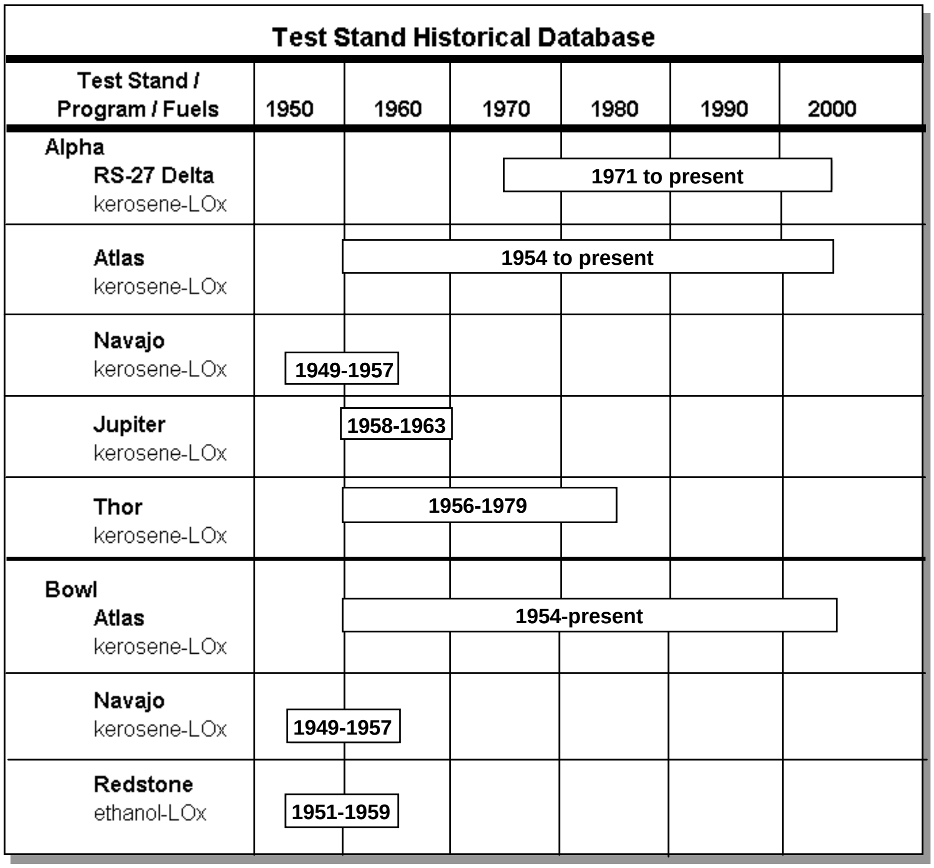

Figure 7 - Schematic of Test Stand Historical Database

3. Personnel Assignment Lists

One challenging aspect of the exposure assessment will be to assign workers to specific engine test sites. The location and use of Personnel Assignment Lists (Figure 8) will be helpful in this regard. The Personnel Assignment Lists look similar to phone books and list individual workers in various occupations at specific test sites.

J-2 Engine Test, D/096-213-Zone 11
Santa Susana Field Laboratory, Dept 096, Group 213

Delta Engineering		**Delta Firing Unit**	
First Shift		**Second Shift**	
Jackson, J.C.	**5416-5419**	**Doe, F.L.**	**5701-5703**
Jackson, C.F.	**5416-5419**	**Doe, V.E.**	**5701-5703**
.	.	.	.
.	.	.	.
.	.	.	.
Delta Pre-Test Mechanics		**Bowl Area Mechanics**	
Third Shift		**First Shift**	
Jones, C.M.	**5701-5703**	**Smith, G.V.**	**5301-5304**
Jones, L.A.	**5701-5703**	**Smith, E.D.**	**5301-5304**
.	.	.	.
.	.	.	.
.	.	.	.

Figure 8 - Abstract of Rocketdyne Engineering Personnel Assignment List (Jan 1965)

4. Worker Interviews

Over 300 interviews are planned. Test stand work and other chemical exposures of the SSFL workforce will be determined. Each worker who consents to be interviewed will be sent a copy of his work history (Figure 6) and, if a test stand worker, asked to recall the corresponding test stand using a prompt as in Figure 7. Groups of workers of the same era are planned to be interviewed together. Others with similar jobs who cannot be interviewed will be assigned to test stands if their co-workers can recall working with them. We plan to discuss this approach at union, retirement and other worker meetings to ask for their advice and support. All occupations with potential exposure to chemicals will be evaluated.

The Interviews will be conducted over a time period of approximately one year.

There are three objectives for the interviews:

- To gain a clear understanding of the chemicals, work practices, engineering controls and respiratory protection used at the various engine test stands and other work locations throughout the years at Santa Susanna;

- To help fill in gaps in the Test Stand History Database that is being developed to detail the chronological history of various engine test programs, fuels and chemicals used;

- To identify specific individuals who worked at specific test stands during specific years.

To better fulfill these objectives, certain tasks must be completed before the interviews begin. Emphasis is on the test stand workers who likely had the greatest potential for chemical exposures but all occupations will be evaluated. The Test Stand History Database should be populated with all existing information so that we have a framework and starting point to support the discussions. Individual work histories should be provided to each employee to facilitate recall. Work histories will need to be abstracted from the 33,400 Kardex images in this regard. In addition, lists of all test mechanics that worked during specific time periods should be available so that the interviews will assist in placing specific individuals at specific test stands. It will likely be 6 to 9 months before this information will be completely available.

The information should be assembled and sent out to each interviewee prior to conducting the interview to give the interviewee time to review the materials, refer to historical documents that they may have or talk to other former workers who may help refresh their memories. Historical photographs will be available as an additional memory help. The interviews should be structured and focused on a specific test stand or area. For example, an interview could focus on the Alpha test stand and the interviewees would all have worked at Alpha sometime during their career. Some will have worked at other locations also and we will gather information about these other sites during the interview. The interview should be conducted in-groups of 4 to 6 individuals that have similar work histories and last 2 to 4 hours.

Various technology resources will be considered to best facilitate the discussions. For example, a digital projector (LCD) attached to a portable computer could be used to project the Test Stand History Database so that additions and changes could be made in real time, in front of all participants. Thus, consensus could be reached by the group on any changes made while the group is still assembled.

5. Estimate Potential For Exposure

Estimates will take into account calendar years worked, program, engine, fuels, job title and all other relevant information as described previously. Reliance will be on job histories, interviews, and historical data available on chemical use.

We have learned that hydrazines were not used by all Propulsion Test Mechanics/Technicians. Hydrazines apparently were not used in great quantity or uniformly, and only at a few test stands. Hydrazines were used mostly on small rocket engines, although not exclusively. Direct hydrazine exposures may have been limited to periodic tasks, i.e., sampling.

Trichloroethylene (TCE) was used in much greater quantity and more extensively to flush engines at a number of test stands and as a parts cleaner and to wash hands. TCE exposure levels may have changed over time due to process change and use of respiratory protection.

Job titles alone are not adequate to characterize exposure and thus assignments to test stands will be essential. Construction of a Job/Exposure Matrix will be challenging, but we believe that we will be able to reliably reconstruct what chemicals were used at which test stand during specific time periods. The interviews, phone books and other sources of information will be used to place individual workers at specific test stands in specific years as described above.

6. Size of “chemical workers” cohort

There were approximately 6,600 non-radiation workers at SSFL, including an estimated 2,000 who worked with engine tests. These engine test personnel would have the highest potential for exposures to fuels, such as hydrazine, and solvents, such as TCE. The other 4,600 SSFL workers will also be evaluated, however, for their potential chemical exposure.

D. Smoking Assessment

Medical records contain information on smoking of various levels of completeness over the years. Smoking was routinely collected only for certain years, but some special surveys were conducted and notations occasionally appeared in the medical notes. From 1963 to about 1967, it appears that the fact of cigarette smoking was recorded in the worker's preemployment self-administered medical form. Medical records from later years seem to have more detailed information, although not on all employees. These data will be abstracted from the medical records on the eligible workforce and on a sample of the non-exposed comparison group. Confounding will be assessed by looking for variations in smoking patterns by job title, and within categories of estimated chemical or radiation dose. In addition, contrasts can be made with smoking prevalence data for the general population. Although adjustment for smoking at an individual level may not be possible, we plan to perform qualitative evaluations of smoking (e.g., compare smoking habits of rocket engine test mechanics to other occupational groups at Rocketdyne) and can evaluate the extent to which smoking will be an important confounding factor to be adjusted for in subsequent mortality analyses.

E. Tracing

A comprehensive approach to tracing includes use of company records, California death tapes and microfiche, NDI+, Social Security Administration, Health Care Financing Administration, TransUnion credit bureau, Departments of Motor Vehicles, and state Departments of Vital Statistics (Figure 9). All deaths will be coded for cause of death. Alive status will be confirmed. The shaded boxes represent current evaluations.

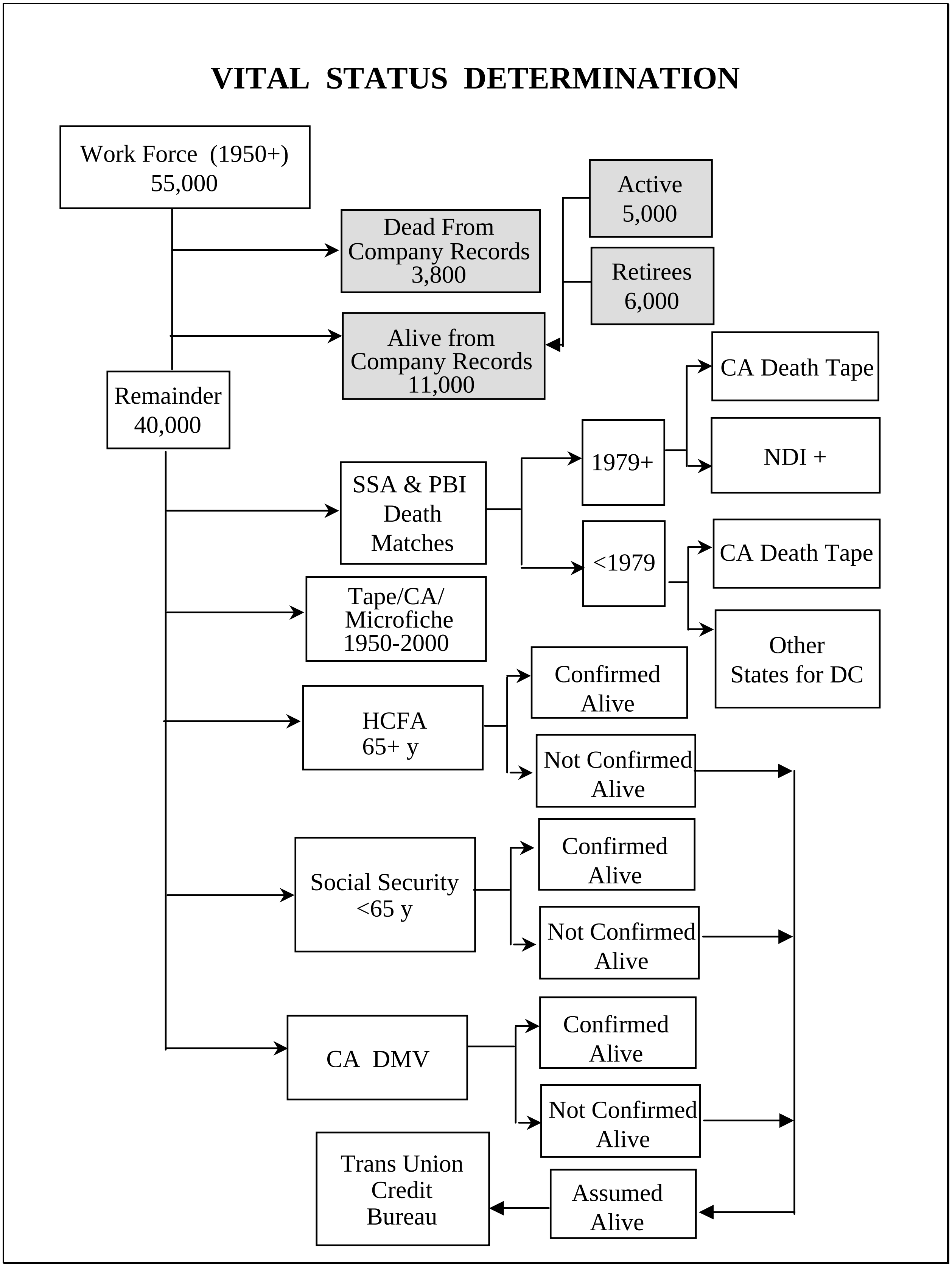

Figure 9 – Schematic of Vital Status Determination

F. Summary

There are approximately 55,000 workers available for study since 1950. Recognizing the need for an efficient allocation of resources in order to maximize the information in this followup study, we will:

- Trace all eligible 55,000 workers at the level of mortality and vital status

- Conduct comprehensive exposure assessment on the 10,000 SSFL workers, i.e., the radiation workers and the 6,600 test stand or other workers.

- Radiation, external. This assessment is straightforward and cumulative dose can be obtained on the entire radiation cohort from existing records. There are about 5,000 radiation workers from SSFL, De Soto and Canoga Park facilities. We are imaging all worker folders in the HPRMP filing cabinets to facilitate selection of all eligible workers.

- Radiation, internal. There are 2300 workers monitored for internally received radionuclides (U, Pu, Cs, Sr, fission products).

  - We are imaging all worker bioassay records

  - ORNL will evaluate the images of the worker records and select those for whom detailed computerization is required (currently estimated to be several hundred). Not all those monitored had positive bioassays so that this approach is reasonable and cost effective.

  - The comprehensive internal radiation dosimetry would be conducted for all organs, including lung, bone marrow, kidney, bladder, lymph system, and esophagus.

- Chemical. The approximately 6,600 SSFL workers would be characterized as to the potential for exposure to hydrazine and TCE, as well as to other fuels and chemicals. This would be done mainly by assigning workers to specific test stands over time, but all occupations with potential for chemical exposure will be evaluated. We believe we'll be able to do this in a cost effective manner by use of a test stand "questionnaire", by identifying "phone books" or "Personnel Assignment Listings" of years past which place individual workers at specific test stands, by interviewing workers themselves as well as long term employees familiar with the workforce of years past, and by using information in organizational charts and Kardex work histories. For those workers with job classifications involving rocket engine testing, we would send a listing of each worker's work history, including job title and dates, and ask him to list to the best of his recollection which test stand (alpha, bravo, caco, delta, bowl, tree, STL4, etc) he was working at during this period. This information would supplement the interview responses and assist in assigning the potential for certain chemical exposures (hydrazine, kerosene, LOx FLOx, TCE, alcohols, etc.). To enhance the response rate would discuss the approach at union, retirement and other worker meetings and ask their advice and support.

- Other chemical. To the extent possible, other chemicals would be evaluated from the job titles, building and work history information. This would include asbestos potential (which seems small), beryllium (which also seems to involve small numbers), chromates, and other.

- Other factors. Information available on pre-employment forms and medical records would be assessed, such as cigarette smoking, and prior work histories.

- Comparison Group. It appears feasible to assemble a comparison group from the 48,000 workers at SSFL, Canoga, De Soto and other facilities not included in the exposed cohorts.

II. Reconsider whether an incidence component to the study might be worthwhile.

A. Previous Comments

Previously, in response to a request from Boeing whether to include an incidence study or justify why not, we wrote for distribution at the February 2001 meeting:

"We have enhanced our proposal and "scope of work" to address the issue of adding a cancer incidence component, which is discussed below:

> Cancer incidence. Adding a cancer incidence component was considered but decided against for the following reasons. Cancer registration during the calendar years of study is incomplete in California and the U.S. as a whole and the results would not differ materially from a comprehensive and complete mortality study. Prior to 1988, the cancer registration in California is spotty and doesn't exist at all prior to 1972 for the LA area.
>
> A comprehensive cancer incidence study would be prohibitively expensive. Since the U.S. does not have a national cancer registration system, we would have to contact all workers or their next of kin and inquire about cancer diagnoses. We would then have to validate the self-reported cancers through review of hospital records. The statewide California cancer registry began in 1988 and the Los Angeles county registry in 1972. A geographically limited cancer incidence study, restricted to cancer occurring in the 1990s among residents of California, for example, would also be problematic because of its incomplete coverage, the need for complete residential histories (to know the proper denominator), and the likely small numbers of anticipated incident cancer cases. A limited cancer incidence study would require knowledge of the number of workers continually residing in the California and/or the Los Angeles catchment area. Linkage with the cancer registries could determine observed numbers of cases, but computing the expected number would require an intense effort to learn these residential histories. We have not included a budgetary item for the expense needed for the residential history determination.
>
> The *a priori* cancers of interest are lung cancer, leukemia and lymphoma. Survival for lung cancer is poor, hence mortality data would be a good reflection of incidence. Similarly, survival for the myelogenous leukemias and certain lymphomas are also poor. For example, the 5-year relative risk survival rate for lung cancer in 1950-54 was 5% and in 1989-95 was only 13%. Thus, a comprehensive and complete mortality study of the worker population would be a better indicator of possible health effects than the incomplete and potentially biased evaluation of cancer incidence in limited areas and over restricted calendar years.

Computer linkage of data files available from the Los Angeles Cancer Registry and the California Cancer Registry, however, could be used to validate a sample of the cancer deaths of workers who died in California. If a nested case-control study of a particular cancer is launched after the cohort study is completed, the registry may be used to obtain detailed information on histologic type of the malignancies.

Assistance in the validation and assessment of cancer diagnoses made within the Rocketdyne workers residing in Los Angeles County is available from the Cancer Surveillance Program of Los Angeles County (LA-CSP). Operated by the University of Southern California (USC), the LA-CSP has a complete repository of pathology reports for all histologically confirmed cases of cancer occurring in the County since 1972. In 1992, LA-CSP was designated a Surveillance, Epidemiology and End Results (SEER) Registry by the National Cancer Institute."

B. Further discussion on limitations of an incidence component.

We continue to believe that an incidence component would provide only minimal scientific gain, and would require a substantial increase in cost. The key issues are:

1. Incomplete coverage

There is uncertainty and difficulty in identifying workers who lived in the catchment areas during the periods when cancer incidence would be recorded. We know that we are dealing with a mobile population. Based on our initial tabulation of over 3,000 deaths among Rocketdyne employees, we find that 27% of all deaths occurred in states other than California. Based on our tabulations of over 26,000 zip codes, we find that about 30% of the population lives/lived outside of California and a much larger percentage lives/lived outside of Los Angeles county. Furthermore, even for lifetime Los Angeles residents, all cancer incidences in 1950-1970s would be missed. Los Angeles County Registry coverage began in 1972 but LA-CSP became a SEER Registry (National Cancer Institute) only in 1992. The California Registry began in 1988 and consists of regional population-based registries.

2. High Mortality for Cancers of Interest

The mortality study will detect the large majority of lung cancers, the cancer of *a priori* interest because of possible radiation and chemical etiology. The 5-year relative survival rate for lung cancer was 5% for cases diagnosed 1950-54 and 13% in 1989-95 (SEER, NIH Publ 99-2789, p.17, p. 53).

For leukemia, the 5-year relative survival rate was 10% for cases diagnosed in 1950-54 and 44% in 1989-95 (SEER, NIH Publ 99-2789, p. 17, p. 53). For acute myeloid leukemia the most radiosensitive cell type, 5-year survival during 1989-95 was only 12%.

For NHL the 5-year relative survival rate for cases of NHL was 33% for cases diagnosed in 1950-54 and 52% in 1989-95 (SEER, p. 17, p.53).

For cancer of the esophagus the 5-year relative survival rate was 4% in 1950-54 and 13% in 1989-95 (SEER, p. 17, p. 53).

The relatively poor survival rates for these cancers mean that only a small percentage of incident cases will be missed by the proposed mortality analyses.

3. Comprehensive Mortality Coverage

The mortality coverage will be 99% complete over the entire followup period, based on our experience with the Lockheed Martin aerospace worker cohort. While there are recognized limitations associated with death certificate coding, cancers, and especially those of *a priori* interest, are more accurately recorded than other diseases (Percy C, Stanek E, Gloeckler L. Accuracy of cancer death certificates and its effect on cancer mortality statistics. Am J Public Health 1981;71:242-50). Hence, it is unlikely that our mortality searches will miss fatal cancers that would have been detected from cancer incidence searches.

4. Interpreting Living / Dead Subject Information

Including the small number of non-fatal cancers of *a priori* interest who would have been diagnosed in the catchment areas covered by cancer incidence during limited number of calendar years would not provide an incremental gain in knowledge commensurate with the effort involved. Further, this hybrid design would not be straight forward because of the absence of residence histories for Rocketdyne workers, hampering interpretation. We have serious reservations related to potential biases associated with a study of cancer incidence in a select subset of the cohort. Differential effects may be involved in that persons of higher SES might be more likely to leave California than remain, and exposure doses appear related to SES (i.e., pay grade). A limited incidence component combining living and dead cases and comparing less precise (because of the limited coverage) incidence data with the more stable mortality data is not a straightforward maneuver.

C. Conclusion.

We are sympathetic to the suggestions to incorporate an incidence component into the study. At the end of the day, however, we believe that the potential benefits would not outweigh the very real costs and complexities. Today, cancers are recorded with high precision on death certificates, so 1990s cancer registry data will be adding non-fatal tumors, but the cancers of interest, and in particular lung cancer, have a high fatality rate. Because of incomplete cancer incidence registrations over the years and in various counties, the large majority of cancers diagnosed between 1950 and the 1980s would be missed in an incidence survey. Furthermore, the absence of residential histories for Rocketdyne workers would hamper interpretation of an incident component that combines living and dead cases, increasing the likelihood that biases might creep in. Finally, we performed an incidence substudy within the Lockheed cohort and learned that the additional cases identified were too few to be informative with regard to the comprehensive mortality investigation.

III. Reassess rationale for contacting workers via mail questionnaire and requesting information on other jobs and health habits.

We have carefully considered the request of the Science Committee and now agree that there would be little marginal gain in information or study quality by contacting those who are living, even with a brief questionnaire on job history and lifestyle factors. Thus, we no longer plan to send such a questionnaire.

IV. Consider comparisons with the previous UCLA study to classify why there might be differences in results.

We agreed to make comparisons at the end of the study with the UCLA cohort to the extent possible. However, as we have acquired knowledge on both the UCLA cohort and the Rocketdyne workforce, we believe such a comparison will be problematic for the following reasons listed below and would like to bring this to the attention of the Scientific Committee.

1. Our definition of the radiation-exposed workforce is not the same.

   Unlike UCLA, we will not include radiation workers who were employed less than 6 months, nor will we include visitors or non-Rocketdyne/AI personnel. We will not exclude workers who also tested rocket engines.

2. Our assessment of external and internal doses will be substantially different.

   Unlike UCLA, we will not use committed dose to the lung as a surrogate for all organ-specific doses from internal sources, but we will compute individual organ doses up to the time of cancer death with appropriate lag intervals. We will include lifetime radiation doses obtained before and after Rocketdyne employment.

3. Our definition of the eligible workers with potential for chemical exposures is not the same.

   For the chemical cohort, we will require that each worker be employed for at least 6 months at SSFL. We will not exclude a worker because he was at one time monitored for radiation by the HPRMP, and we will include women.

4. Our assessment of the potential for chemical exposure will be substantially different.

   Unlike UCLA we will not assume that any job title involving rocket tests meant hydrazine exposure. We will assign workers to specific test stands for specific calendar years and assess the potential for exposure to specific fuels, solvents and other chemicals. We will conduct over 300 interviews to assist in the chemical exposure assessment of test stand, laboratory and other workers.

These differences will make it difficult for us to make meaningful comparisons. For example, our preliminary evaluation of the radiation workers' files suggests that we might include more than 500 additional workers in the radiation cohort.

ROCKETDYNE WORKER HEALTH STUDY

Appendix I

INTERNATIONAL EPIDEMIOLOGY INSTITUTE

Institutional Review Board and Other Human Subjects Committee Approvals

July 13, 2005

Table of Contents - Appendix I

Appendix I. Institutional Review Board and Other Human Subjects Committee Approvals

Department of Energy approval for linkage with dosimetry records (Oct 2003)

Nuclear Regulatory Commission approval for linkage with dosimetry records (Dec 2001)

Study description (PHS 398, Page 2)

Letter of support from Steve Lafflam, Division Director, Safety, Health & Environmental Affairs, Rocketdyne, The Boeing Company (Jan 2001)

Institutional Review Board approval from Vanderbilt University (Dec 2002)

Institutional Review Board approval from The Boeing Company (Jan 2001)

Institutional Review Board approval from Oak Ridge National Laboratory (Jan 2002)

National Center for Health Statistics approval for mortality linkage (Apr 2001)

Social Security Administration approval for vital status linkage (Feb 2001)

Health Care Financing Administration (Centers for Medicaid & Medicaid Services) approval for vital status linkage (Dec 2003)

United States Air Force approval for dosimetry linkage (Feb 2004)

Recent IRB Approval from Vanderbilt University (through 12 October 2005)

INTERNATIONAL EPIDEMIOLOGY INSTITUTE, LTD.

October 9, 2003

Craig A. Refosco, Maj, USAF, BSC
Health Physicist
Radiation Protection Division
USAF Radioisotope Committee Secretariat
Air Force Medical Operations Agency
Office of the Surgeon General
AFMSA/SGPR
110 Luke Avenue, Room 405
Bolling AFB, DC 20032-7050

RE: Request to Match Roster of the Rocketdyne Radiation Worker Study with Air Force Dosimetry Records

Dear Major Refosco:

We would like to send our roster of 55,000 former workers at Rocketdyne (Atomics International, Rockwell, Boeing) to the Center for Radiation Dosimetry at Brooks Air Force Base for record linkage and learn how many workers subsequently were employed by the Air Force and were monitored for radiation. Per our discussions, I thought it might be helpful to include more details about our study and the extensive approvals we have received along the way.

The study is sponsored by both the Boeing Company and by the UAW. It is a mortality study and we are attempting to obtain complete career (or lifetime) histories of radiation exposure for the workers. Most of the exposure occurred while employed in the early years of the atomic era at Rocketdyne and subsequent exposure, e.g., at military facilities, was small. The International Epidemiology Institute and Vanderbilt University are conducting the study. I've enclosed the following:

1. Approval from the Department of Energy for linkage with their dosimetry records (Oct 2003)
2. Approval from Nuclear Regulatory Commission for linkage with their dosimetry records
3. Study description (PHS 398, Page 2)
4. Letter of support from Steve Lafflam, Division Director, Safety, Health & Environmental Affairs, Rocketdyne, The Boeing Company
5. Institutional Review Board approval from Vanderbilt University
6. Institutional Review Board approval from The Boeing Company
7. Institutional Review Board approval from Oak Ridge National Laboratory
8. Approval from the National Center for Health Statistics for mortality linkage
9. Approval from the Social Security Administration for vital status linkage

1455 RESEARCH BOULEVARD SUITE 550 ROCKVILLE, MARYLAND 20850 USA TELEPHONE 301-517-4060 FAX 301-517-4063

The 55,000 workers were employed between 1948-1999, and at least 6,000 worked with radiation. The non-radiation workers were in large part involved with rocket engine testing (Saturn Apollo engines, shuttle engine, SNAP, etc). Workers left Rocketdyne over the years and received occupational exposures at different nuclear facilities, and occasionally at military installations. To make our radiation study as valid as possible, we wish to capture all the radiation doses in a worker's career.

What we've done in the past is send our entire roster of 55,000 workers to various agencies for record linkage with their files. We send a file with Social Security number, name, and date of birth. We have done such matching with the Nuclear Regulatory Commission (REIRS files), the Department of Energy (REMS, historical and termination files), 9 different nuclear installations, the Landauer dosimetry company, and most recently the U.S. Army (Redstone Arsenal). We would like to send this file to the Center for Radiation Dosimetry at Brooks Air Force Base for similar linkage.

We would not anticipate a large number of Rocketdyne/Atomic International workers to have been involved with air force activities. If the U.S. Army experience is relevant, the number would be less than 150. Again, our interest is in being as complete as possible in characterizing the radiation exposure histories of these workers and thus would find any experience with the U.S. Air Force important to include. As mentioned, however, including or not including the radiation dose record of the relating small number of workers who were subsequently employed by the U.S. Air Force will not affect the validity of our epidemiologic investigation, only the completeness and quality.

In response to queries raised in your e-mail of last month, unfortunately we do not know which of the 55,000 workers are the approximately 150 who joined the Air Force after employment at Rocketdyne. Further, even if we could identify these workers, it would be extremely difficult to locate them today and obtain any consent. Most worked at Atomics International/Rocketdyne in the 1950s and 1960s, and many have also died; over 11,000 of the workforce have died to date. I suspect the Privacy Issues may not be relevant to those who have died, at least that is our understanding from the federal agencies providing linkages for us. We also have not had any agency consider exposure information (i.e., the dosimetry record) to be part of the medical record of an individual. In fact, our experience at Rocketdyne and other facilities is that these records are physically separated and even stored in different buildings.

I look forward to hearing from you if it might be possible for the U.S. Air Force to help us out.

Sincerely yours,

John Boice

John D. Boice, Jr., Sc.D.
Scientific Director
301-517-4021 (phone)
boicej@compuserve.com

JDB/ra

Enclosures (9)

EXTENSION OF ARRANGEMENT FOR COLLABORATION AMONG

THE DEPARTMENT OF ENERGY OF THE UNITED STATES OF AMERICA

AND THE BOEING COMPANY

AND THE INTERNATIONAL EPIDEMIOLOGY INSTITUTE

The existing agreement (attached) has provisions in Section V (part A) to extend the arrangement for additional periods by mutual agreement.

> "This Arrangement shall become effective upon signature by all Parties, and shall remain in effect for one year. The Parties may extend this Arrangement for additional periods."

The Department of Energy of the United States of America (DOE), the Boeing Company (Boeing), and the International Epidemiology Institute (IEI), agree to extent the existing arrangement for an additional year, effective upon signature by all Parites.

FOR THE DEPARTMENT OF ENERGY OF THE UNITED STATES OF AMERICA:

Beverly A Cook ______________________ **Date:** 10/3/03

Beverly A. Cook
Assistant Secretary
Environment, Safety and Health
Washington, D.C.

FOR THE BOEING COMPANY:

Steve Lafflam ______________________ **Date:** 9/17/03

Steve Lafflam
Division Director
Safety, Health & Environmental Affairs
Canoga Park, CA

FOR THE INTERNATIONAL EPIDEMIOLOGY INSTITUTE:

John D. Boice, Jr.

Dr. John D. Boice, Jr.
Scientific Director
Rockville, MD

Date: 15 Sep 2003

Attachments

2002 signed Arrangement between the Department of Energy, the Boeing Company and the International Epidemiology Institute.

ARRANGEMENT FOR COLLABORATION AMONG

THE DEPARTMENT OF ENERGY OF THE UNITED STATES OF AMERICA

AND THE BOEING COMPANY

AND THE INTERNATIONAL EPIDEMIOLOGY INSTITUTE

The Department of Energy of the United States of America (DOE), the Boeing Company (Boeing), and the International Epidemiology Institute (IEI), hereafter the "Parties":

Noting that IEI is conducting a study involving over 55,000 workers employed at the Rocketdyne facilities in California (now owned by Boeing), to evaluate the cancer risk associated with occupational exposures to ionizing radiation;

Noting that the IEI Rocketdyne Worker Study has a documented protocol that requires each worker's radiation dose to be as complete as possible over the worker's entire career;

Noting that the Rocketdyne Worker Study includes workers who were also included in other DOE worker cohorts such as the Hanford and Oak Ridge National Laboratory cohorts; and

Noting that IEI, which has the approval of the U.S. National Death Index and the Institutional Review Boards of the Boeing Company, Vanderbilt University and the Oak Ridge National Laboratory to participate and conduct the Rocketdyne Worker Study, is responsible for preparing the vital status and dosimetry analysis files,

Have agreed as follows:

I. Purpose

A. The purpose of this Arrangement is to provide a framework for DOE to contribute data from the DOE Radiation Exposure Monitoring System (REMS), to provide as complete information as possible on the total career radiation dose for each U.S. radiation worker included in the Rocketdyne Worker Study.

B. The Parties expect that a successful Rocketdyne Worker Study will provide additional information of health risk at low doses and low dose rates of occupational exposure.

II. Implementing Provisions

A. Pursuant to the Privacy Act, 5 U.S.C. 552a(b)(3), and under Routine Use Number 5 of DOE-35, Personnel Radiation Exposure Records (which permits disclosure to collaborating researchers in the performance of health-related studies), DOE shall provide IEI and Boeing with dosimetry information, as recorded in REMS, for each worker identified as being included in the Rocketdyne Worker Study.

B. IEI and Boeing shall use this information only for the above described research purposes.

C. IEI and Boeing shall maintain the confidentiality of the subject information and make no disclosure of it to third parties without the prior written consent of the DOE. If, during the examination of DOE-provided data, errors or omissions are found and corrected, these corrected data shall be provided back to DOE REMS.

D. IEI and Boeing's obligation to maintain the confidentiality of the DOE-provided information shall remain in effect throughout the term of this Arrangement and after its termination, unless and until the said information and all copies thereof are returned to DOE.

III. Contacts

The principal contact for DOE is Ms. Nirmala Rao, Office of Worker Protection Programs and Hazards Management. The principal contact for Boeing is Dr. Michael Sullivan, Boeing, Santa Susanna Field Station. The principal contact for IEI is Dr. John D. Boice, Jr., Scientific Director.

IV. Management

The Parties shall consult each other whenever they deem it necessary, and shall assess the results of the work carried out and in progress.

V. General Provisions

A. This Arrangement shall become effective upon signature by all Parties, and shall remain in effect for one year. The Parties may extend this Arrangement for additional periods.

B. The terms of this Arrangement may be altered in writing by the Parties. If any Party wishes to cease its activities under this Arrangement, it shall give ninety (90) days advance written notice to the other Parties.

C. Cooperation under this Arrangement shall be in accordance with the applicable laws and regulations under which each Party operates.

D. Unless otherwise agreed in writing, each Party shall assume responsibility for, and provide funding to cover, the costs individually incurred in participating in the collaboration contemplated by this Arrangement. The collaborative activities are subject to the availability of funds and personnel.

FOR THE DEPARTMENT OF ENERGY OF THE UNITED STATES OF AMERICA:

Beverly A Cook

Date: 3/1/02

Beverly A. Cook
Assistant Secretary
Environment, Safety and Health
Washington, D.C.

FOR THE BOEING COMPANY:

Steve Lafflam

Date: 2/18/02

Steve Lafflam
Division Director
Safety, Health & Environmental Affairs
Canoga Park, CA

FOR THE INTERNATIONAL EPIDEMIOLOGY INSTITUTE:

John D. Boice, Jr.

Date: 12 Feb 2002

Dr. John D. Boice, Jr.
Scientific Director
Rockville, MD

Attachments

- Nuclear Regulatory Commission approval to access REIRS
- Boeing letter regarding dosimetry support
- Boeing IRB approval
- Vanderbilt University IRB approval
- Oak Ridge National Laboratory IRB approval
- National Death Index approval

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

December 18, 2001

Dr. John D. Boice, Jr., Sc.D.
Scientific Director
International Epidemiological Institute, Inc.
1455 Research Boulevard
Suite 550
Rockville, MD 20850

Dear Dr. Boice:

This is in response to your request for access to Radiation Exposure Information and Reporting System (REIRS) data for an epidemiological study of radiation-exposed workers at Rocketdyne (Atomic International, Rockwell, Boeing). In your original request of February 23, 2001, you indicated that the purpose of the Study is to determine if radiation exposures might be related to increased mortality risks of certain cancers.

We understand that The Boeing Company and the United Autoworkers have contracted with the International Epidemiological Institute Inc. (IEI) to conduct a Study, involving more than 6,000 workers employed since 1950 at three Rocketdyne facilities in California and compare them to cause of death information obtained from the California Death Index, Social Security Administration, Pension Benefit Information and the National Death Index Plus to estimate directly the cancer risk associated with low dose, protracted exposure to ionizing radiation.

We also understand that IEI, which has the approval of the Social Security Administration, the U.S. National Death Index Plus and The Boeing Company Institutional Review Board to participate in the Study, is the organization responsible for preparing the vital status and dosimetry analysis files for the Rocketdyne workers to be used in the Study.

Pursuant to the Privacy Act, 5 U.S.C. 552a(b)(3) and under Routine Use b, for NRC-27, REIRS Files, which permits return of data provided by a licensee upon request, the NRC will provide Boeing with dosimetry information it supplied for recording in REIRS for each Rocketdyne worker identified as being included in the Study. The NRC will provide as complete information as possible on the dose for each worker.

We would expect Boeing and IEI to maintain the confidentiality of the subject information and make no public disclosure of it to third parties without the prior written consent of the NRC or the individual from whom the information pertains. If, during the examination of NRC-provided data, errors or omissions are found and corrected, we request that these corrected data be provided back to NRC REIRS.

We appreciate the opportunity to support this important health effects research.

Sincerely,

Thomas C King

Thomas L. King, Director
Division of Systems Analysis and Regulatory Effectiveness
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission

cc: Derek Hagemeyer, SAIC

DESCRIPTION: State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project. Describe concisely the research design and methods for achieving these goals. Avoid summaries of past accomplishments and the use of the first person. This description is meant to serve as a succinct and accurate description of the proposed work when separated from the application. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. **DO NOT EXCEED THE SPACE PROVIDED.**

The possible health risks associated with working at the Rocketdyne facilities (Santa Susana Field Laboratory, Conoga Park, and Desoto) have not been fully assessed. We propose a retrospective cohort mortality study of approximately 55,000 former and current Rocketdyne employees to address this issue. In addition, nested-case control studies of specific cancer sites (lung, leukemia, lymphoma and, based on the results of the cohort study, other sites) will be conducted to further characterize workplace exposures and lifestyle factors. The primary goals of this research include: to identify the entire Rocketdyne workforce employed since 1950; to update vital status information for all cohort members; to identify and quantify exposures to important chemicals and physical agents (such as radiation, trichloroethylene, hydrazine, and asbestos); and, to identify appropriate control populations for comparisons with mortality rates among the Rocketdyne exposed workforce (i.e., California general population, "non-exposed" Rocketdyne workforce, Lockheed Martin Burbank workforce). In addition, for workers who were potentially exposed to radiation, we will obtain and integrate complete radiation work histories for employment periods both before and after employment at Rocketdyne (through information from Rocketdyne, the Landauer dosimetry company, the Nuclear Regulatory Commission, and the Department of Energy), estimate radiation doses to specific organs from all sources of radiation (external gamma, neutron, and internal radionuclide), and validate the radiation dosimetry with biological measures of exposures among a sample of workers. The classification of chemical exposures will include the development of a detailed job matrix linking exposure potential to specific jobs and a qualitative exposure score taking into account the variation of exposure potential over calendar years, due to numbers of engine tests, types of engines, chemical use patterns, and introduction of protective equipment.

The study will be conducted by the International Epidemiology Institute (IEI) using rigorous epidemiologic methods in study design, data collection, entry, and analysis, and interpretation and presentation of the study results. The research team assembled includes internationally recognized leaders in radiation epidemiology, dosimetry and occupational studies.

PERFORMANCE SITE(S) (*organization, city, state*)

1. International Epidemiology Institute (IEI), Rockville, MD
2. Oak Ridge National Laboratories (ORNL), Oak Ridge, TN
3. University of Pittsburgh (UPitt), Pittsburgh, PA
4. Lovelace Respiratory Research Institute, Albuquerque, NM
5. University of Southern California (USC), Los Angeles, CA

KEY PERSONNEL. See instructions on Page 11. *Use continuation pages as needed* to provide the required information in the format shown below.

Name	Organization	Role on Project
John D. Boice Jr, ScD	IEI	Primary Investigator
Jon P. Fryzek, PhD	IEI	Field Management
Donald E. Marano, CIH PE	IEI	Senior Industrial Hygienist
Joseph K. McLaughlin, PhD	IEI	Co-Investigator
William, J. Blot, PhD	IEI	Statistician
Keith F. Eckerman, PhD	ORNL	Health Physicist
Richard W. Leggett, PhD	ORNL	Health Physicist
William L. Bigbee, PhD	UPitt	Laboratory analyses (FISH)
Bruce B. Boecker, PhD	Lovelace	Consultant, Radiation Dosimetry
Brian E. Henderson, MD	USC	Consultant, Epidemiologist

Steve Lafflam
Division Director
Safety, Health &
Environmental Affairs

The Boeing Company
6633 Canoga Ave.
P.O. Box 7922
Canoga Park, CA 91309-7922

January 31, 2001

BOEING

To Whom It May Concern:

The Boeing Company and the United Autoworkers Union (UAW) is contracting with the International Epidemiology Institute (IEI) to conduct a health survey of our former workers at the Rocketdyne facility. As such, we would find it most helpful if available dosimetry information could be provided IEI on our workers in order to validate our career dose information and/or provide supplementary information. There were a little over 6,000 workers monitored for radiation at our facilities.

Your assistance is greatly appreciated. If there is additional information needed, I would be happy to provide it.

Sincerely yours,

Steve Lafflam
Division Director,
Safety, Health & Environmental Affairs

SHEA-092193

Vanderbilt University
Institutional Review Board
D-3232 Medical Center North Nashville, Tennessee 37232-2598
(615) 322-2918 Fax: (615) 343-2648
www.mc.vanderbilt.edu/irb

December 6, 2002

John D Boice, Jr., Sc.D.
Medicine
International Epidemiology Institute
Rockville, MD 20850

RE: IRB# 010018 "A Cohort Mortality Study of the Rocketdyne Workforce" (International Epidemiology Institute,)

Dear Dr. Boice,

At its meeting on December 4, 2002, the Institutional Review Board reviewed the Application for Continuing Review identified above. The Committee determined that the study poses minimal risk to participants. The Committee determined the request for waiver of documentation of consent is approved in accordance with 45 CFR 46.116(d). The Committee determined this study can be reviewed in accordance with 45 CFR 46.110(F)(5) and (7) for expedited review in the future.

As the Principal Investigator, you are responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events and unanticipated problems involving risks to participants. The IRB Adverse Event reporting policy II.F. is located on the IRB website at http://www.mc.vanderbilt.edu/irb/. For your convenience, a flowchart is attached.

Please note that approval is for a 12-month period. According to federal regulations, this period is calculated from the date of the convened meeting as noted above. Any changes to the research study must be presented to the IRB for approval prior to implementation.

DATE OF IRB APPROVAL: 12/4/02 **DATE OF IRB EXPIRATION: 12/4/03**

Sincerely,

James T. Forbes, Ph.D., Chair
Institutional Review Board
Health Sciences Committee #2

JTF/jo

The Boeing Company
P.O. Box 3707
Seattle, WA 98124-2207

BOEING

January 29, 2001

John D. Boice, Jr., Sc.D.
International Epidemiology Institute
1455 Research Blvd, Suite 550
Rockville, MD 20850

Dear Dr. Boice:

The Boeing Institutional Review Board has reviewed the January 19, 2001 revision of the protocol for the study entitled "An epidemiologic study of the Rocketdyne workforce." The Board determined that the study involved no more than minimal risk for the study subjects, and authorized Craig Conlon, M.D., Rocketdyne Physician, Frank Mirer, Ph.D., C.I.H., Director of Health and Safety for the United Auto Workers, and J.M. Muhm, M.D., Secretary of the Boeing Institutional Review Board, to conduct an expedited review.

They found that informed consent will be documented in cases where it is appropriate, and the protocol contains adequate provisions for the protection of the privacy of the study subjects. The study protocol is therefore approved by the Boeing Institutional Review Board.

Please notify Dr. Muhm of any future changes in the protocol. We have enjoyed working with you, and appreciated your prompt responses to our suggestions for protocol revisions.

Sincerely,

Eric C. Hisken, M.D.
Chairman of The Boeing Institutional Review Board
Boeing Medical

ORAU
OAK RIDGE ASSOCIATED UNIVERSITIES

Oak Ridge Site-wide
Institutional Review Board
Telephone (865) 576-1725 Facsimile (865) 576-9557
E-mail hawkinsb@orau.gov

TO: Keith Eckerman, Ph.D./Elizabeth Ellis, Ph.D.

FROM: Elizabeth Ellis, Ph.D.
Chair, Oak Ridge Site-wide Institutional Review Board (MPA #1394)

DATE: January 16, 2002

RE: ORNL(01)-64 ROCKETDYNE WORKER HEALTH STUDY

The subject project qualified for continuing review by the expedited process (45 CFR 46; 10 CFR 745). Accordingly, I reviewed the protocol and the progress report for continuation for a period of up to 12 months effective December 1, 2001. At the Board meeting on November 8, 2001, the Full Board of the Oak Ridge Site-wide Institutional Review Board (ORSIRB) unanimously concurred with this continuing approval.

Please be reminded that as the Principal Investigator on this project, you are responsible for immediately informing the Board of any unplanned or unexpected project-related outcomes and/or any proposed changes in the project's protocols or consent forms. Upon being notified of any such events or situations the Board will review them and inform you whether or not the project(s) may proceed. Please understand that in these circumstances you must have the Board's approval for continuation of the protocol before proceeding.

cc: Dr. R Toohey, ORAU
IRB files

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention
National Center for Health Statistics
6525 Belcrest Road
Hyattsville, Maryland 20782-2003

APR 30 2001

Type of NDI search approved		Search#
No	<u>Routine</u> NDI search ONLY	
Yes	NDI *Plus* (vital status unknown)	Y1-X017
Yes	NDI *Plus* (for known decedents)	Y1-K017
Waived	NYC NDI *Plus* approval	

John D. Boice, Jr.
International Epidemiology Institute
1455 Research Blvd., Suite 550
Rockville, Maryland 20850

RE: Approval of NDI Plus Application #Y1-0017
(An Epidemiologic Study of the Rocketdyne Workforce)

Dear Mr. Boice:

Your request to use the National Death Index (NDI) has been approved (see table above) on the basis of the information you provided in your NDI Application Form. To keep your application current, it is important that you notify us in writing whenever there are any planned changes in (1) your project's funding arrangements, (2) your study protocol, (3) your confidentiality provisions, and/or (4) organizations or consultants receiving identifying death record information. You also must contact us whenever you receive (or feel you might soon receive) a subpoena or court order for any identifying information obtained as a result of your use of the NDI.

You may now send your records to our facility in Hyattsville, Maryland. Please refer to the enclosed CHECKLIST when preparing your records for submission. **The 1979-1999NDI *Plus* files are currently available for searches.** The 2000 NDI *Plus* file should be available by March 2002.

We look forward to serving you. Please call Michelle Goodier or me on 301-458-4444 if you have any questions. You may also reach us by e-mail at MGoodier@cdc.gov or RBilgrad@cdc.gov

Sincerely yours,

Michelle Goodier

Robert Bilgrad, M.A., M.P.H.
Special Assistant to the Director
Division of Vital Statistics

Enclosures

SOCIAL SECURITY

TGBA

FEB 2 1 2001

John D. Boice, Jr., ScD
International Epidemiology Institute, Inc.
1455 Research Blvd, Suite 550
Rockville, MD 20850

Dear Mr. Boice,

We have approved your request for our assistance in obtaining epidemiological vital status data for your study "An Epidemiologic Study of the Rocketdyne Workforce." Enclosed is the documentation we need to process your request.

Tab A contains two copies of the Memorandum of Understanding between you and SSA, which delineates our joint responsibilities in sharing data on your study subjects. Of particular importance are the articles covering the security of data and the need to protect the privacy of an individual's vital status data. You are reminded that you are not permitted to re-disclose the SSA data.

Tab B contains two copies of our standard Agreement Covering Reimbursable Services, Form SSA-1235-U5, showing a cost of $4,500.00 for processing 55,000 records (the number you recently gave us). Unit cost for processing is $.165 per record for the first 25,000 records and $.0125 for all records over 25,000. As noted on the reverse side of the agreement, you must send us an advance payment of 100 percent of the stated cost.

To authorize work on this project, please provide the following:

- One signed original Memorandum of Understanding;
- One original Reimbursable Services Agreement form SSA-1235-U5 with:
    - Your Employer Identification Number (EIN) entered;
    - Signed form with your signature; and
    - Signed form by your organization's authorizing official.

  Note: If necessary, change and initial the record count and cost totals.

- A check payable to the Social Security Administration, Office of Finance for the exact amount; and

- Your input data disk.

Send the above to Michael Risha at:

Social Security Administration
4-C-15 Operations Building
6401 Security Boulevard
Baltimore, Maryland 21235

Tab C contains a record specification for use in preparing your input file. You must follow the record layout exactly. Please note that you must put all input data in upper case. If you have questions about any of these instructions, please contact us before submitting your request.

The information to be used in identifying your request for service is as follows:

3 - Requestor ID Code: E0041

4 - Contract Number: SR001009

5 - Batch Number: 01

You must put this information in the first record of your input data file (see record specification).

We look forward to working with you on this project. If you have questions or need assistance in preparing your submission, please contact Michael Risha at 410-966-4868.

Sincerely,

Susan Grad

Susan Grad
Acting Associate Commissioner
for Research, Evaluation, and Statistics

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N1-15-03
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

DQCDD/EDG/OIS/CO

December 12, 2003

Sarah Schweitzer
Statistician
International Epidemiology Institute
1455 Research Blvd.
Suite 550
Rockville, MD 20850

Dear Ms. Schweitzer:

The request for the 2003 Vital Status file created in support of your study has been processed and is enclosed. The file was created on CD, ASCII format.

The file characteristics are as follows:

2003 Vital Status File:

DSN:	IEI-VSTAT.TXT
LRECL:	248
NO. OF RECORDS:	430

SSN To HIC Conversion File:

DSN:	IEI-SSNTOHIC.TXT
LRECL:	248
NO. OF RECORDS:	530

We ask that you validate the media contained within this shipment. You should check that the data are readable and the file specifications (record and block sizes, volsers, and number of records in each file agree with the information contained in the correspondence. It is our policy that CMS will replace defective media or incomplete shipments, providing the media is returned with an explanation of the problem within 60 days following your receipt of the data. Media problems not reported within 60 days become the responsibility of the customer.

It is my obligation to remind you that the data files provided are furnished in accordance with data agreements which mandate specific requirements for their use, storage and return.

In addition, as part of our ongoing data quality assurance activities, we ask that you complete and return the enclosed questionnaire to report any anomalies in these data. Aberrations, inconsistent and/or incongruent data ultimately impact on the utility of the files for decision support or research purposes. Your assistance in pointing out these data problems will be appreciated. All reported anomalies will be reviewed, documented, and if appropriate, referred for corrective action.

Sincerely,

Duane Hudson

Duane Hudson
Computer Specialist
Division of Quality Coordination and Data Distribution
Enterprise Databases Group
Office of Information Services

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N2-04-27
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

OIS/EDG/DPCDD

October 20, 2003

Dr. John D. Boice, Scientific Director
International Epidemiology Institute
1455 Research Blvd., Suite 550
Rockville, MD 20850

Dear Dr. Boice:

Enclosed is the official copy of the signed Data Use Agreement (DUA) you have entered into with the Centers for Medicare & Medicaid Services (CMS). This copy is for your records so that you may refer to it for information regarding the use of the data and/or the data access privileges you have received from CMS. Please refer to DUA number **11541** for the project entitled, **"An Epidemiologic Study of the Rocketdyne Work Force,"** when addressing inquiries of any nature concerning this agreement.

I have also enclosed the CMS DUA Guidelines which outlines your responsibilities in terms of safeguarding the confidentiality of CMS data. If you have any questions about this DUA or the use of CMS data, you may contact me at (410) 786-4285.

Sincerely,

Jeannette Pleines

Jeannette Pleines
Division of Privacy Compliance
Data Development (DPCDD)
Enterprise Databases Group
Office of Information Services

Enclosures

Centers for Medicare & Medicaid Services (CMS)
Data Use Agreement (DUA) Guidelines

1. Requestor agrees to notify CMS if project is completed sooner than the expiration date specified in the DUA.

2. Requestor agrees that any data provided by CMS will not be physically moved or Electronically transmitted in any way from the site indicated in the DUA.

3. Upon completion of project and/or expiration of the DUA, the data must be returned to CMS at the requestor's expense, or destroyed and a statement certifying this action sent to CMS. The Requestor agrees that no data, copies, or parts thereof, shall be retained when the file(s) are returned or destroyed, unless CMS has authorized in writing such retention of said file(s). These options are explained below:

    a. Return data (and any derivative files) to CMS along with a letter delineating the data set names and volume/serial numbers of the files being returned. The letter should reference the DUA number and study name. This letter and the data should be sent to the following address:

        Centers for Medicare & Medicaid Services
        CMS Data Center
        North Building
        Attention: Data Release Area
        7500 Security Boulevard
        Baltimore, Maryland 21244-1850; or

    b. Destroy data and provide a letter CMS on your organization's letterhead certifying that this action has taken place. This letter must also reference the DUA number and study name and delineate the data set names and volume/serial numbers of the files being destroyed. Requestor should forward to:

        Ned Burford, Director DPCDD
        Centers for Medicare & Medicaid Services
        Division of Privacy Compliance
        Data Development (DPCDD)
        Enterprise Databases Group
        7500 Security Boulevard
        Mailstop: N2-04-27
        Baltimore, Maryland 21244-1850

4. If the project is still active and the DUA has expired, a one (1) year extension may be granted. The request for extension will only be granted if the data will continue to be used for the original project purpose and the expiration date has occurred within the past year; otherwise, a new DUA must be negotiated. The letter of request for extension should be directed to the name and address in item 3b above.

5. **Please visit our new website, Privacy Protected Data: Request Policies and Procedures at: http://www.cms.hhs.gov/data/requests/.**

DUA # 11541

DATA USE AGREEMENT

AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA CONTAINING INDIVIDUAL-SPECIFIC INFORMATION)

In order to secure data that resides in a CMS Privacy Act System of Records, and in order to ensure the integrity, security, and confidentiality of information maintained by the CMS, and to permit appropriate disclosure and use of such data as permitted by law, CMS and International Epidemiology Institute enter into this agreement to comply with the following specific paragraphs.

1. This Agreement is by and between the Centers for Medicare & Medicaid Services (CMS), a component of the U.S. Department of Health and Human Services (DHHS), and International Epidemiology Institute, hereinafter termed "User."

2. This Agreement addresses the conditions under which CMS will disclose and the User will obtain and use the CMS data file(s) specified in section 7. This Agreement supersedes any and all agreements between the parties with respect to the use of data from the files specified in section 7 and preempts and overrides any instructions, directions, agreements, or other understanding in or pertaining to any grant award or other prior communication from the Department of Health and Human Services or any of its components with respect to the data specified herein. Further, the terms of this Agreement can be changed only by a written modification to this Agreement or by the parties adopting a new agreement. The parties agree further that instructions or interpretations issued to the User concerning this Agreement or the data specified herein, shall not be valid unless issued in writing by the CMS point-of-contact specified in section 5 or the CMS signatory to this Agreement shown in item 23.

3. The parties mutually agree that CMS retains all ownership rights to the data file(s) referred to in this Agreement, and that the User does not obtain any right, title, or interest in any of the data furnished by CMS.

4. The parties mutually agree that the following named individual is designated as Custodian of the file(s) on behalf of the User and the person will be responsible for the observance of all conditions of use and for establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorized use. The User agrees to notify CMS within fifteen (15) days of any change of custodianship. The parties mutually agree that CMS may disapprove the appointment of a custodian or may require the appointment of a new custodian at any time.

Sarah Schweitzer
(Name of Custodian)

International Epidemiology Institute
(Company/Organization)

1455 Research Blvd, Suite 550
(Street Address)

Rockville, MD 20850
(City/State/ZIP Code)

(301) 517-4048, sarah@iei.ws
(Phone No. - Including Area Code and E-Mail Address, If Applicable)

5. The parties mutually agree that the following named individual will be designated as point-of-contact for the Agreement on behalf of CMS.

Jeannette Pleines
(Name of Contact)

Health Insurance Specialist
(Title/Component)

7500 Security Blvd
(Street Address)

U2-04-27
(Mail Stop)

Baltimore MD 21244-1850
(City/State/ZIP Code)

410-786-4285 JPleines2 @cms.hhs.gov
(Phone No. - Including Area Code and E-Mail Address, If Applicable)

6. The User represents, and in furnishing the data file(s) specified in section 7 CMS relies upon such representation, that such data file(s) will be used solely for the following purpose(s).

Our study, entitled "An Epidemiologic Study of the Rocketdyne Work Force" seeks to identify the entire Rocketdyne work force employed since 1950 and to update vital status information for all cohort members. CMS data files will be used to obtain vital status (alive or dead) and, where applicable, dates of death for cohort members. All information will remain confidential. No individual information will be reported in any report or manuscript. Only aggregate data will be reported.

The User represents further that the facts and statements made in any study or research protocol or project plan submitted to CMS for each purpose are complete and accurate. Further, the User represents that said study protocol(s) or project plans, as have been approved by CMS or other appropriate entity as CMS may determine, represent the total use(s) to which the data file(s) specified in section 7 will be put.

The User represents further that, except as specified in an Attachment to this Agreement or except as CMS shall authorize in writing, the User shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement to any person. The User agrees that, within the User organization, access to the data covered by this Agreement shall be limited to the minimum number of individuals necessary to achieve the purpose stated in this section and to those individuals on a need-to-know basis only.

7. The following CMS data file(s) is/are covered under this Agreement.

File	Year(s)
Vital Status Files	Current
SSN Conversion File	

8. The parties mutually agree that the aforesaid file(s) (and/or any derivative file(s) [includes any file that maintains or continues identification of individuals]) may be retained by the User until September 30, 2008, hereinafter known as the "retention date." The User agrees to notify CMS within 30 days of the completion of the purpose specified in section 6 if the purpose is completed before the aforementioned retention date. Upon such notice or retention date, whichever occurs sooner, CMS will notify the User either to return all data files to CMS at the User's expense or to destroy such data. If CMS elects to have the User destroy the data, the User agrees to certify the destruction of the files in writing within 30 days of receiving CMS's instruction. A statement certifying this action must be sent to CMS. If CMS elects to have the data returned, the User agrees to return all files to CMS within 30 days of receiving notice to that effect. The User agrees that no data from CMS records, or any parts thereof, shall be retained when the aforementioned file(s) are returned or destroyed unless authorization in writing for the retention of such file(s) has been received from the appropriate Systems Manager or the person designated in item number 23 of this Agreement. The User acknowledges that stringent adherence to the aforementioned retention date is required, and that the User shall ask CMS for instructions under this paragraph if instructions have not been received after 30 days after the retention date.

The Agreement may be terminated by either party at any time for any reason upon 30 days written notice. Upon such notice, CMS will cease releasing data to the User under this Agreement and will notify the User either to return all previously released data files to CMS at the User's expense or destroy such data, using the same procedures stated in the above paragraph of this section. Sections 3, 6, 8, 11, 12, 13, 14, 16, 17 and 18 shall survive termination of this Agreement.

9. The User agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is not less than the level and scope of security established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III--Security of Federal Automated Information Systems (http://www.whitehouse.gov/omb/circulars/a130/a130.html), which sets forth guidelines for security plans for automated information systems in Federal agencies. The User acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable or deducible information derived from the file(s) specified in section 7 is prohibited. Further, the User agrees that the data must not be physically moved or transmitted in any way from the site indicated in item number 4 without written approval from CMS.

10. The User agrees that the authorized representatives of CMS or DHHS Office of the Inspector General will be granted access to premises where the aforesaid file(s) are kept for the purpose of inspecting security arrangements confirming whether the User is in compliance with the security requirements specified in paragraph 9.

11. The User agrees that no findings, listing, or information derived from the file(s) specified in section 7, with or without identifiers, may be released if such findings, listing, or information contain any combination of data elements that might allow the deduction of a beneficiary's identification without first obtaining written authorization from the appropriate System Manager or the person designated in item number 23 of this Agreement. Examples of such data elements include but are not limited to geographic indicator, age, sex, diagnosis, procedure, admission/discharge date(s), or date of death. The User agrees further that CMS shall be the sole judge as to whether any finding, listing, information, or any combination of data extracted or derived from CMS's files identifies or would, with reasonable effort, permit one to identify an individual or to deduce the identity of an individual to a reasonable degree of certainty.

12. The User agrees that, absent express written authorization from the appropriate System Manager or the person designated in item number 23 of this Agreement to do so, the User shall make no attempt to link records included in the file(s) specified in section 7 to any other identifiable source of information. This includes attempts to link to other CMS data file(s). The inclusion of linkage of specific files in a study protocol approved in accordance with section 6 is considered express written authorization from CMS.

13. The User agrees to submit to CMS a copy of all findings within 30 days of making such findings. The parties mutually agree that the User has made findings with respect to the data covered by this Agreement when the User prepares any report or other writing for submission to any third party (including but not limited to any manuscript to be submitted for publication) concerning any purpose specified in section 6 (regardless of whether the report or other writing expressly refers to such purpose, to CMS, or to the files specified in section 7 or any data derived from such files). The User agrees not to submit such findings to any third party until

receiving CMS's approval to do so. CMS agrees to make determination about approval and to notify the user within 4 to 6 weeks after receipt of findings. CMS review of the findings is for the sole purpose of assuring that data confidentiality is maintained and that individual beneficiaries could not be identified. CMS may withhold approval for publication only if it determines that the format in which data are presented may result in identification of individual beneficiaries. The User agrees further to submit its findings to the National Technical Information Service (NTIS, 5285 Port Royal Road, Springfield, Virginia 22161) within 30 days of receiving notice from CMS to do so.

14. The User understands and agrees that they may not reuse original or derivative data file(s) without prior written approval from the appropriate System Manager or the person designated in section 22 of this Agreement.

15. The parties mutually agree that the following specified Attachments are part of this Agreement:

____

____

____

16. The User agrees that in the event CMS determines or has a reasonable belief that the User has made or may have made disclosure of the aforesaid file(s) that is not authorized by this Agreement or other written authorization from the appropriate System Manager or the person designated in item number 23 of this Agreement, CMS in its sole discretion may require the User to: (a) promptly investigate and report to CMS the User's determinations regarding any alleged or actual unauthorized disclosure, (b) promptly resolve any problems identified by the investigation; (c) if requested by CMS, submit a formal response to an allegation of unauthorized disclosure; (d) if requested by CMS, submit a corrective action plan with steps designed to prevent any future unauthorized disclosures; and (e) if requested by CMS, return data files to CMS. The User understands that as a result of CMS's determination or reasonable belief that unauthorized disclosures have taken place, CMS may refuse to release further CMS data to the User for a period of time to be determined by CMS.

17. The User hereby acknowledges that criminal penalties under §1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including a fine not exceeding $10,000 or imprisonment not exceeding 5 years, or both, may apply with to disclosures of information that are covered by § 1106 and that are not authorized by regulation or by Federal law. The User further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. § 552a(i) (3)) may apply if it is determined that the Requestor or Custodian, or any individual employed or affiliated therewith, knowingly and willfully obtained the file(s) under false pretenses. Any person found guilty under the Privacy Act shall be guilty of a misdemeanor and fined not more than $5,000. Finally, the User acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641 if it is determined that the User, or any individual employed or affiliated therewith, has taken or converted to his own use data file(s), or received the file(s) knowing that they were stolen or converted. Under such circumstances, they shall be fined under Title 18 or imprisoned not more than ten years, or both; but if the value of such property does not exceed the sum of $1,000, they

shall be fined under Title 18 or imprisoned not more than one year, or both.

18. By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement for protection of the data file(s) specified in section 7, and acknowledges having received notice of potential criminal or administrative penalties for violation of the terms of the Agreement.

19. On behalf of the User the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Dr. John D. Boice, Scientific Director
(Name and Title of Individual - Typed or Printed)

International Epidemiology Institute
(Company/Organization)

1455 Research Blvd, Suite 550
(Street Address)

Rockville, MD 20850
(City/State/ZIP Code)

(301) 517-4021, boice@iei.ws
(Phone No. - Including Area Code and E-Mail Address, If Applicable)

John D Boice, Jr 29 Sep 2003
(Signature) (Date)

20. The Custodian, as named in paragraph 4, hereby acknowledges his/her appointment as Custodian of the aforesaid file(s) on behalf of the User, and agrees to comply with all of the provisions of this Agreement on behalf of the User.

Sarah Schweitzer, Biostatistician
(Typed or Printed Name and Title of Custodian of File(s)

Sarah J Schweitzer 9/29/03
(Signature) (Date)

21. The disclosure provision(s) that allows the discretionary release of CMS data for the purpose(s) stated in paragraph 6 follow(s). (To be completed by CMS staff.)

22. On behalf of ________________________________ the undersigned individual hereby acknowledges that the aforesaid Federal agency sponsors or otherwise supports the User's request for and use of CMS data, agrees to support CMS in ensuring that the User maintains and uses CMS's data in accordance with the terms of this Agreement, and agrees further to make no statement to the User concerning the interpretation of the terms of this Agreement and to refer all question of such interpretation or compliance with the terms of this Agreement to the CMS official named in item number 23 (or to his or her successor).

____
(Typed or Printed Name and Title of Federal Representative)

____
(Signature) (Date)

____
(Phone No. - Including Area Code and E-Mail Address, If Applicable)

23. On behalf of CMS the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Jeannette Plemes Health Insurance Specialist
(Typed or Printed Name and Title of CMS Representative)

Jeannette Plemes 10/20/08
(Signature) (Date)

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0734. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, N2-14-26, Baltimore, Maryland 21244-1850 and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

MEMORANDUM OF UNDERSTANDING
AMONG

THE UNITED STATES AIR FORCE

AND
THE BOEING COMPANY

AND
THE INTERNATIONAL EPIDEMIOLOGY INSTITUTE

The United States Air Force (USAF), the Boeing Company (Boeing), and the International Epidemiology Institute (IEI), hereafter the "Parties":

Noting that IEI is conducting a study involving over 55,000 workers employed at the Rocketdyne facilities in California (now owned by Boeing), to evaluate the cancer risk associated with occupational exposures to ionizing radiation;

Noting that the IEI Rocketdyne Worker Study has a documented protocol that requires each worker's radiation dose to be as complete as possible over the worker's entire career;

Noting that the Rocketdyne Worker Study includes workers who subsequently were employed in the United States military, including the USAF; and

Noting that the USAF maintains radiation dosimetry records "for use in epidemiological and statistical studies to determine the effectiveness of Air Force wide radiological health programs, trends in exposure doses, exposure experience of selected occupational groups and similar studies;

Noting that the USAF radiation dosimetry records are Privacy Act protected data to be treated in accordance with the Privacy Act; and

Noting that IEI, which has the approval of the Department of Energy of the United States, the Nuclear Regulatory Commission, U.S. National Death Index, and the Institutional Review Boards of the Boeing Company, Vanderbilt University and the Oak Ridge National Laboratory to participate and conduct the Rocketdyne Worker Study, is responsible for preparing the vital status and dosimetry analysis files,

Have agreed as follows:

I. Purpose

A. The purpose of this Memorandum of Understanding is to provide a framework for USAF to contribute data from the USAF Center for Radiation Dosimetry, to provide as complete information as possible on the total career radiation dose for each U.S. radiation worker included in the Rocketdyne Worker Study.

B. The Parties expect that a successful Rocketdyne Worker Study will provide additional information of potential health risk at low doses and low dose rates of occupational exposure.

II. Implementing Provisions

A. Pursuant to the Privacy Act, 5 U.S.C. 552a(b)(3), and in accord with the applicable system notice which permits disclosure for use in epidemiological and statistical studies, the USAF shall provide IEI and Boeing with dosimetry information, as recorded in the USAF Center for Radiation Dosimetry, for each worker identified as being included in the Rocketdyne Worker Study.

B. IEI and Boeing shall treat the USAF radiation records in accordance with the Privacy Act and agree that there will be no disclosure of any Privacy Act information.

C. IEI and Boeing shall use this information only for the above described research purposes.

D. IEI and Boeing shall maintain the confidentiality of the subject information and make no disclosure of it to third parties without the prior written consent of the USAF. If, during the examination of USAF-provided data, errors or omissions are found and corrected, these corrected data shall be provided back to the USAF Center for Radiation Dosimetry.

E. IEI and Boeing's obligation to maintain the confidentiality of the USAF-provided information shall remain in effect throughout the term of this Memorandum of Understanding and after its termination, unless and until the said information and all copies thereof are returned to USAF.

III. Contacts

The principal contact for USAF is Lt Col Scott Nichelson, Air Force Institute for Operational Health (AFIOH) Radiation Surveillance Division. The principal contact for Boeing is Mr. Steve Lafflam, Boeing, Santa Susanna Field Station. The principal contact for IEI is Dr. John D. Boice, Jr., Scientific Director.

IV. Management

The Parties shall consult each other whenever they deem it necessary, and shall assess the results of the work carried out and in progress.

V. General Provisions

A. This Memorandum of Understanding shall become effective upon signature by all Parties, and shall remain in effect for one year. The Parties may extend this Memorandum of Understanding for additional periods.

B. The terms of this Memorandum of Understanding may be altered in writing by the Parties. If any Party wishes to cease its activities under this Memorandum of Understanding, it shall give ninety (90) days advance written notice to the other Parties.

C. Cooperation under this Memorandum of Understanding shall be in accordance with the applicable laws and regulations under which each Party operates.

D. Unless otherwise agreed in writing, each Party shall assume responsibility for, and provide funding to cover, the costs individually incurred in participating in the collaboration contemplated by this Memorandum of Understanding. The collaborative activities are subject to the availability of funds and personnel.

FOR THE UNITED STATES AIR FORCE:

______________________ Date: 12 Feb 04

JOSEPH E. KELLEY
Major General, USAF, MC, CFS
Assistant Surgeon General, Health Care Operations
Office of the Surgeon General
Bolling AFB, DC

FOR THE BOEING COMPANY:

______________________ Date: 24 Feb 04

Steve Lafflam
Division Director, Safety, Health & Environmental Affairs
Canoga Park, CA

FOR THE INTERNATIONAL EPIDEMIOLOGY INSTITUTE:

John D. Boice, Jr. Date: 23 Feb 2004

Dr. John D. Boice, Jr.
Scientific Director
Rockville, MD

Attachments
Approval from the Department of Energy for linkage with their dosimetry records (Oct 2003)
Approval from Nuclear Regulatory Commission for linkage with their dosimetry records
Study description (PHS 398, Page 2)
Letter of support from Steve Lafflam, Division Director, Safety, Health & Environmental Affairs, Rocketdyne, The Boeing Company
Institutional Review Board approval from Vanderbilt University
Institutional Review Board approval from The Boeing Company
Institutional Review Board approval from Oak Ridge National Laboratory
Approval from the National Center for Health Statistics for mortality linkage
Approval from the Social Security Administration for vital status linkage

Vanderbilt University
Institutional Review Board
D-3232 Medical Center North Nashville, Tennessee 37232-2598
(615) 322-2918 Fax: (615) 343-2648
www.mc.vanderbilt.edu/irb

October 12, 2004

John D Boice, Jr., Sc.D.
International Epidemiology Institute
1455 Research Blvd. Suite 550
Rockville, MD 20850

RE: IRB# 010018 "A Cohort Mortality Study of the Rocketdyne Workforce" (International Epidemiology Institute)

Dear Dr. Boice:

A sub-committee of the Institutional Review Board reviewed the Application for Continuing Review for the research study identified above. The sub-committee determined the study poses minimal risk to participants. Approval is extended for the Application for Continuing Review dated October 7, 2004, the IRB Proposal Description dated December 20, 2000. The study meets 45 CFR 46.110 (F) category (5) and (7) for expedited review. The study meets 45 CFR 46.116 (d) for waiver of the requirements to obtain informed consent.

It is the understanding of the IRB enrollment for the study is closed, therefore approval is not extended to the Consent Form(s). If enrollment should reopen, submission of an amendment and IRB approval would be required prior to any additional accrual. Federal regulations require the original copy of the participant's consent be maintained in the principal investigator's files and that a copy be given to the participant at the time of consent. An additional record (i.e., case report form, medical record, database, etc.) of the consent process should also be maintained in a separate location for documentation purposes.

As the Principal Investigator, you are responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events and unanticipated problems involving risks to participants or others. The IRB Adverse Event reporting policy III.G is located on the IRB website at http://www.mc.vanderbilt.edu/irb/. For your convenience, a flowchart is attached.

Please note that approval is for a 12-month period. Any changes to the research study must be presented to the IRB for approval prior to implementation.

DATE OF IRB APPROVAL: October 12, 2004 DATE OF IRB EXPIRATION: October 12, 2005

Sincerely,

Todd W. Rice, M.D., Chair
Institutional Review Board
Health Sciences Committee #2

TWR/led