



Department of Energy

Washington, DC 20585

MEMORANDUM FOR MEMBERS OF THE INTERAGENCY WORKING GROUP ON HUMAN RADIATION EXPERIMENTS

FROM: Tara O'Toole, M.D., M.P.H.
Assistant Secretary
Environment, Safety and Health

DATE: March 9, 1994

SUBJECT: Plan For Managing Advisory Committee on Human Radiation
Experimentation Information

Introduction

This memorandum outlines a plan for long-term management of information collected by the Advisory Committee on Human Radiation Experiments. It is necessary to ensure that this data remains available to the public, both in hard copy and through the Internet, after the committee terminates later this year.

The data held by the committee consists of documents collected from the Department of Energy (DOE), other members of the Interagency Working Group, and various other sources. About 65 percent of the committee's documents came from DOE; most of the remainder came from the Department of Defense (see the attachment for an individual agency breakdown). This collection consists of about 300 cubic feet, much of which is made up of photocopies of agency files. Copies of reports, journal articles, and other materials are also present. In addition, the committee has built some electronic databases and other files; some of these files are linked to the hard copy documents. All this material must be identified and decisions must be made about its short and long term disposition.

Proposed Plan

Included in the plan are projected actions and costs associated with consolidating committee data with that already publicly available on the Internet through the department, making hard copy information available at an east and a west cost repository, and transferring information to the National Archives and Records Administration (NARA). DOE will provide 2-3 full-time equivalents (FTE) to accomplish this work, as well as the overhead expenses associated with our information management system. The Department will, however, require some assistance and funding from the other members of the Interagency Working Group to accomplish these tasks. The actions and costs associated with this work are noted below. Note that this plan assumes a continuance of 2-3 DOE FTE to this effort; the cited costs are over and above these FTE. The



costs could perhaps be pro-rated among agencies according to the relative volume of material held by the committee.

Actions/Costs

- Identify committee's information holdings (develop inventory, compare with agency holdings, analyze information overlap and redundancy)/ \$100 K
- Transfer committee's databases and hard copy documentation to DOE custody and ongoing maintenance/\$50 K
- Ensure that data and documents remain accessible to the public through user-friendly information and archival systems (eg, Internet applications, public reading rooms, persons to provide reference and assistance)/\$300 K
- Work with National Archives to determine what parts of the committee's information to preserve/\$25 K
- Arrange for eventual transfer of information to National Archives custody/\$25 K

Breakdown of costs

- Personnel technical support: \$425 K
- Computer-related (hardware/software, data conversion, document imaging/indexing, etc.): \$50 K
- Miscellaneous (travel, shipping, storage, etc.): \$25 K
- Total: \$500 K

Funding

A commitment to continued accessibility of the documents collected from all of the agencies will certainly be part of the "good news" associated with the Interagency and White House announcement at the end of the committee's term. DOE has funded all of the work of the Advisory Committee to date; it is equitable that the costs of this effort be shared by the other agencies. I propose that the Department of Defense fund \$400,000.00 and that HHS and the VA each fund 50,000.00.

We are advised by the DOE General Counsel that funding from the agencies should go to a third party rather than to DOE. We propose that Argonne National Laboratory receive the funds

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Conclusion

I recommend that the members of the Interagency Working Group adopt this plan for the proper and economical disposition of the committee's information. Public interest in this information likely will remain strong for at least several months after the committee terminates, and we must all ensure that the material remains accessible. The overall success of the Administration's efforts regarding human radiation experiments will be strongly enhanced if we can demonstrate establishment of a permanent information archive that will decisively document this subject. Further credit and recognition will also flow from the unified, cutting-edge technology we are using to place this information on the Internet World-Wide Web.

A decision is requested by March 31, 1995 in order to notify the Advisory Committee for its personnel planning.

Please contact Ellyn Weiss at 202-254-5020 if further information is needed.

Attachment

Document Collection - Accessions\Volume by Agency

Agency	Paper <i>HA3</i>
Advisory Committee On Human Radia	1.28
Baylor University	0.33
Boston University	0.44
Central Intelligence Agency	0.74
Commonwealth of Massachusetts	0.13
Congress	0.99
Corporation	4.67
Department of Defense	69.43
Department of Energy	169.58
Department of Health and Human Ser	9.24
Department of Justice	0.80
Department of Veterans Affairs	16.59
Environmental Protection Agency	0.06
George Washington University	0.03
Harvard University	0.58
Individual	4.48
Massachusetts Institute of Technolog	1.05
National Academy of Sciences	0.20
National Aeronautics and Space Admi	5.05
National Archives and Records Admin	5.43
Nuclear Regulatory Commission	0.70
Smithsonian Institution	0.20
State of California	0.01
State of Oregon	0.05
State of Washington	0.04
Texas A&M University	0.13
University of California Los Angeles	2.09
University of Chicago	0.05
University of Cincinnati	7.01
Vanderbilt University	0.10
Virginia Commonwealth University	0.29
	<u>301.77</u>

March 22, 1995

MEMO TO: GORDON SOPER
CLAUD BAILEY
D.A. HENDERSON
LILY ENGSTROM
PHIL CAPLAN

FROM: ELLYN WEISS
OFFICE OF HUMAN RADIATION EXPERIMENTS
202-254-5020

SUBJECT: MEMO ON MANAGING ADVISORY COMMITTEE
INFORMATION

Attached you will find a NEW copy of the memo from Tara. Please note that this memo REPLACES the memo you received at the recent Search Group meeting. We found a small mistake and wanted to send you a corrected version.

If you have questions, please give me a call.

Thanks!

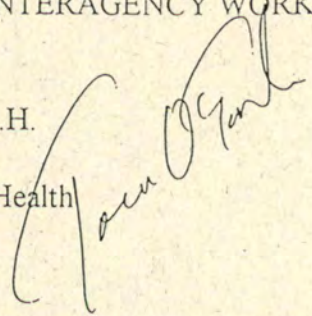
Attachment



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Assistant Secretary
Environment, Safety and Health 

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State of California	0.01
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State of Washington	0.04
Texas A&M University	0.13
University of California Los Angeles	2.09
University of Chicago	0.05
University of Cincinnati	7.01
Vanderbilt University	0.10
Virginia Commonwealth University	0.29
	<u>301.77</u>

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Washington, DC
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OFFICE OF THE GENERAL COUNSEL

U.S. DEPARTMENT OF ENERGY

WASHINGTON, D.C.

FAX #:
CONL:

 Date: 5-15-95

TO: Phil Caplan
W. H.

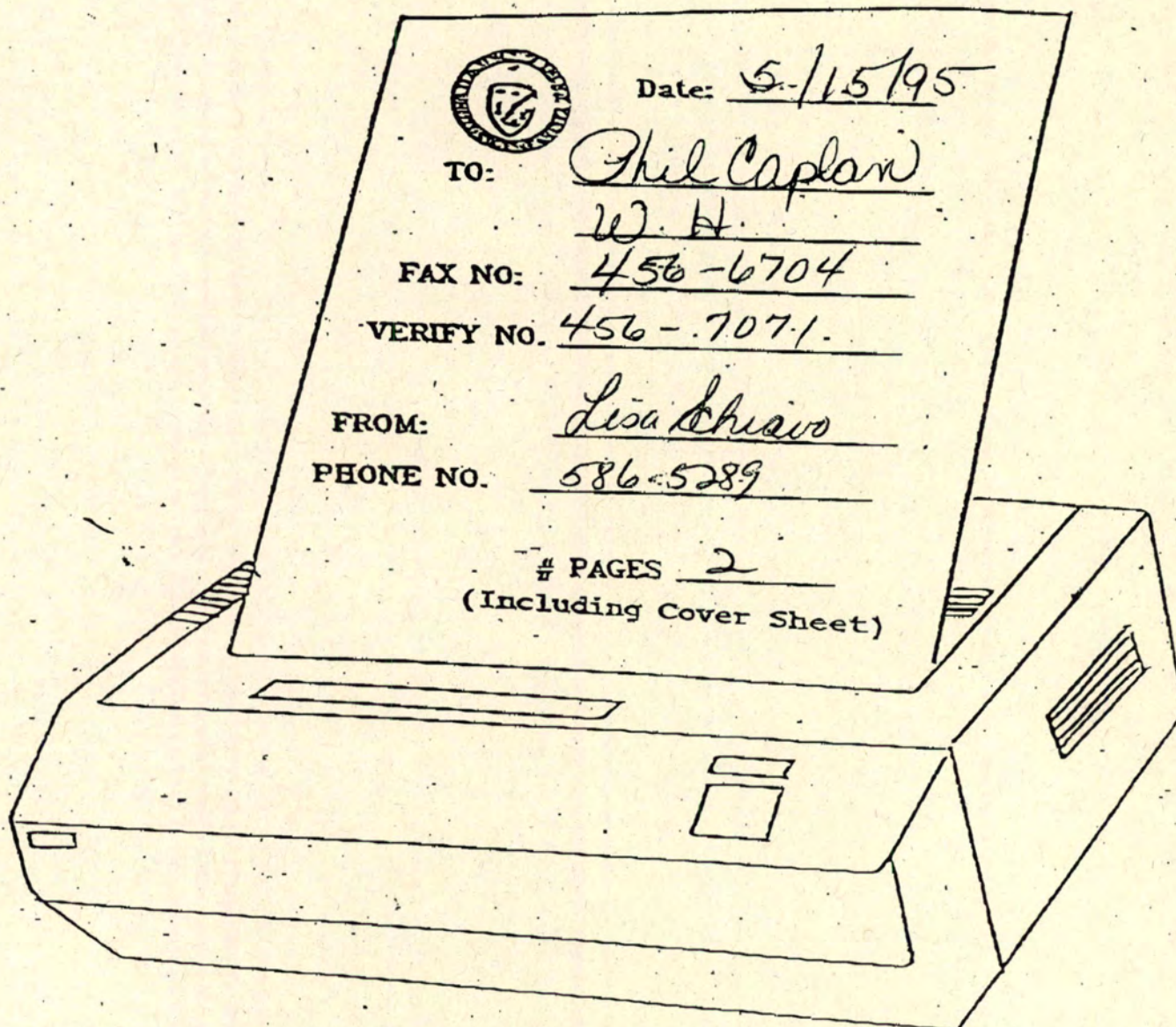
FAX NO: 456-6704

VERIFY NO. 456-7071

FROM: Lisa Chiavio

PHONE NO. 586-5289

PAGES 2
(Including Cover Sheet)



REMARKS: Ltr to Ruth Folen

05/15/95

17:05

202 586 7736

DOE EX SEC

002



The Secretary of Energy
Washington, DC 20585

May 15, 1995

Dr. Ruth R. Faden, Chair
Advisory Committee on Human Radiation Experiments
1726 M Street, NW #600
Washington, DC 20036

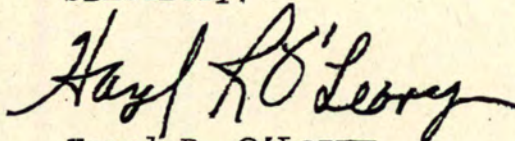
Dear Dr. Faden:

The Human Radiation Interagency Working Group is in receipt of your request dated May 8, 1995 that the charter of the Advisory Committee on Human Radiation Experiments be extended to September 15, 1995, with the final report issued no later than that date. Your letter stated that the additional time sought is necessary to ensure a product that preserves the integrity of the Committee and its process, and that provides answers to questions posed by the Interagency Working Group.

The final report submission date was April 21, 1995, and the charter is now due to expire on May 21, 1995. The Advisory Committee's Charter, at paragraph 5, authorizes the Interagency Working Group to extend the time period for submission of the final report. In order to ensure a thorough report that covers all the necessary material, the Interagency Group grants your request to extend until September 15, 1995 the date by which the Advisory Committee shall submit its final report.

Pursuant to paragraph 6 of the Charter, the President shall be extending the Charter's expiration date until 30 days after submission of the final report.

Sincerely,


Hazel R. O'Leary



ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS
1726 M STREET, N.W., SUITE 600
WASHINGTON, D.C. 20036

MEMORANDUM

TO: Interagency Working Group Points of Contact for Review of ACHRE Final Report:

Ellyn Weiss, Department of Energy
Gordon Soper, Department of Defense
Wendy Baldwin, Department of Health and Human Services
Harry Holloway, National Aeronautics & Space Administration
Nancy Tackett, Department of Veterans Affairs
Brian Latell, Central Intelligence Agency
Pat Glynn, Department of Justice
T.J. Glauthier, Office of Management and Budget
Phil Caplan, White House

CC: Ruth Faden

FROM: Dan Guttman
Jeff Kahn
Steve Klaidman
Anna Mastroianni

DATE: May 9, 1995

RE: Delivery of Outline of Final Report Supplemental Volumes and a Supplemental Volume Chapter: Oversight Policies and Practices of Human Subjects Research in Six Federal Departments and Agencies (Revised: May 3, 1995)

In this delivery, we enclose the tentative Outline of Final Report Supplemental Volumes and a Supplemental Volume Chapter titled Oversight Policies and Practices of Human Subjects Research in Six Federal Departments and Agencies. Additional chapters of the Supplemental Volumes will be circulating shortly. These materials are undergoing essentially continuous revision, which include development and checking of facts. We would appreciate your review solely for any factual errors that bear on your agency that you believe require correction.

If there are specific factual errors regarding your agency, we would appreciate your provision of alternative language. Comments should be sent to the attention of Anna Mastroianni by May 24. She can be reached by fax (202/254-9827), telephone (202/254-9827) and e-mail (amastroi@achre.gov).

Thank you.



Advisory Committee on Human Radiation Experiments

1726 M Street, NW, Suite 600
Washington, DC 20036
202/254-9795
Fax: 202/254-9827

FAX TRANSMISSION COVER SHEET

Date: April 27, 1995
To: Phil Caplan
Steven Galson
Fax: 456-6704
586-0956
Re: Draft Letter to Inter-Agency Working Group
Sender: Anna Mastroianni

*YOU SHOULD RECEIVE 2 PAGE(S), INCLUDING THIS COVER SHEET. IF
YOU DO NOT RECEIVE ALL THE PAGES, PLEASE CALL 202/254-9795.*

Ruth asked that I forward this draft to you. A draft workplan will follow. Please call Dan or me with comments. Or, if you wish to speak with Ruth directly, please call Melissa at the Advisory Committee offices to arrange a time. Thank you.

cc: Ruth Faden
Dan Guttman
Jeffrey Kahn
Stephen Klaidman

◆ DRAFT ◆ DRAFT ◆ DRAFT ◆ DRAFT ◆ DRAFT ◆ DRAFT ◆ DRAFT ◆

April 25, 1995

Dear Members of the Human Radiation Interagency Working Group:

This letter is to outline the intentions of the Advisory Committee on Human Radiation Experiments for completion of its mandate and issuance of its final report. In our Interim Report of October 21, 1994, we indicated several additional months might be necessary to answer as fully as possible the questions posed to the Committee. It is now clear that this is the case. Specifically, we respectfully request that our Charter be extended to September 15, with our final report to be issued no later than this date. *No problems but simply volume & quality of work*

Please note that after May 31 we expect to be operating with a significantly reduced staff and will be issuing no further new requests for documents except under extraordinary circumstances. Nevertheless, we feel that the attached workplan and timetable will enable us to responsibly fill our charge. Specifically, we expect to have identified the relevant ethical and scientific standards for evaluating human radiation experiments and to address the question of notification of former subjects for health protection purposes. We also are homing in on judgments about the extent of harm to the public's health attributable to human radiation experiments. What has become clear is that while the number of experiments in which subjects may have realized physical harm may be limited to a small proportion of experiments performed, the increasingly compelling issue is not harm to physical health but a very real and serious harm to the public's trust of government. This is compounded by a failure to accurately communicate the risks of participation to potential subjects. ~~This latter problem may persist even up to today, as suggested by the early results of the Committee's two projects assessing contemporary research practices.~~

The additional time sought should guarantee that we have a level of confidence about our conclusions on these matters that the American people no doubt expect, and certainly deserve. We believe that a September release date will ensure a product that preserves the integrity of the Committee and its process and delivers to the Interagency Working Group solid answers to the questions it has posed.

I know I speak for my colleagues in expressing my appreciation for the Interagency Working Group's continued support of the Committee's work. I would be happy to discuss these or any other issues with you at your convenience. Please feel free to contact me.

Sincerely,

Ruth R. Faden, PhD, MPH
Chair

cc: Members of the Advisory Committee on Human Radiation Experiments

Enc.

DISTRIBUTION LIST:

		Phone:	Fax:
DOE:	Rich Rosenzweig	586-6210	586-7644
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HHS:	Kevin Thurm	690-6133	690-7755
NASA:	Chris Dunn	358-1827	358-2810
DOJ:	Nancy McFadden	514-9500	514-4371

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Marcia Hale, 2FL WW
John Podesta, GFL WW
Joel Klein, 2FL WW
Steve Neuwirth, 130 OEOB
George Tenet, NSC, 300 OEOB
Sylvia Matthews, 2FL WW
T.J. Glauthier, 246 OEOB
Holly Gwin, 428.5 OEOB
Pat Glynn (fax: 208-0976)

Radiation Interagency Working Groups

January 1994

January 9	SUNDAY	January 16
January 10 9:30am Legal Issues Working Group (472 OEOB) 10:00am Public Inf. & Communications (472 OEOB) 12:00pm Steering Committee Conference Call 4:00pm Interagency Working Group (180 OEOB)	MONDAY	January 17
January 11 10:00am Congressional Group Conference Call 1:00pm Congressional Briefing (450 OEOB) 3:00pm Congressional Briefing (450 OEOB) 4:00pm Ethical & Scientific Standards (476 OEOB)	TUESDAY	January 18 Energy & Power Subcommittee (2123 RHOB/Time TBD) 12:00pm Records & Records Retrieval (472 OEOB) 4:00pm Interagency Steering Committee (Rm TBD)
January 12 11:00am-12:30pm Compensation Working Group (248 OEOB)	WEDNESDAY	January 19
January 13 10:30am Fernald Hearing (Boston)	THURSDAY	January 20 Senate Governmental Affairs (Rm/Time TBD)
January 14 12:00pm Records & Retrieval Working Group (472 OEOB) 2:30pm Ethics & Scientific Standards (476 OEOB)	FRIDAY	January 21
January 15	SATURDAY	January 22

Interagency Radiation Working Group

January 1994

January 2	SUNDAY	January 9
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	9:30am Legal Issues Working Group (472 OEOB) 10:00am Public Inf. & Communications (472 OEOB) 12:00pm Steering Committee Conference Call 4:00pm Interagency Working Group (180 OEOB)	
January 4	TUESDAY	January 11
	1:00pm Congressional Briefing (450 OEOB) 3:00pm Congressional Briefing (450 OEOB)	
January 5	WEDNESDAY	January 12
3:00pm Ethical & Scientific Standards (422 OEOB) 4:00pm Congressional Working Group Conference Call 5:15pm Legal Issues Working Group (Roosevelt Rm)	11:00am-12:30pm Compensation Working Group (248 OEOB)	
January 6	THURSDAY	January 13
10:00am Public Info. & Communications (476 OEOB) 1:00-2:30pm Records & Retrieval Working Group (180 OEOB) 2:30pm Ethical & Scientific Standards (422 OEOB) 4:00pm Steering Committee (180 OEOB) 5:30pm Follow-up Legal Issues Meeting (Rm TBD)		
January 7	FRIDAY	January 14
11:00am Congressional Group Conference Call 11:00am Compensation Working Group (246 OEOB) 11:00am Public Info. & Communications Conference Call 2:30pm Ethical & Scientific Standards Follow-up (422 OEOB)		
January 8	SATURDAY	January 15

DATE:

96 JUN 27 15:39

ASSISTANT SECRETARY
OFFICE OF ENVIRONMENT, SAFETY AND HEALTH
U.S. DEPARTMENT OF ENERGY
1000 INDEPENDENCE AVENUE, S.W.
WASHINGTON, D.C. 20585

OFFICE: (202) 586-6151

FAX: (202) 586-0956

TO:

IAWG STAFF / WHITE HOUSE ATTENDEE

FROM:

ELIX MELAMED

NO. OF PAGES TO FOLLOW:

7☒ For your information☐ Please call upon receipt

As requested

For review and comment

Original copy to follow via mail

COMMENTS/MESSAGES:

ATTACHED, W PREPARATION FOR THE FRIDAY
MEETING IS (1) MATERIAL FROM DOD ON NP
RADIUM THERAPY (2) ADDITIONAL INFO FROM
DOD ON URANIUM MINERS. MARSHALL
ISLANDS INFO WILL FOLLOW. ALSO, UPDATED
WHITE PAPER WILL BE DISTRIBUTED
AT THE MEETING. CALL IF QUESTIONS
202 586-6857



Department of Defense
Radiation Experiments Command Center
6801 Telegraph Road
Alexandria, Virginia 22310-3398

JUN 27 1996

RECC

MEMORANDUM FOR INTERAGENCY WORKING GROUP
ATTN: ELLY MELAMED

SUBJECT: Treatment of Aerotitis Media in Submariners and Aircrews

Background on Nasopharyngeal (NP) Radium Therapy

During the 1920s, physicians at Johns Hopkins University developed a new technique using radium which enabled them to successfully treat children for hearing impairment caused by chronic inflammation of the middle ear (otitis media). Called nasopharyngeal (nose and pharynx) therapy, this procedure involved routing a radium tipped applicator through the nasal passage, positioning it adjacent to the eustachian tube and leaving it in place for several minutes before removal. Treatments were routinely repeated over a period of months as determined by tissue response to the therapy.

Both civilian and military facilities used this procedure from the late 1920s until the 1960s. In the early 1940s military medical personnel performed NP radium therapy on Navy submariners/aviators and Army Air Force aviators as a treatment for inflammation of the middle ear due to pressure changes (aerotitis media) and upper respiratory infections. This therapy was particularly valuable during World War II and played a significant role in keeping air crews and submariners available for duty. However, one major epidemiological study suggests that treated individuals may be at increased risk for the development of head and neck malignancies. It is also possible that the treatment may result in other types of diseases such as endocrine disorders.

DOD actions to date

- On 31 March 1994, the Bureau of Medicine and Surgery (BUMED) Supplemental Report on Human Radiation Experiments identified a study using nasopharyngeal irradiation on Submariners, labeled "Study #SMRL-01". It identified a test population 732 but provided no further personal identifying data.
- On 30 April 1996, the original log book of the Aerotitis Media Study was located at the Medical Research Laboratory in New London, Connecticut.
- The DOD is in the process of analyzing this log. A meeting was held between DOD and VA on 31 May 1996 to start efforts of further identifying and following up on participants of this study. The DOD agreed to develop a database of the individuals listed in the log book.
- The DOD identified 1611 names in the log book who may have been involved in the research. The Nautilus Submarine Museum in Groton, Connecticut has copies of student data cards for the time frame in question. The DOD sent researchers there 12-25 June 1996 to identify possible matches. There were 1039 possible matches (965 enlisted and 74 officer). This corresponds to a 65% match of log names with student data cards.

- The DOD will take this list of matches and attempt to locate corresponding service and medical records at the National Personnel Record Center. These records will be reviewed and the information passed to the VA for further follow-up.

VA actions to date

- The VA co-sponsored (with the CDC and Yale University) a workshop entitled "The Public Health Response to Nasopharyngeal Irradiation" held in New Haven CT on 27-28 September 1995.
- The VA's Environmental Epidemiology Service (EES) examined the feasibility of an epidemiological study of Navy personnel treated with radium. Prior to the discovery of the researcher's log book, this was not considered feasible.
- VA officials authored or co-authored articles in major medical publications (including the Journal of the American Medical Association and the Morbidity and Mortality Weekly Report) to inform health professionals about NP radium.
- Information on NP radium has been sent to major veterans service organizations for publication in their newsletters.

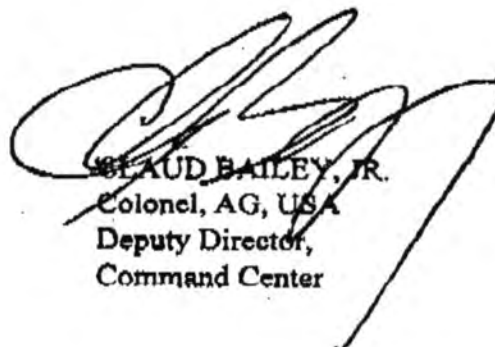
VA actions in progress

- A legislative proposal has been drafted which will make veterans treated with NP radium in the service eligible to participate in the VA's Ionizing Radiation Registry Examination program and have priority eligibility for treatment of conditions possibly related to radiation exposure.
- VA's EES is examining the feasibility of an epidemiological study of Army Air Force veterans treated with NP radium.
- The VA is collaborating with the CDC to present a satellite teleconference on NP radium to further inform health professionals. This is scheduled for 5 September 1996

Follow-up VA actions

- In light of the recent retrieval of the Navy log book, VA's EES will re-examine the feasibility of an epidemiological study of Navy personnel treated with NP radium.
- VA will also re-examine the feasibility of notification of individual veterans treated with NP radium.

FOR THE DIRECTOR:



CLAUDE BAILEY, JR.
Colonel, AG, USA
Deputy Director,
Command Center

RECOMMENDATIONS REGARDING THRESHOLD EXPOSURE
CRITERIA FOR URANIUM MINERS WITH LUNG CANCER

1. Background of Problem:

The Radiation Exposure Compensation Act (RECA) presently requires uranium miners seeking compensation for lung cancer to meet minimum radon progeny exposure thresholds; the thresholds vary by the smoking status of the miner and the age of the miner at the time of diagnosis of lung cancer (attained age). The RECA Committee has proposed new threshold exposure criteria, using the latest scientific data and analytical methods. The new criteria indicate that the relative risk of lung cancer due to radon progeny decreases with attained age, and decreases as time since last exposure increases. As a consequence, the new eligibility criteria for miners who developed lung cancer over the age of 60 and who have been out of the mines for more than 20 years are significantly higher than the present statutory criteria. Most (though not all) of the miners who are applying for compensation now (or who have applied since 1991) fall into the affected group. The practical consequence is that any miner in the affected group applying today likely will be denied compensation.

2. Basis for Modifying Proposed Criteria:

Although the RECA Committee recognized the consequences of the new lung cancer compensation criteria, it specifically avoided modifying the criteria to account for political or other policy-based factors. The recommended criteria simply represent the Committee's best "technical" judgment where the line for compensation should be drawn, based on the premise that Congress sought in the Act to compensate only those miners whose lung cancer more likely than not was the result of their exposure to radon progeny in the course of their employment in underground uranium mines.

There are a number of reasons that justify the Administration in modifying the proposed criteria to ease or eliminate any added burden to eligibility imposed on miners now contracting lung cancer.

a. First, and foremost, the criteria proposed by the Committee do not account for uncertainties associated with the data. The Committee did take into account the uncertainty due to the statistical sampling process. However, the Committee did not factor in the potential error due to inaccuracy or imprecision of the underlying data. In the case of the exposure-based criteria, that uncertainty is likely to be significant; the historical radon measurements in the mines are widely believed to be

inaccurate and imprecise measures of claimants' exposures in many cases.¹

b. Second, the RECA is designed to provide compassionate payments to persons presumably injured as a result of the government's proven failure to protect its citizens. It is remedial legislation -- as such, the risk of uncertainty should be imposed on the government, and the benefit of the doubt given to the aggrieved parties (the miners).

c. Third, the new criteria, to the extent they raise the threshold requirements for compensation, run counter to settled expectations in the affected communities. While citizens generally have no enforceable or politically plausible "right of expectation" in government legislation, in this case the affected communities may have effectively been "duped" into not challenging earlier the analytical process employed by the Committee. The criticisms presented to Congress and the Advisory Committee did not explicitly note the likelihood that some criteria would rise under a more rigid scientific analysis. Moreover, the new methodology was not discussed in detail before congressional committees or the Advisory Committee, so neither claimants nor their advocates realistically could have been prepared for what they will surely see as a breach of good faith. Because the government made no effort to advise them of this outcome, and instead allowed optimistic expectations to solidify, the claimants and their advocates have had no opportunity to advocate to the Advisory Committee or the IAWG some policy-based parameters to guide the Committee's investigation.

3. Possible Alternative Criteria

a. Allow claimants to qualify under either the present statutory criteria or the newly proposed criteria

Under this proposal, no claimant will be adversely affected by the new criteria. The Program will use that set of criteria that sets the lowest threshold standard for the claimant, based on their smoking history, age, and mining history. This proposal will maximize the number of claimants who will be eligible for compensation.

Though this will solve the problem in practice, it is theoretically objectionable. First, the new criteria were developed because it was agreed that the present criteria do not

¹ Of course, any error associated with the mine exposure data is eliminated by using criteria based on employment duration. The employment data, however, has an associated error not accounted for.

accurately quantify the risk of lung cancer to uranium miners, and thus do a poor job of effecting congressional intent -- getting the money to deserving claimants. The lack of a firm scientific foundation for the criteria -- likely the result of political compromise -- was the impetus behind the Advisory Committee's Recommendation 7 and the creation of the RECA Committee. If we continue to use the present criteria, even partially, we create a system that is prone to the same criticism that led to the current undertaking.

Second, if we use the present criteria for some miners, we sanction a set of standards we acknowledge do not accurately quantify the risks to miners, and thus do not accurately effect congressional intent. Indeed, allowing a claimant to qualify based on the "old" standards where the new standards are higher has the effect of compensating a claimant our best information indicates does not deserve compensation.

Third, if we use both set of criteria, we create a problem of comparability within the class of miners. Miners who opt to use the present standards where they are more liberal than the new criteria will be compensated though the probability of causation is less than fifty percent. On the other hand, many miners will use the new criteria because for their age, smoking status and employment history, these criteria are lower than the present statutory criteria. The new criteria, however, embody the fifty percent probability standard. Thus, some miners are compensated only if they meet the fifty percent probability, while other miners for whom the present criteria are more advantageous are compensated at a lower standard of probability.

b. Grandfather in all claimants with claims that are pending or accrued as of some date

Under this proposal, any claimant who has a claim pending with the program or whose claim has "accrued" as of some date would be entitled to use the present statutory criteria, if they are more advantageous. The question here is how to define when a claim "accrues." One definition is when the compensable disease was or could have been diagnosed -- i.e., when the claimant develops the disease. By setting the date for a change in the standards some period of time after the amendment of the Act (i.e., two years), you can provide a window of comfort to ensure you include claimants whose lung cancer is manifesting presently, and avoid violating reasonable expectations among many claimants.

This proposal, however, will not help claimants who develop lung cancer some years in the future, and who perceive that they have been unfairly treated. Claimants are thus divided into two groups with differing threshold standards, depending solely on the quixotic factor of when their disease manifested (a factor already accounted for in the development of the criteria).

c. Modify the criteria tables to account for additional uncertainties in the data

The Committee's recommended criteria factor into account uncertainties in the statistical process by developing "levels of assurance," described above. The Committee did not take into account the uncertainty associated with the underlying data. It is probable that the confidence intervals calculated to account for this uncertainty will be greater for the more recent miners because the Colorado cohort is weighted toward older, more highly exposed miners. Thus, there is some theoretical justification for giving a larger "break" to miners who were exposed later and to smaller amounts -- which will be many of the miners now coming down with lung cancer.

While this approach is theoretically defensible and has the virtue of being, like the criteria themselves, "science-based," it may not be practical. Confidence intervals reflecting the uncertainty associated with radon progeny exposure estimates cannot be calculated. There are a host of uncertainties associated with this estimate process, and statistical models to determine the error are only now being developed. In the words of one of the statisticians on the Committee, the problem is "not trivial."

Additionally, dropping the exposure criteria for some miners will not work for the employment-based standards, which the Committee strongly recommends be used in conjunction with the exposure-based criteria. The employment data is much more precise than the mine data, so there is little uncertainty, yet the employment-based criteria for older miners are still quite high.

d. Propose criteria based on a different standard of causation

As noted above, the Committee developed the new criteria based on the premise that Congress intended to compensate claimants whose lung cancer more likely than not was caused by exposure to radon progeny during employment in underground mines. Lowering the standard of causation to a figure less than 50% will result in lower threshold exposure or employment duration criteria. The Administration can propose to Congress that the Act be amended to establish a lower causation standard given the uncertainties associated with the data and the recognized injustice done to the miners. This approach could be part of a broader effort to deal with the recognized "comparability problem" -- the compensation criteria in the Act effectively set three different probabilities of causation for the three eligible classes, with the uranium miners required to meet the highest standard.

This approach may well be unwarranted because it asks Congress to redebate one of the fundamental propositions underlying the Act. The legislative history suggests that there is some strenuous opposition to any scheme that explicitly purports to compensate individuals where the probability of causation is less than 50%. Reopening this debate, in light of recent data on the relative risks to the downwind and onsite participant populations, might jeopardize the compensation scheme for these two groups and would create extensive collateral political problems.

DATE:

ASSISTANT SECRETARY
OFFICE OF ENVIRONMENT, SAFETY AND HEALTH
U.S. DEPARTMENT OF ENERGY
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TO:

I A W G STAFF / WHITE HOUSE ATTENDEES

FROM:

ELLY MELAMED

NO. OF PAGES TO FOLLOW:

4☐ For your information☐ Please call upon receipt☐ As requested☐ For review and comment☐ Original copy to follow via mail

COMMENTS/MESSAGES:

MARSHALL ISLANDS PIECE FOR
FRIDAY MEETING.

**From: Elly Melamed
Department of Energy**

Date: June 27, 1996

Subject: Revised Briefing Paper on the Marshall Islands (Recommendation 8)

Background

The Advisory Committee made four recommendations concerning the Marshall Islands:

- 1) to continue the current DOE surveillance program limited to those Marshallese exposed to fallout from US atomic tests, as long as the exposed population remains alive;
- 2) to review the program to determine if other atolls should be added;
- 3) to establish an independent panel to review the current program for providing medical care to the exposed population;
- 4) to involve the Marshallese in the design of any further medical research.

DOE agrees with each of these recommendations. The first and the last are, and will continue to be, carried out. The fundamental problem in terms of expanding the program is one of funding: the Department does not have the resources to expand the medical care program; nor does it have funds to do the type of independent study that the Marshallese have requested. New efforts will have new costs and the Marshallese are already concerned that the current program is not funded at a sufficient level.

The Current Medical Program

There are currently three separate and distinct programs that provide medical care to the Marshallese. The Department of Energy recognizes the difficulties and inequities in the quality of care each program provides.

DOE Program. DOE supports a special, intensive medical program which at present serves the 133 individuals from the atolls of Rongelap and Utrik who were inadvertently exposed to high amounts of atmospheric fallout from the Castle BRAVO test in 1954. The objective of this program is to thoroughly assess the health of these individuals that who may have problems related to radiation exposure from the Castle BRAVO test. This is a high quality medical program that uses the best and latest examination and laboratory techniques. The Department offers these examinations twice a year, utilizing a team of US physicians from Brookhaven National Laboratory, academic centers, and Federal agencies such as the PHS and DOD.

177 Health Care Program (four atoll program). Supported through the Department of Interior, this program was created to provide *year-round general* medical care and treatment to residents of the four atolls most directly affected by the *overall* U.S. weapons testing program in the South Pacific. It now provides care for approximately 11,500 individuals with a total annual budget of \$2.0 million, or roughly \$174 per patient per year. Additional people have been added, including children, without increasing the level of funding.

Marshallese Program. The Government of the Republic of the Marshall Islands has a general Ministry of Health medical delivery system operating primarily out of hospitals in Majuro and Ebeye. This program, we believe, is in need of improvements as it struggles under the burden of a lack of sufficiently trained personnel and crumbling facilities. The Marshallese would like better health for those covered by this RMI system, especially for those who live in the atolls of Ailuk, Likiep, and Wotho.

The Marshallese are interested in more local control of services provided by DOE and an extensive expansion of medical care facilities and services available in the Marshall Islands, including construction of a new hospital. This need for medical care is real and is not directly linked to past radiation exposures.

If the medical care program were to be significantly expanded, DOE is concerned that it is not the appropriate agency to undertake a broad medical delivery effort; other agencies have more expertise and experience in this matter. There are indications that the Marshallese agree with this position.

There are complicated scientific, logistic, and financial issues that need to be addressed before the U.S. can agree to expanding the current program. There are no indications that Congress intends to act to expand the DOE program or the four atoll program, although they would like to see this latter work more effectively.

Issues Involving the Review Panel

The Marshallese would like DOE to fund a study that would be performed by the National Academy of Sciences and would retrospectively consider the past program rather than focus on future options. This would be an expensive and time-consuming undertaking. DOE would prefer to set up a "blue ribbon group" that would focus on the current program and how to help build infrastructure and self-sufficiency for the Marshallese medical program. In addition, DOE does not have sufficient funds to underwrite an NAS study.

Actions Taken

DOE has been actively working with the Marshallese and has affirmed its plans to continue the current program, its willingness to support efforts to review the issue of adding further atolls, and its desire to establish an independent panel to review the direction and scope of the surveillance program. DOE has also agreed to work with the

Marshallese and involve them in any decision making and to allocate funds according to their priorities. The Marshallese have been responsive to these assurances.

DOE has also met with Department of Interior staff who administer the medical care services to the Marshallese in efforts to better coordinate US efforts and answer the needs of the Marshallese.

If the DOE program were expanded to include the 3500 Bikini and Enewetak populations, it is anticipated, based on Straub Clinic older adult care costs, that it would cost at least \$5000 per patient per year. Approximately \$4500 would be needed to provide the medical care and another \$500 in logistics costs would be required to get patients to appropriate medical care facilities. Thus a program of this magnitude would likely cost about \$17.5 million annually. This budget could be higher if medical referrals facilities outside the Marshall Islands are needed. Such a program would best be executed through a Public Health Service contract and administered by a medical care delivery entity.

Options

1. Let the Congressional inquiries play out, continue active negotiations with the Marshallese that would support the Marshallese desire for more local control of program directions and implementation, but do not advance or propose legislation calling for a greatly expanded budget and health care program in the absence of Congressional Initiative.

- Pro
 - Would continue to provide medical care to the acutely exposed population under the Department of Energy's (DOE's) program.
 - Would meet DOE's current Congressional mandate.
 - Would allow Congress to decide on eligibility criteria for inclusion in the program.
 - Would leave Congress in the position of deciding what level of funding is needed to meet the concerns expressed.
 - Would enable DOE to continue to build on improved relationships with the RMI.
- Con
 - Would not address the RMI coverage concerns expressed during the Advisory Committee's review.
 - Would leave a poorly functioning "177" medical care delivery system intact for the bulk of the Marshallese populations also exposed to some fallout dose, while continuing to provide high quality medical care to a very few.

2. Propose legislation supporting Marshallese desire for medical coverage of all Marshallese believed to be exposed and who are experiencing radiation related health effects. (Assumes adding patients to the current DOI 177 Health Care Program and increasing patient care levels to \$5,000/patient/year.)

- Pro - Would continue in the spirit of trying to find an equitable way to deal with the U.S. Government moral commitment to provide at least a minimal level of primary medical care to all deserving Marshallese citizens.
- Would honor Departmental commitments to work toward a solution that can ameliorate, in some fashion the inadequate status of medical care delivery in the Marshall Islands.
- Offers the opportunity to bring in a federal agency more qualified to provide health care delivery program of this magnitude.
- Con - Would cost the Administration some \$17.5M annually to add just the 3,500 Bikini and Enewetak proposed by Senator Murkowski (Amendment 4039 to S. 1804) which proposes to add the 3500 Marshallese to the current DOE Medical Program, or
- If the additional populations of Ailuk, Likiep and Wotho (some 1900 additional people) are added, costs would be driven to \$66.9M annually. This assumes treatment of the some 13,370 patients (11,470 plus 1,900).

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

23-May-1996 09:43am

TO: Diane Regas
TO: Elizabeth E. Drye

FROM: Phillip M. Caplan
 Office of the Staff Secretary

SUBJECT: Interagency radiation meeting

We should sit down and talk sometime late next week to plan for the June 6 meeting.

I think it should be mostly your meeting (it would be great if Carol could come too), but there are two items we should address (not necessarily at the meeting):

1) the victims' groups have sent a letter to the President (I'll send you copies) asking for a meeting with WH staff -- something we have been declining on the advice of counsel because of the litigation. We need to figure out how to respond.

2) Chris Klein of Glenn's staff wants to meet; I think Glenn and Stevens are feeling the Administration has taken too long in responding to the Committee's report. Klein told me they are looking for some sort of "policy statement" in response to the report. I told him we would have some sort of response in the coming weeks/months but that we could update him at some point.

Let's talk next week.

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

23-May-1996 09:36am

TO: (See Below)

FROM: Phillip M. Caplan
Office of the Staff Secretary

SUBJECT: Human Radiation Interagency Working Group Meeting

There will be an working group meeting on Thursday, June 6 at 11:00 am in Room 472, OEOB.

Elizabeth Drye and Diane Regas, both of DPC, have begun the process of running an interagency policy process in order to come to closure on several of the outstanding issues related to the Advisory Committee's recommendations.

Please RSVP to my office at 62702.

Thanks.

Distribution:

TO: Stephen R. Neuwirth
TO: T J Glauthier
TO: Tracey E. Thornton
TO: Eric L. Macris
TO: Rachel E. Levinson

CC: Elizabeth E. Drye
CC: Diane Regas
CC: Carol H. Rasco



66 MAR 18 P 6:12

**ASSISTANT SECRETARY
OFFICE OF ENVIRONMENT, SAFETY & HEALTH**

**U.S. DEPARTMENT OF ENERGY
1000 INDEPENDENCE AVENUE, SW
WASHINGTON, DC 20585**

TO: IAWG STAFF

FROM: Lori Azim 202-586-5319, 202-586-0956 (fax)

DATE: March 18, 1996

NO. OF PAGES TO FOLLOW: 16

☐ For your information only

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☐ For review & comment

COMMENTS/MESSAGES:

Materials for IAWG meeting Tuesday, March 19th at 10 am. Meeting at DOE Forrestal Bldg, 1000 Independence Ave, SW Room 7A-097, O'Toole's office. Call if you have questions. Thanks (Also came to you via e-mail)

SOME ACTIONS FOR THE IAWG TO CONSIDER IN LIGHT OF THE STAKEHOLDER WORKSHOP AND STEVENS HEARING

The following are **preliminary** thoughts from DOE in preparation for the IAWG staff meeting on Tuesday. They are not meant to be complete (nothing is included for compensation and current research, for example) but are simply a place to begin.

Attached to this document are ideas from agencies on specific areas including openness (DOE), medical notification and follow-up (DOE), current research (HHS) and atomic veterans (VA and DOD).

Again, all of this material is meant to be **preliminary** and to provide a starting point for Tuesday's brainstorming meeting.

- **Better publicize the Advisory Committee Report.**

Both the workshop and the hearing revealed a tremendous ignorance about the extent of the work done by the Advisory Committee and what precisely is included in the 900 page report. (One suggestion at the post-workshop teleconference was to hold public meetings across the country to talk about the report.) The IAWG staff may need to develop a communications plan for carrying out this task of publicizing the report.

- **Clarify a number of specific issues where there is misinformation**

One example of this is the Marshall Islands program. It was evident at the hearing that what DOE has done in the past, is doing, and its possible future actions, may not have been effectively communicated to the Congress and to others as well. DOE needs to make sure that its perspective is clearly articulated and publicized as a first step in ensuring that the ACHRE recommendation pertaining to this group is reasonably carried out. Other agencies may have similar specific communication issues and the IAWG staff may want to do joint planning.

- **Move quickly on those issues where there is a (relatively) clear path forward and publicize these efforts**

By acting quickly where we can, the IAWG staff can buy time to sort out the more difficult issues such as notification and medical follow-up (and perhaps compensation?). We probably need to regularly publicize our progress and activities to interested congressional staff, stakeholders and others to ensure they

are aware that the government is working actively to respond to the Advisory Committee recommendations. Recommendations that may fall into this category are those relating to Veterans, Uranium Miners and Marshall Islands where there is a structure for action/redress in place that needs to be modified and/or expanded. These are also areas where we received a significant number of specific proposals from the stakeholders.

- **Look for cost-effective solutions that most directly benefit stakeholder/citizens.**

One criticism of previous government efforts that a number of officials found persuasive was that large amounts of money have gone for studies and dose reconstruction and relatively small amounts have gone to those who were presumably harmed. The challenge for the government is to develop new kinds of responses that are equitable and reasonable taking this criticism into account.

- **Capitalize on openness**

An area where we are receiving high marks from Congress and some acknowledgement from stakeholders is in the efforts of Federal agencies to proactively provide information using a variety of media, to declassify documents, and to be responsive to public inquiries. By continuing this effort wherever possible (and perhaps expanding it to related areas of interest) we can both generate good will and fulfil the administrations's promise of open government. (some specific openness suggestions are attached).

- **Consider stakeholder/citizen involvement in the follow-up process**

At the workshop, the stakeholders consistently asked for more involvement in the "process" of implementing the Advisory Committee recommendations. Clearly, they have a specific idea of what this involvement entails. They are not satisfied with the citizen representation included on the Advisory Committee nor presumably with what is planned for NBAC. They want people associated with the Task Force, that is, someone from the radiation survivors/radiation experiments community, to be included on committees, review groups, etc. They proposed some kind of citizens advisory group at the workshop and Cooper Brown, at the hearing, proposed a group modeled on the committee to oversee the release of the Kennedy assassination papers. Whether and in what way it is feasible to respond to this request for more involvement needs to be considered by the IAWG.

- **Confront the issue of notification and follow-up**

This difficult issue came up regularly at the workshop and again at the hearing. Although Senator Glenn acknowledged the difficulties in this notification issue, he nonetheless reiterated several times that if he had been involved in an experiment he would want to know. The IAWG staff probably needs to determine if it believes there is an obligation to notify and if any level of notification beyond what has already been done - the Advisory Committee report itself, publicizing this effort, responding to helpline calls, and providing agency lists of experiments - is possible or appropriate. Does the IAWG staff want to propose going beyond the Advisory Committee report in this area? In any case, we will need a clear and detailed statement on what we do and don't plan to do and why.

- **Determine if we want to propose legislation**

Senator Glenn indicated that he would like to hear from the agencies in terms of potential legislation. He is concerned that time is running out. The IAWG staff may want to consider whether we have, or will have in the near future, anything to report to him.

- **Aggressively set an agenda of follow-up actions to be proposed to the President**

The IAWG staff may want to consider an active approach that helps the IAWG set the proposed agenda, rather than actions being primarily defined by congressional requests, GAO reviews, and stakeholder demands. All of these are important but the IAWG staff is in the best position to develop a strong, balanced response. One approach would be to plan to produce a second version of the white paper over the next few months which is far more comprehensive in reviewing options, perhaps includes some new approaches, and is more direct in proposing some solutions to the President while rejecting others.

An important part of this process may be to use the information provided by the Advisory Committee's extensive review to better prioritize our responses. Where is action required most urgently? The Advisory Committee has 18 equal recommendations but we may want to do some analysis and sorting based on the information both in the Committee's report and that available to the IAWG staff through other sources.

SOME OPENNESS IDEAS:**Recommendation 17(1)**

- Propose the transfer to the National Archives not only of documents located for this search but of those series (collections) of records from which they were retrieved which document important activities of Federal agencies. (For example, DOE is negotiating the transfer of the records of the Division of Biology and Medicine to the Archives, not simply some documents pulled for this project.)
- Any closely related older series of records with potential historical value should be offered to the National Archives as well. In other words, the IAWG may want to use this opportunity to locate important collections of historical records still in agency custody broadly relating to experimentation, including policy records, and offer these to the Archives as part of the openness effort.

Recommendation 17(2)

- DOE is currently locating finding aids to important series of older records still in agency custody across the DOE complex and making these records available in public reading rooms. (Finding aids are file folder listings, SF-135 used to transfer records to Federal Record Centers, or any other kind of information that tells the researcher what type of information are included in a collection.) Other agencies may want to consider similar projects.

Recommendation 17(3)

- As a result of the recent Executive Order 12958, Federal agencies are undertaking a major effort to review for declassification records that are thirty years or older. IAWG staff members may want to keep in touch with progress made in declassification so they can report on numbers and types of documents declassified in relation to this openness effort.

Recommendation 17(4)

- The IAWG staff informally agreed that the appropriate response here is to schedule all human subject research records as permanent. This effort has to be done separately by each agency..

Recommendation 17(5)

- This is the issue of reviewing and developing public policies concerning access to records generated or held by private contractors and institutions receiving Federal funding. What does the IAWG staff want to do about this, if anything? Would it be appropriate to establish a subgroup to look into it?

Other Ideas

- We may be worn out from sponsoring workshops, but we might want to consider a different type: a workshop on how to do research in government records. This would be part of the process of helping citizens to access hre and other types of information. We could work with the National Archives and other groups and could develop this with a number of audiences in mind: stakeholder citizens, historians, attorneys and librarians. It could include but not be solely focussed on hre information. This workshop could be linked to attempts to publicize the Advisory Committee report, as could the next effort.
- We could also develop a booklet on doing research in government records primarily for citizens and based on the HRE model. This would be a more accessible and reworked version of the information provided by the Advisory Committee in its report.
- The IAWG agencies are currently in the process of making their documents available on the Internet on the model of the DOE effort. Once that is completed we will need to publicize the ready availability of this large amount of material on the Internet. We may want to discuss ways that we can keep this site current and interesting to stakeholders and Web users in general. Maybe there are other kinds of information - testimony for instance - that might be put on the Internet.
- Continue to facilitate speedy responses to FOIA requests from citizens that relate to HRE to ensure prompt responses - perhaps find some way to institutionalize this expedited treatment.
- Per a request at the stakeholder's workshop, develop an oral history project to interview those who identify themselves as victims of human radiation experiments on the model of the Advisory Committee and DOE projects that interviewed researchers and scientists.

- Investigate the possibility of government provided Internet access for those who cannot afford it or who are not near any other accessible source. (Perhaps it could be available in public reading rooms, for example.)
- Look for additional ways to get stakeholder input in the openness effort that stay focussed on the path forward rather than past failures.

From Gary Ellis, HHS:

ACHRE RECOMMENDATIONS 9-15

Protection of the Rights & Interests of Human Subjects in the Future

The principal response of the Executive Branch to these ACHRE findings and recommendations was the October 3, 1995 creation of the **National Bioethics Advisory Commission (NBAC)**. As a first priority, NBAC shall direct its attention to protection of the rights and welfare of human research subjects. Human radiation experiments, per se, are not referenced in NBAC's charter.

Although its chartering was catalyzed by the ACHRE report, NBAC, in fact, represents the reinstitution by the President of an entity that has been absent since 1983. That entity is a national, deliberative body of private citizens that provides advice and recommendations to the government on bioethical issues arising from research on human biology and behavior, and the applications of that research. As such, NBAC can be expected to pursue various issues identified in these ACHRE recommendations based on their merits, as judged by NBAC.

Specific actions

- 1) DOE, DOD, DHHS, NASA, VA, CIA, and DOJ (and many other agencies) are providing NBAC with reports that are fully responsive to the President's October 3, 1995, Executive Order. This information will permit NBAC to begin a critical assessment of the **implementation of the 1991 Federal Policy for the Protection of Human Subjects ("Common Rule")**. Such independent analysis is critically needed, 5 years after the promulgation of the regulations.
- 2) The IAWG recommends to NBAC that it begin an early assessment of **compensation for research-related injury**. Despite being addressed before by the HEW Secretary's Task Force (1977) and the President's Commission (1982), a definitive resolution of this long-standing social policy issue remains elusive.
- 3) NIH is leading an interagency initiative to fund the development of new knowledge related to the **informed consent process**. Despite the vigor with which all parties embrace the informed consent process, little is actually known or understood about it. Much of the ACHRE's commentary on current human subjects research is centered on informed consent, and NIH, NASA, VA, DOE, and DOD are committed to supporting research that will more fully illuminate the process.

- 4) ACHRE makes several recommendations to **Institutional Review Boards (IRBs)**. OPRR leads a national educational effort to showcase the ACHRE message. OPRR collaborates closely with Public Responsibility in Medicine & Research (PRIM&R), a Boston-based private, nonprofit organization, to stage an annual public meeting for individuals interested in the governance of human subjects research. More than 600 people attended the October 1995 PRIM&R meeting, at which the ACHRE recommendations were presented for the first time to the IRB community. OPRR has scheduled presentations and discussions of the ACHRE recommendations at upcoming national workshops in Atlanta (Apr. 11-12), Oklahoma City (June 3-5), Honolulu (July 25-26), Peoria (Sept. 26-27), and Houston (Nov. 1-2). The November 1995 PRIM&R annual conference (San Diego) is expected to address IRB implementation of the ACHRE recommendations. The IAWG is pleased to note the recent placement of the ACHRE report on the World Wide Web, where IRBs can examine its full text.
- 5) At a March 12 hearing, both the Chairman and Ranking Minority Member of the U.S. Senate Committee on Governmental Affairs expressed concerns about **human subjects protections in nonfederally funded research** -- a specific ACHRE concern, as well. ACHRE called for the IAWG to take steps to ensure that all human subjects are adequately protected, and the IAWG will work closely with the Committee as it pursues this issue. NBAC, too, can be expected to address this issue.

3/13/96 GBE
c:\mmlAWG

To: IAWG Staff
From: Steven Galson, Chief Medical Officer, DOE
Date: 18 March 1996
Subject: Draft options for notification and follow-up

We have assembled this information for discussion purposes only. Its purpose is to stimulate thought. This is **not** an all-inclusive list. Please **do not circulate or copy** this material.

DRAFT Options for Notification and Follow-Up
DO NOT CIRCULATE

OPTION	ADVANTAGES	ROADBLOCKS	COSTS
1. Identify, locate, notify & provide health care and psychological services to all research subjects & their families.	Meets demands of stakeholders including family members. Compensates research subjects for prior govt wrongs. Satisfies people's desire for information, to extent possible.	Enormous govt effort & expenditure. Funnels \$\$ away from prevention activities. Creates inequalities in treatment of persons harmed by govt activities.	Extremely high.
2. Identify, locate, notify & provide limited health benefits at VA hospitals to all research subjects.	Only covers those physical conditions that could reasonably be related to subjects' radiation exposure.	Enormous, expensive task. Requires legislation to expand access to VA medical system. Limits on coverage → litigation.	Very high.
3. Identify, locate, notify & provide research records to all research subjects. Provide medical follow-up to those who were under age 20 at time of study.	Benefits those at risk for longest period of time. Conforms with National Research Council recommendations concerning Alaska thyroid research.	Enormous, expensive task. No medical testing, intervention or special care available to most persons notified.	Very high.

4. Identify & locate those persons who received nasopharyngeal radium treatments during childhood; provide health care or other benefits.	Provides benefit to those at greatest elevated risk of death.	No screening procedures available for CNS, head and neck cancers. Singles out subset for notification and compensation.	High.
5. Locate & offer benefit to few research subjects already identified. Provide discount medical screening or health care services and automatic compensation for certain illnesses.	Satisfies demands of some of identified stakeholders if offers large benefit package.	Only covers persons in tiny fraction of 4000 documented experiments. Inequalities created among former research subjects → litigation.	High.
6. Resolve everything with lump-sum payment in class action suits.	Helps research subjects to finance their own medical monitoring and follow-up - if so desired - even if not medically warranted. Penalizes government for former wrongdoing. Concludes at least some cases.	Fails to satisfy all the stakeholders. May require ongoing funding mechanism to compensate subjects identified in future.	Medium → High.
7. Expand eligibility under Medicare to include research subjects.	Provides benefit to research subjects. Covers about half the costs of medical care.	Requires legislation. Politically very difficult. Creates inequalities in treatment. Hospital trust fund may run out of \$\$ soon.	High.

DRAFT -- DO NOT CIRCULATE

8. Expand eligibility under Medicaid to include research subjects.	Provides benefit to research subjects.	Requires legislation. Politically extremely difficult at state and federal levels. Medicaid designed for low-income/welfare population, only. Programs underfunded. Medicaid participation refused by many doctors.	High.
9. Establish reduced-cost primary health clinics in towns/regions where larger experiments took place.	Provides benefits to some research subjects and general public in identified areas.	Offers no benefit to persons who have moved away from identified areas. Ongoing effort with no end point.	High.
10. Establish a trust fund financed by a special tax or by federal \$\$.	Could follow model of black lung or vaccine injury trust funds. Compensates research subjects.	Potentially costly, ongoing effort.	Medium→High.
11. Guarantee eligibility (but not payment) for health insurance at reasonable rate.	Ensures that most research subjects are able to afford health care.	Insurance companies must sign on.	Medium.
12. Provide benefits to persons who prove they were radiation research subjects.	Compensates some stakeholders.	Places burden on American public. May → scramble to identify and locate claimants.	Medium.

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13. Offer other benefits (e.g., low-dose dental x-ray equipment) to towns/regions where larger experiments took place.	Compatible with tradeable emissions approach. Acknowledges lack of available interventions & near-impossibility of identifying & locating individual research subjects. Benefits at least part of target population as well as general public in identified locations.	Offers no benefit to persons who have moved away from identified areas.	Low→Medium.
14. Sponsor large-scale nationwide health education/cancer prevention campaigns re: testes & thyroid testing.	Enhances health status of all Americans including research subjects. Follows preventive public health framework. Acknowledges the near-impossibility of identifying and locating individual research subjects.	Fails to compensate individual stakeholders.	Low.
15. Provide neither notification nor follow-up.	Conforms with recommendations of Advisory Committee. Acknowledges low level of risk & lack of available interventions.	Angers stakeholders. Fails to satisfy people's desires to know what happened and to receive some form of compensation.	Low.

DRAFT -- DO NOT CIRCULATE

Submitted by Neil Otchin, VA:

Rev. 3/14/96

DRAFT
TALKING POINTS RELATING TO ATOMIC VETERANS FOR DISCUSSION
AT MEETING OF HUMAN RADIATION INTERAGENCY WORKING GROUP
(IAWG) STAFF, MARCH 19, 1996

In response to Recommendation 6 in the ACHRE Final Report concerning atomic veterans, a Department of Veterans Affairs (VA) Human Radiation Interagency Working Group (VAWG) has been established, led by the Under Secretary for Benefits, and met for the first time on March 13, 1996.

Although this meeting was open to the public and input from veterans and members of the public was solicited, no one submitted any comments. But proposals made at the Radiation Stakeholders Workshop, held on February 26-27, 1996, were provided to the VAWG for their consideration.

The mission of the VAWG is to consider updating and expanding the radioepidemiological tables. It will also review current laws and regulations relating to compensation of atomic veterans, consider the best balance for allocating resources between compensation and administrative costs, and make recommendations for improvements, if necessary.

The report of the VAWG is expected to be completed in the late spring of 1996.

It should be noted that major changes (such as adding illnesses to the presumptive list or extending the presumptions to veterans exposed in other radiation-risk activities) may require legislative action by Congress. Possible legislative remedies will be considered by the VAWG.

RESPONSES TO PROPOSALS FROM THE RADIATION STAKEHOLDERS
WORKSHOP RELATING TO ATOMIC VETERANS

Summary of Proposals relating to Recommendation 6 (from DOE)

1. All victims be compensated for the same illnesses - the presumptive list of diseases for miners should be the same as for veterans.

DRAFT -- DO NOT CIRCULATE**RESPONSE:**

The VAWG was established specifically to address ACHRE Recommendation 6 and met for the first time on March 13, 1996. The meeting was open to the public and input from veterans and the public was invited. The VAWG will consider updating and expanding the radioepidemiological tables. It also will review current laws and regulations relating to compensation of Atomic Veterans, consider the best balance for allocating resources between compensation and administrative costs, and will make recommendations for improvements. This and other relevant proposals from the Radiation Stakeholders meeting have been provided to the VAWG for their consideration. It should be noted that major changes (such as adding illnesses to the presumptive list or extending presumptions to veterans exposed in other radiation-risk activities) may require legislative action by Congress.

2. A registry should be established for the offspring of atomic veterans who may have developed genetic or mutagenic health problems as a result of the parent or grandparent's exposure.

RESPONSE:

See response to proposal 1.

3. Eleven additional radiation risk activities now identified should be included for compensation under existing laws and time constraints should be widened to include all these exposures.

RESPONSE:

See response to proposal 1.

4. The radioepidemiological tables should be updated by an independent non-governmental or quasi-governmental scientific panel.

RESPONSE:

See response to proposal 1.

5. All persons covered under RECA should be awarded the highest sum (\$100,000) now awarded only to uranium miners.

RESPONSE:

This proposal is beyond the scope of Recommendation 6. RECA is administered by the DOJ. We defer to them to address this proposal.

DRAFT -- DO NOT CIRCULATE

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RESPONSE: See response to proposal 5.

7. After all radiogenic illnesses have become presumptive, repeal 98-542 so that money goes to veterans, not contractors (not do dose reconstruction which is inaccurate, expensive, and veterans records are missing and incomplete).

RESPONSE: See response to proposal 1.

8. Survivors of veterans should receive money equivalent to the medical, hospital, burial and other expenses incurred in the veterans' final illnesses.

RESPONSE: See response to proposal 1.

9. On site presence should be sufficient criteria for compensation in the absence of evidence to the contrary.

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10. Fifty percent minimum service-connected disability should be granted with all associated rights and privileges.

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11. Nothing in this proposal precludes individual veterans or their families from pursuing any other remedies available to them.

RESPONSE: Not within the purview of the VA.

12. A process of fairness in the Atomic Veteran community that allows veterans to participate. Positions are desired on NBAC and any future related committees.

RESPONSE: See response to proposal 1.



96 MAR 18 PG: 12

**ASSISTANT SECRETARY
OFFICE OF ENVIRONMENT, SAFETY & HEALTH**

**U.S. DEPARTMENT OF ENERGY
1000 INDEPENDENCE AVENUE, SW
WASHINGTON, DC 20585**

TO: IAWG STAFF

FROM: Lori Azim 202-586-5319, 202-586-0956 (fax)

DATE: March 18, 1996

NO. OF PAGES TO FOLLOW: 16

☐ For your information only

☐ Call upon receipt

☐ As requested

☐ For review & comment

COMMENTS/MESSAGES:

Materials for IAWG meeting Tuesday, March 19th at 10 am. Meeting at DOE Forrestal Bldg, 1000 Independence Ave, SW Room 7A-097, O'Toole's office. Call if you have questions. Thanks (Also came to you via e-mail)

**SOME ACTIONS FOR THE IAWG TO CONSIDER IN LIGHT OF THE
STAKEHOLDER WORKSHOP AND STEVENS HEARING**

The following are **preliminary** thoughts from DOE in preparation for the IAWG staff meeting on Tuesday. They are not meant to be complete (nothing is included for compensation and current research, for example) but are simply a place to begin.

Attached to this document are ideas from agencies on specific areas including openness (DOE), medical notification and follow-up (DOE), current research (HHS) and atomic veterans (VA and DOD) .

Again, all of this material is meant to be **preliminary** and to provide a starting point for tuesday's brainstorming meeting.

- **Better publicize the Advisory Committee Report.**

Both the workshop and the hearing revealed a tremendous ignorance about the extent of the work done by the Advisory Committee and what precisely is included in the 900 page report. (One suggestion at the post-workshop teleconference was to hold public meetings across the country to talk about the report.) The IAWG staff may need to develop a communications plan for carrying out this task of publicizing the report.

- **Clarify a number of specific issues where there is misinformation**

One example of this is the Marshall Islands program. It was evident at the hearing that what DOE has done in the past, is doing, and its possible future actions, may not have been effectively communicated to the Congress and to others as well. DOE needs to make sure that its perspective is clearly articulated and publicized as a first step in ensuring that the ACHRE recommendation pertaining to this group is reasonably carried out. Other agencies may have similar specific communication issues and the IAWG staff may want to do joint planning.

- **Move quickly on those issues where there is a (relatively) clear path forward and publicize these efforts**

By acting quickly where we can, the IAWG staff can buy time to sort out the more difficult issues such as notification and medical follow-up (and perhaps compensation?). We probably need to regularly publicize our progress and activities to interested congressional staff, stakeholders and others to ensure they

are aware that the government is working actively to respond to the Advisory Committee recommendations. Recommendations that may fall into this category are those relating to Veterans, Uranium Miners and Marshall Islands where there is a structure for action/redress in place that needs to be modified and/or expanded. These are also areas where we received a significant number of specific proposals from the stakeholders.

- **Look for cost-effective solutions that most directly benefit stakeholder/citizens.**

One criticism of previous government efforts that a number of officials found persuasive was that large amounts of money have gone for studies and dose reconstruction and relatively small amounts have gone to those who were presumably harmed. The challenge for the government is to develop new kinds of responses that are equitable and reasonable taking this criticism into account.

- **Capitalize on openness**

An area where we are receiving high marks from Congress and some acknowledgement from stakeholders is in the efforts of Federal agencies to proactively provide information using a variety of media, to declassify documents, and to be responsive to public inquiries. By continuing this effort wherever possible (and perhaps expanding it to related areas of interest) we can both generate good will and fulfil the administrations's promise of open government. (some specific openness suggestions are attached).

- **Consider stakeholder/citizen involvement in the follow-up process**

At the workshop, the stakeholders consistently asked for more involvement in the "process" of implementing the Advisory Committee recommendations. Clearly, they have a specific idea of what this involvement entails. They are not satisfied with the citizen representation included on the Advisory Committee nor presumably with what is planned for NBAC. They want people associated with the Task Force, that is, someone from the radiation survivors/radiation experiments community, to be included on committees, review groups, etc. They proposed some kind of citizens advisory group at the workshop and Cooper Brown, at the hearing, proposed a group modeled on the committee to oversee the release of the Kennedy assassination papers. Whether and in what way it is feasible to respond to this request for more involvement needs to be considered by the IAWG.

- **Confront the issue of notification and follow-up**

This difficult issue came up regularly at the workshop and again at the hearing. Although Senator Glenn acknowledged the difficulties in this notification issue, he nonetheless reiterated several times that if he had been involved in an experiment he would want to know. The IAWG staff probably needs to determine if it believes there is an obligation to notify and if any level of notification beyond what has already been done - the Advisory Committee report itself, publicizing this effort, responding to helpline calls, and providing agency lists of experiments - is possible or appropriate. Does the IAWG staff want to propose going beyond the Advisory Committee report in this area? In any case, we will need a clear and detailed statement on what we do and don't plan to do and why.

- **Determine if we want to propose legislation**

Senator Glenn indicated that he would like to hear from the agencies in terms of potential legislation. He is concerned that time is running out. The IAWG staff may want to consider whether we have, or will have in the near future, anything to report to him.

- **Aggressively set an agenda of follow-up actions to be proposed to the President**

The IAWG staff may want to consider an active approach that helps the IAWG set the proposed agenda, rather than actions being primarily defined by congressional requests, GAO reviews, and stakeholder demands. All of these are important but the IAWG staff is in the best position to develop a strong, balanced response. One approach would be to plan to produce a second version of the white paper over the next few months which is far more comprehensive in reviewing options, perhaps includes some new approaches, and is more direct in proposing some solutions to the President while rejecting others.

An important part of this process may be to use the information provided by the Advisory Committee's extensive review to better prioritize our responses. Where is action required most urgently? The Advisory Committee has 18 equal recommendations but we may want to do some analysis and sorting based on the information both in the Committee's report and that available to the IAWG staff through other sources.

SOME OPENNESS IDEAS:**Recommendation 17(1)**

- Propose the transfer to the National Archives not only of documents located for this search but of those series (collections) of records from which they were retrieved which document important activities of Federal agencies. (For example, DOE is negotiating the transfer of the records of the Division of Biology and Medicine to the Archives, not simply some documents pulled for this project.)
- Any closely related older series of records with potential historical value should be offered to the National Archives as well. In other words, the IAWG may want to use this opportunity to locate important collections of historical records still in agency custody broadly relating to experimentation, including policy records, and offer these to the Archives as part of the openness effort.

Recommendation 17(2)

- DOE is currently locating finding aids to important series of older records still in agency custody across the DOE complex and making these records available in public reading rooms. (Finding aids are file folder listings, SF-135 used to transfer records to Federal Record Centers, or any other kind of information that tells the researcher what type of information are included in a collection.) Other agencies may want to consider similar projects.

Recommendation 17(3)

- As a result of the recent Executive Order 12958, Federal agencies are undertaking a major effort to review for declassification records that are thirty years or older. IAWG staff members may want to keep in touch with progress made in declassification so they can report on numbers and types of documents declassified in relation to this openness effort.

Recommendation 17(4)

- The IAWG staff informally agreed that the appropriate response here is to schedule all human subject research records as permanent. This effort has to be done separately by each agency..

Recommendation 17(5)

- This is the issue of reviewing and developing public policies concerning access to records generated or held by private contractors and institutions receiving Federal funding. What does the IAWG staff want to do about this, if anything? Would it be appropriate to establish a subgroup to look into it?

Other Ideas

- We may be worn out from sponsoring workshops, but we might want to consider a different type: a workshop on how to do research in government records. This would be part of the process of helping citizens to access hre and other types of information. We could work with the National Archives and other groups and could develop this with a number of audiences in mind: stakeholder citizens, historians, attorneys and librarians. It could include but not be solely focussed on hre information. This workshop could be linked to attempts to publicize the Advisory Committee report, as could the next effort.
- We could also develop a booklet on doing research in government records primarily for citizens and based on the HRE model. This would be a more accessible and reworked version of the information provided by the Advisory Committee in its report.
- The IAWG agencies are currently in the process of making their documents available on the Internet on the model of the DOE effort. Once that is completed we will need to publicize the ready availability of this large amount of material on the Internet. We may want to discuss ways that we can keep this site current and interesting to stakeholders and Web users in general. Maybe there are other kinds of information - testimony for instance - that might be put on the Internet.
- Continue to facilitate speedy responses to FOIA requests from citizens that relate to HRE to ensure prompt responses - perhaps find some way to institutionalize this expedited treatment.
- Per a request at the stakeholder's workshop, develop an oral history project to interview those who identify themselves as victims of human radiation experiments on the model of the Advisory Committee and DOE projects that interviewed researchers and scientists.

- Investigate the possibility of government provided Internet access for those who cannot afford it or who are not near any other accessible source. (Perhaps it could be available in public reading rooms, for example.)
- Look for additional ways to get stakeholder input in the openness effort that stay focussed on the path forward rather than past failures.

From Gary Ellis, HHS:

ACHRE RECOMMENDATIONS 9-15

Protection of the Rights & Interests of Human Subjects in the Future

The principal response of the Executive Branch to these ACHRE findings and recommendations was the October 3, 1995 creation of the **National Bioethics Advisory Commission (NBAC)**. As a first priority, NBAC shall direct its attention to protection of the rights and welfare of human research subjects. Human radiation experiments, per se, are not referenced in NBAC's charter.

Although its chartering was catalyzed by the ACHRE report, NBAC, in fact, represents the reinstitution by the President of an entity that has been absent since 1983. That entity is a national, deliberative body of private citizens that provides advice and recommendations to the government on bioethical issues arising from research on human biology and behavior, and the applications of that research. As such, NBAC can be expected to pursue various issues identified in these ACHRE recommendations based on their merits, as judged by NBAC.

Specific actions

- 1) DOE, DOD, DHHS, NASA, VA, CIA, and DOJ (and many other agencies) are providing NBAC with reports that are fully responsive to the President's October 3, 1995, Executive Order. This information will permit NBAC to begin a critical assessment of the **implementation of the 1991 Federal Policy for the Protection of Human Subjects ("Common Rule")**. Such independent analysis is critically needed, 5 years after the promulgation of the regulations.
- 2) The IAWG recommends to NBAC that it begin an early assessment of **compensation for research-related injury**. Despite being addressed before by the HEW Secretary's Task Force (1977) and the President's Commission (1982), a definitive resolution of this long-standing social policy issue remains elusive.
- 3) NIH is leading an interagency initiative to fund the development of new knowledge related to the **informed consent process**. Despite the vigor with which all parties embrace the informed consent process, little is actually known or understood about it. Much of the ACHRE's commentary on current human subjects research is centered on informed consent, and NIH, NASA, VA, DOE, and DOD are committed to supporting research that will more fully illuminate the process.

- 4) ACHRE makes several recommendations to **Institutional Review Boards (IRBs)**. OPRR leads a national educational effort to showcase the ACHRE message. OPRR collaborates closely with Public Responsibility in Medicine & Research (PRIM&R), a Boston-based private, nonprofit organization, to stage an annual public meeting for individuals interested in the governance of human subjects research. More than 600 people attended the October 1995 PRIM&R meeting, at which the ACHRE recommendations were presented for the first time to the IRB community. OPRR has scheduled presentations and discussions of the ACHRE recommendations at upcoming national workshops in Atlanta (Apr. 11-12), Oklahoma City (June 3-5), Honolulu (July 25-26), Peoria (Sept. 26-27), and Houston (Nov. 1-2). The November 1995 PRIM&R annual conference (San Diego) is expected to address IRB implementation of the ACHRE recommendations. The IAWG is pleased to note the recent placement of the ACHRE report on the World Wide Web, where IRBs can examine its full text.
- 5) At a March 12 hearing, both the Chairman and Ranking Minority Member of the U.S. Senate Committee on Governmental Affairs expressed concerns about **human subjects protections in nonfederally funded research** -- a specific ACHRE concern, as well. ACHRE called for the IAWG to take steps to ensure that all human subjects are adequately protected, and the IAWG will work closely with the Committee as it pursues this issue. NBAC, too, can be expected to address this issue.

3/13/96 GBE
c:\mmlAWG

To: IAWG Staff
From: Steven Galson, Chief Medical Officer, DOE
Date: 18 March 1996
Subject: Draft options for notification and follow-up

We have assembled this information for discussion purposes only. Its purpose is to stimulate thought. This is **not** an all-inclusive list. Please **do not circulate or copy** this material.

DRAFT Options for Notification and Follow-Up
DO NOT CIRCULATE

OPTION	ADVANTAGES	ROADBLOCKS	COSTS
1. Identify, locate, notify & provide health care and psychological services to all research subjects & their families.	Meets demands of stakeholders including family members. Compensates research subjects for prior govt wrongs. Satisfies people's desire for information, to extent possible.	Enormous govt effort & expenditure. Funnels \$\$ away from prevention activities. Creates inequalities in treatment of persons harmed by govt activities.	Extremely high.
2. Identify, locate, notify & provide limited health benefits at VA hospitals to all research subjects.	Only covers those physical conditions that could reasonably be related to subjects' radiation exposure.	Enormous, expensive task. Requires legislation to expand access to VA medical system. Limits on coverage → litigation.	Very high.
3. Identify, locate, notify & provide research records to all research subjects. Provide medical follow-up to those who were under age 20 at time of study.	Benefits those at risk for longest period of time. Conforms with National Research Council recommendations concerning Alaska thyroid research.	Enormous, expensive task. No medical testing, intervention or special care available to most persons notified.	Very high.

4. Identify & locate those persons who received nasopharyngeal radium treatments during childhood; provide health care or other benefits.	Provides benefit to those at greatest elevated risk of death.	No screening procedures available for CNS, head and neck cancers. Singles out subset for notification and compensation.	High.
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15. Provide neither notification nor follow-up.	Conforms with recommendations of Advisory Committee. Acknowledges low level of risk & lack of available interventions.	Angers stakeholders. Fails to satisfy people's desires to know what happened and to receive some form of compensation.	Low.

DRAFT -- DO NOT CIRCULATE

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Rev. 3/14/96

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RESPONSE: See response to proposal 1.

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Fax Cover Sheet

~~06-MAR-18~~ PG: 26

Please Deliver to:

Phil Caplan

Fax #: 94562215
Company: WH

From:

AZIM, LORI

Fax #: 000-000-0000
Phone:

Pages: 17

Message:

Materials for IAWG meeting on Tuesday, March 19th at 10 am.

The meeting will be held in Tara O'Toole's office at Dept.
of Energy Forrestal building, 1000 Independence Ave, SW, Roo
m 7A-097. If you have questions call me at 202-586-5319 or
Elly Melamed at 202-586-6857. Thanks

This fax was sent using Castelle's FaxPress network fax server.

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are aware that the government is working actively to respond to the Advisory Committee recommendations. Recommendations that may fall into this category are those relating to Veterans, Uranium Miners and Marshall Islands where there is a structure for action/redress in place that needs to be modified and/or expanded. These are also areas where we received a significant number of specific proposals from the stakeholders.

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SOME OPENNESS IDEAS:

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From Gary Ellis, HHS:

ACHRE RECOMMENDATIONS 9-15

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The principal response of the Executive Branch to these ACHRE findings and recommendations was the October 3, 1995 creation of the **National Bioethics Advisory Commission (NBAC)**. As a first priority, NBAC shall direct its attention to protection of the rights and welfare of human research subjects. Human radiation experiments, per se, are not referenced in NBAC's charter.

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- 1) DOE, DOD, DHHS, NASA, VA, CIA, and DOJ (and many other agencies) are providing NBAC with reports that are fully responsive to the President's October 3, 1995, Executive Order. This information will permit NBAC to begin a critical assessment of the **implementation of the 1991 Federal Policy for the Protection of Human Subjects ("Common Rule")**. Such independent analysis is critically needed, 5 years after the promulgation of the regulations.
- 2) The IAWG recommends to NBAC that it begin an early assessment of **compensation for research-related injury**. Despite being addressed before by the HEW Secretary's Task Force (1977) and the President's Commission (1982), a definitive resolution of this long-standing social policy issue remains elusive.
- 3) NIH is leading an interagency initiative to fund the development of new knowledge related to the **informed consent process**. Despite the vigor with which all parties embrace the informed consent process, little is actually known or understood about it. Much of the ACHRE's commentary on current human subjects research is centered on informed consent, and NIH, NASA, VA, DOE, and DOD are committed to supporting research that will more fully illuminate the process.

- 4) ACHRE makes several recommendations to **Institutional Review Boards (IRBs)**. OPRR leads a national educational effort to showcase the ACHRE message. OPRR collaborates closely with Public Responsibility in Medicine & Research (PRIM&R), a Boston-based private, nonprofit organization, to stage an annual public meeting for individuals interested in the governance of human subjects research. More than 600 people attended the October 1995 PRIM&R meeting, at which the ACHRE recommendations were presented for the first time to the IRB community. OPRR has scheduled presentations and discussions of the ACHRE recommendations at upcoming national workshops in Atlanta (Apr. 11-12), Oklahoma City (June 3-5), Honolulu (July 25-26), Peoria (Sept. 26-27), and Houston (Nov. 1-2). The November 1995 PRIM&R annual conference (San Diego) is expected to address IRB implementation of the ACHRE recommendations. The IAWG is pleased to note the recent placement of the ACHRE report on the World Wide Web, where IRBs can examine its full text.
- 5) At a March 12 hearing, both the Chairman and Ranking Minority Member of the U.S. Senate Committee on Governmental Affairs expressed concerns about **human subjects protections in nonfederally funded research** -- a specific ACIIRE concern, as well. ACIIRE called for the IAWG to take steps to ensure that all human subjects are adequately protected, and the IAWG will work closely with the Committee as it pursues this issue. NBAC, too, can be expected to address this issue.

3/13/96 GBE
c:\mmIAWG

To: IAWG Staff
From: Steven Galson, Chief Medical Officer, DOE
Date: 18 March 1996
Subject: Draft options for notification and follow-up

We have assembled this information for discussion purposes only. Its purpose is to stimulate thought. This is **not** an all-inclusive list. Please **do not circulate or copy** this material.

DRAFT Options for Notification and Follow-Up
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OPTION	ADVANTAGES	ROADBLOCKS	COSTS
1. Identify, locate, notify & provide health care and psychological services to all research subjects & their families.	Meets demands of stakeholders including family members. Compensates research subjects for prior govt wrongs. Satisfies people's desire for information, to extent possible.	Enormous govt effort & expenditure. Funnels \$\$ away from prevention activities. Creates inequalities in treatment of persons harmed by govt activities.	Extremely high.
2. Identify, locate, notify & provide limited health benefits at VA hospitals to all research subjects.	Only covers those physical conditions that could reasonably be related to subjects' radiation exposure.	Enormous, expensive task. Requires legislation to expand access to VA medical system. Limits on coverage → litigation.	Very high.
3. Identify, locate, notify & provide research records to all research subjects. Provide medical follow-up to those who were under age 20 at time of study.	Benefits those at risk for longest period of time. Conforms with National Research Council recommendations concerning Alaska thyroid research.	Enormous, expensive task. No medical testing, intervention or special care available to most persons notified.	Very high.

4. Identify & locate those persons who received nasopharyngeal radium treatments during childhood; provide health care or other benefits.	Provides benefit to those at greatest elevated risk of death.	No screening procedures available for CNS, head and neck cancers. Singles out subset for notification and compensation.	High.
5. Locate & offer benefit to few research subjects already identified. Provide discount medical screening or health care services and automatic compensation for certain illnesses.	Satisfies demands of some of identified stakeholders if offers large benefit package.	Only covers persons in tiny fraction of 4000 documented experiments. Inequalities created among former research subjects → litigation.	High.
6. Resolve everything with lump-sum payment in class action suits.	Helps research subjects to finance their own medical monitoring and follow-up - if so desired - even if not medically warranted. Penalizes government for former wrongdoing. Concludes at least some cases.	Fails to satisfy all the stakeholders. May require ongoing funding mechanism to compensate subjects identified in future.	Medium → High.
7. Expand eligibility under Medicare to include research subjects.	Provides benefit to research subjects. Covers about half the costs of medical care.	Requires legislation. Politically very difficult. Creates inequalities in treatment. Hospital trust fund may run out of \$\$ soon.	High.

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8. Expand eligibility under Medicaid to include research subjects.	Provides benefit to research subjects.	Requires legislation. Politically extremely difficult at state and federal levels. Medicaid designed for low-income/welfare population, only. Programs underfunded. Medicaid participation refused by many doctors.	High.
9. Establish reduced-cost primary health clinics in towns/regions where larger experiments took place.	Provides benefits to some research subjects and general public in identified areas.	Offers no benefit to persons who have moved away from identified areas. Ongoing effort with no end point.	High.
10. Establish a trust fund financed by a special tax or by federal \$\$.	Could follow model of black lung or vaccine injury trust funds. Compensates research subjects.	Potentially costly, ongoing effort.	Medium >High.
11. Guarantee eligibility (but not payment) for health insurance at reasonable rate.	Ensures that most research subjects are able to afford health care.	Insurance companies must sign on.	Medium.
12. Provide benefits to persons who prove they were radiation research subjects.	Compensates some stakeholders.	Places burden on American public. May → scramble to identify and locate claimants.	Medium.

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13. Offer other benefits (e.g., low-dose dental x-ray equipment) to towns/regions where larger experiments took place.	Compatible with tradeable emissions approach. Acknowledges lack of available interventions & near-impossibility of identifying & locating individual research subjects. Benefits at least part of target population as well as general public in identified locations.	Offers no benefit to persons who have moved away from identified areas.	Low→Medium.
14. Sponsor large-scale nationwide health education/cancer prevention campaigns re: testes & thyroid testing.	Enhances health status of all Americans including research subjects. Follows preventive public health framework. Acknowledges the near-impossibility of identifying and locating individual research subjects.	Fails to compensate individual stakeholders.	Low.
15. Provide neither notification nor follow-up.	Conforms with recommendations of Advisory Committee. Acknowledges low level of risk & lack of available interventions.	Angers stakeholders. Fails to satisfy people's desires to know what happened and to receive some form of compensation.	Low.

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Submitted by Neil Otchin, VA:

Rev. 3/14/96

DRAFT**TALKING POINTS RELATING TO ATOMIC VETERANS FOR DISCUSSION
AT MEETING OF HUMAN RADIATION INTERAGENCY WORKING GROUP
(IAWG) STAFF, MARCH 19, 1996**

In response to Recommendation 6 in the ACIIRE Final Report concerning atomic veterans, a Department of Veterans Affairs (VA) Human Radiation Interagency Working Group (VAWG) has been established, led by the Under Secretary for Benefits, and met for the first time on March 13, 1996.

Although this meeting was open to the public and input from veterans and members of the public was solicited, no one submitted any comments. But proposals made at the Radiation Stakeholders Workshop, held on February 26-27, 1996, were provided to the VAWG for their consideration.

The mission of the VAWG is to consider updating and expanding the radioepidemiological tables. It will also review current laws and regulations relating to compensation of atomic veterans, consider the best balance for allocating resources between compensation and administrative costs, and make recommendations for improvements, if necessary.

The report of the VAWG is expected to be completed in the late spring of 1996.

It should be noted that major changes (such as adding illnesses to the presumptive list or extending the presumptions to veterans exposed in other radiation-risk activities) may require legislative action by Congress. Possible legislative remedies will be considered by the VAWG.

**RESPONSES TO PROPOSALS FROM THE RADIATION STAKEHOLDERS
WORKSHOP RELATING TO ATOMIC VETERANS****Summary of Proposals relating to Recommendation 6 (from DOE)**

1. All victims be compensated for the same illnesses - the presumptive list of diseases for miners should be the same as for veterans.

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RESPONSE: The VAWG was established specifically to address ACHRE Recommendation 6 and met for the first time on March 13, 1996. The meeting was open to the public and input from veterans and the public was invited. The VAWG will consider updating and expanding the radioepidemiological tables. It also will review current laws and regulations relating to compensation of Atomic Veterans, consider the best balance for allocating resources between compensation and administrative costs, and will make recommendations for improvements. This and other relevant proposals from the Radiation Stakeholders meeting have been provided to the VAWG for their consideration. It should be noted that major changes (such as adding illnesses to the presumptive list or extending presumptions to veterans exposed in other radiation-risk activities) may require legislative action by Congress.

2. A registry should be established for the offspring of atomic veterans who may have developed genetic or mutagenic health problems as a result of the parent or grandparent's exposure.

RESPONSE: See response to proposal 1.

3. Eleven additional radiation risk activities now identified should be included for compensation under existing laws and time constraints should be widened to include all these exposures.

RESPONSE: See response to proposal 1.

4. The radioepidemiological tables should be updated by an independent non-governmental or quasi-governmental scientific panel.

RESPONSE: See response to proposal 1.

5. All persons covered under RECA should be awarded the highest sum (\$100,000) now awarded only to uranium miners.

RESPONSE: This proposal is beyond the scope of Recommendation 6. RECA is administered by the DOJ. We defer to them to address this proposal.

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6. There should be no offset under RECA for benefits such as social security, VA benefits, etc.

RESPONSE: See response to proposal 5.

7. After all radiogenic illnesses have become presumptive, repeal 98-542 so that money goes to veterans, not contractors (not do dose reconstruction which is inaccurate, expensive, and veterans records are missing and incomplete).

RESPONSE: See response to proposal 1.

8. Survivors of veterans should receive money equivalent to the medical, hospital, burial and other expenses incurred in the veterans' final illnesses.

RESPONSE: See response to proposal 1.

9. On site presence should be sufficient criteria for compensation in the absence of evidence to the contrary.

RESPONSE: See response to proposal 1.

10. Fifty percent minimum service-connected disability should be granted with all associated rights and privileges.

RESPONSE: See response to proposal 1.

11. Nothing in this proposal precludes individual veterans or their families from pursuing any other remedies available to them.

RESPONSE: Not within the purview of the VA.

12. A process of fairness in the Atomic Veteran community that allows veterans to participate. Positions are desired on NBAC and any future related committees.

RESPONSE: See response to proposal 1.

Fax Cover Sheet

=====96 MAR 18 PG: 26=====

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Pages: 17

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Message:

Materials for IAWG meeting on Tuesday, March 19th at 10 am.
The meeting will be held in Tara O'Toole's office at Dept.
of Energy Forrestal building, 1000 Independence Ave, SW, Roo
m 7A-097. If you have questions call me at 202-586-5319 or
Elly Melamed at 202-586-6857. Thanks

This fax was sent using Castelle's FaxPress network fax server.

SOME ACTIONS FOR THE IAWG TO CONSIDER IN LIGHT OF THE STAKEHOLDER WORKSHOP AND STEVENS HEARING

The following are **preliminary** thoughts from DOE in preparation for the IAWG staff meeting on Tuesday. They are not meant to be complete (nothing is included for compensation and current research, for example) but are simply a place to begin.

Attached to this document are ideas from agencies on specific areas including openness (DOE), medical notification and follow-up (DOE), current research (HHS) and atomic veterans (VA and DOD).

Again, all of this material is meant to be **preliminary** and to provide a starting point for Tuesday's brainstorming meeting.

- **Better publicize the Advisory Committee Report.**

Both the workshop and the hearing revealed a tremendous ignorance about the extent of the work done by the Advisory Committee and what precisely is included in the 900 page report. (One suggestion at the post-workshop teleconference was to hold public meetings across the country to talk about the report.) The IAWG staff may need to develop a communications plan for carrying out this task of publicizing the report.

- **Clarify a number of specific issues where there is misinformation**

One example of this is the Marshall Islands program. It was evident at the hearing that what DOE has done in the past, is doing, and its possible future actions, may not have been effectively communicated to the Congress and to others as well. DOE needs to make sure that its perspective is clearly articulated and publicized as a first step in ensuring that the ACHRE recommendation pertaining to this group is reasonably carried out. Other agencies may have similar specific communication issues and the IAWG staff may want to do joint planning.

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- 2) The IAWG recommends to NBAC that it begin an early assessment of **compensation for research-related injury**. Despite being addressed before by the HEW Secretary's Task Force (1977) and the President's Commission (1982), a definitive resolution of this long-standing social policy issue remains elusive.
- 3) NIH is leading an interagency initiative to fund the development of new knowledge related to the **informed consent process**. Despite the vigor with which all parties embrace the informed consent process, little is actually known or understood about it. Much of the ACHRE's commentary on current human subjects research is centered on informed consent, and NIH, NASA, VA, DOE, and DOD are committed to supporting research that will more fully illuminate the process.

- 4) ACHRE makes several recommendations to **Institutional Review Boards (IRBs)**. OPRR leads a national educational effort to showcase the ACHRE message. OPRR collaborates closely with Public Responsibility in Medicine & Research (PRIM&R), a Boston-based private, nonprofit organization, to stage an annual public meeting for individuals interested in the governance of human subjects research. More than 600 people attended the October 1995 PRIM&R meeting, at which the ACHRE recommendations were presented for the first time to the IRB community. OPRR has scheduled presentations and discussions of the ACHRE recommendations at upcoming national workshops in Atlanta (Apr. 11-12), Oklahoma City (June 3-5), Honolulu (July 25-26), Peoria (Sept. 26-27), and Houston (Nov. 1-2). The November 1995 PRIM&R annual conference (San Diego) is expected to address IRB implementation of the ACHRE recommendations. The IAWG is pleased to note the recent placement of the ACHRE report on the World Wide Web, where IRBs can examine its full text.
- 5) At a March 12 hearing, both the Chairman and Ranking Minority Member of the U.S. Senate Committee on Governmental Affairs expressed concerns about **human subjects protections in nonfederally funded research** -- a specific ACIIRE concern, as well. ACIIRE called for the IAWG to take steps to ensure that all human subjects are adequately protected, and the IAWG will work closely with the Committee as it pursues this issue. NBAC, too, can be expected to address this issue.

3/13/96 GBE

c:\mmIAWG

To: IAWG Staff
From: Steven Galson, Chief Medical Officer, DOE
Date: 18 March 1996
Subject: Draft options for notification and follow-up

We have assembled this information for discussion purposes only. Its purpose is to stimulate thought. This is **not** an all-inclusive list. Please **do not circulate or copy** this material.

DRAFT Options for Notification and Follow-Up
DO NOT CIRCULATE

OPTION	ADVANTAGES	ROADBLOCKS	COSTS
1. Identify, locate, notify & provide health care and psychological services to all research subjects & their families.	Meets demands of stakeholders including family members. Compensates research subjects for prior govt wrongs. Satisfies people's desire for information, to extent possible.	Enormous govt effort & expenditure. Funnels \$\$ away from prevention activities. Creates inequalities in treatment of persons harmed by govt activities.	Extremely high.
2. Identify, locate, notify & provide limited health benefits at VA hospitals to all research subjects.	Only covers those physical conditions that could reasonably be related to subjects' radiation exposure.	Enormous, expensive task. Requires legislation to expand access to VA medical system. Limits on coverage → litigation.	Very high.
3. Identify, locate, notify & provide research records to all research subjects. Provide medical follow-up to those who were under age 20 at time of study.	Benefits those at risk for longest period of time. Conforms with National Research Council recommendations concerning Alaska thyroid research.	Enormous, expensive task. No medical testing, intervention or special care available to most persons notified.	Very high.

4. Identify & locate those persons who received nasopharyngeal radium treatments during childhood; provide health care or other benefits.	Provides benefit to those at greatest elevated risk of death.	No screening procedures available for CNS, head and neck cancers. Singles out subset for notification and compensation.	High.
5. Locate & offer benefit to few research subjects already identified. Provide discount medical screening or health care services and automatic compensation for certain illnesses.	Satisfies demands of some of identified stakeholders if offers large benefit package.	Only covers persons in tiny fraction of 4000 documented experiments. Inequalities created among former research subjects → litigation.	High.
6. Resolve everything with lump-sum payment in class action suits.	Helps research subjects to finance their own medical monitoring and follow-up - if so desired - even if not medically warranted. Penalizes government for former wrongdoing. Concludes at least some cases.	Fails to satisfy all the stakeholders. May require ongoing funding mechanism to compensate subjects identified in future.	Medium → High.
7. Expand eligibility under Medicare to include research subjects.	Provides benefit to research subjects. Covers about half the costs of medical care.	Requires legislation. Politically very difficult. Creates inequalities in treatment. Hospital trust fund may run out of \$\$ soon.	High.

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8. Expand eligibility under Medicaid to include research subjects.	Provides benefit to research subjects.	Requires legislation. Politically extremely difficult at state and federal levels. Medicaid designed for low-income/welfare population, only. Programs underfunded. Medicaid participation refused by many doctors.	High.
9. Establish reduced-cost primary health clinics in towns/regions where larger experiments took place.	Provides benefits to some research subjects and general public in identified areas.	Offers no benefit to persons who have moved away from identified areas. Ongoing effort with no end point.	High.
10. Establish a trust fund financed by a special tax or by federal \$\$.	Could follow model of black lung or vaccine injury trust funds. Compensates research subjects.	Potentially costly, ongoing effort.	Medium >High.
11. Guarantee eligibility (but not payment) for health insurance at reasonable rate.	Ensures that most research subjects are able to afford health care.	Insurance companies must sign on.	Medium.
12. Provide benefits to persons who prove they were radiation research subjects.	Compensates some stakeholders.	Places burden on American public. May → scramble to identify and locate claimants.	Medium.

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13. Offer other benefits (e.g., low-dose dental x-ray equipment) to towns/regions where larger experiments took place.	Compatible with tradeable emissions approach. Acknowledges lack of available interventions & near-impossibility of identifying & locating individual research subjects. Benefits at least part of target population as well as general public in identified locations.	Offers no benefit to persons who have moved away from identified areas.	Low→Medium.
14. Sponsor large-scale nationwide health education/cancer prevention campaigns re: testes & thyroid testing.	Enhances health status of all Americans including research subjects. Follows preventive public health framework. Acknowledges the near-impossibility of identifying and locating individual research subjects.	Fails to compensate individual stakeholders.	Low.
15. Provide neither notification nor follow-up.	Conforms with recommendations of Advisory Committee. Acknowledges low level of risk & lack of available interventions.	Angers stakeholders. Fails to satisfy people's desires to know what happened and to receive some form of compensation.	Low.

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Submitted by Neil Otchin, VA:

Rev. 3/14/96

DRAFT**TALKING POINTS RELATING TO ATOMIC VETERANS FOR DISCUSSION
AT MEETING OF HUMAN RADIATION INTERAGENCY WORKING GROUP
(IAWG) STAFF, MARCH 19, 1996**

In response to Recommendation 6 in the ACIIRE Final Report concerning atomic veterans, a Department of Veterans Affairs (VA) Human Radiation Interagency Working Group (VAWG) has been established, led by the Under Secretary for Benefits, and met for the first time on March 13, 1996.

Although this meeting was open to the public and input from veterans and members of the public was solicited, no one submitted any comments. But proposals made at the Radiation Stakeholders Workshop, held on February 26-27, 1996, were provided to the VAWG for their consideration.

The mission of the VAWG is to consider updating and expanding the radioepidemiological tables. It will also review current laws and regulations relating to compensation of atomic veterans, consider the best balance for allocating resources between compensation and administrative costs, and make recommendations for improvements, if necessary.

The report of the VAWG is expected to be completed in the late spring of 1996.

It should be noted that major changes (such as adding illnesses to the presumptive list or extending the presumptions to veterans exposed in other radiation-risk activities) may require legislative action by Congress. Possible legislative remedies will be considered by the VAWG.

**RESPONSES TO PROPOSALS FROM THE RADIATION STAKEHOLDERS
WORKSHOP RELATING TO ATOMIC VETERANS****Summary of Proposals relating to Recommendation 6 (from DOE)**

1. All victims be compensated for the same illnesses - the presumptive list of diseases for miners should be the same as for veterans.

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RESPONSE: The VAWG was established specifically to address ACHRE Recommendation 6 and met for the first time on March 13, 1996. The meeting was open to the public and input from veterans and the public was invited. The VAWG will consider updating and expanding the radioepidemiological tables. It also will review current laws and regulations relating to compensation of Atomic Veterans, consider the best balance for allocating resources between compensation and administrative costs, and will make recommendations for improvements. This and other relevant proposals from the Radiation Stakeholders meeting have been provided to the VAWG for their consideration. It should be noted that major changes (such as adding illnesses to the presumptive list or extending presumptions to veterans exposed in other radiation-risk activities) may require legislative action by Congress.

2. A registry should be established for the offspring of atomic veterans who may have developed genetic or mutagenic health problems as a result of the parent or grandparent's exposure.

RESPONSE: See response to proposal 1.

3. Eleven additional radiation risk activities now identified should be included for compensation under existing laws and time constraints should be widened to include all these exposures.

RESPONSE: See response to proposal 1.

4. The radioepidemiological tables should be updated by an independent non-governmental or quasi-governmental scientific panel.

RESPONSE: See response to proposal 1.

5. All persons covered under RECA should be awarded the highest sum (\$100,000) now awarded only to uranium miners.

RESPONSE: This proposal is beyond the scope of Recommendation 6. RECA is administered by the DOJ. We defer to them to address this proposal.

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6. There should be no offset under RECA for benefits such as social security, VA benefits, etc.

RESPONSE: See response to proposal 5.

7. After all radiogenic illnesses have become presumptive, repeal 98-542 so that money goes to veterans, not contractors (not do dose reconstruction which is inaccurate, expensive, and veterans records are missing and incomplete).

RESPONSE: See response to proposal 1.

8. Survivors of veterans should receive money equivalent to the medical, hospital, burial and other expenses incurred in the veterans' final illnesses.

RESPONSE: See response to proposal 1.

9. On site presence should be sufficient criteria for compensation in the absence of evidence to the contrary.

RESPONSE: See response to proposal 1.

10. Fifty percent minimum service-connected disability should be granted with all associated rights and privileges.

RESPONSE: See response to proposal 1.

11. Nothing in this proposal precludes individual veterans or their families from pursuing any other remedies available to them.

RESPONSE: Not within the purview of the VA.

12. A process of fairness in the Atomic Veteran community that allows veterans to participate. Positions are desired on NBAC and any future related committees.

RESPONSE: See response to proposal 1.



Department of Energy
Washington, DC 20585

MEMORANDUM FOR DISTRIBUTION

FROM: Tara O'Toole, M.D., M.P.H.
Assistant Secretary
Environment, Safety and Health

A handwritten signature in black ink, appearing to read "Tara O'Toole", is written over the typed name and title.

SUBJECT: Status of Interagency Working Group Activities

At our last teleconference, on March 19, 1996, we discussed a number of Advisory Committee on Human Radiation Experiments recommendations including the problems presented by notification and medical follow-up (recommendation 4). Although there was no consensus on whether additional activities can or should be undertaken, it was agreed that we need to directly confront this recommendation by developing a detailed written discussion of the issues it presents.

Therefore, please provide a relatively detailed written description of what, if anything, your agency has done in terms of notification and follow-up; what, if any, plans you have for future activities in this area; and your general views on this subject. Please send this information to Elly Melamed. Her phone number is 202-586-6857 and her fax number is 202-586-3552 or 2268. Her Internet address is elly.melamed@hq.doe.gov.

In addition, it is important that we keep the draft "white paper" updated so that we are ready to provide information on our follow-up activities to the White House whenever it is required, and to others who may request it. Please send this information to Elly Melamed as well. A relatively detailed account of your activities would be useful. Please describe not only your efforts on the specific recommendations that relate to your agency, but also your activities in relation to those recommendations that apply to all agencies such as current research and openness.

Please send all this information to Elly Melamed no later than May 3, 1996. She will consolidate it and provide it back to you for review.



2

It is our understanding that the General Accounting Office is opening an additional investigation on follow-up to the Advisory Committee recommendations. They have asked us to schedule an Interagency Working Group teleconference at which they can initiate discussions with all the agencies at one time. They will then follow-up with individual visits to agencies (or you may hear from them sooner). This teleconference is scheduled for May 9, 1996 at 10:00 am.

Please call Elly if you have any questions.

Attachment

Distribution:

**Brian Latell
John Pereira**

**Gordon Soper
Joan Ma Pierre
Claud Bailey**

**Bob Nordhaus
Steve Galson
Lori Azim
Lisa Schiavo Blatt**

**Eva Plaza
Pat Glynn**

**D.A. Henderson
Wendy Baldwin
Gary Ellis**

**Harry Holloway
Earl Ferguson
Janis Stoklosa**

**T.J. Glauther
Eric Macris**

**Harold Gracey
Susan Mather
Neil Otchin
Bob Devesty**

**Phil Caplan
Rachel Levinson**

Barry Breen

Department of Energy
Assistant Secretary for Environment, Safety and Health
Office of Human Radiation Experiments

96 AUG 20 P 1 : 49

Presents

**Researching Human Radiation Experiments:
A Workshop for the Public**

- WHO:** Anyone interested in researching government records relating to human radiation experiments.
- HOW:** Please sign up by calling Kim McLeod at (202)586-9024 (seating is limited)
or
Write to: Department of Energy -- 7A-075
Office of Human Radiation Experiments (EH-8)
1000 Independence Ave., SW
Washington, D.C. 20585
- WHEN:** Friday, September 27, 1996, 9:00 a.m. -- 4:30 p.m.
- WHERE:** Room 6E-081, Department of Energy, 1000 Independence Ave, SW
Washington, D.C. 20585.
- WHAT:** Topics to be Covered
- Overview of the Department of Energy Human Radiation Experiment Project
 - Overview of Research Techniques
 - How to Find Records Pertinent to the Individual
 - How to Find Records of the Experiments
 - How to Find Records in Broad Topics Related to Human Radiation Experiments.
 - Using the Internet
 - Using the National Archives
 - How to perform research in medical literature
 - Accessing original records
 - Finding Aids -- what are they and how to use them
 - Using the records of the Advisory Committee on Human Radiation Experiments
 - Discussion of other repositories that may be useful to your research needs.



For Your Information



The Department of Energy's Office of Human Radiation Experiments is planning a workshop designed to help people research records located as part of the government-wide human radiation experiments project.

This workshop is part of the Department of Energy's continuing commitment to openness in government. It will be held in Washington DC on September 27, 1996 at the Forrestal Building.

The workshop is directed to members of the public who are interested in researching their own or a family members potential involvement in human radiation experiments. Researchers interested in specific experiments or groups of experiments as well as in the broader historical context in which experiments took place will also find it useful. The focus of the workshop will be on records of the Department of Energy but it will also include some information about records held by other Federal agencies and in private repositories.

The workshop will also provide an opportunity for participants to make suggestions for improving access to this and related material.

There is no fee for the workshop but registration is limited. More information is provided in the enclosed flyer. No travel or lodging assistance is available.

The attached brochure is being sent to key stakeholders to inform them of this opportunity. We welcome your participation. Please let us know if you know if you or your colleagues would like to attend or if you have any suggestions for people to be included in this mailing.

If you would like more information about the human radiation experiments workshop, please contact Karoline Gourley on (202) 586-1988 or Cindy Shindledecker on (202) 586-8230.

Thank you for your support.

Elly Melamed
Director, Office of Human Radiation Experiments
Office of Environment, Safety and Health
Department of Energy

Fax Cover Sheet

96 FEB 22 A 7:59

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Please Deliver to:

Phil Caplan

Fax #: 94562215
Company: WH

From:

AZIM, LORI

Fax #: 000-000-0000
Phone:

Pages: 25

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Message:

HUMAN RAD. EXP. STAKEHOLDER WKSHP
Attached please find: Confirmation letter
for workshop (an unsigned version),
prelim. draft Fed. response, and most
recent draft of the agenda. All
items are current as of 6 PM 2/21/96.
If you have questions, call me at
202/586-5319. Thanks!

This fax was sent using Castelle's FaxPress network fax server.

February 20, 1996

Dear Workshop Participant:

Thank you for agreeing to take part in the Human Radiation Experiments Stakeholder Workshop, sponsored by the Interagency Working Group on Human Radiation Experiments. This letter confirms your participation. The Workshop is scheduled for February 26-27, 1996 in Washington, DC at the United States Department of Agriculture Administration Building, 14th and Jefferson, on the Mall, Room 107. This building is located at the Smithsonian Metro stop, on the Orange Line. Exit the Metro on the Mall side.

The Workshop will be an information exchange between the government, experts, and citizens who believe they have been subjects in government-sponsored radiation research. Agencies involved have participated in the Interagency Working Group, established by President Clinton in January 1993 to research government records for information pertaining to these experiments. Included in the Working Group are the Departments of Energy, Defense, Veterans Affairs, Justice, and Health and Human Services, the Central Intelligence Agency, the National Aeronautics and Space Administration, and the Office of Management and Budget. Some congressional staff have also been invited.

The Interagency Working Group plans to discuss the Federal government's response to the recommendations of the independent Advisory Committee on Human Radiation Experiments. The Advisory Committee's final report was released last fall. The Workshop will provide a forum for stakeholder input into the Federal response to this report. I have enclosed a draft agenda, copies of the Interagency Working Group Staff's draft proposed response, and the Advisory Committee's Findings and Recommendations.

If you have materials for distribution at the Workshop, please bring at least 70 copies.

If you have any questions, please do not hesitate to call me at 202/586-6151 or Elly Melamed, Department of Energy, at 202/586-6837.

Sincerely,

Lori Azim
Environment, Safety and Health

Enclosures

**INTERAGENCY WORKING GROUP STAFF
STAKEHOLDER WORKSHOP
DRAFT AGENDA**

February 26th
Opening Day

- 8:00-9:00** Registration
- 9:00-9:15** Welcome and introductions by **Claud Bailey**, Deputy Director, Radiation Experiments Command Center, Department of Defense (DOD), and Conference Moderator
- 9:15-9:45** Opening Remarks by **Tara O'Toole**, Assistant Secretary for Environment, Safety and Health, Department of Energy (DOE), representing the Interagency Working Group; remarks to include a brief summary of the history and responsibilities of the IWG and expected products from this workshop
- 9:45-10:15** Conference Overview and Presentation of Ground Rules by **Doris Campos-Infantino**, Conference Facilitator
- 10:15-10:45** Panel Presentation/Discussion on Medical Monitoring and Notification (recommendation 4 of the ACHRE report)
Moderator: **Paul Seligman**, Deputy Assistant Secretary, Health Studies, Office of Environment Safety and Health, DOE
- Panelists: **Steven Galson**, Chief Medical Officer, DOE;
- Paul Schulte**, Acting Director, Education and Information Division, National Institute for Occupational Safety and Health (NIOSH);
- *Richard Miller**, Oil Chemical and Atomic Workers Union
- David Egilman**, CARS
- Stuart Farber**, Public Health Sciences

**Geoffrey Sea, Atomic Reclamation and
Conversion Project**

Topics to be discussed include: background on the medical monitoring and notification issues relating to human experiment subjects from both the government and the stakeholder perspective; government and stakeholder positions on responding to recommendation 4 including responses from the subjects of biomedical experiments who will discuss the impact of this recommendation.

Comments and questions from the audience will be solicited at the end of the panel.

Discussion Leaders: **Harold Bibeau**, Oregon Prisoner
Experiment Victims

Roy Campbell, Trinity Post

10:45-11:00 Break

11:00-12:00 Medical Monitoring, continued

12:00-1:30 Lunch

1:30-3:00 Panel Presentation/Discussion on Atomic Veterans and
Hanford Downwinders

(recommendations 5 and 6)

Moderator: **Susan Mather**, Assistant Chief Medical
Director for Public Health and Environmental Hazards,
Veterans Health Administration (VHA), Department of
Veterans Affairs (VA)

Panelists: **Neil Otchin**, Office of Public Health and
Environmental Hazards, Veterans Health
Administration, VA

Joan Ma Pierre, Director of Electronic
Systems, Defense Nuclear Agency

Henry Falk, Director, Center for
Environmental Health

Lincoln Grafhis, National Association of
Radiation Survivors

Oscar Rosen, National Association of Atomic
Veterans

Anthony Guarisco, Alliance of Atomic
Veterans

Tom Baile, Hanford Downwinders

Topics to be covered include: presentation of specific government initiatives in response to the ACHRE recommendations; a brief discussion of downwinder issues; presentations from affected groups who will discuss the impact on their communities and provide input on the government response along with alternative proposals for responding to the recommendations; scientific issues that impact recommendations 5 and 6. Comments and questions from the audience will be solicited at the end of the panel.

Discussion Leaders: **Walter Dasheno**, Pueblo
Indians

Pat Broudy, National
Association of Atomic Veterans

3:00-3:15

Break

3:15-4:45

Stakeholder Presentation and Open Forum

Moderators: **Claud Bailey**, DOD and **Acie Byrd**, National
Association of Atomic Veterans

Panelists: **Janet Gordon**, Citizens Call

Joseph Nardello, Survivors of Medical
Radiation Experiments

Gloria Nelson, Cincinnati Families of
Radiation Victims Organizations

Darcelle Sollars, Hanford Downwinders

Fred L. Boyce, Fernald "Science" Club

Ron Hamm, Vanderbilt Experiment Survivors

Gerald E. Mousso, Rochester Radiation
Victims/Survivors

This session is an opportunity for stakeholders to offer comments on the Advisory Committee report that go beyond responding to specific recommendations. Comments and questions from the audience will be solicited at the end of the panel.

4:45-5:00

First Day Wrap Up by **Claud Bailey** and **Doris Campos-Infantino**

February 27th
Second Day

8:00-8:15 Opening Remarks by **Claud Bailey**

8:15-9:45 Panel Presentation/Discussion on Issues in Current Human Research (recommendations 9 through 15)
Moderator: **Harry Holloway**, National Aeronautics and Space Administration (NASA)

Panelists: **Gary Ellis**, Department of Health and Human Services (HHS)

Susan Rose, Office of Energy Research, DOE

Gary L. Chadwick, Associate Director for Human Subject Protection, Office of Health Affairs, Food and Drug Administration

Sandra Reid, Oak Ridge Health Liaison

Jackie Kittrell, American Environmental Health Studies Project

Caroline Szeterla, Medical Ethicist, Ph.D. Candidate, University of TN

Topics to be covered include: presentation of specific agency initiatives in response to ACHRE recommendations on current human research; discussion of NBAC and other pending initiatives; issues of national security and human research; perspective of stakeholders on all aspects of the ACHRE recommendations on current human research. Comments and questions from the audience will be solicited at the end of the panel.

Discussion Leaders: **Thomas Ensign**, Citizen Soldier

Sandra Marlow, CARS

9:45-10:00 Break

10:00-11:30

Panel Presentation/Discussion on Uranium Miners, Marshall
Islanders and Alaskan Natives
(recommendations 7 and 8)

Moderator: **Eva Plaza**, Deputy Assistant Attorney General,
Department of Justice

Panelists: **Paul Yanowitch**, Department of Justice

Rick Hornung, Acting Director for Energy
Related Health Research, NIOSH

Thomas Bell, Director, Health Physics
Program Division, Office of Health Studies,
DOE

Dan Brown, Chief of Clinical Investigations,
Office of the Surgeon General, Air Force

Phil Harrison, Navaho Indians

Banny deBrun, Ambassador Designate of the
Marshall Islands

David Harding, Special Assistant to Mayor
George N. Ahmaogak, Sr., Alaskan North
Slope Borough

Topics to be covered include: presentation of specific
agency initiatives in response to recommendation 7 and 8;
perspective of indigenous peoples who will discuss the
impact on their community and provide input to the
government response; scientific issues that impact
recommendations 7 and 8. Comments and questions from
the audience will be solicited at the end of the panel.

Discussion Leaders: **Tim Benally**, Navaho Indians

Ray Koonuk, Mayor, Point
Hope, AK

Manual Pino, Pueblo Indians

11:30-1:00

Lunch

1:00-2:30Panel Presentation/Discussion on Openness in Government
(recommendation 17)Moderator: **Elly Melamed**, Acting Director, Office of
Human Radiation Experiments, DOEPanelists: **Roger Anders**, Office of Human Radiation
Experiments, DOE**Claud Bailey**, DOD**Mary Ronan**, National Archives and Records
Administration**Clifford Honicker**, American Environmental
Health Studies**Willa Nell Woodson**, Concerned Relatives of
Cancer Study Patients**Fred Allingham**, National Association of
Radiation Survivors

Topics to be covered include: continuing agency initiatives to ensure stakeholder access to government information; accessing records in the National Archives; accessing government information electronically; stakeholder perspectives on government openness and access to records; stakeholder input to agency access policies and efforts; declassification initiatives. Comments and questions from the audience will be solicited at the end of the panel.

Discussion Leader: **Dot McLeod**, I.T.S.O.R.**William Bires**, Alliance of Atomic
Veterans**2:30-2:45**

Break

2:45-3:30Open discussion on next steps, moderated by **Claud Bailey**

3:30-3:45Closing Remarks by **Phil Caplan** of the White House

NOTE ON PANELS: * indicates that the speaker has not yet been confirmed. With the exception of the stakeholder panel at the end of the first day, panels are one and a half hours and include six to eight panelists and a moderator who represent a mix of government, expert, and stakeholder perspectives. It is suggested that each panelist speak for no more than 7 to 10 minutes, followed by 15 minutes of discussion among panelists and 15 minutes of audience comments and questions. Panel moderators may reallocate the time according to the needs of their particular subject.

**INTERAGENCY WORKING GROUP STAFF
PRELIMINARY DRAFT RESPONSE TO THE
RECOMMENDATIONS OF THE
ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS**

BACKGROUND

The Advisory Committee on Human Radiation Experiments (ACHRE), chaired by bioethicist Dr. Ruth Faden of Johns Hopkins University, was established by President Clinton in January, 1994. Acting in cooperation with Federal agencies, which were directed by the President to search for records related to human radiation research and provide them to the Advisory Committee, the Committee was charged to provide expert advice to the Cabinet-level Interagency Working Group (IAWG) on scientific and ethical issues related to biomedical experiments involving ionizing radiation and to a list of intentional environmental releases of radiation. The Committee was to focus on the period 1944-1974 (when government-wide regulations on human subjects research were adopted) but was permitted to go beyond.

FINAL REPORT OF THE ADVISORY COMMITTEE

The Committee's report began by identifying the ethical standards that applied to the government and to the medical and research professions in the post-war period. Several "case studies" were then reviewed in detail, including the injections of plutonium into 18 hospital patients during World War II, research with prisoners, and research funded by the military on patients who had previously been exposed to total body irradiation in clinical settings. Intentional environment releases of radioactivity were also reviewed.

The Committee also considered issues related to some radiation exposures associated with government activities that are not experiments; that is, persons were not exposed for the purpose of research. These include atomic veterans, uranium miners, and residents of the Marshall Islands exposed to fallout from U.S. weapons testing.

Finally, the Committee reviewed 125 current or recent Federally-funded studies (not limited to radiation research) and interviewed patients at selected hospitals in order to gauge the adequacy of procedures for obtaining informed consent

from subjects and evaluating research risks and to sample attitudes toward human subject research.

The Advisory Committee's recommendations fall into three major areas: biomedical experiments and population exposures (1944-1974); current human subject protection; and secrecy and openness.

BIOMEDICAL EXPERIMENTS AND POPULATION EXPOSURES

Recommendation 1: Apology and compensation for three specific experiments where secrecy was involved and thus, individuals were denied the opportunity to pursue alleged grievances. These experiments involved Department of Energy (DOE) predecessor agencies and contractors only.

Recommendation 2: Apology and compensation where harm can be established, and where there was no prospect of direct medical benefit to the subject of the experiment. Several experiments and categories of experiments were proposed as candidates by the Committee.

Summary Response: The affected agencies, in coordination with the Department of Justice, are engaged in ongoing discussions with numerous claimant representatives concerning compensation issues.

Recommendation 3: Apology (without compensation) for experiments in which subjects were wronged but not harmed, i.e. where no consent or inadequate consent was obtained or the selection of the subjects constituted an injustice. One experiment was proposed as a candidate with the indication that there may be many others.

Summary Response: At the ceremony in which Dr. Faden presented him the report, President Clinton formally apologized on behalf of the government to the victims of human radiation experiments.

Recommendation 4: No need for subject notification and medical follow-up with criteria for subsequent notification if new experiments come to light.

Summary Response: The IAWG staff agrees with the Advisory Committee that no further response is warranted at this time and that the criteria set forth by the Committee is appropriate for evaluating future cases. The IAWG staff recognizes that this recommendation has generated a great deal of controversy among stakeholders and is soliciting stakeholder input.

Recommendation 5: Working with Congress to amend the Radiation Exposure Compensation Act of 1990 (RECA) to cover other exposed populations including Hanford.

Summary Response: The IAWG staff agrees with the Advisory Committee's concern about treating exposed populations fairly. Studies are underway that look at communities near the Hanford nuclear facility and at other sites including Fernald, Savannah River, Rocky Flats, and Oak Ridge. If information is forthcoming showing increased cancer resulting from the operation of DOE facilities, the government will work with Congress to amend existing laws to cover those affected.

Recommendation 6: Updating the epidemiologic tables that govern relief for veterans and improving the administration of the current laws governing compensation.

Summary Response: The Department of Veterans Affairs (VA) is establishing a Task Force led by the Undersecretary for Benefits to evaluate the likelihood of injury due to exposure to ionizing radiation. Representatives will be included from the Department of Defense (DOD) and the Department of Health and Human Services (HHS). The Task Force will also evaluate the efficacy of the current law and regulations relating to compensation of veterans whose illnesses or deaths may be attributable to their radiation exposures while in military service. The report is expected to be completed in the late spring of 1996. Specifically, the report will recommend the most feasible way to accomplish updating the epidemiologic tables; describe the administration of laws governing compensation of Atomic Veterans; and if appropriate recommend legislative and administrative changes that address the concerns identified by the Advisory Committee.

Recommendation 7: Working with Congress to possibly amend the Radiation Exposure Compensation Act of 1990 (RECA) relating to uranium miners. The changes would involve a widening of eligibility for compensation and a loosening of documentation requirements.

Summary Response: A committee of government scientists and attorneys with appropriate experience and expertise has been established to review the provisions in RECA that relate to compensation for uranium miners. The committee will also review DOJ's implementing regulations under RECA to ensure that they are not unduly restrictive. The committee consists of four scientists from the National Institute of Occupational Safety and Health (NIOSH) and the National Cancer Institute (NCI), and three attorneys from DOJ. The committee has held several meetings and anticipates submitting a report in late April 1996.

Recommendation 8: Continuing the current medical monitoring and treatment program for citizens of the Marshall Islands as long as any member of the exposed population remains alive. In addition, consideration should be given to adding the populations of other exposed atolls to the south and east; to involving the Marshall Islanders in the design of any further medical research conducted on them; and establishing an independent panel to review the adequacy of the current monitoring and treatment program.

Summary Response: Extensive analyses to date of radiation exposures in the Marshall Islands have indicated that the exposures to inhabitants of Ailuk and other northern Marshall Island atolls were a factor of 30-90 times less than at Rongelap and about 10-25 percent of those at Utirik based upon external dose measurements and on estimates of thyroid doses. The connection between radiation exposure and thyroid disease is the subject of several ongoing studies sponsored by DOE and managed by the Centers for Disease Control (CDC). If new data is developed to indicate that residents of atolls south and east of Bikini other than Rongelap and Utirik are at increased health risk, the U.S. Congress would need to consider expanding the current medical surveillance program.

The planned Joint Commission for Accreditation of Healthcare Organizations (JCAHO) review of the DOE Marshall Islands Program, administered by the Brookhaven National Laboratory, has recently been suspended. At the request

of the Government of the Republic of the Marshall Islands (RMI), the mechanism for such a review is being reevaluated based on further input from RMI. Discussions with the RMI Ambassador to the United States are currently being planned. RMI has requested a broader review that might be done by the National Research Council/National Academy of Sciences. The Department is considering the use of a Blue Ribbon Panel as another possible mechanism for this review.

CURRENT HUMAN SUBJECT PROTECTION

Overview: Responses to these recommendations involve a wide range of approaches, some of which are activities internal to the agencies and others which call upon external resources for implementation.

Among the responses are activities that are being implemented in the near term while others will require preliminary groundwork prior to full implementation. A third group of responses involve referring certain recommendations to the National Bioethics Advisory Commission (NBAC), an independent body established by the President through Executive Order 12975. (Presidential appointments to NBAC are pending.)

In general, agency activities in response to these recommendations fall into the following categories:

- Remanding specific Advisory Committee recommendations to NBAC which will provide expert advice on issues of bioethics;
- Developing educational programs in concert with external groups such as medical schools, universities, scientific societies, and others to strengthen activities in human subjects protection, to provide a forum for addressing ongoing as well as emerging issues in human subjects research, and to familiarize professionals engaged in non-Federally funded research with the ethical considerations in conducting research involving human subjects;

- Implementing training programs within Federal agencies to educate senior level officials on regulations and policies governing human subjects research;
- Reminding institutions conducting Federally funded research of their ongoing responsibilities with respect to Institutional Review Board (IRB) review;
- Pooling resources across agencies to conduct pilot projects to improve the efficiency and effectiveness of IRB review and to evaluate the government's system for the protection of human subject, and to establish processes for oversight or review of compliance;
- Considering the proposal of legislation to remedy some of the gaps in the current system for protecting human subjects.
- Implementing educational workshops and an active dialogue with international partners with whom Federal agencies cooperate in human research to develop common ethical principles and to ensure the rights of human subjects are protected, e.g. specific activities proposed by NASA.

Individual Recommendations and Summary Responses:

Recommendation 9: Efforts to ensure centrality of ethics in the conduct of human subjects research.

Summary Response: NBAC will provide advice and make recommendations to the National Science and Technology Council and other appropriate government entities in the areas of bioethical issues arising from research on human biology and behavior and the clinical applications of that research. NBAC will also identify broad principles to govern the ethical conduct of research. The IAWG staff has identified activities carried out in recent years to address this issue as well as major new efforts to upgrade or expand these activities that will be carried out by HHS, DOE, DOD, and the National Aeronautics and Space Administration (NASA). These are discussed below.

Recommendation 10: Changes IRBs in five critical areas: better focus on studies that pose more than minimal risk; better mechanisms for providing information to potential subjects that distinguishes research from treatment; realistically explain benefits, and clearly describe the potential for discomfort and pain; better mechanisms for providing information to potential subjects on sponsors and purposes of the research; better mechanisms for providing information to potential subjects on financial implications; and recognition that the IRBs must determine if the quality of the science justifies the risk.

Summary Response: The IAWG staff has agreed that agencies will instruct IRBs to be responsive to these recommendations and will provide oversight and review to ensure compliance. The IAWG staff will work with NBAC and the National Science and Technology Council in carrying out these recommendations.

Recommendation 11: A mechanism for the continuing interpretation of ethical rules in a public forum.

Summary Response: It is expected that NBAC will develop and maintain a forum for implementing this continuing review and interpretation of ethical rules.

Recommendation 12: Improving the rights and interests of military personnel with respect to human subject research by reviewing policies and procedures, educating officers and investigators, maximizing voluntariness, and maintaining a registry of volunteers.

Summary Response: DOD has agreed to a number of specific steps including revising directives or Military Department regulations to meet these proposals and incorporating appropriate training into courses for commanders and senior leadership as well as those involved in human subjects research.

Recommendation 13: Improving the current Federal system for protecting the rights and interests of human subjects in the areas of oversight, sanctions, and scope.

Summary Response: In addition to Federal agencies undertaking specific activities in response to this recommendation, some of which are described below, it is expected that NBAC will fully address this recommendation in carrying out its responsibilities.

Recommendation 14: Resolving the longstanding issue of whether and how all persons injured in the future from Federally funded research should be compensated.

Summary Response: It is expected that NBAC will address this issue.

Current Agency Activities: As part of the Executive Order, all agencies that are involved in current human subject research (not only those agencies represented on the IAWG) are required to review this research in the light of the Advisory Committee recommendations and report to NBAC. Agencies are currently completing this review. The following are specific activities that have been undertaken by IAWG agencies in relation to, or as a result of, this review.

The Department of Energy:

- Developed a newly revised handbook on protecting human subjects which is in pre-publication review. The handbook specifically addresses issues raised by the Advisory Committee on informed consent and classified research.
- Has begun a program of regular site visits, for education and review, to its facilities performing human subjects research. Each site will be visited approximately once every three years.
- Requested all DOE laboratories to provide a sample of current informed consent documents. These will be reviewed by a team charged with improving and monitoring the quality of these documents.
- Requested all laboratories to provide plans that detail local activities to improve the human subjects research review system.

- Issued a brochure to educate the DOE community on human subjects protection, updated its human subjects research database, held its annual human subjects workshop and created a World Wide Web Home Page on human subject programs.

The Department of Defense:

- Reviewed in detail DOD's existing policies and procedures for the protection of human subjects of research and has undertaken extensive revision of DOD Directive 3216.2, "Protection of Human Subjects in DOD Supported Research."
- Proposed changes to current policies that would:
 - Adopt investigator assurances of familiarity with the Nuremberg code, the Belmont Report, the Common Rule and related requirements;
 - Incorporate research ethics into graduate medical education curricula at Military Department teaching hospitals;
 - Include specific language in the revised directive that would emphasize the expedited review process for certain categories of minimal risk research that are detailed in the Common Rule (32 CFR 219);
 - Require education in human subjects regulations: in the executive level of training for commanders and senior civilians who may be involved in human subjects research and for individual investigators, IRB members, research administrators, and support personnel; and
 - Ensure that officers and senior NCOs in the chain of command not be present during research recruitment briefings of personnel under their command, and that an ombudsman be present at group recruitment briefings.

The National Aeronautics and Space Administration:

- Established an external Bioethics Policy Task Force to review all NASA human use research policies and procedures, chaired by Baruch Brody, Ph.D., Leon Jawarski Professor of Biomedical Ethics and Director of the Center for Ethics, Medicine and Public Issues at Baylor College of Medicine. The final report of the Task Force was provided on February 14, 1996. In collaboration with the Task Force, NASA enhanced the conduct of human subjects research so that it satisfies the requirements both of the Federal Common Rule and of the highest principles of research ethics.
- Updated the NASA Management Instruction (NMI) on the conduct of Human Research, issued on August 8, 1995, to reflect the Federal Common Rule and incorporate the relevant recommendations reflected in the Advisory Committee's final report. NASA Headquarters has also established a process for oversight and assurance.
- Conducted internal reviews at Headquarters, Johnson Space Center, and Ames Research Center to ensure that elements of the Common Rule and Advisory Committee recommendations were incorporated into agency and Center instructions.
- Because much of its future space research will be conducted with its partners on the International Space Station, has conducted the first in a series of forums to inform NASA's international biomedical community on issues related to the ethics of human subjects research. These workshops will effect a transnational understanding of the sensitivity to ethical issues in human research and ensure that all international partners support common ethical principles regarding the protection of human subjects. A common consent form for use on the international space station was agreed upon and will undergo periodic review.
- Initiated ethics forums on the Common Rule and protection of human subjects for its domestic biomedical research community.

The Central Intelligence Agency:

- Obtained the services of a prominent ethicist from the academic community to become a permanent voting member of the Agency's Human Subject Research Panel (HSRP).
- Revised agency regulations to indicate that all research carried out or sponsored by the Agency that utilizes human subjects shall be brought to the HSRP for approval. The Chairman must certify as exempt or approve a research proposal before it can proceed, and final approval rests with the Agency Director.
- Disseminated an Agency Bulletin to all employees specifying the rationale and function of the panel and necessity of referring human subject research to it for approval.
- Revised the Agency's Contracting Manual to guarantee that HSRP approval is obtained prior to approval of any contract involving human subject research.

The Department of Health and Human Services:

- Designated the Office for Protection from Research Risks, National Institutes of Health, to coordinate the preparation of the NBAC report with information drawn from the Public Health Service agencies and other operating divisions.
- Began activities to improve the procedures for protecting human subjects; for example, CDC is developing an on-line education system in research integrity and ethics that will be mandatory for investigators.
- Ensured that the Food and Drug Administration will respond to NBAC, not only as part of the Department, but also in its capacity as a regulator of research done by private industry.

Other Agencies:

- VA has planned IRB site visits to review procedures and their Office of Research and Development is reviewing its policy manual to identify any needed revisions.
- The Department of Education anticipates reporting to NBAC on ongoing training activities, and efforts to disseminate information through guidance documents and establish networks within that Department.
- The Environmental Protection Agency (EPA) is planning to issue an internal order implementing the Common Rule.
- The Consumer Product Safety Commission is updating and changing its internal documents and policies.

SECREC Y AND OPENNESS

Recommendation 15: a) No waiver of informed consent for classified research and informing the potential subjects of the identity of the sponsoring agency and that classified research is involved and b) For classified research, establishing an independent panel, whose records are permanent, to review scientific merit, risk/benefit, consent, and whether subjects need a security clearance.

Summary Response: The IAWG staff proposes that the President and/or Agency Head direct all departments and agencies that, effective immediately, there will be no waivers of informed consent for Federally funded classified research. Also, in all Federally funded classified research, two additional elements of information be provided when consent is sought from potential human subjects: 1) the identity of the sponsoring Federal agency and 2) a statement that the project involves classified information.

NBAC should then evaluate whether the Federal rules governing human subjects protection should be revised to codify these directives.

The IAWG staff is reluctant to propose creating a new oversight body for 15(b) but proposes to use the current IRB system which already must include at least

one member not affiliated with the institution. The IRBs could be directed to ensure that participation of non-government persons in reviewing the classified research by establishing a dedicated panel or ensuring that all IRB members have the necessary clearances.

Recommendation 16: a) Review by an independent panel of any planned environmental release where any aspect involves secrecy and b) Environmental oversight of classified programs (now done by EPA) should include keeping review records permanently and reporting to Congress.

Summary Response: EPA, in conjunction with Federal agencies conducting classified programs, has an initiative underway to improve environmental oversight and establish more rigorous regulatory procedures for classified facilities. Creating a new regulatory entity would add to the bureaucratic complexities of ensuring environmental safety but the views of EPA will be sought on whether additional steps are necessary to ensure robust environmental oversight of classified facilities and programs.

It is the understanding of the IAWG staff that the Advisory Committee is not asking for an expansion of EPA's authority under current laws. The IAWG staff proposes that permanent files on classified environmental impact statements and environmental review of classified activities be maintained by EPA.

Recommendation 17: Ensuring historical records are organized and accessible by 1) hastening movement of records to Archives; 2) making indexes and finding aids readily available; 3) improving public access to records in the custody of agencies; 4) maintaining records of document destruction; and 5) reviewing policies governing access to records of grantees and contractors.

Summary Response: For 1, 2, 3, and 5, the IAWG staff agrees with moving aggressively down the path to openness exemplified by this project and will work to make government records more accessible including using new technology to enhance access. For 4, the IAWG staff would propose making the records themselves of classified human subject research permanent and the records of destruction of all human subject research permanent.

Current Agency Activities: IAWG members have initiatives underway to ensure that information retrieved for the human radiation experiments project is readily available to the public, and to respond to specific Advisory Committee recommendations on openness.

The Department of Energy:

- The Department has produced three publications which include background information, record series descriptions, topical essays, a list of over 400 experiments, and oral histories. Most of this information, along with over 250,000 scanned historical documents, is located on the Internet, with paper copies of all documents at the Coordination and Information Center (CIC) in Nevada.
- In response to Advisory Committee recommendations, DOE is
 - Transferring over 3,000 cubic feet of records to the National Archives; and
 - Making finding aids to records still in agency custody more readily available to the public, and has prepared records access guidance.

The Department of Defense:

- The Department is preparing a guide similar to the DOE *Roadmap* that will describe DOD documents found during the human radiation records search. These documents will be available on the Internet and hard copies will be deposited at the CIC.
- DOD is expediting its response to Freedom of Information Act requests concerning human radiation experiment subjects.

The National Aeronautics and Space Administration:

- NASA will maintain a permanent collection of human radiation experiment records and database at Johnson Space Center and a process for submission of an response to requests for information has been developed.

- The agency is also working to make radiation research documents available on the Internet. The agency is creating a NASA Radiation Review Homepage which summarizes the agency's search and findings.

The Central Intelligence Agency:

- The CIA is transferring approximately 1,000 pages of declassified documents and a CIA Inspector General report on human subject research procedures to the National Archives. The documents will also be available on the Internet.
- The agency is reviewing for declassification a few documents relevant to the MKULTRA program that had not been previously declassified and released. An independent review of the CIA's record system has been undertaken by the National Archives and will be completed in approximately six months.

Health and Human Services and the Department of Veterans Affairs:

- These agencies are preparing documents for availability on the Internet sometime in the spring or summer of 1996. Paper copies have been transferred to the National Archives.

Recommendation 18 : a) Review of CIA recordkeeping by CIA Inspector General or other groups with special attention to facilitating public access and b) Priority given to declassification of CIA historical records such as MKULTRA.

Summary Response: The National Archives has begun a scheduled review of CIA's records management program, including records access issues and the CIA has agreed to give top priority to declassification of human subjects research records.

THE WHITE HOUSE
WASHINGTON

Phil - Here's the draft,
which I will give to
Mac Reed today.

CIA has concerns about
appeals process, c(2),
but suggests I circulate
as is. Call me with any
suggestions. Thanks
— Elizabeth.
6-5573

- stronger statement & clarity
- Appeal right to be with? maybe 2 steps → to
App, need first
- Needs to be part of larger package

--- DRAFT ---

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES THAT CONDUCT OR SUPPORT HUMAN SUBJECTS RESEARCH

SUBJECT: Strengthened Protections for Human Subjects of Classified Research

I have worked hard to restore trust and ensure openness in government. This memorandum will further our progress toward these goals by strengthening the Federal Government's protections for human subjects of classified research.

Advisory Committee
In January, 1994 I established the Advisory Committee on Human Radiation Experiments (ACHRE) to examine reports that the government had funded and conducted unethical human radiation experiments during the Cold War. I directed ACHRE to uncover the truth, recommend steps to right past wrongs, and propose ways to prevent unethical human subjects research from occurring in the future. In its October, 1995, final report, the Committee recommended, among other things, that the government modify its policy governing classified research on human subjects ("Recommendations for Balancing National Security Interests and the Rights of the Public," Recommendation 15, *Final Report, Advisory Committee on Human Radiation Experiments*). This memorandum sets forth policy changes in response to those recommendations.

ACHRE acknowledged that it is in the nation's interest to continue to allow the government to conduct classified research using human subjects where such research serves important national security interests. The Committee found, however, that classified human subjects research should be a "rare event" and that the "subjects of such research, as well as the interests of the public in openness in science and in government, deserve special protections." ACHRE was concerned about "exceptions to informed consent requirements and the absence of any special review and approval process for human research that is to be classified." ACHRE recommend that all classified research meet the following requirements:

- 1 - obtain informed consent from all human subjects;
- 2 - inform subjects of the identity of the sponsoring agency;
- 3 - inform subjects that the project involves classified research; and
- be approved by an "independent panel of nongovernmental experts and citizen representatives, all with the necessary security clearances."

addresses and implements these recommendations -
This memorandum implements recommendations 1-3. For classified research, it prohibits waiver of informed consent, requires researchers to disclose that the project is classified, and requires researchers to inform subjects of the sponsoring agency.

The memorandum also responds to ACHRE's call for a special review process for classified human subjects research. The memorandum requires that institutional review boards for secret projects include a non-governmental member, and establishes an appeals process so that any member of a review board that believes a project should not go forward can appeal the board's decision to approve it. This approach is less burdensome than that recommended by ACHRE but addresses ACHRE's underlying concerns.

Finally, this memorandum sets forth additional steps to ensure that classified human subjects research is rare. It requires the heads of Federal agencies to disclose annually the number of secret human subjects research projects undertaken by the agency. It also prohibits agencies from conducting secret human subjects research without first issuing the Federal Policy for the Protection of Human Subjects.

These steps, set forth in detail below, will preserve the government's ability to conduct any necessary classified research involving human subjects while ensuring adequate protection of research participants.

Sec 1. Modifications to the Federal Policy for the Protection of Human Subjects as it affects Classified Research. All agencies that conduct or support research involving human subjects shall, within 60 days, publish in the Federal Register the following revisions to the 1991 Federal Policy for the Protection of Human Subjects ("Common Rule") as it affects classified research.

(a) The agencies shall jointly propose to prohibit waiver of informed consent for classified research.

(b) The agencies shall jointly propose to require that in classified research involving human subjects, two additional elements of information be provided to potential subjects when consent is sought from subjects:

- 1) the identity of the sponsoring Federal agency; and
- 2) a statement that the project is classified.

(c) The agencies shall jointly propose to modify the institutional review board (IRB) approval process for classified human subjects research as follows:

(1) The Common Rule currently requires that each IRB "include at least one member who is not otherwise affiliated with the institution and who is not part of the a immediate family of a person who is affiliated with the institution." For classified research, the agencies shall define "not otherwise affiliated with the institution," as a non-governmental member with the appropriate security clearance.

(2) Under the Common Rule, research projects are approved by the IRB if a "majority of those [IRB] members present at a meeting" approve the project. For classified research, the agencies shall propose to permit any member of the IRB who does not believe a specific project should be approved by the IRB to appeal a majority decision to approve that project to the Director of the White House Office of Science and Technology Policy ("OSTP"). The Director of OSTP shall review the IRB's decision and approve or disapprove the project, or, at the Director's discretion, convene an IRB made up of non-governmental officials, each with the appropriate security clearances, to approve or disapprove the project.

Sec 2. Final rules Agencies shall, within one year, after considering any comment, promulgate final rules on the protection of human subjects of classified research. ⁸

Sec 3. Agency head approval of classified research projects. Agencies may not conduct a classified human subjects research project unless the agency head has personally approved the specific project.

- move up front
- not required
note?
need intro
like other
§5

Sec 4. Annual public disclosure of the number of classified research projects. Each agency head shall inform the Director of OSTP by September 30 of each year of the number of classified research projects involving human subjects underway on that date and of the number completed in the previous 12-month period. The Director of OSTP shall report the total number of classified research projects in each category to the President. The President shall transmit this number to Congressional armed services and intelligence committees and shall publish this number in the Federal Register.

Sec 5. Definitions. For purposes of this order, the terms "research" and "human subject" shall have the meaning set forth in the Common Rule.

Sec 6. No classified human subjects research without common rule. No agency shall conduct or support classified human subjects research without first proposing the Common Rule, including the changes set forth in this memorandum and any subsequent amendments and promulgating a final rule on the protection of human subjects of classified research. ⁹

E X E C U T I V E O F F I C E O F T H E P R E S I D E N T

02-Dec-1996 02:48pm

TO: (See Below)

FROM: Elizabeth E. Drye
 Domestic Policy Council

SUBJECT: Radiation experiments

Diane and Regas and I would like to reschedule this meeting for tomorrow, Tuesday, at 3:00 pm, room 222 OEOB. The meeting's purpose is to bring you up to date on the summary report, legislation, regulations, and Presidential memorandum agencies have developed in response to the Advisory Committee's recommendations, and to ask for your input on timing/form of a possible POTUS event and on necessary prior consultations.

PLEASE RSVP. THANKS

Distribution:

TO: Phillip Caplan
TO: Jonathan Foster
TO: Rachel E. Levinson
TO: Elgie Holstein
TO: Tracey E. Thornton
TO: David B. Fein
TO: T J. Glauthier
TO: Eric L. Macris

CC: Diane Regas

ACHRE Recommendation Follow-up
December 3, 1996

Introduction

Status of Pending Actions

Report Responding to ACHRE

✓ Summary

Outstanding issues

✓ Process for interagency approval

Legislation

✓ Radiation Exposure Compensation Act

✓ VA Bill - *Neuropharmacological Radiation - repropose bill*

✓ Possible Glenn bill - *not funded by Adm Gov't*

Regulations

✓ DOJ Regulations on RECA

Presidential memorandum on Classified Research

Next Steps

Public Stakeholders

Congressional Committees

Press event (timing, participation, outline)

*Comments by Mark Dec 9
then OMB interagency review process*

Comments

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THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS.

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Workshop Participants

Last	First	Affiliation
Albert	Tom	North Slope Borough, Alaska
Allingham	Fred	National Association of Radiation Survivors
Anders	Roger	Department of Energy
Azim	Lori	Department of Energy
Bailey	Claud	Department of Defense
Baldwin	Wendy	Department of Health and Human Services
Ballot	Joseph	Manillaq Association
Barker	Holly	Assistant to the Ambassador Designate of the Marshall Isla
Bell	Thomas	Department of Energy
Benally	Tim	Office of Navajo Uranium Workers
Bibeau	Harold	Oregon Prisoner Experiment Victims
Bires	William	Alliance of Atomic Veterans
Boyce	Fred L.	Fernald "Science" Club
Broudy	Pat	National Association of Atomic Veterans
Brown	Dan	Air Force
Brown	Cooper E.	National Committee for Radiation Victims
Byrd	Acie	National Alliance of Atomic Veterans
Campbell	Roy	Trinity Post
Campos-Infantino	Doris	Conference Facilitator
Caplan	Phil	the White House
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Collier	Kathy	Veterans Administration
Conn	Steve	Alaska Public Interest Research Group
Cummins	H. W.	Human Experiments Litigation Project (HELP)
Dasheno	Lt. Gov. Walter	Pueblo Indians
De Vesty	Bob	Veterans Administration
DeBrun	Banny	Ambassador Designate of the Marshall Islands
Egilman	David	Center for Atomic Radiation Studies (CARS)
Elliot	Anne	Department of Energy
Ellis	Gary	Department of Health and Human Services
England	Don	Veterans Administration
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Farber	Stuart	Public Health Sciences
Ferguson	Earl	NASA
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Glynn	Pat	Department of Justice
Gordon	Janet	Citizens Call
Gourley	Karoline	Department of Energy
Grafhis	Lincoln	National Association of Radiation Survivors
Guarisco	Anthony	Alliance of Atomic Veterans
Hamm	Rev. Ron	Vanderbilt Experiment Survivors

Workshop Participants

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Harrison	Phil	Navajo Uranium Radiation Victims Committee
Hetzler	Greg	Senate Government Affairs
Holloway	Harry	NASA
Honicker	Clifford	American Environmental Health Studies
Hopkins	Ann	Washington, DC
Hornung	Rick	Centers for Disease Control and Prevention
Hosty	Aaron K.	NASA
Jemmott	Adriane	Cummins & Brown
Joe	Ivan	DINE Care
Kelley	John	Washington, DC
Kittrell	Jackie	American Environmental Health Studies Project
Kline	Chris	Senate Government Affairs
Koonuk, Sr.	Mayor Ray	Point Hope, Alaska
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Lewis	Carol	Union Town, PA
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Lynch	Les	Bishopville, MD
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Martin	Conrad	Fund For Constitutional Government
Mather	Susan	Department of Veterans Affairs
McCarthy	Joan	National Association of Atomic Veterans
McCoy	David	Executive Court Reporters
McDermott	Joe	Department of the Interior
McKay	Charles	National Association of Atomic Veterans
McLeod	Dot	I.T.S.O.R.
McLeod	Kim	Department of Energy
Melamed	Elly	Department of Energy
Mendenhall	Carl	Department of Defense
Miller	Richard	Oil Chemical and Atomic Workers Union
Mouso	Gerald	Rochester Radiation Victims/Survivors Association
Nardella	Joseph	Survivors of Medical Radiation Experiments
Nelson	Gloria	Cincinnati Families of Radiation Victims Organizations
Nordhaus	Bob	Department of Energy
O'Toole	Tara	Department of Energy
Olson	Mary	Nuclear Information Resource Services
Otchin	Neil	Veterans Administration
Pereira	John	Central Intelligence Agency
Peroff	Kathy	Office of Management and Budget
Pierre	Joan Ma	Defense Nuclear Agency
Pino	Manual	Pueblo of Laguna
Plair	Gwendon	Concerned Relatives of Cancer Study Patients

Workshop Participants

Plaza	Eva	Department of Justice
Prather	Susan	North Slope Borough, Alaska
Purley	Dorothy	Pueblo at Paquate
Ramirez	Louise	Hiroshima/Nagasaki Peace Committee
Reid	Sandra	Oak Ridge Health Liaison
Ronan	Mary	National Archives and Records Administration
Roper	Dennis	North Slope Borough, Alaska
Rose	Susan	Department of Energy
Rosen	Oscar	National Association of Atomic Veterans
Russell	Walter	Manillaq Association
Schiavo	Lisa	Department of Energy
Schulte	Paul	National Institute for Occupational Safety and Health (NIOSH)
Sea	Geoffrey	Atomic Reclamation and Conversion Project
Seligman	Paul	Department of Energy
Shamoo	Adil	University of Maryland
Silverman	Maury	Silver Spring, MD
Smith	James	Centers for Disease Control and Protection
Smith	Tom	National Association for Atomic Veterans
Sollars	Darcelle	Hanford Downwinders
Soper	Gordon	Department of Defense
Stanley	Marilyn	I.T.S.O.R.
Steinbach	John	Hiroshima/Nagasaki Peace Committee
Stocklosa	Janis	NASA
Szeterla	Carolyn	University of TN
Thompson	John	Veterans Administration
Tucker	Kitty	Health & Energy Institute
Vogel	R.J.	Veterans Administration
Waconda	Al	Pueblo Laguna
Wallace	Mary Ann	Department of Energy
Weaver	Brenda	Hanford Downwinders
White	Robert	Veterans Administration
Wilkerson	Phil	American Legion
Williams	Don	Department of Defense
Winter	Celia	Veterans Administration
Woehrle	Mrs. Nelson	McClean, VA
Woodson	Willa Nell	Concerned Relatives of Cancer Study Patients
Yanowitch	Paul	Department of Justice
Zacchero	Mary Jo	Department of Energy
Zielinski	Bob	Department of Energy
Zill	Anne	Fund for Constitutional Government

DATE:

ASSISTANT SECRETARY
OFFICE OF ENVIRONMENT, SAFETY AND HEALTH
U.S. DEPARTMENT OF ENERGY
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TO:

STEVE NEWWIRTH
PHIL CAPLAN, TRET SCHROEDER

FROM:

EIN MELAMEL 586-6857
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NO. OF PAGES TO FOLLOW:

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7024

DRAFT AGENDA FOR INTERAGENCY WORKING GROUP STAKEHOLDER WORKSHOP

February 26th
Opening Day

8:00-9:00 Registration

9:00-9:15 Welcome and introductions by **Colonel Claud Bailey**, Deputy Director, Radiation Experiments Command Center, Department of Defense (DOD), and Conference Moderator

9:15-9:45 Opening Remarks by **Tara O'Toole**, Assistant Secretary for Environment, Safety and Health, Department of Energy (DOE), representing the Interagency Working Group; remarks to include a brief summary of the history and responsibilities of the IWG and expected products from this workshop

9:45-10:15 Conference Overview and Presentation of Ground Rules by **Doris Campos-Infantino**, Conference Facilitator

10:15-10:45 Panel Presentation/Discussion on Medical Monitoring and Notification (recommendation 4 of the ACHRE report)

Moderator: **Paul Sellman**, Deputy Assistant Secretary, Health Studies, Office of Environment Safety and Health, DOE

Panelists: **Steven Galson**, Chief Medical Officer, DOE;
Paul Schulte, Director, Education and Information Division, National Institute of Occupational Safety and Health (NIOSH)
Richard Miller, Oil Chemical and Atomic Workers Union
Three nominees from stakeholder groups

Topics to be discussed include: background on the medical monitoring and notification issues from both the government and the stakeholder perspective; government and stakeholder positions on responding to recommendation 4 including responses from the subjects of biomedical experiments. Comments and questions from the audience will be solicited at the end of the panel.

10:45-11:00 Break

11:00-12:00 Medical Monitoring, continued

12:00-1:30 Lunch

1:30-3:00 Panel Presentation/Discussion on Atomic Veterans, Marshall Islanders and Downwinders (recommendations 5, 6 and 8)

Moderator: **Susan Mather**, Assistant Chief Medical Director for Public Health and Environmental Hazards, Veterans Health Administration (VHA)

Panelists: **Neil OtchIn**, Office of Public Health and Environmental Hazards, VHA

Thomas Bell, Director, Health Physics Program Division, Office of Health Studies, DOE

John D. Boyce, Jr., Chief, Radiation Epidemiology Branch, Division of Cancer Etiology, National Cancer Institute

Three nominees from stakeholder groups

Topics to be covered include: presentation of specific VHA and DOE initiatives in response to the ACHRE recommendations; a brief discussion of downwinder issues; presentations from affected groups on their reaction to the recommendations and to the government response, along with alternative proposals for responding to the recommendations; scientific issues that impact recommendations 5, 6, and 8. Comments and questions from the audience will be solicited at the end of the panel.

3:00-3:15 Break

3:15-4:45 Stakeholder Presentation on Issues that the ACHRE failed to address or inadequately addressed

Moderator: **Colonel Bailey**, DOD

Panelists: **Five nominees from stakeholder groups**

This session is an opportunity for stakeholder groups to articulate to government representatives their concerns and/or criticisms of the Advisory Committee that go beyond responding to specific recommendations. This session provides an opportunity to comment on the general framing of remedies as articulated by the ACHRE, bias in their approach, and any other topics that the stakeholders choose. Comments and questions from the audience will be solicited at the end of the panel.

4:45-5:00 First Day Wrap up by **Colonel Bailey** and **Doris Campos-Infantino**

February 27th
Second Day

8:00-8:15 Opening Remarks by Colonel Bailey

8:15-9:45 Panel Presentation/Discussion on Issues in Current Human Research
(recommendations 9 through 15)

Moderator: Harry Holloway, National Aeronautics and Space
Administration (NASA)

Panelists: Gary Ellis, Department of Health and Human Services (HHS)
Susan Rose, Office of Energy Research, DOE
David Rothman, Columbia University, author of *Strangers at the*
Bedside
Three nominees from stakeholder groups

Topics to be covered include: presentation of specific agency initiatives in response to ACHRE recommendations on current human research; discussion of NBAC and other pending initiatives; issues of national security and human research; historical perspective on problems in current research; perspective of stakeholders on all aspects of the ACHRE recommendations on current human research. Comments and questions from the audience will be solicited at the end of the panel.

9:45-10:00 Break

10:00-11:30 Panel Presentation/Discussion on Uranium Miners, Alaskan Natives
and related issues (recommendation 7)

Moderator: Eva Plaza, Assistant Attorney General, Department of Justice

Panelists: Paul Yanowich, Department of Justice

Rick Hornung, Associate Director for Energy Related Health
Research, NIOSH

 **Jonathan Samet, School of Hygiene and Public Health, John Hopkins**
University

Three nominees from stakeholder groups

Topics to be covered include: presentation of specific agency initiatives in response to recommendation 7; perspective of indigenous peoples and their representatives to ACHRE recommendations; scientific issues that impact recommendation 7. Comments and questions from the audience will be solicited at the end of the panel.

11:30-1:00 Lunch

**1:00-2:30 Panel Presentation/Discussion on Openness in Government
(recommendation 17)**

**Moderator: Elly Melamed, Acting Director, Office of Human Radiation
Experiments, DOE**

**Panelists: Roger Anders, Office of Human Radiation Experiments, DOE
Claud Bailey, DOD
Michael Kurtz, Assistant Archivist for the Office of the National
Archives, National Archives and Records Administration
Three nominees from stakeholder groups**

Topics to be covered include: continuing agency initiatives to ensure stakeholder access to government information; accessing records in the National Archives; accessing government information electronically; stakeholder perspectives on government openness and access to records; stakeholder input to agency access policies and efforts; declassification initiatives. Comments and questions from the audience will be solicited at the end of the panel.

2:30-2:45 Break

2:45-3:30 Open discussion on next steps, moderated by Colonel Bailey

3:30-3:45 Closing Remarks by Phil Caplan of the White House

Note on panels: With the exception of the stakeholder panel at the end of the first day, panels are one and a half hours and include six panelists and a moderator who represent a mix of government, expert, and stakeholder perspectives. It is suggested that each panelist speak for no more than 10 minutes, followed by 15 minutes of discussion among panelists and 15 minutes of audience comments and questions. Panel moderators may reallocate the time according to the needs of their particular subject.

E. Cooper Brown
Task Force on Radiation and Human Rights
8935 Laurel Avenue
Takoma Park, MD 20912

edits
called into
Belly
2/13

Dear Cooper:

In order to avoid any misunderstandings about the Stakeholder Workshop that will be offered by the Interagency Working Group (IWG) on February 26th and 27th, I want to describe to you the purposes, products, and potential results that have been jointly agreed upon by the members of the IWG.

Most importantly, this workshop is an opportunity for us to listen to your ideas and concerns. We come to this workshop with an open mind and are ready to spend two days in dialogue with your task force and other stakeholders about how to respond appropriately to the recommendations of the Advisory Committee on Human Radiation Experiments (ACHRE). In order for this process to work effectively, however, it is important that you understand certain parameters.

First, the IWG has been chartered by the President to respond to the recommendations of the ACHRE. The IWG does not have the authority to rework these recommendations or in any way reopen the task assigned to the Advisory Committee. I do understand that the Task Force has broad criticisms of the work of the Committee and the workshop will offer you an opportunity to express these views. Please understand, however, that the IWG is ~~not the appropriate body to respond substantively to these concerns.~~

cannot cage for ACHRE's report

The primary purpose of this workshop is to listen to your ideas about the ACHRE recommendations before the IWG develops its response ~~for the President.~~ I would therefore emphasize that the more specifically you can direct your comments to responses to individual recommendations, the more likely you are to have a real impact on implementation.

on behalf of
the
agency

Second, the products of the workshop will be a full transcript of what is said which we will make available to all attendees; a revised and expanded report ~~to the President~~ written by the IWG after reflecting on what occurred at the workshop; and based on the potential identification of some areas where continuing dialogue with the stakeholders will be useful, a plan for implementing this dialogue. I want to be clear, however, that although we are fully committed to careful listening and reflection, the IWG has the responsibility to make the final decision about the response to the President.

draft
agency
response

Finally, the IWG can make no commitments about the shape or extent of the ongoing dialogue that may result from this workshop. Certainly one of our purposes is to look for areas in which this dialogue can usefully occur, but this may very likely be of a more limited nature than some Task Force members envision. This does not reflect a lack of respect for Task Force involvement but simply the realities of time, money and staff support.

The Government expended considerable resources and effort through the work of the Advisory Committee to review the issues associated with human radiation experiments, to solicit public comment, and to listen to stakeholder testimony and ideas. Sensible public policy and resource constraints make it imperative that our efforts from this point forward are focused on specific activities that are directed to recommendation implementation.

Let me close by saying that within these parameters, I have every hope that we can work effectively together to ensure that the openness initiative championed by the President and by the Secretary of Energy continues to result in real benefits for all citizens. I believe that the agenda we have developed and the products we envision reflect a reasonable accommodation to your proposals tempered by the realities of our purposes and resources. I look forward to seeing you at the end of February.

Sincerely,

Tara O'Toole, M.D., M.P.H.
Assistant Secretary
Environment Safety and Health
Department of Energy

— Lori Azum - Veteran's panel

ATOMIC VETERANS WORKING GROUP *Recommendations*

1. All radiation victims be compensated for the same illnesses and in the same amount -- regardless of site of exposure and that all illnesses be presumptive.
2. A registry be established for the offspring of Atomic Veterans who may have developed genetic or mutagenic health problems as a result of his/her parents or grandparents.
3. The 11 other additional radiation risk activities revealed by the Veterans Affairs Committee on Environmental Hazards be included for compensation in the existing laws. That the time constraints in those laws be widened to include all Atomic Veterans exposed in any fashion to ionizing radiation and that they be candidates under those laws or any other laws promulgated in the future for the benefit of Atomic Veterans.
4. That the radioepidemiological tables be updated by an independent non-governmental or quasi-governmental scientific panel.
5. We recommend that all persons covered under RECA be awarded the highest sum (\$100,000) now awarded only to uranium miners.
6. That there be no offset to any compensation awarded under RECA (Social benefits, VA benefits or any other governmental benefits that this law currently requires be offset.
7. After all the radiogenic illnesses have become presumptive -- that Public Law 98-542 be repealed. The contractors and personnel of NTPR have received over \$110,098,939 for doing dose reconstructions -- and only a handful of veterans and widows have been awarded benefits..
8. That survivors of Atomic Veterans be awarded monetary sums equivalent to the medical, hospital, burial and other expenses incurred in the veteran's final illness.
9. Onsite presence will be presumed sufficient criteria for compensation. That the Veterans Administration respect its commitment, i.e., presumption of correctness by veterans in the absence of evidence to the contrary.
10. That 50% (minimum) service-connected disability be granted with all attending rights and privileges.
11. Nothing in this proposal precludes individual veterans or their families from pursuing any other remedies available to them.
12. A process of fairness in the Atomic Veteran community that allows veterans to participate. We feel that we should have positions on the Bioethics Committee and any future related committees.

URANIUM MINERS: ISSUES FOR DECISION

The Radiation Exposure Compensation Act (RECA) Committee recommended changes to the statute and implementing regulations in its Final Report to the IAWG. The recommendations that raise the more difficult issues or are likely to be controversial are listed below, with salient pro and con points to aid the IAWG in reaching a final decision. The recommendations that are more straightforward and are likely to be widely accepted are listed at the end without additional comment; the explanation in the Executive Summary should prove sufficient.

1. Should the Administration propose legislation amending the RECA by adopting the threshold exposure criteria for lung cancer cases proposed by the Committee?

- the exposure criteria generated and proposed by the Committee reflect the latest credible evidence and scientific methodology;
- the proposed exposure criteria will compensate some miners denied compensation under the present statutory criteria;
- the proposed criteria will significantly raise the exposure criteria for some miners over the current RECA criteria, making it more difficult for these claimants to receive compensation; the affected miners would be those who get lung cancer at age sixty or older, and whose last exposure to radon progeny was more than twenty years ago;
- the Department of Justice will know by the end of the month the approximate percentage of miners who will be newly enfranchised and newly disenfranchised by the Committee's recommended criteria;

Subissue 1(a): Should the Administration propose threshold criteria based on radon progeny exposure (WLMs) or duration of employment?

- employment data is likely to be more accurate than historical mine radon measurements;
- concern about limited historical mine radon measurements led Advisory Committee to recommend use of employment-based criteria;
- radon progeny exposure criteria are more "accurate" -- they better fit the observed data;

- Committee recommends that if duration of employment criteria are proposed by Administration, exposure criteria also be adopted (i.e., a claimant would qualify under either set of criteria);

Subissue 1(b): What "level of assurance" should the Administration require for proposed criteria?

- "levels of assurance" is a crude relative of statistical confidence intervals, and accounts for uncertainty inherent in the statistical process; it denotes the range of values within which, to the defined degree of assurance, the true criterion lies;
- the higher the level of assurance demanded, the lower the resulting criteria imposed on the claimants, and, consequently, the more claimants eligible;
- the Committee generated three sets of criteria for IAWG consideration: without any added level of assurance, with an 80% level of assurance, and with a 90% level of assurance;
- if criteria unmodified for any level of assurance are used, 83% of lung cancer cases in the known study cohorts are eligible; if the 80% level of assurance criteria are used, 85% of lung cancer cases are eligible; if the 90% level of assurance criteria are used, 86% of lung cancer cases are eligible;
- Committee made no recommendation because the selection of the appropriate set of criteria is a policy choice.

2. Should the Administration propose legislation amending RECA by incorporating new threshold exposure criteria for nonmalignant respiratory disorders unrelated to radon progeny exposure?

- Committee concluded that the evidence linking radon exposure and NMRDs is ambiguous and insufficiently persuasive, at best; NMRDs most likely related to dust and agents in mining environment;
- it may be possible to generate more accurate and "fair" criteria based on employment duration;

- Committee recommended that the IAWG task some qualified body or agency to attempt to generate new criteria;
 - legislation proposing new criteria for NMRDs based on duration of employment may have collateral political effect; underground hard rock miners, other than uranium miners, also at risk for NMRDs.
3. Should the Attorney General modify the regulations to create a rebuttable presumption that all Navajo miners were nonsmokers?
- nonsmokers have to meet significantly lower threshold exposure criteria than smokers; rebuttable presumption would aid many Navajo now probably misclassified as smokers;
 - evidence indicating most Navajo smoked at rate less than minimum set in regulations for definition of smoker (one pack-year) comes from wide range of credible sources, including scientific studies performed prior to 1980;
 - use of ethnic-based classifications could pose legal (equal protection problem); could also create political problems among White miners who were light smokers.
4. Should the Attorney General modify in some fashion the regulations that require claimants to submit radiological proof of the presence of a compensable NMRD read by two NIOSH-certified "B"-readers?
- (a) Objections to present regulatory scheme
- (1) the interpretation of chest radiographs for pneumoconiosis is very subjective, and there is reasonable interreader variability, even among "B"-readers;
 - (2) the requirement that claimants have the chest radiograph read by "B"-readers is unnecessarily burdensome and oppressive;
 - (3) the Program's practice of selectively auditing certain "B"-readers, and having their interpretations reevaluated by NIOSH-selected "B"-readers, is unfair and unwarranted;

(b) Potential alternative procedures

(1) Do away with requirement of radiological proof of disease process entirely; require only proof of functional impairment;

- eliminates ambiguous, problematic means of proof, and minimizes burdens on claimants;
- Committee strongly opposes a scheme relying solely on functional impairment as proof of compensable disease
 - tests for functional impairment are not specific to the compensable NMRDs -- if functional impairment alone is required, will compensate many miners with noncompensable restrictive lung diseases and obstructive lung diseases (COPD, emphysema);
 - although radiographic interpretation is subjective and variable, can protect claimants from principal danger -- false negative interpretations -- by allowing claimants with functional impairment to submit high-resolution CT scans;

(2) Do away with requirement that chest radiographs be interpreted by "B"-readers only; accept interpretations of any radiologist or treating physician

- minimizes the burden on claimants
- if physician treating patient for compensable NMRD, should be sufficiently reliable diagnosis
- Committee supports continued exclusive use of "B"-readers to interpret radiographs
 - diagnosis by treating physician insufficient; standard treatment minimal, and difficult to devise effective check to eliminate insufficiently credible relationships
 - subjectivity and interreader variability significant where interpretations are by non-"B"-readers; these drawbacks and dangers of false negatives/positives

minimized where interpretation is by "B"-readers;

- limited number of "B"-readers submitting interpretations allows for some check on quality and potential fraud; allowing interpretations by any physician or radiologist would make any auditing process minimally effective, if at all;
 - burdens on claimants minimal; can send chest radiographs through mail, and many claimants represented by attorneys
- (3) Retain requirement of radiological proof of disease, but require HRCTs instead of chest radiographs
- HRCTs much more selective and sensitive than chest radiographs; significantly decrease the rate of false negative/positive interpretations;
 - Committee recommends retaining chest radiograph requirement in first instance:
 - HRCTs expensive (\$600) and appreciable (and potentially unnecessary) dose of radiation
 - can insure against risk of false negative by allowing claimants with functional impairment and negative chest radiograph to submit HRCTs; gives claimants benefit of false positives;
- (4) Accept diagnosis of compensable NMRD if made by federal physician (i.e., IHS radiologist)
- where diagnosis by federal physician, little risk of fraud;
 - meets Program concern with fraudulent or unprofessional interpretations, but does not meet concern that difficulty of interpretation requires experts -- "B"-readers;
 - will help only claimants with access to federal medical facilities (Navajo, veterans); will not solve problem for most miner-claimants;
 - could impose severe strain on limited federal resources in affected communities -- i.e., one radiologist for all IHS facilities on Navajo reservation

- (5) Modify Program audit procedure to bar selective auditing of specific "B"-readers; instead, have all "B"-readers regularly audited to ensure readings are within the bounds of reasonable professional interpretation
- Committee recommendation
 - selective auditing and rereading by Program consultants has resulted in perception in affected community that Program biased against compensation;
 - selective audit procedure does not eliminate problematic or biased readers from submitting additional readings;
 - modifying audit procedure in tandem with acceptance of HRCTs (if functional impairment and negative chest radiograph) would meet most of claimants' objections to "B"-reader requirement;
 - deferential standard of review on audit would allow claimants to continue to choose "B"-readers whose interpretations fall in more "liberal" end of spectrum of acceptable, reasonable interpretations.

Non-controversial Recommendations

5. Should the Administration propose an amendment to the RECA to broaden coverage for silicosis and pneumoconiosis to all miners covered by the statute, not just miners who mined on Indian Reservations?
6. Should the Attorney General be requested to modify the regulations to define the term nonsmoker to include lung cancer claimants who stopped smoking 15 years or more before the date of diagnosis?
7. Should the Attorney General be requested to modify the regulations to accept high-resolution CT scans as proof of the presence of a compensable NMRD?
8. Should the Attorney General be requested to modify the regulations to accept as proof of a compensable disease the results of a lung biopsy?
9. Should the Attorney General be requested to modify the regulations to adopt ethnic-specific pulmonary function

standards to determine functional impairment in NMRD claimants?

10. Should the Attorney General be requested to modify the regulations to define functional impairment for NMRD claimants consistent with the American Thoracic Society recommended definition of impairment?

RADIATION EXPOSURE COMPENSATION ACT COMMITTEE

FINAL REPORT EXECUTIVE SUMMARY

SUBMITTED TO THE
HUMAN RADIATION INTERAGENCY WORKING GROUP
JUNE 6, 1996

RADIATION EXPOSURE COMPENSATION ACT COMMITTEE

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EXECUTIVE SUMMARY

On October 15, 1990, Congress passed the Radiation Exposure Compensation Act of 1990 (RECA or Act), which provided for compassionate payments to individuals who suffered from specified diseases presumably as a result of exposure to radiation in connection with the federal government's nuclear weapons testing program. Among those eligible for compensation under the Act are individuals who were employed in underground uranium mines in Arizona, Colorado, New Mexico, Utah or Wyoming during the 1947 to 1971 time period, who were exposed to specified minimum levels of radon, and who contracted specified lung disorders. The Department of Justice administers the RECA through the Radiation Exposure Compensation Program (Program).

The provisions of the RECA defining compensation for uranium miners have been characterized by critics as unfair and inconsistent with current scientific information. The regulations of the Department of Justice implementing the statute have also been criticized as being unnecessarily stringent and unreasonably burdensome. These criticisms were noted, and in some cases affirmed, by the President's Advisory Committee on Human Radiation Experiments, charged by the President to investigate the history of human radiation experimentation conducted by the federal government during the Cold War period. In its Final Report, issued on October 3, 1995, the Advisory Committee recommended, among other things, that the Administration review the provisions of RECA governing compensation for uranium miners and the implementing regulations

to ensure that they are fair, consistent with current scientific evidence, and compatible with the objectives of the Act.

In response to this recommendation, the Human Radiation Interagency Working Group established a committee of government scientists and attorneys to study the RECA provisions relating to underground uranium miners and the Department's implementing regulations. The Interagency Working Group charged the committee to respond within six months with a list of recommended statutory amendments and modifications to the regulations. The accompanying Report is intended to fulfill this obligation.

Listed below is a summary of the Committee's recommendations for changes to the statute and implementing regulations.

I. Proposed Amendments to the Statute

RECOMMENDATION 1: Amend the Act to incorporate a new set of compensation criteria for lung cancer based on minimum levels of radon exposure

The legislative history of the RECA convinces us that Congress set the exposure criteria at a level it thought would compensate those miners whose lung cancer more likely than not was caused by their exposure to radon progeny in the mines. The latest epidemiological data suggest that the current exposure criteria do not accurately distinguish among lung cancer cases on a "more likely than not" basis, and, therefore, do not effectively implement congressional intent. The present statutory criteria, we conclude, exclude some deserving miners and inappropriately compensate others.

In place of the present criteria, we recommend alternative exposure-based criteria that more accurately effect congressional intent. To generate these criteria we modified a relative risk model developed by the National Research Council's Committee on the Biological Effects of Ionizing Radiations (BEIR IV), and applied it to updated cohorts of Colorado Plateau and New Mexico underground uranium miners. The model conditions compensation on the variables that the latest data indicate most significantly affect the risk of lung cancer in underground uranium miners: cumulative exposure to radon progeny, attained age (the age at which the claimant developed cancer), and time since last exposure.

RECOMMENDATION 2: Amend the Act to incorporate an alternative set of criteria conditioning compensation on minimum duration of employment

The present RECA criteria and the alternatives discussed in Recommendation 1, above, are based in part on a measure of the claimant's cumulative exposure to radon, which is calculated from historical measurements of radon levels in the mines. These historical measurements are widely believed to be inaccurate and imprecise measures of miners' true exposures; for many mines, measurements either do not exist at all or do not exist for all work areas. Using the modified BEIR-IV risk model, we generated compensation criteria for lung cancer based on duration of employment underground in uranium mines, instead of cumulative exposure.

The exposure-based criteria we propose better "fit" the observed data, and will, therefore, result in a more valid

characterization of a miner's risk than the proposed employment duration-based criteria. Nonetheless, we recommend a claimant should be allowed to qualify under either the exposure or duration standard.

RECOMMENDATION 3: Amend the Act to condition compensation for nonmalignant respiratory disease on different criteria

The present statutory criteria require that a claimant prove exposure to minimum levels of radon as a condition for compensation for one of the specified nonmalignant respiratory diseases (NMRD) -- pulmonary fibrosis, corpulmonale related to fibrosis, silicosis and pneumoconiosis. Although it is physiologically plausible that radon causes pulmonary fibrosis, or contributes to the development of silicosis, the two principal compensable NMRDs, the prevailing hypothesis in the scientific community is that the more likely cause of these diseases is exposure to various agents in the mining environment, most notably silica and other dusts. The radon levels in a mine are not believed to be a good proxy for dust levels, so there is no scientifically justifiable reason to tie NMRDs to radon exposure levels.

Unlike the case with lung cancer, above, we do not recommend specific alternative criteria in this case. It is unclear whether and to what extent reliable data are available, and whether appropriate standards can be derived from available data. The Committee did not have the time to identify and analyze the extant data. We recommend that such a project be undertaken.

RECOMMENDATION 4: Amend the Act to extent compensation for silicosis or pneumoconiosis to all miners covered by the Act

The RECA limits compensation for two NMRDs -- silicosis and pneumoconiosis -- to miners who were employed in mines on an Indian reservation. The principal risk factor for silicosis (or pneumoconiosis) is the amount of silica released in the mining environment. The mines both off and on the Navajo Reservation were in silica-bearing rock, and there is no reason to believe the risk of silicosis was any greater in mines on than off the Reservation. We recommend that this statutory limitation be eliminated.

II. Recommended Modifications to the Department of Justice Regulations

RECOMMENDATION 5: Modify the regulations to presume all Native Americans are nonsmokers, absent evidence to the contrary

The existing compensation criteria for both lung cancer and NMRDs set different minimum exposure levels depending on a claimant's smoking status; smokers must meet a higher exposure threshold, presumably to offset the risks from smoking. The regulations define a smoker as one who has smoked one pack-year of cigarettes or more. Smoking status is generally derived from references in historical health records. Most smoking information in the records is self-reported. The overwhelming number of Native American underground uranium miners were Navajo. Navajo generally smoked only for ceremonial purposes or not at all; those who smoked did so at substantially lower rates than their White counterparts. Nonetheless, many Navajo reported themselves as smokers, though their consumption was less than one pack-year. We recommend, therefore, that all Native American's be considered nonsmokers, absent evidence in any individual's record of a smoking rate greater than one pack-year.

RECOMMENDATION 6: Modify the definition of nonsmoker in the regulations to include certain ex-smokers

The regulations presume that once a smoker, always a smoker. The latest evidence suggests that the risk of lung cancer in an ex-smoker declines over time, approaching, though possibly never returning, to the background risk of a nonsmoker. The rate of decline of risk depends, among other factors, on the number of cigarettes smoked per day, the number of years the individual smoked, their age at time of cessation, and the years since cessation. We recommend that a claimant be classified as a nonsmoker if he can prove he stopped smoking at least 15 years before diagnosis of lung cancer.

RECOMMENDATION 7: Modify the regulations to allow proof of NMRD by HRCT scans

The regulations require that a claimant prove both physical changes indicating the presence of a compensable NMRD and functional pulmonary impairment. Proof of the presence of disease is made by submitting chest radiographs (x-rays) interpreted by two "B"-readers, physicians specially certified by National Institute for Occupational Safety and Health (NIOSH) as proficient in the classification of radiographic evidence of pneumoconioses (occupational dust-induced lung diseases). It is

well established that chest radiographs, even when interpreted by "B"-readers, have significant false negative and false positive rates. Thus, a claimant with evidence of functional impairment may be denied compensation because a chest radiograph does not show evidence of disease; conversely, a chest radiograph may falsely be read to show evidence of a compensable disease though that disease is not in fact present. Because of the false negative rate associated with the detection of pneumoconioses by chest radiograph, some critics argue that the Program should dispense with the requirement that the claimant submit radiographic evidence of disease process.

We recommend that the Program continue to require radiographic proof of disease. We further recommend that the Program accept high-resolution computed tomography (HRCT) scans as proof of change to lung structure where the claimant has proven physiological pulmonary impairment yet chest radiographs are negative. HRCT is a more sensitive and specific diagnostic technology: in an appreciable number of cases, it will pick up disease that does not appear on chest radiographs, and allows for more accurate diagnosis.

RECOMMENDATION 8: Modify the regulations to allow proof of disease process by biopsy from all miners

The regulations allow surviving beneficiaries to prove a deceased miner had a compensable NMRD through biopsy results, but do not allow living miners to submit this form of proof. This was done to avoid creating an incentive among living miners for invasive and dangerous surgery. Biopsy results, however, are the "gold" standard for diagnosis. We recommend that where a biopsy is performed for a medically-justified reason independent of the desire for compensation, it be accepted as proof of lung abnormality. We also recommend the Program reserve the right to demand appropriate medical evidence demonstrating the justification for the procedure.

RECOMMENDATION 9: Modify the regulations to establish a random audit procedure for "B"-reader reports

The diagnosis of fibrosis or pneumoconiosis by chest radiograph is an inexact science. It is well established that there is significant variability in radiographic interpretation among readers, including "B"-readers, particularly where the disease is in a mild state. The Program has the interpretive reports of some "B"-readers reviewed by experts selected by NIOSH where there may be a question about the accuracy of the interpretation. Some in the affected community perceive the

Program as selectively reviewing the reports of the most "liberal" "B"-readers, and thus evidencing a bias against compensation. Some critics also recommend dispensing with the "B"-reader requirement as unnecessary.

We recommend that the Program retain the requirement that chest radiographs be interpreted by certified "B"-readers. We further recommend that the Program adopt an audit procedure that will provide for the review of all "B"-readers, and thus protect against the possibility of improper application of the professional diagnostic standards, yet eliminate the possibility of selective enforcement.

RECOMMENDATION 10: Modify the regulations to adopt ethnic-specific pulmonary function standards for proof of impairment

To prove pulmonary impairment, a claimant must demonstrate reduced lung function as measured by pulmonary function tests or arterial blood gas studies. The regulations define impairment on pulmonary function tests as 25% or more reduction in lung function measured against standard values derived from "normal" population, normed by age, gender and height. The regulations use one set of standard values for pulmonary function for all claimants. Pulmonary function can vary by ethnicity and race, however. Standards for Southwest Native Americans are significantly different than those derived from Whites. We recommend that separate pulmonary function criteria derived for Southwest Native Americans be adopted.

RECOMMENDATION 11: Modify the pulmonary function standards in the regulations to define impairment consistent with the recommendations of the ATS

As noted in Recommendation 10, above, the regulations define impairment as 25% or more reduction in lung function as measured by pulmonary function tests. The American Thoracic Society (ATS) and American Medical Association (AMA) recommend guidelines that define impairment as more than a 20% reduction, measured against standard reference values. We recommend that the regulations be modified to define impairment consistent with the guidelines recommended by the ATS and AMA.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Chief of Staff

Washington, D.C. 20201

FACSIMILE

DATE JUN 27 1994

TO: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):
Phil Caplan
Office of Cabinet Affairs
The White House
PHONE
PHONE: 456-2572

FROM: (NAME, ORGANIZATION, CITY/STATE AND PHONE NUMBER):
Jill Hargis
DHHS
PHONE: 690-6133

RECIPIENT'S FAX NUMBER: () 456-6704

NUMBER OF PAGES TO SEND (INCLUDING COVER SHEET): 3

COMMENTS:

SENT BY:

6-23-94 : 4:08PM :

CDC policy co-ord.-

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Date: 6/23/94		Time: 4:08 PM	
To: Mr. Chuck Brocius		From: Dave Utterbach	
Subject: INEL Research Bureau		Phone: 208-533-5346	
Address: P.O. Box 110		Fax: 208-533-5340	
City: Troy, Idaho 83271			

Dave Utterbach NIOSH

1-513-841-4400

June, 1994

4470 fsg

Mr. Chuck Brocius
INEL Research Bureau
P.O. Box 110
Troy, Idaho 83271

Dear Mr. Brocius:

This is in response to your March 22, 1994 letter to the President regarding studies being conducted by the Centers for Disease Control (CDC) at the Idaho National Engineering Laboratory (INEL). Your letter was forwarded to this office for response.

As you state in your letter, two studies are being conducted at the INEL in cooperation with the Department of Energy. One study involves determining the radiation doses to the public near DOE facilities from operations at these facilities. This is referred to as the "dose reconstruction" study. The second study involves evaluating the health of workers at DOE facilities, referred to as the "worker" study.

With regard to the dose reconstruction study, the Naval Nuclear Propulsion Program agreed at the inception of the study two years ago that the Naval Reactors Facility (NRF) should be included in the study of off-site doses. CDC has had full access to all classified and unclassified NRF records pertaining to radionuclide emissions, and has fully included NRF in their study. CDC has visited NRF to review records on several occasions, most recently in May, 1994. This has been explained to you in various public meetings by CDC. This study is ongoing and the concerns you have identified are not shared by the people performing the work.

NRF is not included in the INEL worker study because the NRF facility is unlike any other INEL facility. In the first place, NRF is primarily a Navy training facility. The vast majority of people at NRF, who might be included in such a study, are Navy sailors, not DOE employees or contractors. Students typically spend six months at the site and are then transferred to fleet assignments. Navy staff spend only a few years at the site. Thus, the population is quite different than at other INEL sites. In fact, including this large population of short term, very low exposure personnel in the study, would likely skew the data base, resulting in a lower average lifetime exposure for a "typical" INEL worker.

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6-23-94 : 4:10PM :

CDC policy co-ord.-

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Second, as a training, vice production facility, students and workers at NRP do not routinely process chemically hazardous or radioactive materials. Thus, health considerations at NRP would not be related to those elsewhere at INEL.

Third, independent researchers have previously conducted health studies of workers and sailors in the Naval Nuclear Propulsion Program. These studies, which included the majority of Naval personnel who have been stationed at NRP, and appropriately included any exposures received there, have not indicated any adverse health effects related to Naval Nuclear Propulsion Program work.

With regard to the civilians working at NRP, typically they have not worked at other INEL facilities. For the few cases where former NRP workers are employed at other INEL facilities, pertinent records are being made available for review and inclusion in the INEL worker study.

Both NRC and the Naval Nuclear Propulsion Program believe that our approach best serves reaching the mutual goal of an efficient, thorough, and scientifically valid worker study.

I trust this responds to your concerns.

Sincerely,

Jonathan Kiell
Naval Reactors

THE WHITE HOUSE
WASHINGTON

June 14, 1994

MEMORANDUM FOR JILL HARGIS
GORDON SOPER

FROM: Phil Caplan *TC*
SUBJECT: INEL Dose Reconstruction Study

John Podesta received the attached letter requesting information about the US Navy Nuclear Propulsion Program and a CDC dosimetry data study.

I would appreciate it if you could please respond directly to the letter and coordinate a response between yourselves if this becomes necessary.

Please send me a copy when the response is complete. I will let John know I have referred the letter to you.

Thank you.

cc: Paul Richard, Office of the Staff Secretary



Environmental Defense Institute

P.O. Box 220
Troy, ID 83871
208-835-6152

91 MAY 28 AM 10:04

John Podesta
Assistant to the President
The White House
Washington, DC 20500

May 23, 1994

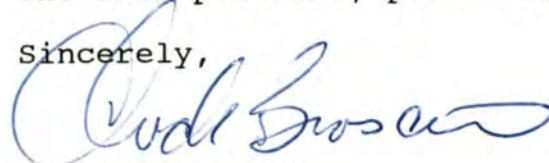
Dear Mr. Podesta,

I promised to send you information explaining the background to a question I asked you at the National Press Club symposium on openness and secrecy May 18.

The question I asked you was this. The US Navy Nuclear Propulsion Program has refused to release its worker exposure records and dosimetry data to the Centers for Disease Control's National Institute for Occupational Safety and Health (NIOSH) which is conducting an INEL Dose Reconstruction study. Do you consider this a contradiction to the new policy you have laid out today and the President's openness policy?

Enclosed please find a copy of a letter to President Clinton that explains current problems of access to classified and other wise restricted information at the Department of Energy's Idaho National Engineering Laboratory (INEL).

I would greatly appreciate an answer to the above question and any additional rational that your answer is based on. If there is any additional information I can send to further explain the INEL problems, please feel free to call.

Sincerely,


Chuck Brosious
Executive Director

cc:
Brian Siebert, Director, DOE Declassification
David Satcher, Director, Centers for Disease Control

INEL Research Bureau

P.O. Box 220
Troy, Idaho 83871
208-835-6152

Project of
Environmental
Defense Institute, Inc

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Moscow, ID

Wood River
Chapter
Idaho
Conservation
League
Ketchum, ID

Honorable
Bill Clinton
President
1600 Pennsylvania Av.
Washington, DC 20500

March 28, 1994

Dear President Clinton,

RE: Declassifying DOE and Navy documents for use in CDC's
Dose-Reconstruction study

The INEL Research Bureau respectfully requests that you intervene in a dispute between executive departments over declassification of documents essential to health studies nearing Phase I completion.

The Centers for Disease Control (CDC) initiated in October 1992 a full scale dose-reconstruction health study at the Department of Energy's (DOE) Idaho National Engineering Laboratory (INEL). Two of CDC's centers are involved in these studies. The National Center for Environmental Health (NCEH) is focused on off-site impacts and the National Institute for Occupational Safety and Health (NIOSH) is focused on on-site INEL worker studies.

Phase I of CDC's INEL dose-reconstruction study is nearing its two year completion. The primary tasks in Phase I is document retrieval and review and the creation of a document data base. NCEH has requested that DOE/Idaho initiate declassification reviews as documents are identified. NCEH's request was based on three rationales. First, the agency has publicly committed to using only declassified documents in its research. Second, the agency wanted to prioritize which documents were to be declassified first. Third, the agency wanted DOE-ID to start immediately on declassification so that the work load for both NCEH and DOE would be spread over the full two year Phase I period. Additionally, NCEH wanted to eliminate any lack of resource excuse DOE may generate to delay the declassification process.

DOE/ID informed NCEH that they would only consider one complete request for declassification. This obfuscation has effectively made it nearly impossible to include all 400+ identified classified documents into the Phase I document retrieval/review and inclusion into the document data base. Westinghouse Idaho has also on multiple occasions refused access by CDC researchers to document repositories at INEL.

NIOSH is faced with similar resistance in its INEL worker dose-reconstruction study. The Naval Reactor Facility, a major employer on the INEL site, has refused access by NIOSH to its worker exposure/dosimeter records. The Navy is claiming exemption under the Memorandum of Understanding between HHS and DOE that established the transfer of analytic health research to HHS. Inclusion of these Navy records is essential to a comprehensive INEL worker dose-reconstruction study.

Mr. President, your intervention is immediately needed because the departments have been unable to resolve these issues despite nearly two years of negotiations. Additionally, the public demands for a full accounting of fifty years of secret nuclear operations is evident in every media outlet throughout the country. It is unconscionable that despite recent revelations of America's sordid nuclear history, that there continues to be resistance to full disclosure.

Sincerely,

Chuck Broschious
Coordinator

cc:

Hazel O'Leary, Secretary Department of Energy
Donna Shalala, Secretary Department of Health and Welfare
John Dalton, Secretary of Navy
David Satcher, Director Centers for Disease Control
Mike Sage, National Center for Environmental Health
Rick Hornug, National Institute for Occupational Safety and
Health
J.M. Wilcynski, Acting Manager Idaho Operations Office



Environmental Defense Institute

P.O. Box 220
Troy, ID 83871
208-835-6152

Brian Siebert
Director of Declassification
US Department of Energy
1000 Independence Av.
Washington, DC 20585

May 23, 1994

Dear Mr. Siebert,

Thank you for calling today concerning the INEL Research Bureau letter dated March 28 to President Clinton on declassifying DOE documents for CDC's INEL Dose Reconstruction study.

Enclosed please find a copy of INEL Dose Reconstruction Working Group 3/24/94 meeting transcript that shows the discussion between CDC, CDC contractor, and working group members on the topic of declassification of DOE documents. Also enclosed is a copy of Sanford Cohen and Associates 1/31/94 quarterly report to CDC that shows the problems encountered by the contractor in gaining DOE/ID's cooperation in declassification.

I have left a message with CDC's Mike Sage office to call me concerning the current status of INEL document declassification. It is entirely possible that the INEL Research Bureau (IRB) letter to the President generated a settlement to the dispute. Notwithstanding this possibility, the fact remains that between 10/92 and 4/94, DOE/ID was not cooperating with CDC and CDC was not actively seeking resolution to the problem from higher decision makers. Therefore, it was incumbent upon the IRB to bring this problem to the attention of President Clinton and request his intervention.

As I said on the phone, the next INEL Dose Reconstruction Study Working Group meeting in Coeur d' Alene 5/25/94 may generate a formal CDC response to the status of the declassification process. I will call you after the meeting and report if there has not been a resolution to the problem. In the mean time I wanted to send this information on to you.

Sincerely,

Chuck Broschious
Executive Director

INEL DOSE RECONSTRUCTION
WORKING GROUP MEETING

BOISE, IDAHO

MARCH 24, 1994

Harrop = rep. for Sanford Cohen & Ass.
Contractor for CDC

Wood = rep. for CDC / Nat. Inst. Env. Health

Hayball = rep. for Shoshone-Paiute Tribes

Richards = Working Group member

Broscious =

NANCY SCHWARTZ REPORTING
2421 Anderson Street
Boise, Idaho 83702
208-345-2773

classified problem
pg 2 to 4
28 to 30

we're (22) continuing database development; we've got several (23) - well, about 200 people left to interview, and (24) each one of those interview forms are written up (25) and put in the database; and then we have project

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- (1) management issues to deal with.
 (2) So that's really all that remains on
 (3) the project.
 (4) Any questions on that?
 (5) (Mr. Broschious joined the meeting.)
 (6) MR. HARROP: Chuck, I was just giving (7) everybody a very quick overview. I think you can (8) probably catch it up in the slide. If you have (9) any particular questions after you look through (10) that, feel free to ask and we'll deal with them.
 (11) MR. BROSCIOUS: Okay.
 (12) MR. HARROP: C.M., did you want to say (13) anything?
 (14) MR. WOOD: (Shaking head negatively.)
 (15) MR. HARROP: We had a public meeting (16) yesterday and a couple of issues were raised. I (17) will just mention them quickly and then we can (18) deal with them as we get to them.
 (19) One of the people that attended the (20) meeting was concerned that we weren't looking in (21) every box, you know, that we've got something like (22) 40,000 boxes that have been generated from INEL (23) activities over the years and we're looking at (24) about 15,000 of those boxes total. The concern (25) was that there might be some documents hidden away

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- (1) in these other boxes.
 (2) We've explained in the past SC&A's (3) methodology for looking through boxes and the (4) rationale for looking at only 15,000 out of (5) 40,000, and I don't - there hasn't been any (6) reservation, real reservation expressed by this (7) group as far as I know about that, but if you want (8) to revisit that issue, we can do it.
 (9) There was also a concern that the (10) classified records might not be made available to (11) us or that DOE might throw roadblocks in our way (12) of trying to get at classified information that's (13) relevant to a dose reconstruction.
 (14) I had talked as recently as last week (15) with Carl Robertson from DOE

about what the (16) timetable was for getting access to those (17) declassified records, and he didn't think they (18) would be available till the end of the summer.

(19) They don't have the declassification (20) plan approved yet, but it should be a provide any (21) week. And once that happens then they've got to (22) get a team of people going through the records and (23) declassifying the entire record or portions of the (24) record as appropriate. And that process is going (25) to take some time to complete.

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- (1) MR. WOOD: Okay. I'll talk to Eddie (2) Chew. That timetable is a problem. We need to (3) have a database that we can start sending to (4) potential bidders on Phase 2 around that time (5) frame. If they're not going to start (6) declassifying until then, that's a problem.
 (7) MR. HARROP: He said they would be (8) declassified by the end of summer.
 (9) MR. WOOD: Okay. By the end of the (10) summer we'll have all the documents in your (11) database ready to start sending Clarion disks out (12) with the documents in them.
 (13) MR. HARROP: Carl Robertson said that, (14) not I.
 (15) MR. WOOD: Okay. I'll talk to Eddie. (16) We may need to...
 (17) MR. BROSCIOUS: But the reality is that (18) they have known this was coming down the pike, you (19) know, from the very beginning - from the very (20) beginning of this - even of this project. And to (21) think that they're still in the process of putting (22) together a declassification team is pretty crazy (23) and should be taken to beyond DOE Idaho. That (24) problem should be taken to O'Leary's office.
 (25) DR. RICKARDS: I was curious the other

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- (1) way around. I thought some of you all had (2) clearance to go into those files, as opposed to (3) declassifying the files, having you all take out (4) pertinent information. Was I wrong about that or (5) - I'm just curious. It seems like it gives them (6) an opportunity to comb through their files and (7) take out anything really good.

(8) MR. WOOD: No, we have clearance and (9) are looking at the classified documents and saying (10) based on this document we want it for dose (11) reconstruction.

(12) The problem is, by our marching orders (13) we have decided we are not going to use a document (14) in dose reconstruction that is not available to (15) the public.

(16) In other words, the Phase 2 contractor (17) - so if it ain't released to the public, if you (18) can't read it, then I'm not going to base any of (19) my calculations on it for dose reconstruction. So (20) there are workarounds, this is not a mortal blow, (21) I don't - it's an aggravation. I would classify (22) it as an aggravation more than a problem.

(23) They have been saying for a year that (24) they wanted to get our entire list before they (25) started anything towards declassifying, and we've

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- (1) been saying we weren't real happy with that (2) approach, we wanted them to declassify the stuff (3) as we've told them about it.
 (4) So this is not a new revelation. It's (5) been a known aggravation for many, many months, (6) still an aggravation. I don't think we're going (7) to get the documents - I am concerned that we (8) will not have the documents in the database, the (9) abstracts and stuff. And some of those, even (10) though they're still classified, the documents are (11) already in the database.
 (12) My next deadline where this is going to (13) cause me a problem is at the end of the summer (14) I've got to start making copies of the database (15) available to any contractor that wants to bid on (16) Phase 2.
 (17) If we can't do that, there's a danger (18) - I know John's company wants to bid on it too (19) - there's a danger they're going to end up (20) making themselves ineligible because they've got (21) the inside track. They see the classified (22) documents, they've got the database, and some (23) outsider does not have access to the same (24) information they do.
 (25) So he's in trouble potentially by

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- (1) making him - either I've got to hold off on (2) putting out requests for bids

for Phase 2, or SC&A (3) may end up being ineligible to bid because they've (4) got the inside track, or we can get DOE to get (5) with it and start declassifying documents.

(6) And so I'll talk to Eddie and express (7) our concern over this, but it's not a mortal (8) blow.

(9) No, they are not combing through (10) documents before we get them. If they were going (11) to do that, they could have done it a year ago, (12) but right now we've already seen the documents, (13) we've already listed them as saying we want these (14) declassified.

(15) DR. RICKARDS: Okay. I see what you (16) mean.

(17) MR. WOOD: We've got lists of some of (18) them, abstracts of some of them already in the (19) unclassified database, and it's just a matter of (20) having them say, okay, it's okay to take these (21) out, you know, we'll scratch out secret and take (22) them out and put them in the reading room.

(23) MS. BURGESS: How many documents are on (24) the list?

(25) MR. HARROP: The total number of

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(1) documents is about 1,500.

(2) MS. BURGESS: On the classified list?

(3) MR. HARROP: Right. But the problem is (4) that that includes documents that NIOSH identified (5) also. And for reasons that I don't understand, (6) DOE has taken the approach that they're going to (7) declassified NIOSH and CDC documents at the same (8) time. So not all of those 1500 are the ones we (9) identified. About 1,000 are the ones we (10) identified.

(11) MR. HAYBALL: I don't see any other (12) alternative than to have DOE just get with it.

(13) MR. WOOD: We need to come out and have (14) a meeting too. I've got another concern. We may (15) need to come out, Charles Miller and I may need to (16) come out and meet with DOE and talk about the (17) classification issue.

(18) Are we asking for stuff that is (19) irrelevant, which I've heard from DOE; are we not (20) asking for stuff that maybe has got some good (21)

information in it, which I've also heard from DOE; (22) and can they take the list we've given them and (23) actually get it done in time to support requests (24) for quotes for Phase 2 contracts.

(25) The worst thing that can happen I see

Page 14

(1) coming out of this is delaying the dose (2) reconstruction, not something being lost forever (3) or some irreparable harm to the project. As I see (4) it the worst - we've already looked at the (5) documents. We know what's there.

We may or may (6) not have asked for all of the documents we need (7) and we may have asked for documents we don't (8) need.

(9) We may not get them declassified in (10) time to get a new contract out when we would like (11) to do so, but the worst thing I can see happening (12) is not the documents will be lost forever, the (13) worst thing I can see happening is that the dose (14) reconstruction will be delayed, which I don't want (15) to happen either.

(16) MR. BROSCIOUS: I would suggest that (17) you're wasting your time going - coming back (18) here. You should go to bloody D.C. Go - you (19) know, you tried to negotiate with them and they (20) have not produced. You've got to go over them. (21) You've got to march right down to the Farsall (22) Building and go up the elevator and start banging (23) on doors. (24) MR. WOOD: I don't like to scream (25) unless I know what I'm screaming about. I will

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(1) confess that I have not gone out and looked at the (2) list of what we've asked for to be declassified or (3) - you know, I need to get - that's why I want (4) to come out and meet with them. I want to get (5) more involved in the details of what the issue is (6) before I scream about it.

(7) I'm not afraid to do what you suggest, (8) and if it's necessary I'll do it, but right now I (9) will confess to you I don't know what I'm talking (10) about and I want to come out and see what the (11) issues are before I - I'd rather save my silver (12) bullets. I want to find out what the real issue (13) is before I scream about it.

(14) MR. BROSCIOUS: So can we

assume then (15) that if you're not satisfied that within a number (16) of days that you will then get an airline ticket (17) to D.C.?

(18) MR. WOOD: No, I won't, but I'll - let (19) me - I'll get back to you with what it is. I (20) want to come out and find out what the problem (21) is.

(22) I'm concerned right now that what we're (23) doing is going to - may cause some delay in dose (24) reconstruction. Let me find out whether that's a (25) valid fear or not.

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(1) MR. BROSCIOUS: This is a ridiculous (2) process where they're defining the rules. And, (3) you know, that's got to turn around. There's got (4) to be - you know, for them to make an ultimatum (5) that we're not going to start declassifying until (6) we have the entire list, and then when you've got (7) a big list, oh, we've got to go hire a bunch of (8) people to do this, you know, when they could have (9) been doing it with resources that they had on a (10) progressive basis and if they needed a few more (11) people at the - you know, the end, fine, but, you (12) know, they could have had two-thirds of them (13) already declassified with the reviewers that (14) they've got.

(15) MR. WOOD: Well, I don't entirely (16) agree. Yeah, they - if they had gotten - if (17) they had started declassifying when we first (18) started giving them name of documents, they (19) probably - I think they could have had the thing (20) declassified by now, like you said. However, in (21) fairness to DOE, nothing they have done so far has (22) caused any delay in the project, and if nothing (23) they do does cause a delay, then I'm willing to (24) work with them within that constraint on the (25) system.

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(1) Now, if it turns out that they do end (2) up messing up the project, then you're welcome to (3) write anybody you want that C.M. Wood (4) intransigence caused a delay in the project. But (5) right now they have not done anything that has (6) actually caused a delay in anything we're doing (7) and I want to go talk to them and make sure they (8) don't.

(9) MR. BROSCIOUS: Get that in writing (10) that they will commit to

declassifying any and all (11) requested documents by such and such a date.

(12) MR. WOOD: That's what I want to do is (13) get them to commit to having it done. I want to (14) make sure they're aware of when I have to have the (15) documents in hand to keep this thing on track, and (16) try to get them to commit to having that done.

(17) And if it looks like that's going to be (18) a problem, I'll let you all know.

(19) MR. HARROP: C.M., based on the volume (20) of documents that we have listed, if we get all of (21) those documents from the Department of Energy on (22) the 1st of August, let's say, it would probably (23) take us two to three weeks to get them into the (24) database. So there's, you know, that further (25) delay that should be counted in there if you're

Page 18

(1) looking at putting something out for bid.

(2) MR. WOOD: Um-hmm.

(3) MR. HAYBALL: Could you explain a (4) little bit about the criteria on these classified (5) docks on which you selected the 1500 or whatever (6) number as an interest to SC&A and CDC and the (7) whole dose reconstruction plan?

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(19) If it talked about a system description (20) that would help develop what the source term was, (21) that would be a Pertinence 3 document and we (22) definitely want it.

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classified.

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(13) MR. HARROP: I haven't really seen very (14) much in terms of human experiment classification, (15) human experiment documents. The only ones I've (16) seen myself are the few we found in Seattle and (17) the ones you saw at the Central Facilities Area. (18) Those were not classified. And I don't recall (19) myself seeing any classified records having to do (20) with human experiments.

(21) Now, Wayne Britz did a lot of these (22) documents too and he may have. He may have seen (23) that. But I don't remember it specifically.

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(1) category of records, experiments or anything, (2) differently than anything else.

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otherwise, just treat it like you (22) would any other document and go on about your (23) business.

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(7) If we find any more that are really (8) juicy, I'll let you all know, but right now I only (9) know of one out of the INEL. That's the one we (10) told you about last night.

(11) MR. HAYBALL: Have you spoken to (12) Richard Dickson pertaining to that, from the (13) INEL?

(14) MR. WOOD: No.

(15) MR. HAYBALL: Because supposedly he's (16) kind of the oversight head of that particular (17) subject.

(18) MR. WOOD: No.

(19) MR. HAYBALL: As a matter of fact, he (20) coming down to the tribe, Shoshone-Bannock Tribe, (21) and giving a presentation on what they do know.

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(8) MR. WOOD: It possibly falls under (9) NIOSH's bailiwick if it's exposure to workers, not (10) us. If it's exposure to off-site population, such (11) as a deliberate release, like some of the things (12) they did at Hanford, that does fall under our (13) bailiwick and we're putting those in the database (14)

curious on that level if, because it (18) came from Nevada DOE, that would be out of your (19) scope of things. But the whole question of (20) resuspension of particles, massive doses of (21) whatever blowing through the neighborhood, CCM, (22) et cetera, whatever, I wanted to ask you, how does (23) that set with you? Is that part of the study or (24) not?

(25) MR. HARROP: I don't know. I think

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(1) it's up to CDC to define whether it would be part (2) of the study, but I will reiterate that we are (3) going to include in the database the environmental (4) sampling records that were a result of the Public (5) Health Service and Environmental Measurement (6) Laboratory sampling of Idaho. And that sampling (7) was done because of the atmospheric nuclear test, (8) so you should have that information.

(9) Now, how that is incorporated into a (10) dose reconstruction, I don't really know. I don't (11) know what CDC's plans are.

(12) DR. RICKARDS: It just seems to me that (13) in every situation at the INEL that you're (14) researching, you're researching the actual (15) physical materials, the releases, the filtering at (16) the time, everything.

(17) And in that sense, Idahoans were (18) exposed to have the bomb blasts from there. So (19) knowing the dose that came out from the bomb blast (20) just seems extremely relevant to the dose Idahoans (21) got.

(22) And I don't know if it's (23) jurisdictional, whether it's the release source (24) that you have to be concerned about, but if it did (25) set off every alarm, I don't - I bet John Horan

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(1) would confirm that story. I don't think that's a (2) big secret. But it's something I haven't thought (3) of to ask you before, but it does seem pertinent (4) that we should clarify if it's definitely not part (5) of ours, or if that's just a huge other contract (6) for you all to fulfill researching the bomb (7) blasts, wind directions at the time of the (8) blasts. The weather is random or not, the (9) leukemia rates were in the top ten percent right (10) there in southern Idaho.

(11) MR. WOOD: I hope I can avoid getting (12) too tangled up with the Nevada tests. When I do (13) the calculation for a dose reconstruction for the (14) source term, I'll try to do it by mathematically (15) modeling the process.

(16) In other words, they had this reactor (17) operating this power level to generate this many (18) fission products, we know they had a leak in a (19) fission failure, they had a stack monitor and it (20) sampled the stuff was going up the stack and these (21) were the numbers, somehow based on what's going on (22) inside a facility, calculate what would have been (23) released. And then from that, calculate the dose (24) to the people.

(25) Once we have done that calculation,

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(1) then later you go back and you get environmental (2) samples and say, well, if our calculations are (3) good, this much should have been deposited in the (4) environment. Let's see what the real samples they (5) got in that time period said. That validates our (6) calculations.

(7) Well, if you have fallout, that (8) complicates the validation problem, but it doesn't (9) complicate the calculation of the release itself.

(10) DR. RICKARDS: I guess what I'm asking (11) are you going to calculate releases from bomb (12) testing or not.

(13) MR. WOOD: No.

(14) DR. RICKARDS: Why not, if it dosed (15) Idahoans, which it did?

(16) MR. WOOD: Right now, the dose (17) reconstruction from the INEL is to just that, (18) model the process and calculate the dose to (19) Idahoans from operations of the INEL.

(20) Now, two things could cause us to go (21) and start going some more with fallout. One is (22) our study of the health effects of the fallout (23) from the bomb testing gets added to our research (24) agenda, and they're - you know, we could do (25) Los Alamos, go do Pantex in Texas, do fallout from

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(1) the bomb tests, there are other things we could be (2) called on to study, but right now we're not. And (3) one of those things we're not called on to study (4) right now is fallout from the

bomb tests.

(5) MR. HAYBALL: Even to complicate it (6) more you would have to go not just from site to (7) site, any affected public from a bomb blast.

(8) MR. WOOD: Yeah. Now, the other thing, (9) we do not have on our research agenda right now to (10) go beyond - right now, not to say we can't later, (11) just right now - we do not have on our research (12) agenda to go find people in Idaho and see what (13) their health effects actually were and compare (14) that to the dose they got, like we're doing at (15) Hanford.

(16) If we have to go start studying health (17) effects for people in Idaho, then in my personal (18) opinion we cannot do that study without (19) calculating doses they received from all sources.

(20) But right now our charter is to (21) calculate the dose to the people in Idaho from (22) operations of the INEL. And maybe we will add to (23) that or change that later.

(24) DR. RICKARDS: Okay. Well, I (25) appreciate your explanation.

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(1) MR. HARROP: Okay. The fifth quarter (2) report. Instead of just, you know, going through (3) this and asking questions page by page, is there (4) anything anybody would like to discuss in (5) particular?

(6) MR. BROSCIOUS: Has there been any (7) change in NRF's willingness to release the (8) dosimetry to NIOSH, the worker dosimetry?

(9) MR. HARROP: I don't know that.

(10) MR. BROSCIOUS: They apparently have (11) refused to or are playing games with their worker (12) records, not being willing to release them, the (13) dosimetry.

(14) MR. HARROP: I'm really not privy to (15) the discussion that went on between NRF and the (16) NIOSH folks about the releasability of the (17) dosimetry information. I heard the comment from (18) the NIOSH worker at the December 13 meeting, but I (19) haven't done anything more.

(20) I did tell him, though, that if he (21) would like to discuss how to approach NRF and (22) Theron Bradley, I'd be happy to spend some time (23) with him. But that's where I left it. It's (24) really not our issue to deal with, unless

you see (25) some reason why we should be involved.

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(1) MR. BROSCIOUS: Well, the question is (2) more directed to C.M. than you, I mean, since (3) Bill's not here, but again, it's a real (4) frustration that this is still going on. You (5) know, a year and a half into this project, and DOE (6) or the Navy or whoever else is still playing games (7) with their information.

(8) MR. WOOD: Well, perhaps my outlook (9) here is kind of parochial, but I'm getting access (10) to all the documents that I need to do my study, (11) so I'm not - if they want me to help, I would be (12) glad to do so, but in the absence of an appeal for (13) help from NIOSH, you know, if NIOSH doesn't want (14) me to help, then I'm not going to push it on my (15) own. I've got access to the documents I need, (16) which is probably a calloused - sounds like a (17) calloused attitude, but -

(18) MR. BROSCIOUS: So you have access to (19) the worker dosimetry?

(20) MR. HARROP: Yes.

(21) MR. WOOD: Yes.

(22) MR. BROSCIOUS: Well, not just access, (23) but can you remove that information for - to plug (24) into your data?

(25) MR. WOOD: I don't plan to do that.

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(1) MR. BROSCIOUS: You're not going to (2) use -

(3) MR. WOOD: I'm not using worker (4) dosimetry in any of our dose reconstructions, but (5) I don't need it for any calculations we're doing.

(6) Now, they're making an X and noting - (7) remember, they're doing Phase 1, the database, and (8) when they find records that are relative to NIOSH, (9) they enter the data with a little X that says (10) relevant to NIOSH.

(11) MR. BROSCIOUS: Okay. So your focus is (12) off site and NIOSH's is on site.

(13) MR. WOOD: My focus is off site, NIOSH (14) is on site. When we find records that they need (15) or they find records we need, the deal between us (16) is I won't make copies or extracts of something (17) for them, they won't make copies or extracts or (18) anything for me, we will just note the presence of

(19) records the other one needs, take it off, you (20) know, here's a record in a location and tell it to (21) the other one. And how they get their documents (22) or how I get my documents is our own problem to (23) work out.

(24) So it's just - it's just - if it's a (25) problem, it's not my problem.

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(1) MR. BROSCIOUS: Well, okay. The point (2) remains that there is a problem getting - the (3) dosimetry, you would think that the dosimetry that (4) NRF has on its own work force would be of interest (5) to NIOSH.

(6) MR. WOOD: It is.

(7) MR. HARROP: It is.

(8) MR. BROSCIOUS: Okay. The fact that (9) NRF is still playing games in releasing that (10) dosimetry to NIOSH is a problem, isn't it?

(11) MR. HARROP: For NIOSH.

(12) MR. WOOD: For NIOSH.

(13) MS. HANSON: All they're saying, Chuck, (14) is that NIOSH has to take care of its own (15) problem. And if there's information there on (16) those workers, that's not this dose (17) reconstruction. I mean, it's a bad problem. It's (18) bad for those workers. There is no question about (19) that.

(20) DR. RICKARDS: In a sense though, the (21) NIOSH people are usually at these meetings, aren't (22) they?

(23) MR. WOOD: Which meetings?

(24) MR. HARROP: They were at the (25) 13 December Boise meeting, there was a NIOSH

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(1) person there.

(2) DR. RICKARDS: Yeah. I thought there (3) was somebody there.

(4) MR. HARROP: We're not collecting (5) dosimetry information from any part of INEL, not (6) just NRF, but not anybody, for dose (7) reconstruction. And I guess it's not being (8) collected at any dose reconstruction anywhere in (9) the country. For an off-site release it's just (10) not relevant.

(11) But again, if NIOSH wants to come to (12) CDC or come to SC&A and say, hey, we'd really like (13) to get access to this information at NRF, could (14) you give us some assistance, I've already extended (15) that offer and so has CDC and they haven't taken (16) us up on it, so I don't know what more to say.

(17) DR. RICKARDS: That sounds good to me, (18) but it does sounds like those NIOSH people need a (19) little kick there. Is that Bill Murray? Is he on (20) NIOSH?

(21) MR. BROSCIOUS: Right.

(22) MR. WOOD: Well, there's no question (23) that -

(24) MR. BROSCIOUS: Shall we get even a (25) little more basic? The whole reason for this

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(1) working group is to bring all the public health (2) agencies and everyone doing research at the site (3) to the same table, so that you can get some kind (4) of reflection about what's going on.

(5) And you act like this thing about NIOSH (6) is totally irrelevant, don't talk to me about (7) that, and NIOSH isn't here, so blow it off.

(8) MR. WOOD: Well, NIOSH is called -

(9) MR. BROSCIOUS: All I want is I want in (10) that public record is that it's obscene that any (11) agency doing research at the site is still having (12) problems getting information out in order to do (13) its work.

(14) It's obscene that DOE is still calling (15) the shots in terms of when and how they're going (16) to declassify records for this stuff, and they're (17) still laying out the guidelines and all that sort (18) of stuff as to how and when and where they're (19) going to do it.

(20) You know, that's got to be - every (21) time it comes up it's got to be nailed and the (22) agencies have got to be on guard that we don't (23) have a whole lot of sympathy when you play ball (24) with those kinds of characters.

(25) And you don't - you just bypass the

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(1) local operations office and you go up to Dalton, (2) you go to O'Leary, or whoever; and don't wait (3) around to do it.

(4) DR. RICKARDS: Can I ask you a (5) question? Is this working panel group here, do we (6) advise only CDC or do we advise NIOSH, too? I'm a (7) little confused. If - and my basic point is if (8) we are an advisory group for a joint effort (9) between ATSDR, NIOSH and CDC, then we should as a (10) group do this ourselves. I can sort of

declassifying any and all (11) requested documents by such and such a date.

(12) MR. WOOD: That's what I want to do is (13) get them to commit to having it done. I want to (14) make sure they're aware of when I have to have the (15) documents in hand to keep this thing on track, and (16) try to get them to commit to having that done.

(17) And if it looks like that's going to be (18) a problem, I'll let you all know.

(19) MR. HARROP: C.M., based on the volume (20) of documents that we have listed, if we get all of (21) those documents from the Department of Energy on (22) the 1st of August, let's say, it would probably (23) take us two to three weeks to get them into the (24) database. So there's, you know, that further (25) delay that should be counted in there if you're

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See
Pg 10
de Classified
delays

January 31, 1994

Ms Leeann Denham, Project Officer
Centers for Disease Control and Prevention
MS F35
4770 Buford Highway NE
Atlanta, Georgia 30341-3724

Subject: QUARTERLY REPORT, October-December, 1993
Contract No. 200-92-0538

Dear Ms Denham:

Enclosed is the fifth quarterly progress and financial report for the phase 1 INEL dose reconstruction project. A description is provided of progress during the fifth contract quarter, our plans for the next quarter, and a discussion on problems, solutions, and effort needed to complete Phase I. Also enclosed is a completed Form HHS-646.

The report is submitted in fulfillment of (1) Section C, part C., Specific Tasks which identifies quarterly reports for certain tasks; (2) Item 13 in Section F.2 (Public Involvement); and (3) Section H.2 (Contract Financial Report) of Contract No. 200-92-0538.

Very truly yours,

Wayne Britz
Project Manager

Attachment-Quarterly Report

c: Martin F. Hirsch, Contracting Officer, CDC

see Pg 2

WORK PROJECTED FOR THE FIFTH CONTRACT QUARTER - January to March, 1994

- Finalize search and retrieval in all areas except the box searches in the CFA and FRC.
- Prepare and review drafts of the final report for the contract.
- Train personnel for the box search in the CFA and FRC beginning January 3, then commence retrieving and documenting pertinent information.
- Continue working group meetings.

POTENTIAL PROBLEM AREAS AND PROPOSED SOLUTIONS

1) Problem:

- The request for additional funds to perform the retrieval and documentation of boxes in the CFA and FRC needs to be processed.

2) Problem:

- The declassification of classified documents identified needs to be accomplished soon to permit preparing *Document Identification Forms* (DIFs) on these documents. It seems that there may be other priorities for declassification and that this project's declassification effort may be delayed. Such a delay will result in the documents not being entered into the database by the end of the contract period.

Solution:

- CDC should follow up with DOE to assure timely declassification.