November 8, 2004

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Germantown, MD 20585-0270

CONTRACT NO. DE-AC05-00OR22750: FY04 FINAL REPORT FOR THE FORMER RADIATION WORKER MEDICAL SURVEILLANCE PROGRAM AT ROCKY FLATS

The enclosed subject final report prepared by Joe M. Aldrich is submitted as stated in the Fiscal Year 2004 Field Work Proposal for the Former Radiation Worker Medical Surveillance Program at Rocky Flats. This is the final report for this program.

If you have any questions, please contact me at (303) 423-9585, ext. 238 or Joe M. Aldrich at (303) 423-9585, ext. 227.

Sincerely,

Duane E. Hilmas, D.V.M., Ph.D.
Technical Director

Enclosure

cc: Donna Cragle
Robert Bistline

November 8, 2004

DISTRIBUTION

FISCAL YEAR 2004, FINAL REPORT* OF THE FORMER RADIATION WORKER MEDICAL SURVEILLANCE PROGRAM AT ROCKY FLATS AND MANAGED BY OAK RIDGE ASSOCIATED UNIVERSITIES (ORAU) OAK RIDGE INSTITUTE FOR SCIENCE AND EDUCATION (ORISE) (FORMERLY ROCKY FLATS ENVIRONMENTAL TECHNOLOGY SITE)

The purpose of the attached correspondence is to provide this final report of the Former Radiation Worker Medical Surveillance Program at Rocky Flats.

If you have any questions concerning the attached final report, please contact me at (303) 423-9585, ext. 227.

Sincerely,

Joe M. Aldrich
ORAU
BAR/CER-RFETS

Attachment:
As Stated

* This document was produced under a contract between the United States Department of Energy and Oak Ridge Associated Universities.

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Page 2

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FINAL REPORT
FORMER RADIATION WORKER MEDICAL SURVEILLANCE PROGRAM AT ROCKY FLATS
For Department of Energy Programs

EXECUTIVE SUMMARY:

The Former Radiation Worker Medical Surveillance Program at Rocky Flats was conducted in Arvada, CO, by Oak Ridge Associated Universities through the Oak Ridge Institute for Science and Education under DOE Contract DE-AC05-00OR22750. Objectives of the program were to obtain information on the value of medical surveillance among at-risk former radiation workers and to provide long-term internal radiation dosimetry information to the scientific community. This program provided the former radiation workers of the Rocky Flats Environmental Technology Site (formerly Rocky Flats Plant) an opportunity to receive follow-up medical monitoring and a re-evaluation of their internal radiation dose. The former Rocky Flats radiation worker population is distinctive because it was a reasonably stable work force that received occupational exposures, at times substantial, over several decades. This report reflects the summation of health outcomes, statistical analyses, and dose assessment information on former Rocky Flats radiation workers to the date of study termination as of March 2004.

A total of 1,166 former workers volunteered to participate in the program; however, two participants chose not to fulfill their dosimetric requirements (submittal of urine samples). Although 1,164 dose assessments were performed, the final 16 dose assessments were not completed until after the cutoff date for preparing the final analysis file. Therefore, the final descriptive analysis was based on the 1,148 participants with available dose assessments. In addition, Standardized Prevalence Ratios (SPRs) were calculated for the 1,072 white males whose date of last exam was in 1992 or later, comparing prevalence of self-reported cancer and non-cancer medical conditions to occurrences in U.S. white males. Statistically significant SPR elevations were found for bladder cancer [SPR=1.66, 95% confidence interval (1.01, 2.55)] and prostate cancer [SPR=1.33, 95% confidence interval (1.06, 1.65)]. Sixteen of the 18 bladder cancers occurred in smokers. All male program participants were offered prostate-specific antigen tests since 1998, which may have contributed to the increased detection of prostate cancer.

The program provided:

- At least one medical examination, modern internal dosimetry measurements, and internal radiation dose re-evaluation to all program participants

- Repeat medical examinations (approximately every 3 years) to workers whose total effective dose equivalent (TEDE) is twenty (20) rem or more and to others for whom review of their health physics record indicated a need for additional information.
- Repeat medical examinations to workers with TEDE values between 10 and 19 rem if they had a potentially understated neutron dose from work in plutonium-related buildings in the period 1952-1970
- Repeat medical examinations and internal dose updates to those workers whose lifetime dose is 100 rem or greater.

BACKGROUND:

The United States Department of Energy (DOE) Rocky Flats Environmental Technology Site (RFETS, formerly known as the Rocky Flats Plant) produced nuclear weapons components from 1952 to 1989 (Daugherty, et. al., 2001). Work-related activities, including incidents and accidents, from 1952 to present day decommissioning efforts have resulted in internal depositions of radioactive materials and external exposure to penetrating radiation.

In 1980 staff members in the occupational health section of the Rocky Flats prime contractor initiated an informal dosimetry recall program for dosimetrically interesting former workers who had known or documented long-term plutonium or americium systemic or lung depositions. As an incentive to participate in this informal program, volunteers were offered medical examinations similar to those routinely provided to them while they were active workers.

In 1992 the Department of Energy's (DOE) office of Occupational Medicine and Medical Surveillance provided support to formalize what had been an informal dosimetry recall program into a medical surveillance program with additional emphasis on health outcomes. In 1993 a technical advisory committee was established to offer independent external review and recommendations for the program (Daugherty, et. al., 2001).

On October 23, 1992, Congress passed Public Law 102-484, "National Defense Authorization Act for Fiscal Year 1993," directing that "The Secretary [of Energy] shall establish and carry out a program for the identification and on-going medical evaluation of current and former Department of Energy employees who are subject to significant health risks as a result of the exposure of such employees to hazardous or radioactive substances during employment". Also in 1992, 42 USC Sec. 7274i, codified the medical monitoring sections of PL 102-484, requiring DOE to determine the appropriate number, scope, and frequency of medical evaluations and laboratory tests to be provided to current and former employees who were subject to significant health risks as a result of being exposed to radioactive substances.

Even though the Former Radiation Worker Medical Surveillance Program at Rocky Flats was initiated prior to the passage of PL 102-484, it was responsive to the intent of this law with regard to exposures to radioactive materials by former radiation workers of Rocky Flats (Daugherty, et. al., 2001). The Former Radiation Worker Medical Surveillance Program at Rocky Flats responded to this legislation by providing medical examinations and updated dose assessments to a higher percentage of individuals exposed to plutonium and americium than were generally available from other DOE sites and by verifying with DOE the feasibility and cost effectiveness of distinct aspects of the medical surveillance examinations, such as the adoption of the three year recall frequency.

As new laws are adopted over time (e.g., 42 USC Sec. 7384 – EEOICPA – 2000), the focus of individual medical surveillance programs are modified to align program goals with any new directives. Nonetheless, the overall focus of the Former Radiation Worker Medical Surveillance Program at Rocky Flats was to provide data and information to; the program participants that might lead to early medical intervention, the DOE, and the scientific community for future research and evaluation of medical surveillance programs.

Support to Other Programs

A cooperative agreement with the United States Transuranium and Uranium Registries (USTUR), documented by a Memorandum of Understanding (MOU DEH-012-98), has been in place since February 1998. This agreement has allowed the program to share information about the USTUR with participants and to collaborate with the USTUR staff concerning internal dosimetry data and analyses for participants in both programs.

The program is closely related to the Rocky Flats Neutron Dose Reconstruction Project (NDRP), a program that is re-evaluating the neutron doses for workers who worked in plutonium-related buildings at Rocky Flats in 1952-1970. Many of the participants in the program are also members of the cohort of workers for the NRDP.

METHODS:

The Former Radiation Worker Medical Surveillance Program at Rocky Flats provided former Rocky Flats workers with long-term medical surveillance and an update to the calculation of their lifetime internal radiation doses.

Eligibility Criteria

During the first several years of operation the former radiation workers were invited to participate in the program if they met any of the following initial criteria:

- a measurable lung deposition of plutonium or americium
- a plutonium plus americium Maximum Permissible Body (systemic) Burden of at least 10%, based on the radiation dosimetry system that was in use through 1989
- an old wound that contained residual plutonium or americium at the wound site
- an annual effective dose equivalent (AEDE) of 0.5 rem or more, based on lung and systemic burdens present at the end of calendar year 1989
- a cumulative external whole body dose of 20 rem or more
- a TEDE of 20 rem or more from a combination of external and internal sources
- a review of their exposure or work record indicated a significant likelihood that an internal deposition or external dose may have occurred that was not well evaluated in the past.

Corresponding to these initial program entrance criteria, a participant received only an initial exam if the participant's updated TEDE was below 20 rem and a review of the participant's health physics record, the most recently updated dose assessment, and the participant's interview did not reveal any areas of potential unrecorded dose. Participants with an updated TEDE of 20 rem or more were invited to return on a periodic basis (about every three years) for subsequent medical examinations, and updates to calculated internal doses were provided for selected participants. In addition, participants with a TEDE between 10 and 20 rem were invited to return on a periodic basis if they had a potentially understated neutron dose from work in plutonium-related buildings during 1952 through 1970.

All eligibility criteria were subject to change over time, dictated by program findings, DOE directives, and available funding. For example, beginning August 10, 2001, DOE authorized an initial examination and dose evaluation for any former Rocky Flats employee, regardless of previously recorded Rocky Flats Plant exposure. Review of previous program results had identified some participants whose exposure records understated what was later determined to be their lifetime TEDE and would have been overlooked based on the previous acceptance criteria. Due to this concomitant increase in eligible candidates, resources previously expended in preliminary reviews of Rocky Flats records were re-directed toward providing medical examinations and dose evaluations to a broader range of potentially exposed former workers. Even when there was open enrollment, the program continued to prioritize potential participants by ranking them from high to low based on exposure history and age. The intent was to solicit participation of former workers whose dose and medical information may have put them at greater risk either from their exposure or their potential inability to participate due to their age. The program exerted every effort to include all former workers who requested to participate.

Data Sources

During its entirety, the program continued its effort to identify, locate and contact potential candidates for participation. Identifying former Rocky Flats radiation workers meeting the initial program participation criteria was complicated by lack of a single data source that included all relevant dosimetry information for Rocky Flats employees during the plant's operational history. As a result, multiple sources of information were used in the initial worker identification process.

Salient sources included:

- Internal and external dosimetry records from the Rocky Flats computerized radiation health record system for employees who terminated their Rocky Flats employment after 1976
- Internal and external dosimetry data extracted from health physics files for all employees who terminated their Rocky Flats employment before 1977
- Lung count and wound count records indicating workers with recorded plutonium depositions
- Historical logs and reports that identified workers involved in incidents involving plutonium contamination or workers with elevated bioassay results.

Recruiting Efforts

If a review of available Rocky Flats records indicated a former employee met one or more of the eligibility criteria, that person's name was added to the database of former radiation workers. Once a former worker was in the database, efforts were made to determine if the candidate was living, obtain a current address or telephone number, and contact the individual to establish whether the candidate was interested in participating in the program.

Vital status and current address and telephone numbers were obtained from:

- Other site employees (to be confirmed by other sources, as listed below)
- Notices in the Rocky Flats site newspaper
- Notices in the Rocky Flats retiree's newsletter, *Rocky Flats Homesteaders*
- The Rocky Flats Human Resources Management System database
- Publicly available databases through Internet search engines
- Searches performed by commercial companies under standing contracts maintained by the Center for Epidemiologic Research, ORISE.

Current addresses of living candidates were added to the database, and initial invitation letters were mailed as openings became available. An additional 200 to 400 potential participant candidates have been identified but were not yet sent an initial contact letter when the program was terminated in 2004. Also, the program had not recalled or reviewed paper health physics files for radiation workers who left Rocky Flats between 1976 and 1992. As a result, only computerized dosimetry records had been used to identify candidates from these more recently-terminated former workers, some of whom might be of a significant interest to the program based on the more complete review of their paper health physics files.

Medical Monitoring

Clinical tests provided to participants typically included analyses of urine and blood samples for selected health indicators, including an optional prostate-specific antigen (PSA) test for male participants; a chest x ray; hearing and vision tests; measurement of height, weight, blood pressure and pulse; a pulmonary function test; an electrocardiogram (ECG); and a colon cancer screening test for occult blood in a stool sample. In addition, the ORISE program physician performed an examination and medical history review at the time of the participant's visit. All participants were sent copies of the results from their medical examinations with the recommendation that they share this information with their personal physicians.

Beginning in February 1999, routine reports for each participant included the following demographic information: unique case identification, date of hire, date of termination, age at date of exam, recorded medical diagnosis, assigned *ICD*-9 coding for each diagnosis where appropriate, and a summary of the job descriptions.

Radiation Dose Re-assessment

The program also provided each participant with an updated dose assessment that typically included at least one lung count for americium (a marker for plutonium) and one urine sample analysis for plutonium and/or americium, using modern measurement and analytical capabilities. Internal dose re-assessments were performed using CINDY© (Code for Internal Dosimetry), an ICRP-30 based biokinetic and dosimetry computer code developed by Battelle, Pacific Northwest Laboratory. The updated internal dose assessment included lung count and urine analysis results acquired as part of the participant's exam, as well as any applicable data found in their plant health physics records. Each participant typically received a print out of results immediately upon lung count completion along with a short explanation by the lung counting technician. Copies of urine analysis results and dose re-assessment were mailed to participant's homes when finished.

Wound counts were performed for participants who had residual contamination at sites of old wounds. During their employment at Rocky Flats, these workers were provided annual wound counts to estimate the rate the plutonium was leaving the wound site, if at all. This program continued to add follow-up measurements to these data sets.

External dose equivalents from measurements made at the time of exposure, were used as recorded (found) in the participant's Rocky Flats records. At the time of program termination, the updated neutron worker exposure data, as generated by the Neutron Dose Reconstruction Project (NDRP) for employees working in plutonium-related buildings in 1952 through 1970, were not yet available for inclusion in the final external dose profile of the participants.

Knowledge gained as the program progressed contributed to further changes in eligibility criteria and program operation. Specifically DOE program management made two decisions in 2000: (1) to eliminate acceptance criteria (see Eligibility Criteria section above for more details); and (2) to minimize the additional bioassay measurements and internal dose re-assessments for repeat participants (typically after the second or third visit). The program had identified participants whose exposure records sometimes understated what was actually determined to be their lifetime TEDE and would have been overlooked based on previous acceptance criteria. Also, the quality and consistency of urine analysis results, lung count results, combined with the participants' reasonably stable plutonium excretion rates per day enabled the program to better project TEDE values into the future. It was determined that two program visits approximately three years apart were the minimum number necessary to collect sufficient urine excretion and lung count data to allow the prediction methodology to be considered as a viable approach.

With the revised program procedures, repeat participants with a TEDE less than 100 rem received an updated dose assessment for their repeat visits only if additional bioassay measurements were specifically requested. Typically, all first-time participants received an internal dose assessment based on measurements from one urine sample, a lung count, and data and other information available in their historical files.

Urine Sample Analyses

From 1992 to November 1993 urine analyses were performed on-site by the Rocky Flats Health, Safety, and Environment Laboratory. Starting in November 1993, commercial laboratories performed urine analyses for plutonium plus occasional americium analytes for all urine bioassay samples for the program, per the specifications of statement of work (SOW) administered by the Analytical Services Division of EG&G (through June 1995) and Kaiser-Hill (July 1995 to present). The SOW rigorously specified the quality assurance and sensitivity requirements for the analyses. For example, the minimum detectable activity (MDA) of 0.02 disintegrations per minute was required to be achieved for $^{239+240}Pu$ for each sample, and the SOW specified how the laboratory was to assess that MDA. Quality assurance oversight was provided by the Analytical Services Division. In addition, the program included a blind blank urine sample and a blind, plutonium spiked, control urine sample with each shipment of participant samples to the off-site laboratory.

Special Measurements

In January 1997, the Advisory Committee for this program recommended that special in vivo measurements, e.g., a skull count or a liver count, be performed for participants with significant internal depositions of plutonium. The reasons for acquiring these data were to capture potentially useful information that would advance the understanding of the biokinetics of plutonium in humans and to gather data to apply a correction to in vivo lung counts in order to account for interference from plutonium in the ribs. Wound counts and other special counts were performed when requested by the senior dosimetry specialist. In general, special measurements were requested for participants for whom the committed dose equivalent (CDE) to the lungs or bone surfaces was 500 rem or greater. Special measurements were performed for 59 participants. Since November 13, 2001, security/access protocols required the program to provide hosting/escort services for participants while they were at RFETS for lung, wound, or special counts.

Institutional Review Board (IRB)

The program protocol, including consent forms, procedures, provisions for confidentiality of data, protection of participant's rights, and reports, was reviewed annually by an Institutional Review Board (IRB). Since formalization of the program under Rocky Flats Management in 1992 and through 1998, the Rocky Flats IRB had responsibility for reviewing its activities annually. Following transfer of program management responsibilities to ORISE on October 1, 1998, the Oak Ridge Site-Wide IRB took over the IRB oversight and annual program review responsibilities.

Advisory Committee

A technical advisory committee was formed and the first subcommittee meeting was held in June 1993. Its purpose was to provide an outside independent technical review of the program for the program management, and to provide comments to DOE regarding the program's conduct and management. This advisory committee remained active throughout the course of this program, as documented in the minutes of 18 full committee and three subcommittee reviews. The committee made significant contributions to the overall program which contributed to its success.

Committee Members:
Breitenstein, Bryce D., Jr., M.D., June 15, 1993 – April 29, 2004
Borak, Thomas B., PhD., October 11, 1994 – Current
Galke, Warren A., PhD., June 3, 2002 – Current
Gillette, Edward L., D.V.M., PhD., June 15, 1993 – November 26, 2001
Hankins, Dale E., M.A., October 10, 1994 – September 11, 2000
Ruttenber, A. James, M.D., PhD., June 15, 1993 – September 11, 2000
Skrable, Kenneth W., PhD., July 24, 2002 – Current

Spitz, Henry B., PhD., June 15, 1993 – November 26, 2001
Thomas, Terry Lynn Duel, PhD., November 30, 2000 – January 2002
Weaver, Jack D., October 8, 2001 – Current

Ad hoc member:
Shore, Roy E., PhD. April 30, 2003

Cumulative Dose and Cancer

Cumulative external and internal occupational radiation doses in rem were calculated for each case of malignant melanoma and cancer of the bladder, colon, lung, and prostate. Except for lung cancer, these were the cancers most commonly reported by program participants. Lung cancer was also selected because of its potential relationship to radiation exposure. These doses were determined by accumulating annual doses through 10 years before the diagnosis date (lag 10) since it is generally accepted that there is a latency period between exposure and cancer diagnosis. The annual internal doses that were accumulated for these analyses were the effective dose equivalents received by the participant from any internal deposition of plutonium, americium, and uranium. The effective dose equivalent is the sum of the dose equivalents from internal radionuclide depositions for each target organ or tissues multiplied by the weighting factor for that organ or tissue. The weighting factor, established by the ICRP (ICRP 26, ICRP 30), represents the ratio of the stochastic risk resulting from the organ or tissue to the total risk when the whole body is irradiated uniformly (ICRP 30).

ICD-9 Coding

A standardized coding methodology based on the *International Classification of Diseases, 9th Revision, Clinical Modification* (ICD-9-CM) system was used throughout this program. Using the ICD-9-CM coding system provided an internationally-recognized, consistent methodology for describing medical results and, once completed, these ICD-9 codes aided in assessing whether any associations could be established between health outcomes and radiation dose.

Initially, a trained team abstracted and coded the backlog of medical data. The staff physician, who was also trained in the use of the ICD-9 codes, has continued with this standardized approach as he reviews each participant's medical file prior to performing the medical examination. Once the medical examination is complete, the physician codes all of the pertinent medical diagnosis and enters this data into the database.

Mortality Data

Death certificates for participants were obtained from the Rocky Flats Benefit Office. Mortality data were tabulated for reporting purposes only after a copy of the death certificate had been obtained. Pending receipt of the death certificate, informal information regarding a participant's death, gathered from a variety of sources, was noted in a comment field within the Health Surveillance Information System (HSIS) database.

Deceased participants since July 1, 1992, w/Death Certificates	135
Total number of deceased participants noted in HSIS	172

Morbidity Comparison Rates

To determine whether rates of cancer and other medical outcomes in program participants were similar to rates in the general population for people of the same age, race, and gender, a search was conducted for data that would provide a suitable basis for comparison. A valid comparison group would have provided self-reported medical outcomes that included both new and chronic conditions, since the medical files of program participants included previously as well as newly diagnosed diseases.

The annual National Health Interview Survey (NHIS) conducted by the National Center for Health Statistics statistically samples non-military, non-institutionalized adults throughout the United States and collects self-reported medical information as well as demographic data such as age, race, and gender, and other supplemental information. A series of survey questions ask whether the subject has ever been told by a health professional that he or she has a specifically named disease. Questions of this type measure the prevalence of a disease in the population at a point in time. More details on these annual surveys can be found at http://www.cdc.gov/nchs/nhis.htm.

Using the NHIS prevalence data from 1997 to 2001 for chronic medical conditions and the sampling weights assigned to each individual in the NHIS databases, prevalence rates in the US population for certain commonly occurring diseases were calculated for five-year age groups. These NHIS-based rates allowed comparison with the prevalence of certain diseases at the date of the last exam for 1072 white male program participants. Medical conditions with sufficient data for analysis were diabetes, emphysema, arthritis, all cancers, as well as selected cancers, including bladder, digestive, lung, melanoma, prostate, and thyroid. The healthy worker effect, the usual bias that occurs when comparing a group of workers to the general population, was not pertinent, since program participants were no longer active workers. The number of participants who were not white males was too small to allow any statistical comparison for other race/gender groups.

Standardized prevalence ratios (SPRs) were calculated using the AMFIT module of EPICURE© (Preston et al., 1988-93). An SPR is defined as O/E*, where O is the sum of the number of participants in each cell who report the medical diagnosis and E* is the sum of the "expected number" of diagnoses for each cell. The "expected number" of diagnoses per cell is the product of the comparison population rate for the cell and the number of participants in the cell. Likelihood ratio methods for Poisson-distributed variables were used to determine 95% confidence levels for SPRs.

RESULTS:

Tables 1a and 1b summarize general program participant and activity information since the initiation of activities in July 1992. A total of 1,166 former radiation workers have participated in at least one medical examination.

Table 1a: Number of Participants

Participants	*Cumulative Number, July 1992 through September 2004*
Participants Having at Least One Medical Exam	1166
Participants Eligible for Repeat Medical Exams	513
Participants Having at Least One Dose Assessment	1164
Participants with Dose Assessment Included in Analysis	1148

Table 1b: Number of Medical Examinations and Dosimetry Measurements

Activity	*Cumulative Number, July 1992 through September 2004*
Medical Examinations	2076
Lung Counts	1699
Wound Counts	93
Skull Counts	59
Urine Samples Submitted	2827

As a result of the medical examinations provided to the participants of this program, several medical findings, some serious, were identified. A final list of these medical conditions or their ultimate outcomes could not be quantified since all participants were referred to their regular health care providers for definitive diagnosis. The following list reflects the different types of health conditions identified in this program.

List of Medical Findings

- Abdominal aneurysm
- Anemia
- Cancer (predominantly prostate)
- Cardiac arrhythmia
- Cataracts
- Diabetes mellitus
- Elevated liver enzymes

- Elevated prostate-specific antigen (PSA)
- Hearing loss requiring hearing aids
- Hypercalcemia
- Hypercholesterolemia
- Hypertension
- Hyperthyroidism
- Hypothyroidism
- Lung nodules
- Obesity
- Occult gastro-intestinal bleeding
- Prostate enlargement
- Pulmonary function deficits
- Renal insufficiency
- Skin lesions, cancer and precancerous
- Urinary tract infections
- Urinary tract obstruction
- Vision defects requiring correction to drive

Descriptive Analysis

All results reported in this section are based on data for 1148 participants for whom data were available when the final analysis file was created. These former workers were older than the average employed population since over 93% of the participants were hired before 1980.

Excluding non-melanoma skin cancers, cancer was self-reported by 170 (15%) of the 1148 program participants. Individuals with cancer included 158 white males, 9 non-white males, 2 white females, and 1 non-white female. As seen in Table 2, at the time of first cancer diagnosis nearly 90% of participants reporting cancer were at least 50 years old, which is the age when cancer rates in the general population begin a steady rise.

Table 2: Age at First Cancer Diagnosis among 170 Participants Reporting Cancer

Age Group	*Percent of Participants with Cancer*
< 50 years old	11
50 – 59	18
60 – 69	43
70 – 79	26
80 or older	1
Unknown	1

Smoking status is of interest because smoking has been shown to raise the risk of developing certain cancers. Among the program participants with cancer 21% had never smoked while 73% were current or former smokers and 5% had unknown smoking status. Smoking status was obtained at the time of first examination.

Table 3 presents the type of cancer first diagnosed for each participant who reported cancer. Genitourinary cancers, which include prostate cancer, were most frequent as would be expected in an aging male group. Although malignant melanomas were the third most commonly reported type of cancer, it is possible that the higher UV exposure due to the thinner atmosphere at Colorado altitudes may be a confounding factor for these cancers.

Table 3: Type of Cancer First Diagnosed in Each Individual

First Cancer Type	*Number (Percent) of Cancer Types for Participants with Cancer (N=170)*
Genitourinary (13 bladder, 2 kidney, 80 prostate, 2 testes, 1 male breast, 1 female breast, 1 cervix)	100 (59%)
Digestive (2 oral, 17 colon, 1 rectum, 1 liver,1 pancreas, 1 general digestive)	23 (14%)
Melanoma	20 (12%)
Respiratory (7 lung, 1 sinus, 3 larynx)	11 (7%)
Lymphopoietic (4 leukemia, 4 lymphoma)	8 (5%)
Other (1 bone, 4 thyroid, 1 endocrine, 1 ill-defined, 1 unknown)	8 (5%)
Total	**170 (100%)**

Among the 170 participants with cancer, 23 individuals reported that a second cancer had been diagnosed and five of these 23 had a third cancer. Sites for these subsequent cancers are presented in Table 4. Altogether 198 cancers were reported by the 1148 participants, including 170 first and 28 subsequent cancers.

Table 4: Subsequent Cancers for 23 Multiple Cancer Site Participants

Type of Cancer	*Number of Cancers*
Bladder	5
Colon	3
Eye*	1
Kidney	1
Lung	2
Lymphopoietic	2
Melanoma**	4
Prostate	2
Unknown/Ill-defined	3
Secondary	5
Total	**28**

*First cancer was thyroid.
**Among 3 individuals.

Table 5 presents the number of cancer cases associated with each dose range. An individual case could be assigned to different external and internal dose ranges depending upon the lag 10 cumulative external and cumulative internal doses acquired at the date of diagnosis.

Table 5: External and Internal Dose Distributions* in Rem for Selected Cancers

	Bladder Cancer		*Lung Cancer*		*Colon Cancer*		*Malignant Melanoma*		*Prostate Cancer*	
Dose Range	Ext	Int	Ext	Int	Ext	Int	Ext	Int	Ext	Int
< 5	8	7	2	3	4	10	9	13	28	38
5 – 9	2	0	2	1	5	4	8	3	12	12
10 – 19	3	5	2	1	4	2	3	0	17	13
20 – 29	3	3	1	1	2	1	1	1	12	4
30 – 49	2	0	0	0	4	1	3	6	9	6
50 +	0	3	0	1	1	2	0	1	2	7
Unknown**			2	2					1	1
Total Cases	**18**	**18**	**9**	**9**	**20**	**20**	**24**	**24**	**81**	**81**

*Annual doses accumulated through 10 years before diagnosis.
**Doses with 10 year lag could not be determined because year of cancer diagnosis was not available.

Prevalence Analysis

All results reported in this section are based on data for 1072 white male participants with last exam no earlier than 1992, the year when the program formally began. There were not enough black female (3), white female (47), or black male (23) participants to include these groups in the prevalence analysis.

Table 6 shows that the observed number of cancers reported by white male participants was similar to what would be expected for men in their age groups. The confidence interval includes 1.00, indicating that the difference between the observed and expected number of cancers can be explained by random variation. Although the SPR was above 1.00 for each specific cancer type examined except digestive, only bladder and prostrate cancers showed statistical evidence of elevation, having a lower 95% confidence level above 1.00. Among non-cancer outcomes it was possible to compare the prevalence of arthritis, diabetes, and emphysema in the white male program participants to the general population. Because the upper 95% confidence levels for these three diseases were below 1.00, the prevalence rates were statistically lower for participants than for other white males their age in the United States.

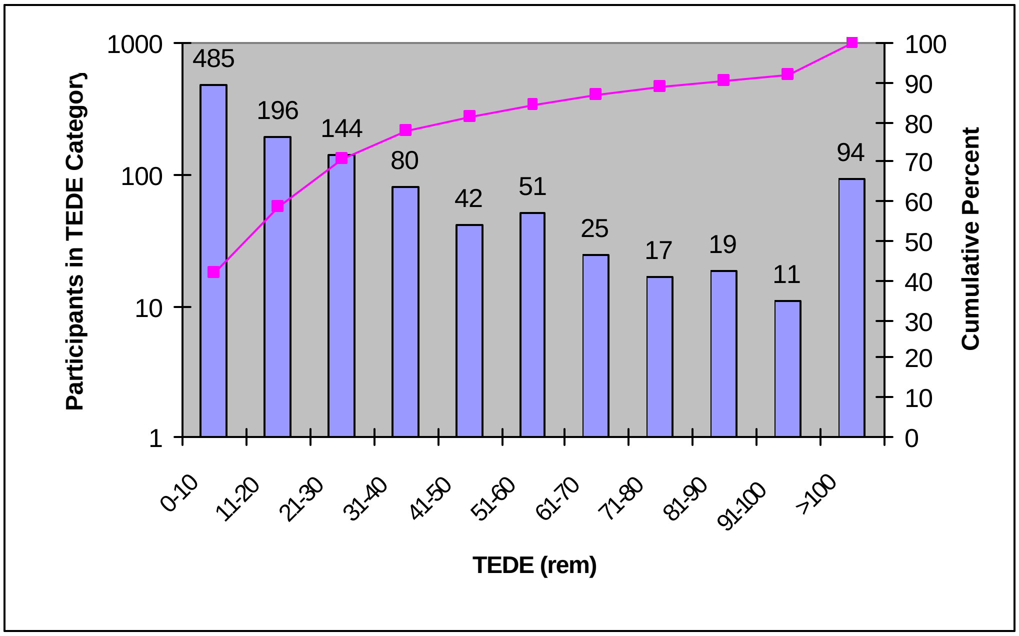
Table 6: Standardized Prevalence Ratios for Selected Medical Outcomes In White Male Participants

Condition	*Observed*	*Expected*	*SPR*	*Lower 95% CL*	*Upper 95% CL*
All Cancers	157	153.36	1.02	0.87	1.19
Bladder Cancer	18	10.82	1.66	1.01	2.55
Digestive Cancer	20	22.41	0.89	0.56	1.34
Lung Cancer	9	8.88	1.01	0.49	1.82
Malignant Melanoma	21	13.30	1.58	1.00	2.35
Prostate Cancer	78	58.49	1.33	1.06	1.65
Thyroid Cancer	3	0.99	3.03	0.75	7.85
Arthritis	393	456.64	0.86	0.78	0.95
Diabetes	102	136.17	0.75	0.61	0.90
Emphysema	29	63.46	0.46	0.31	0.64

Dosimetry Results

The distribution of the total effective dose equivalents (TEDE) is presented in Figure 1 for the 1,164 participants (histogram) who received both a medical exam and an internal dose re-assessment. Also presented is the cumulative percent (single cumulative line) of participants based on their TEDEs from low to high. For example, 681 participants (58.5%) had a TEDE less than or equal to 20 rem while 94 participants (8.1%) had a TEDE greater than 100 rem. The geometric mean of the TEDE for the 1,164 participants was 9.4 rem, and the geometric standard deviation was 8.7 rem. Figure 2 shows the TEDE distribution for the 94 participants in the >100 group from Figure 1.

Figure 1. Distribution of the Total Effective Dose Equivalents (TEDE) for Participants (N = 1164)



The distribution of the TEDEs for the 94 participants with a TEDE greater than 100 rem is shown in Figure 2. Five participants have a TEDE greater than 1000 rem, with the highest TEDE being 2322 rem.

Figure 2. Distribution of Total Effective Dose Equivalent (TEDE) Greater than 100 rem for Participants (N = 94)

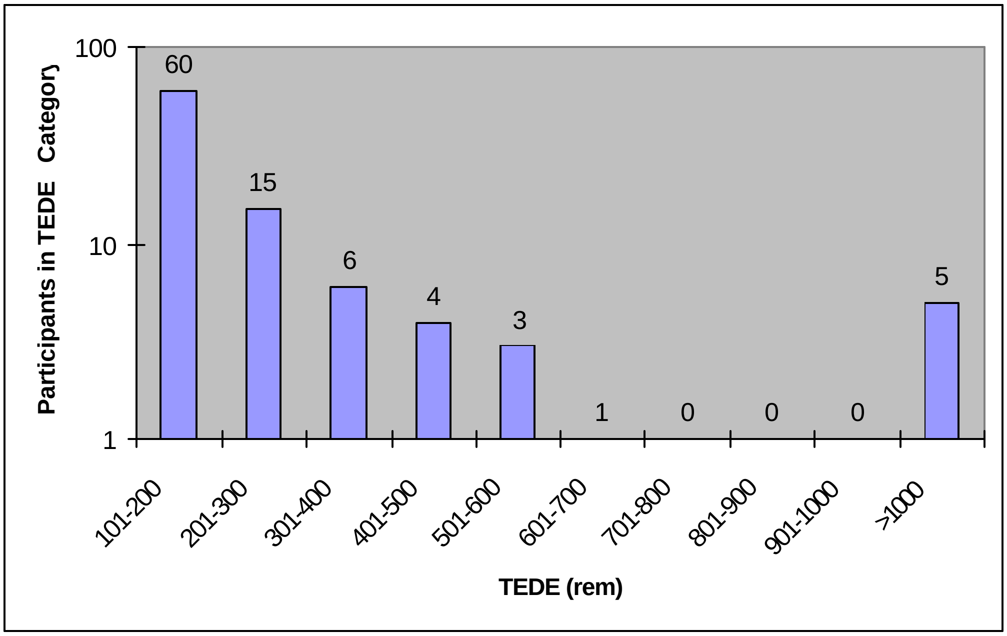
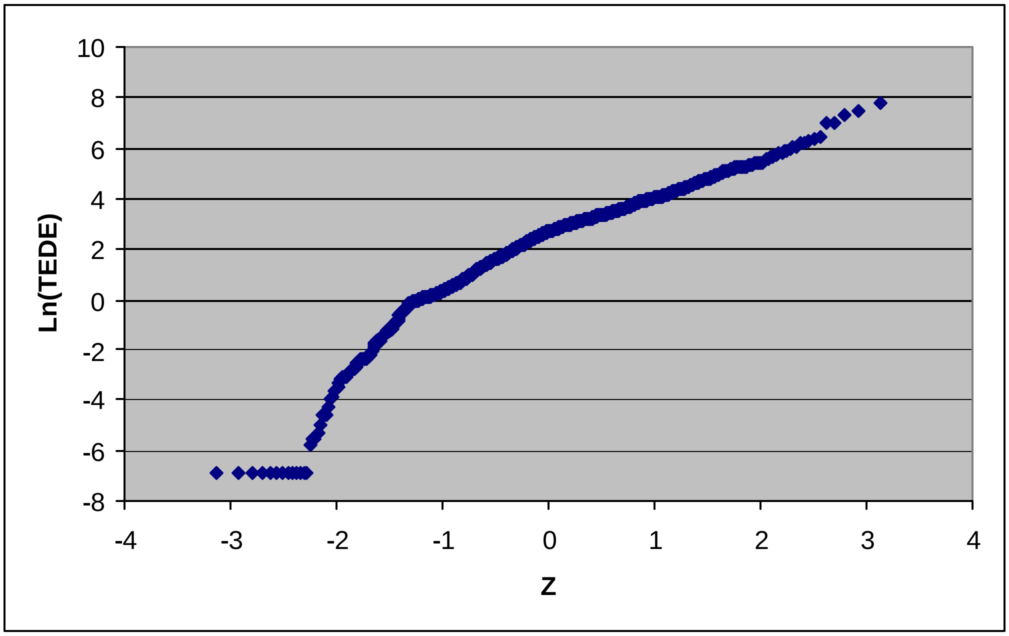


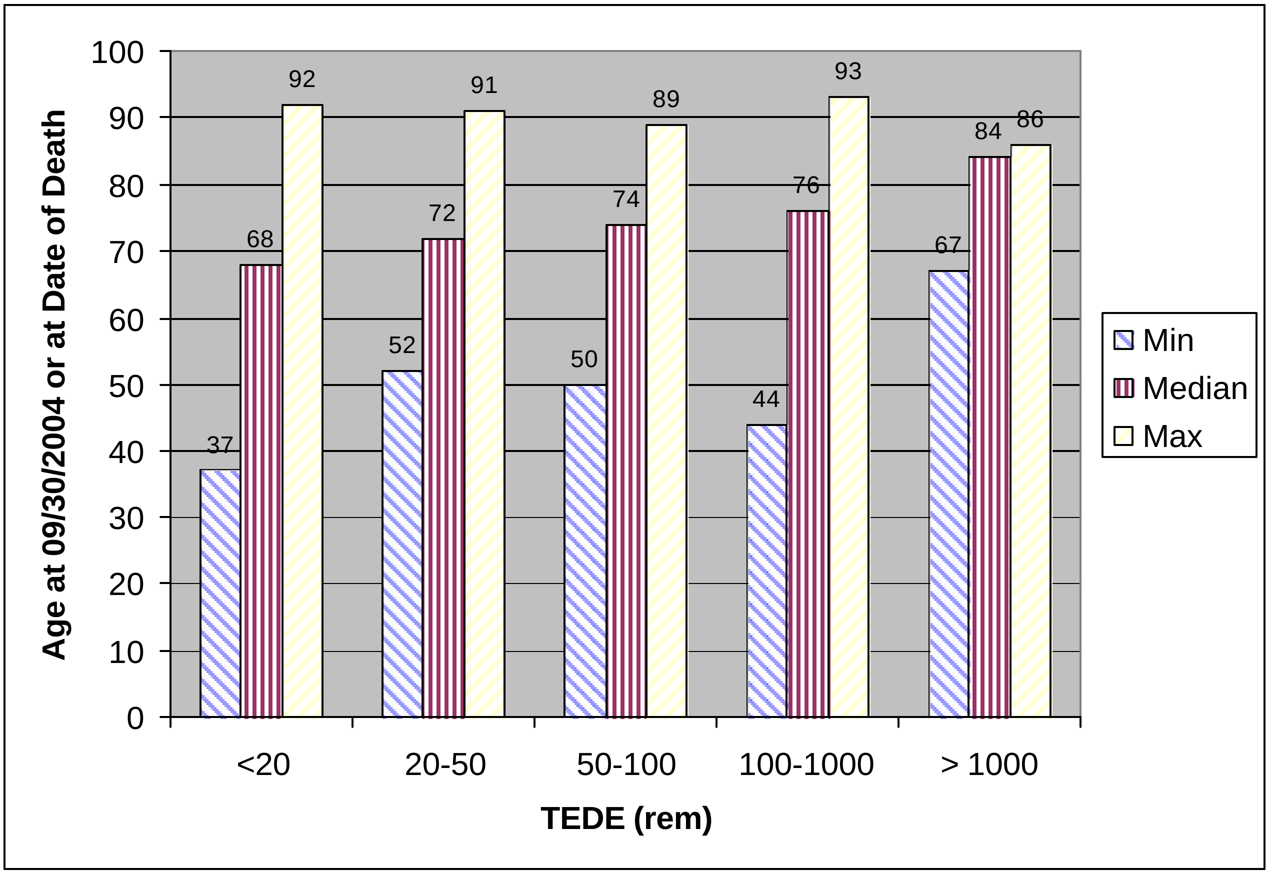
Figure 3 shows a log probability plot of the natural log of the TEDEs versus Z, which are uniform intervals in the standard normal distribution. For this plot, TEDE values of 0.000 rem were set at 0.001 rem to calculate the log of the value. A plot that appears linear would be evidence of a lognormal distribution and support the use of lognormal statistics to summarize the data. This plot appears to be bimodal with the distribution of TEDE values less than 1 rem distinctly different from values greater than 1. As a result, TEDE data are summarized using descriptive statistics that required no assumption about the underlying distribution.

Figure 3. Log Probability Plot of Total Effective Dose Equivalents of Participants



The minimum, median, and maximum ages for all participants (N=1164), categorized by TEDE, are presented in Figure 4. For participants who are currently living, their age was determined as of September 30, 2004. For deceased participants, the age is the age at death. The median age for all participants was 70.

Figure 4. Distribution of Ages of Participants



DISCUSSION:

Results of the SPR analysis must be interpreted with caution. Because of the better medical follow-up for program participants than for typical US white males, additional diagnoses for participants can be expected. On the other hand, an individual must be healthy enough to attend the medical examination, so diagnoses may be missed for unhealthy non-participants. If a potential participant died of cancer before the program began in 1992, then the cancer diagnosis was missed. However, because the NHIS comparison rates are for prevalence, individuals who deceased from cancer and were potential members of the NHIS sample did not contribute to the comparison rates. Follow-up SPR analyses would be beneficial for examining whether the increased prevalence of bladder and prostate cancers persists.

It is important to note that the medical conditions identified by this program are commonly seen in any population of similar age distribution, regardless of radiation exposure. In a number of cases, the participant was aware of a problem but needed encouragement to see his physician to diagnose and treat the problem. Some participants did not have a physician and needed advice on how to find one that was accepting new patients.

Examinations provided by the program did not identify medical problems that could not have been found during a reasonably comprehensive examination obtained from a physician in any community. The benefit to program participants was an opportunity to receive a medical examination that was comprehensive and perceived to be as thorough as the examinations received during active employment. In addition, participants felt assured that their health concerns, from working with uniquely hazardous materials, were being addressed by program and medical staff who were knowledgeable about the work the participants had performed and who had first-hand knowledge of the working conditions. Also, former workers were provided with a mechanism through which they were able to identify, discuss, and allay health concerns potentially related to their previous work environment. Participants expressed appreciation for a program which focused on the occupational health issues of former workers, and for a program group that was very responsive to their needs and concerns. Participants were well aware of the fact that they can get good examinations from their current physicians, but they knew that their physicians were not able to survey enough of the former nuclear-weapons-complex workers to identify any common or excessive problems stemming from their work. Many expressed a desire to add to the body of knowledge of health effects from radiation so future workers could be better protected.

Extreme caution must be used when interpreting the relationship between radiation dose and cancer in program participants. Several biases, some conflicting, are an inherent part of the program participant selection process. Since the first goal of the program was to enroll former Rocky Flats workers who likely had the highest radiation exposures, this would tend to link higher doses with cancers. However, some highly exposed former workers may have become ill with cancer or even died before being invited into the program, causing their cancer occurrences to be missed. Additionally, the incentive of potential monetary compensation from newly legislated compensation programs and the acceptance of volunteers into this program may have increased the participation of worker with cancer. All of these, and possibly other, biases were in operation. Their combined effects on the data were undoubtedly complex, adding ambiguity to any interpretation of results.

Malignant melanoma had a marginally elevated SPR, but this increase may have been related to the higher UV exposure due to the thinner atmosphere at Colorado altitudes that could be confounding the melanoma findings. According to Cancer in Colorado, 1996-2001, the incidence rate for malignant melanomas for males was 33% higher and for females was 40% higher than comparable U. S. rates. A possible explanation for the statistically elevated prostate cancer SPR was that PSA tests were offered to all male program participants since 1998, while many men in the general population do not receive this test. A positive PSA test might lead to a prostate cancer diagnosis that otherwise would be missed, since prostate cancer can exist for many years without causing serious symptoms.

Cigarette smoking is well-established as a cause of bladder cancer with this association being observed in numerous case-control studies and cohort studies (IARC, 1986). Sixteen of the 18 (89%) participants who reported bladder cancer were current or former smokers at the time of diagnosis. Investigating smoking rates in occupational groups, Lee et al. (2004) found that average smoking rates ranged from 58% in roofers to 4% in physicians and that blue-collar workers continue to smoke in large numbers. However, Lee's data included only current smokers, whereas interest in smoking outcomes related to cancer includes former smokers as well as current smokers.

Because bladder cancer has also been associated with certain industrial chemicals, a literature search was undertaken to determine whether any chemicals frequently used at Rocky Flats have been associated with bladder cancer. The most common chemicals at Rocky Flats were carbon tetrachloride, trichloroethylene, tetrachlorothylene, and 1, 1, 1-trichloroethane. None of these agents are known to be bladder carcinogens. Many epidemiologic studies have indicated that workers exposed to benzidene have a higher risk of bladder cancer, but benzidene was rarely if ever used at Rocky Flats (Case et al, 1954, Decarli et al., 1985, Rubino et al., 1982, Boyko et al., 1985, Morrison et al., 1985) The resin curing agent 4, 4'– methylene-dianiline has also been associated with development of the bladder cancer (Schulte et al., 1987), but occupational exposure to this chemical at Rocky Flats was also not likely.

Studies among workers employed as machinists have indicated that their risk of being diagnosed with bladder cancer is potentially greater than that of other skilled workers. In particular, the cutting oils used in the machining process as coolants and lubricants contain possible carcinogenic substances (Silverman et al., 1983, Vineis et al., 1983). Prior to 1980 Rocky Flats machinists in open air non-inert glove-boxes and pipefitters were likely to have been exposed to cutting oils. Four of the 18 (22%) bladder cancer cases may have had such exposure.

Both diabetes screening and the encouragement of healthy lifestyles were a part of the routine occupational health program while these former workers were active workers and continued in the former worker program. It is always hoped that continuous long term reinforcement of good habits has a positive effect by lowering the diabetes rates, which may be the case for program participants. The low SPR for emphysema was unexpected since at least 79% of program participants were current or former smokers. Similarly, the low SPR for arthritis is perplexing. A possible reason for these deficits could be that potential candidates with emphysema and arthritis declined to participate in the program because the pain made mobility difficult. However, there are many examples of participants whose desires to participate in this program were strong enough to ignore painful physical ailments. Some former workers even used wheel chairs so that they could participate.

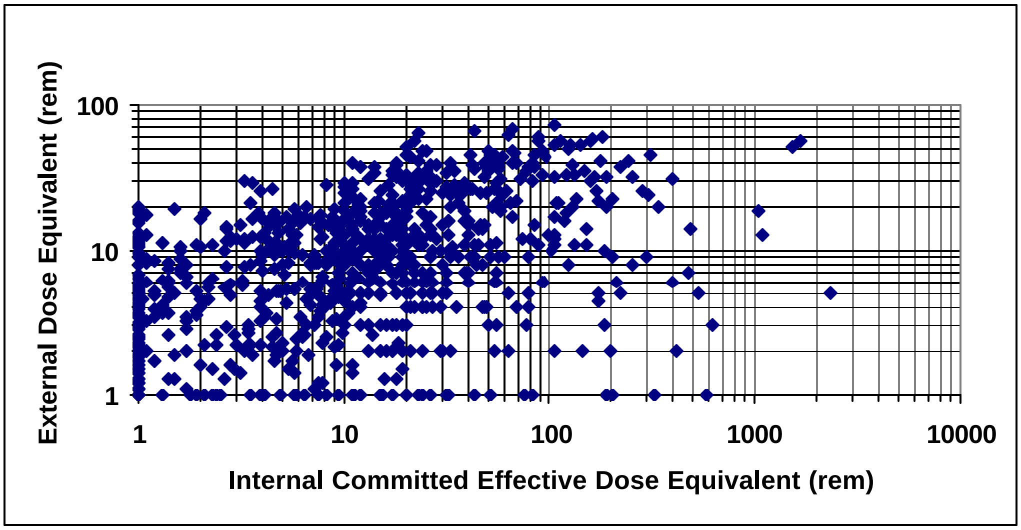
Publications and Presentations

Following is a brief discussion of major publications and presentations that have resulted from program activities to date. Not included are numerous briefings and reports to small groups, including the program's technical advisory committee, Institutional Review Board (both Rocky Flats and Oak Ridge Site Wide IRBs), U. S. Department of Energy staff, Rocky Flats employees, local chapters of professional societies, college and university classes.

- Radiation Doses Received by Workers at the Rocky Flats Nuclear Weapons Facility. R. B. Falk, W. C. Gottschall, C. V. Tuck, J. M. Aldrich, and D. E. Hilmas. Poster session presented by R. B. Falk at the 42nd Annual Meeting of the Health Physics Society; June 30, 1997; San Antonio, TX.

This presentation highlighted the external and internal doses of participants in the program. The following scatter plot (Figure 5), updated for participants through September 2004, summarizes the external dose equivalents and internal committed effective dose equivalents for the program participants. Dose values less than one rem are plotted as one rem. This scatter plot well illustrates the dominance of internal doses, primarily from plutonium inhalation and wound intakes, for many of the program's participants.

Figure 5. Distribution of Internal and External Dose Equivalents for Participants



- Modern Plutonium Urine Data from Former Workers at Rocky Flats with Long-Term Plutonium Systemic Depositions. R. B. Falk, N. M. Daugherty, J. M. Aldrich, D. E. Hilmas. Poster session presented by R. B. Falk at the 2000 American Radiation Safety Conference and Exposition (45th Annual Meeting of the Health Physics Society); June 26-29, 2000; Denver, CO.

One of the benefits of the program was the acquisition of sensitive and high quality plutonium bioassay measurements for workers who terminated employment at Rocky Flats prior to the availability of such measurements. Another benefit was the acquisition of high quality plutonium bioassay data decades after real or potential intakes so that the program can discern, at a sensitive level, whether plutonium internal depositions did occur and, if so, what were the magnitudes of those intakes. This poster session presented plutonium urine bioassay paired data for participants. The data give insight into the total variability of the physiological excretion of plutonium for urine samples excreted close in time but distant by decades from the intake of plutonium, as well as the variability induced by modern analyses performed under the specifications of data quality, one of which was a required minimum detectable activity of 0.020 disintegrations per minute (d/m) of $^{239+240}$Pu per sample. The following plot (Figure 6) presents the results of the paired urine data (values less than 0.0001 d/m are plotted as 0.0001 d/m), and Table 7 presents the analysis of the variability.

Figure 6. Distribution of Plutonium Urine Bioassay Results for Paired Samples (d/m)

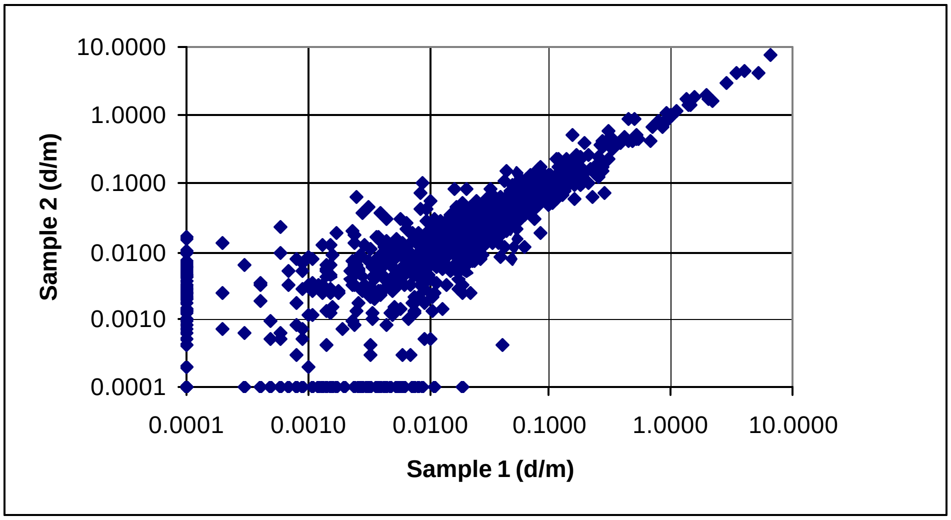


Table 7. Analysis of Paired Plutonium Urine Data

Distribution of the Ratio of Paired Results

Category d/m)	Number of Pairs	Distribution of Ratio (S1/S2) Geometric Mean	Geometric Std.Dev. (x,÷)
³ 1.00	15	0.98	1.17
0.100 to 1.00	127	0.98	1.66
0.500 to 1.00	14	0.87	1.53
0.200 to 0.500	39	1.06	1.62
0.100 to 0.200	75	0.96	1.69
0.0200 to 0.100	317	0.96	2.10
0.0500 to 0.100	115	0.95	1.88
0.0300 to 0.0500	108	1.01	2.16
0.0200 to 0.0300	104	0.91	2.23
0.0100 to 0.0200	146	0.94	4.27
0.0050 to 0.0100	137	1.03	6.61
0.0020 to 0.0050	111	0.82	11.6
£ 0.0020	114	N/A	N/A
Total:	951		

Note:

1. The sample pair of Sample 1 (S1) and Sample 2 (S2) are assigned to a category based on the value of the higher of S1 or S2.
2. For the purpose of calculating the geometric means and standard deviations, negative or zero results were set equal to 0.0001.

- Former Radiation Worker Medical Surveillance Program at Rocky Flats. N. M. Daugherty, R. B. Falk, F. J. Furman, J. M. Aldrich, and D. E. Hilmas. *Health Physics*, Vol. 80, No. 6, June 2001.

This paper, published in *Health Physics*, presented a comprehensive overview of the program.

- Application of a Four-Compartment Wound Model to Wounds Incurred by Former Workers at Rocky Flats. R. B. Falk, N. M. Daugherty, F. J. Furman, J. M. Aldrich, and D. E. Hilmas. Oral paper presented by N. M. Daugherty at the 2002 American Radiation Safety Conference and Exposition (47th Annual Meeting of the Health Physics Society); June 18, 2002; Tampa, FL.

This presentation described data for five program participants who received wounds with significant plutonium contamination in the 1960s and did not receive DTPA chelation treatments that could perturb the biokinetics of excretion of plutonium in the urine. The plutonium urine data for these five cases, including the sensitive, quality urine data collected by the program 10,000 days or longer post-incident, represent valuable data sets for the development of wound models. Figure 7 illustrates the urine data for a wound case along with regression fits to the data, generated by CINDY©, for both the Durbin and the Jones plutonium excretion equations.

Figure 7. Example of Plutonium Urine Data and Modeled Regression Fits For a Wound Case

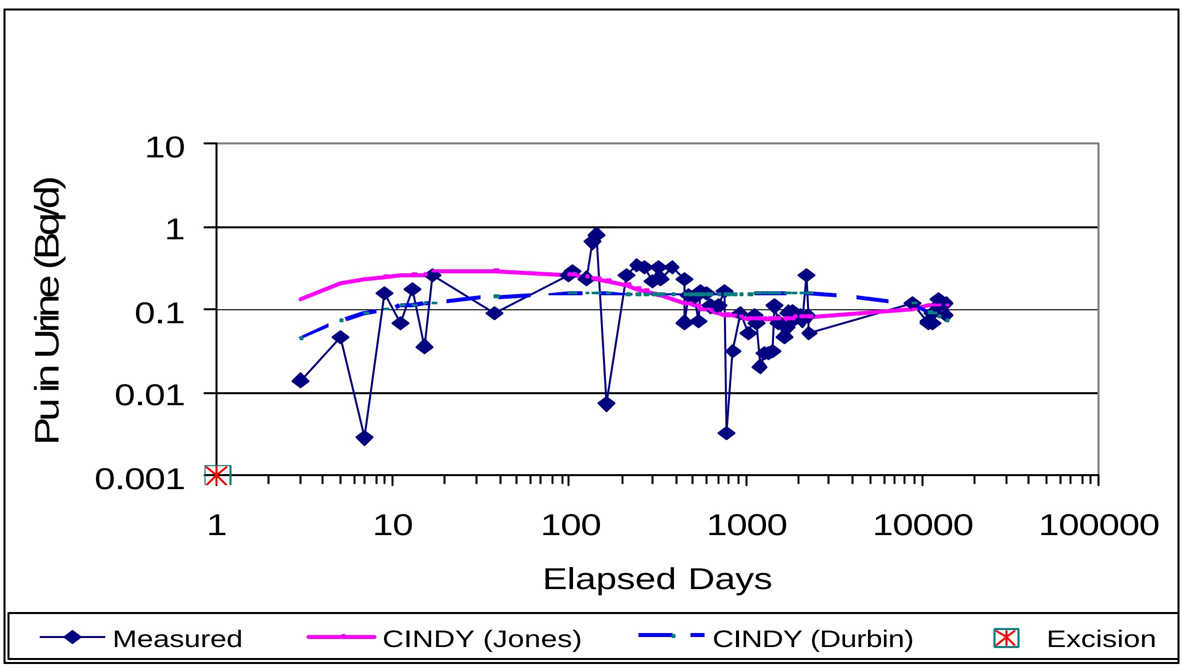
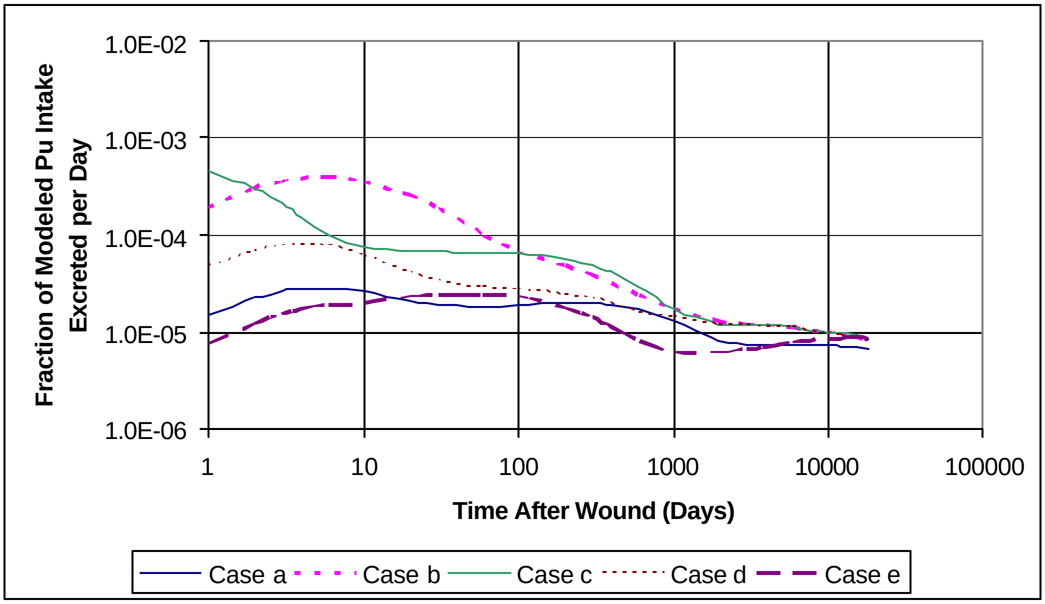


Figure 8 illustrates the regression curves for five wound cases that are normalized to the modeled intake and they are based on the Jones plutonium excretion equation. The disparity between these curves is large at early times after the occurrence of the wound but they tend to be within a factor of 2.0 at 10,000 days or more post-incident.

Figure 8. Normalized Regression Curves for Five Wound Cases



SUMMARY AND CONCLUSIONS:

The Former Radiation Worker Medical Surveillance Program at Rocky Flats was in place for 12 consecutive years (1992 – 2004). During that tenure, the program provided initial medical examinations to 1,166 former workers, performed 910 repeat medical exams, carried out 1,164 dose assessments, analyzed 1,148 participants' data sets for the descriptive purpose, calculated SPRs for 1,072 white male participants, and identified 513 former workers for the recall program based on their Rocky Flats dosimetry records.

The 1,164 participants' ages on September 30, 2004, or at death ranged from a minimum of 37 years old to a maximum of 93 years old, with a median of 70. The TEDE values for the participants ranged from a minimum of 0.000 rem to a maximum of 2,322 rem, with a median of 15 rem and a geometric mean of 9.4 rem. The TEDE for the individual with the highest assessed dose value was nearly a 1,000 rem higher than the TEDE for the next highest person.

The physical review of health physics files from 1952 through 1976, in conjunction with the file reviewers' a priori knowledge of plant operations, led to the discovery that the health physics files did not always reflect an individual's complete exposure status. To identify potential program participants, reviewers of the health physics files focused on the following: the buildings worked in, the worker's job classification, whether the worker's recorded external dose exceeded 1 rem, the magnitude and quality of bioassay data, and incident reports, if any, that indicated the potential for intakes of plutonium or other radionuclides.

Approximately ten percent of the 1,164 participants for whom a dose assessment was performed were determined to have some unrecorded internal dose, and approximately five percent of the participants had a significant unrecorded dose. A significant dose, for the purpose of this report, was a dose value of 20 rem or more. One percent of the participants had an unrecorded internal dose that exceeded 100 rem. The most noteworthy case was a mid-level manager in a major plutonium processing building in the 1950's, whose TEDE of over 500 rem places him seventh on high-to-low TEDE list for participants. The records in his Rocky Flats health physics file and in his medical file are mute regarding the plutonium contamination incident he described in his interview.

Medical examinations and dose re-assessments were provided to many but not all of the available population where known exposures and suspected missed internal dose potentially exist. As a result, the Former Radiation Worker Medical Surveillance Program at Rocky Flats is unable to issue a firm statement on the correlation of medical outcome and radiation exposure as further long-term follow-up would be valued. Based on the data generated by the program to date, there seems to be minimal, if any, direct correlation between internal doses from plutonium depositions and debilitating medical effects. Participants have been very vocal in expressing their appreciation for this program because they are interested not only in their own health but also in the health and welfare of fellow and future workers in nuclear industry. Perhaps more importantly, this program fulfills their need to be recognized as cold war veterans.

This program is a conduit for providing the scientific community with data that had not previously been gathered and documented on perhaps one of the largest population of workers – a group with available plutonium urine excretion results exceeding 10,000 days after an inhalation or a contaminated wound incident. These plutonium urine data are particularly valuable to the International Commission on Radiological Protection (ICRP), the National Council on Radiation Protection and Measurements (NCRP), and the biokineticists who are developing computer models and programs for determining internal doses. To better analyze and interpret these medical and dosimetry data, more information needs to be gathered from a control group of unexposed or minimally exposed elderly workers, since the primary focus of this program has been to assess older workers with the highest known exposure or potential for missed internal doses.

Important Lessons for Future Surveillance Programs

It was fortuitous that a **recall frequency of every three years** was established early on in the program. By offering a medical examination every three years, the participants remained interested, involved and tended to keep the program informed of their changes in residency and phone numbers. Their cooperation reduced the need to perform death index and address searches prior to scheduling their next examination three years later.

The **value of the screening examinations** performed through this program became evident. These examinations were specific enough to catch changes in critical parameters where physiological changes were starting to occur. This benefit was accomplished without excessive costs, did not cause undo stress from more invasive tests, and did not typically lead to other unnecessary examinations.

The **effectiveness of an annual newsletter containing a postage-paid return address update card** proved to be very efficient for maintaining personal demographics. The program mailed a newsletter and address card to each of the participants who had participated during the previous year thanking them for their participation and to all of the recall participants who would be rescheduled during the upcoming two years. The program routinely received an annual return of these postage paid address cards of between 53% and 68%.

Perhaps the single most important lesson learned was **how important a medical examination became to former workers** as they aged. Their concern over their health became increasingly more important to them than information on the exposures that they might have received during employment at Rocky Flats. Often times, the designated recall participants themselves would call the program to ensure that they had not been overlooked or dropped out of the program, and to inform the program that it was time to schedule their three year recall medical examination. The participants as a group realized that as they aged, their health status could change very rapidly over a very short period of time. Also, participants often stated that they preferred the examinations provided by the program over any other general medical examination, and their decisions were not just based on the limited cost to the participant.

Because the potential for high internal deposition of plutonium has been greatly reduced over time, the Rocky Flats former radiation workers, who include many individuals with high exposures, are a group whose medical outcomes are worthy of further study. With that said, the true success of this program has been the willingness of these participants to be followed, their desire to contribute to the scientific community, monitor their own health, and the good will that they engendered within the retiree group and the communities in which they live.

Finally, an intangible, but significant, benefit of the program is the goodwill generated among the former workers toward DOE for caring about their long-term health following measurable exposures to plutonium, a material touted during their working careers as “the most hazardous material known to man”.

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