



Internal Distribution

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D. R. Fisher  
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File/LB

Date March 21, 1979  
To H. M. Parker, Chairman  
Human Subjects Committee  
From A. E. Desrosiers **AED**  
Subject Proposal to Study <sup>230</sup>Th in Uranium Mill Workers

The subject proposal is attached for your review and approval.

The purpose of this study is to determine if inhaled <sup>230</sup>Th is cleared at a different rate than <sup>238</sup>U that is simultaneously inhaled in uranium ore dust. This data is relevant to the adequacy of the special standard for airborne concentrations of uranium ore dust.

We propose to collect samples of urine and feces from 30 test subjects. The samples will be analyzed to determine the ratio of <sup>230</sup>Th to <sup>238</sup>U in the subjects' excreta. The variation in this ratio as a function of the worker's exposure history will be an indicator of the relative biological clearance rates of <sup>230</sup>Th and <sup>238</sup>U. The subjects' identities will not be reported. There is no risk of physical harm to the subjects. The study is not intended to detect overexposures of uranium mill workers to airborne ore dust, nor to evaluate health physics programs at the mills from which the subjects are selected.

Subjects will be selected according to the duration of their employment and exposure to ore dust as well as the interval of time since the last inhalation of ore dust. The characteristics of the mill or the employee will be bases for subject selection. However, smoking histories will be recorded.

AED:ckm

HUMAN SUBJ.

MAR 22 1979

COMMITTEE

REPOSITORY PNL  
COLLECTION Thorium  
BOX No. 2951  
FOLDER HSC 79B

1064189

		INFORMATION FOR APPROVAL OF PROPOSAL Prep Sheet		Proposal No. 0A01348	Amend- ment No.	Revision No.
Proposal Author or Coordinator A. Desrosiers		Phone 6-2589	Project Manager L. Faust	Phone 2-3613	Lead Department or Center O&ES	
Sponsor's Name and Complete Mailing Address U.S. NRC Washington, D.C. 20555				Phone FTS 443-5970	Nationality of Sponsor: <input checked="" type="checkbox"/> U.S. <input type="checkbox"/> Other _____	
Sponsor's Technical Contact Robert E. Alexander		Sponsor's Contract Representative			Date Proposal Due Sponsor 15 Apr 79	
Estimated Cost	Fee	Proposed Contract Amount \$78K	Proposed Contract Period		Planned Starting Date 1 Jun 79	
Work is to be conducted under: <input type="checkbox"/> Use Permit Contract 1831 <input checked="" type="checkbox"/> Operating Contract 1830 (Related Services) <input type="checkbox"/> Other (No use of consolidated lab facilities—explain on back)						
Scope of Scientific Research  Measurements of <sup>230</sup> Th and <sup>238</sup> U in excreta of uranium mill employees						
Title (should be used or should not be used instead of scope on proposal) <sup>230</sup> Th in Uranium Mill Workers						

FOR AMENDMENTS. (Changes to existing agreements) Complete the following IN ADDITION to above, below, and back

Scope Statement Should: <input type="checkbox"/> Not Be Changed <input type="checkbox"/> Be Changed as Indicated Above		Expiration Date of Present Agreement	Proposed Period of Time Extension
New Conditions, if any		Current Total Contract _____	Proposed Additional Funding _____
		Proposed Additional Fee _____	Revised Total For Contract _____
What will be the effect on DOE or other work currently using or sharing facilities?			
Specify all facilities (Bldg. & Room No.) and major equipment under BNW control expected to be used. Specify any DOE equipment to be taken offsite.			
Anticipated usage of services, i.e., type and estimated cost, and facilities controlled by HEDL and other Hanford-Site Contractors. Indicate HEDL Third Level Management Completing Arrangements. (Attach any Documentation of HEDL Concurrence).			
Does Nuclear Research Overhead Apply? <input type="checkbox"/> Yes <input type="checkbox"/> No		Is Quality Assurance Necessary? <input type="checkbox"/> Yes <input type="checkbox"/> No	

MANAGEMENT APPROVALS

Lead Department/Program Mgr.	Date	Amount	Participating Department/Program Mgr.	Date	Amount
			Other Approvals		
			Other Approvals		

FOR CONTRACT SERVICES

TYPE OF CONTRACT	TERMS OF PAYMENT	Scope Filed	Date	Scope Cleared	Date	DOE Notice Filed	
<input type="checkbox"/> Standard Research <input type="checkbox"/> Tech. Services <input type="checkbox"/> Gov't. Prime <input type="checkbox"/> Gov't. Subcontract <input type="checkbox"/> Gov't. Grant <input type="checkbox"/> CPFF <input type="checkbox"/> Fixed Price <input type="checkbox"/> Other (Explain On Back)	<input type="checkbox"/> Fixed Billing Monthly <input type="checkbox"/> Advanced Payment <input type="checkbox"/> Cost Incurred Monthly <input type="checkbox"/> Standard Gov't.	Contract Services		Date	Review Period Complete On		
		Finance & Administration		Date			
		Sponsor Code	Will Cat.	Legal	Date		
		D and B	Risk Assessment Form Required if None, Explain	Occupational and Environmental Safety	Date		

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Indicate kind of request for proposal received, if any, and enclose copy of any written request.

A complete copy of Government RFP with all attachments should be enclosed. RFP No. \_\_\_\_\_

- Sole Source  
 Competitive

None

Describe unpublished DOE information to be used, if any.

None

Describe any security requirements involved such as use of access permit, classified information or requirements related to work location restrictions. Discussed with Security - (Date) \_\_\_\_\_

None

Provide explanation if either inventions owned by Battelle and its subsidiaries or inventions made or conceived at the PNL (either reported or unreported to BNW Patent Office) will be used.

None

Describe briefly necessary or possible subcontracts, including consultant agreements, if any.

None

List equipment, materials or supplies to be furnished by Sponsor, if any.

None

Describe government property or facilities that need to be modified or procured, if any and provide estimate of cost.

Estimated Cost \_\_\_\_\_

None

Present any other helpful information (e.g., health and safety hazards, security requirements, personnel and equipment needs, requirements for insurance, or any other information to permit appropriate contractual protection).

Describe use, including material amounts and quantities of radiation, of following materials and radiation facilities:

Radioactive Material

None

Ionizing Radiation Generating Machine

None

Non-ionizing Radiation Generating Machine

None

Reactor or Critical Facility

None

Radiation Protection Approval By: \_\_\_\_\_

Date \_\_\_\_\_

Additional Remarks

Contract Services - Describe Scientific Objectives

1064191

# U.S. NUCLEAR REGULATORY COMMISSION

## PROGRAM AND BUDGET PROPOSAL

FIN/189a NO.:

 DATE:  
19 March 1979

1. BUDGET ACTIVITY NO.:	2. OFFICE:  SD	3. PROJECT TITLE:  230 <sup>Th</sup> in Uranium Mill Workers
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4. METHOD OF REPORTING:  <input type="checkbox"/> 1. MONTHLY LTR. <input checked="" type="checkbox"/> 4. ANNUAL <input checked="" type="checkbox"/> 2. QUARTERLY <input type="checkbox"/> 5. OTHER <input type="checkbox"/> 3. SEMI ANNUAL	5. PERSON IN CHARGE: (Include FTS No.) L. G. Faust 444-3613	PRINCIPAL INVESTIGATOR(S): (Include FTS No.) A. E. Desrosiers 444-7511, ext. 946-2589 P. O. Jackson 444-3780
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6. CONTRACTOR:  Battelle Memorial Institute Pacific Northwest Laboratory	7. WORKING LOCATION - CITY:  Richland	8. STATE:  Washington
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9. TYPE:  <input type="checkbox"/> 1. INDUSTRIAL <input type="checkbox"/> 4. GOVERNMENT <input checked="" type="checkbox"/> 2. DOE LAB. <input type="checkbox"/> 5. OTHER NONPROFIT <input type="checkbox"/> 3. EDUCATIONAL	10. CONTRACT NO.:  EY-76-C-06-1830	11. TASK NO.: (PNL Proposal No.)  300A01348
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12. CONTRACT TERM - BEGIN:  From    Mo.    Day    Yr. 08    01    79	13. CONTRACT TERM - END:  To       Mo.    Day    Yr. 05    31    80	14. TERMINATION DATE OF FUNDING:  Mo.    Day    Yr.
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15. MANYEARS	FY 79	FY 80	FY
Direct			
Scientific	0.2	0.5	
Other Direct	-	-	
<b>TOTAL</b>	<b>0.2</b>	<b>0.5</b>	

16.a PROGRAM SUPPORT OBLIGATIONS	FY 79	FY 80	FY
a. Direct Salaries	5.8	17.0	
b. Materials & Services	3.5		
c. Subcontracts	5.0	9.9	
d. Travel - Domestic	5.8	2.9	
e. Travel - Foreign			
f. Other Direct Costs	0.9	3.6	
g. Indirect Costs	1.5	4.4	
h. General and Administrative	3.6	11.0	
i. Indirect Services	0.9	1.7	
<b>Total (In Thousands)</b>	<b>27.0</b>	<b>50.5</b>	

16b. EQUIPMENT			
Estimated Capital Equipment			
<b>Total Estimated Program Costs</b>			

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SK ASSESSMENT

PROPOSAL/CONTRACT NO. 300A01348 AMENDMENT NO. WORK AUTHORIZATION NO.

SPONSOR U.S. NRC

SCOPE OR BRIEF DESCRIPTION OF PROGRAM Measurements of 230Th and 238U in excreta of uranium mill workers

A. PAPER STUDY ONLY [ ]

B. CHECK ANY ITEMS INVOLVED IN THE PROPOSED WORK: (PROVIDE DETAILS ON BACK OF FORM.)

- 1. BIOHAZARDS CARCINOGENS, ALLERGENS [ ] [X] 18. FLYING INVOLVED [ ] [X] 35. HAZARDOUS LOCATION [ ] [X]
2. BIOHAZARDS VIRUS, BACTERIA, FUNGUS [ ] [X] 19. WORK (OVER, UNDER, IN) WATER [ ] [X] 36. FOOD [ ] [X]
3. DRUGS OR TOXIC MATERIAL VAPOR DUST [ ] [X] 20. CLIMBING REQUIRED @ 10' ELEV. [ ] [X] 37. RADIOACTIVE MATERIAL [ ] [X]
4. FLAMMABLE OR COMBUSTIBLE LIQUID GASES [ ] [X] 21. NEW OUTSIDE UTILITIES REQUIRED [ ] [X] 38. IONIZING RADIATION GENERATING MACHINE [ ] [X]
5. EXPLOSIVES (LIST QUANTITY & TYPE) [ ] [X] 22. MAJOR UNUSUAL OR PROLONGED CONSTRUCTION ACTIVITY [ ] [X] 39. REACTOR OR CRITICAL FACILITY [ ] [X]
6. RARE OR EXOTIC CHEMICALS [ ] [X] 23. SPACE CONFLICT WITH OTHER RESEARCH [ ] [X] 40. DESIGN INTENDED FOR COMMERCIAL USE [ ] [X]
7. ANY EFFLUENT RELEASE [ ] [X] 24. NEW FACILITY REQUIRED [ ] [X] 41. PROTOTYPE MODEL OR OTHER ITEM TO BE DELIVERED [ ] [X]
8. WASTE DISPOSAL PROBLEMS [ ] [X] 25. FACILITY MODIFICATIONS REQUIRED [ ] [X] 42. SPONSOR-FURNISHED MATERIALS OF HIGH INTRINSIC VALUE [ ] [X]
9. EQUIPMENT DISPOSAL PROBLEMS [ ] [X] 26. SPECIAL VENTILATIONS REQUIRED [ ] [X] 43. DOES SPONSOR HAVE RIGHTS TO SUPERVISE WORK [ ] [X]
10. HUMAN SUBJECTS INVOLVED [ ] [X] 27. HI PRESSURE FACILITY (LIST MAXIMUM PRESSURE) [ ] [X] 44. KNOWN CONFLICT WITH OTHER RESEARCH [ ] [X]
11. THIRD PARTY HAZARDS INVOLVED [ ] [X] 28. HI TEMPERATURE (LIST MAX. TEMP.) [ ] [X] 45. WORK IS SAFETY ANALYSIS OR REC. OF SAFETY PROCEDURES [ ] [X]
12. NOISE [ ] [X] 29. EXCAVATION REQUIRED [ ] [X] 46. WORK IN FOREIGN COUNTRY [ ] [X]
13. HEAT STRESS LIKELY [ ] [X] 30. HIGH VACUUM EQUIPMENT [ ] [X] 47. OTHER [ ] [X]
14. LASER OR OTHER HIGH INTENSITY LIGHT [ ] [X] 31. SPECIAL LICENSE REQUIRED [ ] [X]
15. NON-IONIZING RADIATION (MICROWAVE, ETC.) [ ] [X] 32. SPECIAL TRAINING REQUIRED [ ] [X]
16. SPECIAL ELECTRICAL HAZARDS [ ] [X] 33. OFF-SITE WORK [ ] [X]
17. WORK UNDERGROUND [ ] [X] 34. LARGE QUANTITIES OF MATERIALS SUCH THAT THE QUANTITY ITSELF CREATES A RISK [ ] [X]

C. CHECK (1) OR (2)

- (1) [ ] PROGRAM HAS BEEN DESIGNED TO MINIMIZE RISKS; INVOLVES ONLY NORMAL RISKS; WILL BE PERFORMED WITHIN PNWD FACILITIES; AND DOES NOT INVOLVE AN ITEM ON CHECK LIST TO ANY SIGNIFICANT EXTENT.
(2) [X] PROGRAM INVOLVES OFF-SITE WORK (OTHER THAN ROUTINE BUSINESS TRAVEL) OR UNUSUAL RISKS CHECKED OR OTHERWISE NOTED ABOVE. RISK MANAGEMENT CONFERENCE HAS BEEN HELD AND RISK MANAGEMENT PLAN IS ATTACHED.

(Risk Management Conference including insurance, safety, contracts, legal, or other staff members as appropriate will be documented in a memorandum to be attached to this form. This conference may be initiated by telephone request to Contract Services.)

PROJECT MANAGER APPROVAL: Signature [Signature] Date

DEPARTMENT MANAGER APPROVAL: (or Center Director Approval) Signature Date

O&ES SIGNATURES

INDUSTRIAL SAFETY DATE RADIATION PROTECTION DATE ENVIRONMENTAL DATE

CONTRACT SERVICES:

A. THE PROPOSED WORK IS CLASSIFIED AS:

- [ ] 1. IN-LAB/NORMAL RISK [ ] 3. IN-LAB/UNUSUAL RISK
[ ] 2. OUT OF LAB/NORMAL RISK [ ] 4. OUT OF LAB/UNUSUAL RISK

B. CONTRACT PROVISIONS RECOMMENDED:

- [ ] 1. STANDARD INDUSTRIAL RESEARCH AGREEMENT PROVISIONS [ ] 4. SPECIAL DISCLAIMER
[ ] 2. STANDARD INDUSTRIAL TECHNICAL INVESTIGATION AGREEMENT PROVISIONS [ ] 5. SPECIAL INSURANCE PROVISIONS
[ ] 3. SPECIAL INDEMNITY [ ] 6. OTHER

CONTRACT SERVICES Signature Date

LEGAL COMMENT

LEGAL Signature Date

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10. Excreta to be requested of uranium mill employees
33. This project may involve use of offsite neutron activation facilities (TRIGA reactor) for trace quantity analysis. Firm statement not possible at this time.
39. See #33. Reactor located at Reed College, Portland, OR.

17. COST AND DEVELOPMENT SCHEDULE

a. COST

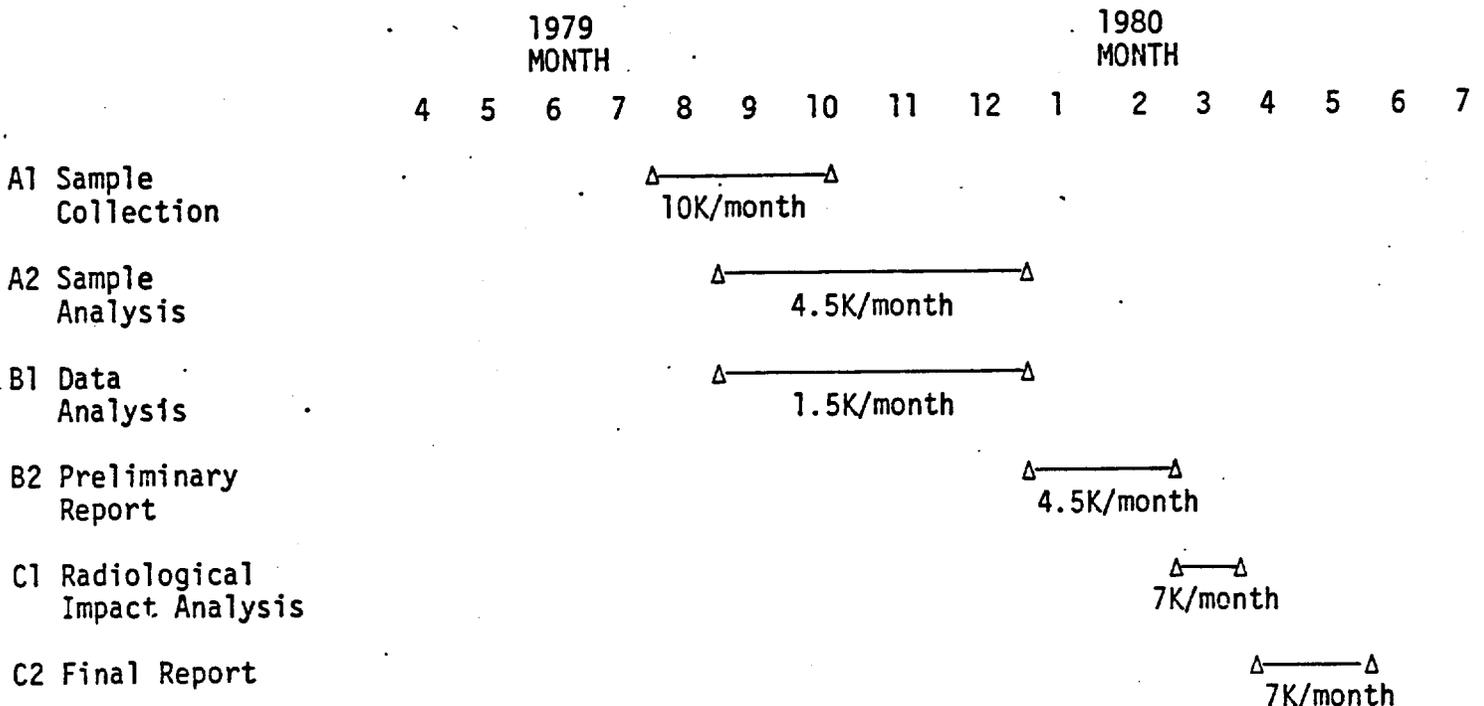
	Prior Years	Fiscal Years						n <sup>2</sup>	Total Estimated Cost
		78	79	80	81	82	.....		
<b>Obligation Schedule<sup>1</sup></b>									
Subtask A			25	16					
Subtask B			2	13.5					
Subtask C				21					
<b>Total Operations (By fiscal year and total cumulative)</b>			<b>27</b>	<b>50.5</b>					

<sup>1</sup>Cost breakdown should be developed such that the detail reflects the components of costs and provides meaningful data for evaluation and long range planning.

<sup>2</sup>The fiscal year in which the project/activity is completed.

b. DEVELOPMENT SCHEDULE

Within this section the contractor is to identify the start and finish dates for each subtask and by the year the major events or milestones associated with each subtask. Identify monthly planned rate of costs for first fiscal year.



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18. Publications

1978: None - new project  
1979: None - new project  
1980: "Measurements of  $^{230}\text{Th}$  in Excreta of Uranium Mill Workers",  
P. O. Jackson, D. R. Fisher and A. E. Desrosiers, Data Report

19. Scope

During this study we will collect and interpret data concerning the degree of accumulation of  $^{238}\text{U}$  and  $^{230}\text{Th}$  in the tissues of uranium mill workers. The specific purpose is to determine whether  $^{230}\text{Th}$  may be present in higher concentrations than  $^{238}\text{U}$  in the tissues of long-term workers and to compare these and other measurements to the predications of ICRP's models of human physiology.

We intend to identify a population of approximately 30 workers who have at least 5 years work experience in crushing operations at approximately 5 uranium mills. We intend to measure the  $^{238}\text{U}$  and  $^{230}\text{Th}$  in the urine and feces of each worker on the first day following a work interruption of at least 4 days. Retired employees will be included in the study if possible. Exposure histories will be recorded, but not identities.

Dust particles which are rapidly cleared from the lung may contain quantities of  $^{238}\text{U}$  and  $^{230}\text{Th}$  that are essentially unchanged relative to the inhaled ore dust. This rapidly cleared material will not be present in the feces sampled at day 4 under this proposal. Rather, the quantity of  $^{230}\text{Th}$  in the feces should reflect a long-term clearance of insoluble material. The quantity of  $^{238}\text{U}$  in the urine samples will result from systemic processes which tend to preferentially remove  $^{238}\text{U}$  from the residual deposits in lung and lymph nodes. The total excretion of  $^{230}\text{Th}$  relative to  $^{238}\text{U}$  will be an index of the degree of accumulation of  $^{230}\text{Th}$  relative to  $^{238}\text{U}$  in the tissues of an exposed individual.

The data will be interpreted and compared to existing models of human physiology as well as to estimates of doses to various tissues from U and  $^{230}\text{Th}$ .

20. PNL is performing measurements of the radiological equilibrium between  $^{238}\text{U}$ ,  $^{234}\text{Th}$  and  $^{230}\text{Th}$  in uranium ore dusts. This effort is critical to the identification of a deficit of  $^{230}\text{Th}$  relative to  $^{238}\text{U}$  in samples of feces. The results of the radiological equilibrium measurements will be available to us as we analyze our results.

Dr. McDonald Wrenn of New York State University is performing measurements of thorium in specimens of lung tissue obtained at autopsy. We will communicate with Dr. Wrenn in order to maintain a current knowledge of the study and include references to pertinent results in the discussion of our data.

21. N/A

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22. Five uranium milling operations will be selected. Arrangements will be made with the resident manager of each mill to visit the site and obtain voluntary urine and feces specimens from mill personnel. The final number of mills included in this study will depend upon the number of participating workers at each mill. The maximum number of workers is 30. Thirty samples are desirable for statistical considerations.

A preliminary visit to each mill will be made by a pair of PNL scientists. During this visit, the potential for airborne exposure to  $^{238}\text{U}$  bearing dusts will be evaluated, and the objectives of the study will be presented to management. After concurrence of management and participants, approximately six operators from each mill will be chosen from employees working close to rock crushing operations. Each subject would be briefed on the study and given instructions on the correct use of the specimen collection containers. A mutually agreeable schedule for specimen collection will be drafted and presented to the management and cooperating individuals.

A Battelle employee will make a return visit to each milling site and collect urine and feces samples of the preselected employees. Samples will consist of daily urine and feces for five consecutive work days. Urine specimens will be dried and fecal specimens will be dried and partially ashed prior to shipment to Battelle.

In addition, three volunteers from a community near a uranium mill will be selected to provide control samples. Five volunteers from the Richland, Washington area will provide samples which will be spiked with ore dust of known U and  $^{230}\text{Th}$  composition to verify the accuracy and precision of the measurements.

We expect the sample collection activities will begin two months after initiation of the program and will be completed within ten weeks. Dr. Darrel Fisher of PNL will assist the principal investigators in the sample collection phase of this study.

Data analysis will also include evaluation of the quality of the data and the possible conclusions. In this context quality refers not only to the accuracy and precision of the data but to an analysis of potential systematic biases and the limits of statistical significance in the data.

We will compare these data to predications based on estimates of  $^{238}\text{U}$  and  $^{230}\text{Th}$  intake and the ICRP models of the lung and gastrointestinal tract. We will report our conclusions concerning the radiological impact of uranium ore dust inhalation. K. R. Heid and R. L. Kathren of PNL will be available to the principal investigators as consultants during this phase of the study.

23. N/A

24. N/A

25. Significant Costs

The sampling protocol envisions approximately 30 analyses of feces and 30 analyses of urine for  $^{238}\text{U}$  and  $^{230}\text{Th}$ . At an estimated cost of \$400 per set of fecal and urine samples, the total cost of these measurements is \$12,000, using traditional methods. The high cost is primarily due to the requirements for  $^{230}\text{Th}$  assays.

The analysis of 8 additional sample sets for quality assurance purposes will require an additional \$3,200.

26. N/A

27. N/A

28. N/A