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**Author**

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**Report/Article Title** Draft Minutes of the Meeting on May 8, 1987, Science Panel of the Agent Orange Working Group (AOWG) with attachments

**Journal/Book Title**

**Year** 1987

**Month/Day**

**Color**

**Number of Images** 16

**Description Notes** Attachments include: Letter from Ronald W. Hart, Chairman, Agent Orange Working Group (AOWG) Science Panel, to Peter E. M. Beach regarding Agenda for May 6, 1987 meeting, Serum Levels of 2,3,7,8 -TCDD table, Worker Participation survey tables, Memorandum to Ronald W. Hart, from Director, Center for Environmental Health, Department of Health and Human Services, regarding NIOSH Proposal for OMB Approval to Proceed with Phase II of Dioxin Study, dated April 29, 1987, Letter to Marilyn A. Fingerhut, NIOSH, CDC, DHHS, from Ronald W. Hart, regarding Phase II of Dioxin Study, dated May 6, 1987, and Letter to Ronald W. Hart, from Mark J. Scally, Acting Director, Agent Orange Projects, Center for Environmental Health, regarding review by AOWG of CDC TCDD Validation Study

\* \* \* \* D R A F T \* \* \* \*

MINUTES OF THE MEETING ON MAY 6, 1987  
SCIENCE PANEL OF THE AGENT ORANGE WORKING GROUP

The Science Panel met from 2:05 p.m. until 3:05 p.m. in Room 729G of the Humphrey Building in Washington, D.C. Dr. Ronald W. Hart, Director of the National Center for Toxicological Research and Chairman of the AOWG Science Panel, presided. Members and guests present at the meeting are listed on the attached sign-in sheet (#1).

An agenda was distributed and is attached (#2). The minutes of the February 10, 1987 Science Panel meeting were approved as modified and circulated.

**NIOSH PHASE I REPORT:** Dr. Marilyn Fingerhut, NIOSH, introduced her co-workers from NIOSH and ATSDR. She gave a brief overview and history of the project. The purpose of this interim report of Phase I has to address concerns expressed by OMB and to request approval from OMB to proceed to Phase II of the NIOSH Dioxin Morbidity and Reproductive Study of U.S. Chemical Workers. The report and support documents were circulated to the Science Panel members prior to this meeting. Dr. Fingerhut introduced the project manager, Dr. Marie Haring Sweeney, who discussed several additional and replacement tables (attachment #3). The new tables included data collected and compiled since the main body of the report was distributed to the Science Panel members.

The discussion of the report was overwhelmingly positive and complimentary toward the NIOSH staff. Dr. Carl Keller, NIEHS, asked about the basis of the TCDD serum level in the first table of the additional handout; Dr. Fingerhut responded that the ppt level is on a lipid-adjusted basis. The positive correlation between the TCDD serum level and both the number of days worked at the NJ plant ( $p < 0.05$ ) and the cumulative exposure rating ( $p < 0.03$ ) was discussed. Dr. Keller pointed out an apparent discrepancy for worker #11 between the calendar years worked and number of days worked; Dr. Fingerhut said it would be checked and corrected. Worker #11 also is aberrant when comparing the cumulative exposure rating and the TCDD serum levels. Dr. Sweeney quickly went through the other replacement tables indicating that they supported the original tables with just a few more individuals added to the totals. The discussion brought out that the participants in this study were only paid \$300 to take the physical exam at Lovelace Medical Foundation in Albuquerque, New Mexico. Dr. Jerome Bricker, DOD, inquired about the two high values in Attachment 8 of the NIOSH documentation; Dr. Fingerhut indicated that these two individuals probably worked with the "still-bottoms" which contained the highest levels of TCDD in the plant. The two workers who had worked longer but had lower TCDD levels were plant supervisors. Dr. Don Barnes, EPA, suggested that the write-up for OMB concern #2 could be strengthened by emphasizing the controls more than was done; Dr. Al Young, OSTP, supported this suggestion. Dr. Hart inquired about Dr. Vernon Houk's, CDC, suggestion that since plasma levels may be used as biological markers of exposure, the number of

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controls may be able to be reduced (attachment #4); Dr. Fingerhut responded that they had considered this possibility but to keep the statistical power at an acceptable level for most comparisons, they preferred to keep the number of controls at the same level as workers. Dr. Barnes inquired about funding and timing for Phase II; Dr. Fingerhut stated that the funding was being applied for in mid-June along with the OMB request for approval. She anticipated a completion of the project in late 1989 or early 1990, if there is no delay in approval and funding of Phase II. Dr. Hart asked for and received a motion to accept and endorse the NIOSH report; the approval was unanimous. It was suggested that a letter to Dr. Fingerhut, indicating the Science Council approval of the report and recommendation to proceed to Phase II as soon as possible, would be appropriate. This letter was drafted and hand-carried to OMB by Dr. Al Young immediately after the meeting (attachment #5).

**TCDD HALFLIFE STUDY:** Dr. George Stebbing, DOD, reported briefly that 209 Ranch Handers had donated blood for this project. His understanding was that all the samples had been analyzed but he didn't recall the exact numbers at this time. He felt that Dr. Houk would report the findings as soon as they were available.

**AO PROJECT STATUS REPORT:** Dr. John Young, NCTR, reported that the majority of the updates have been completed, including those that were received today. There are a few outstanding that will be turned in soon. The online computer system is still being setup but will not be accessible until after the written report is produced and approved by the AOWG Domestic Council. A draft copy of the complete report will be circulated to the Science Panel members who contributed to the document to assure that the proper information has been included.

**NEXT SCIENCE PANEL MEETING:** A tentative date of Tuesday, August 25th, has been set to review the CDC AO Validation Study report. Dr. Mark Scally, CDC, has requested this meeting and will distribute the report toward the end of July (attachment #6). [The meeting was subsequently changed to Thursday, August 6th.]

**NEW/OLD BUSINESS:** Dr. Julianne Byrne, NCI, reported that Dr. Robert Miller is recovering from a heart attack and should be going home from the hospital soon. Dr. Miller has had a rough time, but is hopefully on the road to recovery. Dr. Hart expressed the feelings of the Science Panel by wishing Dr. Miller a speedy recovery.

Dr. Al Young inquired as to Dr. Hart's contact with the NATO dioxin efforts and felt that Dr. Hart should be the AOWG representative to the NATO group. Dr. Hart agreed to that suggestion and stated that he would keep the Science Panel informed. Dr. Don Barnes is also involved with the NATO effort.

\* \* \* \* D R A F T \* \* \* \*

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Dr. Barclay Shepard, VA, reported that the VA Mortality Study had been submitted for publication with JAMA and the reviewers comments were being presently addressed. In accordance with the Science Panel procedure of reviewing studies prior to publication, Dr. Shepard will distribute the report just prior to the JAMA publication. If possible, a special Science Panel meeting will be called to discuss the report or the discussion may be included with the August meeting if the timing is appropriate.

Ms. Helen Gelband, OTA, inquired as to the likelihood of the Science Panel reviewing the TCDD halflife study data. Dr. Hart felt that it would be desirable and indicated he felt that Dr. Houk would present the data as soon as it was available. There was some discussion as to the possibility that the halflife data would be presented along with the Validation Study data.

Dr. Shepard inquired as to the status of the NIOSH Mortality Study; Dr. Fingerhut indicated that the data collection phase probably would be completed and submitted to internal NIOSH review by the end of this year.

Dr. Peter Beach informed the Science Panel members that Dr. Shepard had been presented with an agency distinguished service award at the AOWG Domestic Council meeting of April 14. This may be Dr. Shepard's last Science Panel meeting as his present VA appointment ends on June 10th. Dr. Hart expressed his appreciation to Dr. Shepard and invited him to future meetings in either an official or unofficial capacity.

Having no other business to address, the meeting was adjourned at 3:05 p.m.

Prepared by John F. Young, Ph.D.  
Executive Secretary  
AOWG Science Panel

\_\_\_\_\_  
DATE: May 6, 1987

Approved by Ronald W. Hart, Ph.D.  
Chairman  
AOWG Science Panel

\_\_\_\_\_  
DATE: May 6, 1987





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

Phone: (501) 541-4000  
(FTS) 542-4000

April 8, 1987

National Center  
For Toxicological Research  
Jefferson AR 72079

Dr. Peter E.M. Beach  
Executive Secretary  
Division of Veterans Affairs  
Office of the Under Secretary  
Room 632-P, HHH Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Peter:

The next meeting of the Science Panel of the Agent Orange Working Group will be held on Wednesday, May 6, 1987 at 2:00 p.m. in Room 729G of the Humphrey Building in Washington, D.C.

ASH Conf. Rm

The agenda will include the following items:

Lead Person

- 1) Phase I of the NIOSH Medical Study of Dioxin Exposed Workers [a document will be distributed by April 29th] Marilyn Fingerhut
- 2) TCDD Half-life Study - Update and comments on protocol Vernon Houk
- 3) AO Project Status Reports John Young

If you have any comments or additions, please contact John Young at 501/541-4304 (FTS 790-4304).

We will attempt to limit the meeting to one hour as usual.

Sincerely,

*Ronald W. Hart*  
for Ronald W. Hart, Ph.D.  
Chairman, AOWG Science Panel  
Director, NCTR

*lipid-adjusted* ↓

SERUM LEVELS OF 2,3,7,8-TCDD (~~whole weight basis~~) IN  
FOURTEEN PHASE I PARTICIPANTS

	Age	Calendar Years Employed	# Days Worked at NJ Plant	Cumulative Exposure Rating	TCDD Serum levels (ppt)	Average TCDD levels (ppt)
<b>Referents</b>						
	1.	44		0	3	
	2.	50		0	4	
	3.	43		0	4	
	4.	64		0	8	
	5.	63		0	13	
	6.	59		0	17	

8.4

**Workers**

	7.	47	6/05/61 - 9/08/61	68	6.04	8	
	8.	44	6/14/65 - 3/01/67	446	39.73	28	
	9.	64	8/13/56 - 5/09/58	210	58.45	44	
	10.	63	5/01/52 - 8/17/56	1121	3851.86	545	
	<u>11.</u>	52	→ 9/30/67 - 8/01/69 ←	<u>1062?</u>	<u>58.45</u>	→ 360 ←	- ?
	12.	61	8/05/54 - 2/01/60	1389	1664.25	174	
	13.	59	9/24/51 - 4/22/66	3726	4152.22	280	
	14.	64	4/01/53 - 9/09/68	4029	371.33	343	

*- lab tech  
- chemist*

254.6

*C<sub>2</sub> = .62  
P<sub>2</sub> = .05*

*C<sub>2</sub> = .7  
P<sub>2</sub> = .03*

First table 8

# 3a



## ATTACHMENT 9

Table 1

## Participation of Workers in the In-Home Interviews

	<u>April 1</u>	<u>April 24</u>
1. Workers Requested to Participate in the in-home interview.	73	74
2. Worker interviews completed.	68	70
Workers deceased. (proxy interviews)	2	2
Workers medically unable to complete the in-home interview. (proxy interviews)	3	3
3. Workers refused interview.	3	3
4. Overall participation rate as of April, 1987.	93.2% (68/73)	94.6% (70/74)
5. Worker interviews scheduled but not completed.	2	1
6. Anticipated participation rate.	95.9% (70/73)	96.0% (71/74)

Table 2

Participation of Workers in the Medical Examination

	<u>April 1</u>	<u>April 24</u>
1. Workers invited during interview to participate in Medical Exam (does not include 2 deceased).	66	68
2. Workers scheduled for or completed medical examination.	52	56
3. Workers to be scheduled for examination	5	1*
4. Workers refused medical examination.*	9	11
5. Participation rate for completed exam as of April, 1987.	78.8% (52/66)	82.4% (56/68)
6. Anticipated participation rate	86.4% (57/66)	83.8% (57/68)

\* One interviewed worker has agreed to participate in the examination, but because funding permits only 56 workers to be examined during Phase I, this worker will be examined in Phase II.

\*\* Reasons for refusals:

Physically or mentally incapacitated	5	5
Unavailable due to work conflict	1	1
Unavailable (other reasons)	1	1
Refused	2	4

Table 3

## Participation of Referent in the In-Home Interview and Medical Examination

	<u>April 1</u>	<u>April 24</u>
1. Total number of workers for whom referents have been sought.	44	51
2. Number of matched referents agreeing to participate in the interview and the examination.	44 (100%)	51 (100%)
3. Total number of matched individuals requested to participate in the interview and the examination.	101	110
4. Total # matched individuals requested to participate <u># participating referents</u>	$\frac{101}{44} = 2.3$	$\frac{110}{51} = 2.2$
5. Number of matched referents scheduled for or completed medical examination as of April, 1987.	30	41*

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\*Funding permits 48 referents to be examined during Phase I. Other Phase I referents who agree to participate in the examination, will be examined in Phase II.

ATTACHMENT 10 (Update)

May 6, 1987

In Attachment 10 of the package we sent to you, we evaluated the comparability of the study participants for three variables: education, current income and self-perceived health status for 63 workers, 38 referents and 18 nonrespondents for whom we had received completed interviews, as of April 1. Although prior to the interview the workers and referents are matched by age (+ 5 years), race, gender and resident community of the worker, we wished to determine how well the study participants were matched relative to other sociodemographic factors.

Using the Chi<sup>2</sup> statistic, we found that the workers and referents who participated in the demographic and occupational history interview were similar for all three characteristics. Likewise, we found that the 38 participating referents were similar to the 18 nonrespondents who were identified as eligible referents but who refused to participate in the study.

We performed a reanalysis of these same sociodemographic characteristics using interview data for 63 workers, 47 referents and 27 nonrespondents received as of May 1. Again there were no statistically significant differences between workers and referents and referents and nonrespondents relative to educational level, income and self-perceived health status.



Memorandum

Date April 29, 1987

24- (25)

Rec'd  
5/4/87  
JH

From Director  
Center for Environmental Health

cc: J. Young

Subject NIOSH Proposal for OMB Approval to Proceed to Phase II of the NIOSH Dioxin  
Morbidity and Reproductive Study of the US Chemical Workers

To Ronald W. Hart, Ph.D.  
Chairman, Agent Orange Science Panel

I have reviewed the NIOSH document and had some phone discussion with Marilyn Fingerhut. I strongly support the continuation of the study. The serum dioxin levels from the pilot phase, for which Dr. Fingerhut will provide the numbers available, suggest that with biological markers, exposed and non-exposed categories and variation inbetween can be identification.

*John:*  
to be  
revised  
AOSP meeting  
this week. by  
myself if I can  
or rep. is not  
there - please remind  
me of same.

In addition, since there appears possible a biological marker of exposure now, Dr. Fingerhut may want to relook at the numbers of controls and the power calculations to see if they remain appropriate. It is my understanding that because of the potential of misclassification the numbers of controls were increased. They may not be necessarily decreased now, but at least the issue should be revisited before the final protocol.

*necessity for*

Vernon N. Houk, M.D.  
Assistant Surgeon General

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DEPARTMENT OF HEALTH & HUMAN SERVICES  
Public Health Service  
Food and Drug Administration  
National Center for Toxicological Research  
Jefferson, AR 72079

May 6, 1987

Dr. Marilyn A. Fingerhut  
Chief  
Epidemiology Section I  
Industrywide Studies Branch  
Division of Surveillance, Hazard  
Evaluations and Field Studies  
NIOSH/CDC/DHHS  
Robert A. Taft Laboratories  
4676 Columbia Parkway  
Cincinnati, OH 45226-1998

Dear Dr. Fingerhut,

On May 8, 1987 the Science Panel of the DHHS Agent Orange Working Group met in the HH Humphrey Building in Washington, D.C. to discuss your document entitled "Request for OMB Approval to Proceed to Phase II of the NIOSH Dioxin Morbidity and Reproductive Study of U.S. Chemical Workers". It is the opinion of the Science Panel that your experience with Phase I of this study has strongly indicated that Phase II should be initiated as soon as possible without any lag time between phases.

The Science Panel felt that your document adequately addressed the three major concerns of OMB.

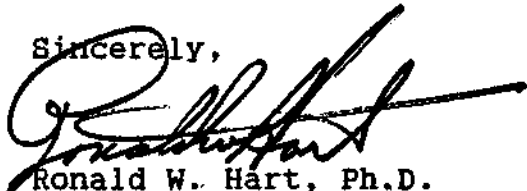
1) Exposure model: Extensive work has gone into developing the exposure model prior to the initiation of the work. Detailed work experience categories were defined and used to calculate exposure indices for individual workers. Detailed questionnaires were designed to check and compare with these work record exposure indices. Levels of TCDD measured in serum of participants demonstrate clearly that the workers are highly exposed and the referents have only background levels of TCDD. The high correlation reported in the CDC adipose tissue/blood level TCDD study (Correlation of 2,3,7,8-tetrachlorodibenzo-p-dioxin in adipose tissue and serum in humans, 6th International Conference on Chlorinated Dioxins and Related Compounds, Sept 16-19, 1986, Fukuoka, Japan) justifies the use of serum as a measure of exposure.

2) Controls: Adequate controls have been found to balance the worker population. The method of choosing and evaluating the controls is well designed and implemented. The Science Panel has no reservations concerning NIOSH's ability to locate and utilize an adequate number of controls in Phase II of the study.

3) Survey instruments: The questionnaires, interview procedures, and medical exams are sound. The checks and cross-checks are designed to minimize errors and locate discrepancies in the various pieces of data. Sufficient data is being gathered to make the correlation between exposure and health effects.

The Science Panel would like to commend you, your staff, and contractors on the timeliness and quality of Phase I. We wish to encourage the minimization of the transition from Phase I into Phase II of this study.

Sincerely,



Ronald W. Hart, Ph.D.  
Chairman, AOWG Science Panel  
Director, NCTR



#6

Centers for Disease Control  
Atlanta GA 30333

April 27, 1987

*Rec'd  
5/1/87  
vw*

Dr. Ronald W. Hart  
Chairman, AOWG Science Panel  
Director, National Center for Toxicological Research  
Country Road #3  
Jefferson, Arkansas 72079

Dear Dr. Hart:

The purpose of this letter is to update you on the progress of the Centers for Disease Control's (CDC) TCDD Validation Study and to discuss the timeframe for the Agent Orange Working Group (AOWG) Science Panel review of the final report from this study.

The interviews and medical examinations, which include the collection of blood for TCDD analysis, have proceeded very well with respect both to the time schedule and participation rates. Research Triangle Institute completed the interview component on February 28, 1987; interviews were completed on 840 veterans, representing an 87.5% participation rate. The medical examination component will be completed on May 1 and approximately 750 veterans will have been examined, representing a response rate of over 70%. To date, there have been only four examined veterans who were not able, for medical reasons, to provide the blood specimen necessary for TCDD analysis. The laboratory analyses of the blood specimens at CDC is also proceeding on schedule.

Since all aspects of this study are progressing on a timely basis, CDC will submit the study's final report to AOWG Science Panel during the week of July 27-31, 1987, as originally scheduled. We would ask that you set up an expedited review of this report during the month of August 1987, if possible. CDC's staff will be available for presentation and/or discussion of this report as necessary, with the exception of the week August 17-21 when the American Statistical Association is holding its annual meeting.

I look forward to hearing from you once you have established the dates for the ~~OTA~~ review. Thank you for your cooperation in this matter.

*AOWG*

*John  
Prepare response for  
my signature &  
coordinate as needed.*

Sincerely yours,

*Mark J. Scally*

Mark J. Scally  
Acting Director  
Agent Orange Projects  
Division of Chronic Disease Control  
Center for Environmental Health

cc: Mr. Robert L. Raclin  
Ms. Hellen Gelband  
Dr. Vernon N. Houk



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AGENT ORANGE WORKING GROUP  
SCIENCE PANEL DISTRIBUTION LIST

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. Ronald W. Hart  
Chairman, Science Panel  
Director, National Center for Toxicological Research  
Jefferson, AR 72079  
FTS 790-4517 or (501) 541-4517

Dr. John F. Young  
Executive Secretary, Science Panel  
Director, Division of Reproductive and Developmental Toxicology  
National Center for Toxicological Research  
Jefferson, AR 72079  
FTS 790-4304 or (501) 541-4304

Dr. Peter E.M. Beach  
Executive Secretary  
Division of Veterans Affairs  
Office of the Under Secretary  
Room 632-P, HHH Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201  
FTS 245-2210 or (202) 245-6156

Dr. James S. Dickson, III  
Senior Advisor for Environmental Affairs  
Office of the Assistant Secretary for Health  
Department of Health and Human Services  
200 Independence Avenue, S.W.  
Room 701-H, HHH Building  
Washington, D.C. 20201  
FTS 245-6811 or (202) 245-6811

Dr. Marilyn Fingerhut  
Section Chief  
NIOSH - EPI I  
4676 Columbia Parkway  
Mail Stop R-15  
Cincinnati, OH 45226  
FTS 684-4411 or (513) 841-4411

Dr. Peter Greenwald  
Director, Division of Cancer Prevention and Control  
National Cancer Institutes, NIH  
Building 31, Room 4432  
Bethesda, MD 20892-3100  
FTS 496-6616 or (301) 496-6616

Dr. Vernon Houk  
Director, Center for Environmental Health  
Centers for Disease Control  
1600 Clifton Road, N.E.  
Chamblee, Building 27  
Atlanta, GA 30333  
FTS 236-4111 or (404) 452-4111

Dr. Carl Keller  
Agent Orange Working Group  
Epidemiologist, NIEHS  
Room 2B55, Building 31  
National Institutes of Health  
Bethesda, MD 20205  
FTS 496-3511 or (301) 496-3511

Dr. Robert W. Miller  
Chair, Advisory Committee  
Clinical Epidemiology Branch  
National Cancer Institute - NIH  
Room 8C41, Landow Building  
Bethesda, MD 20817  
FTS 496-5785 or (301) 496-5785

Dr. Julianne Byrne  
Clinical Epidemiology Branch  
National Cancer Institute - NIH  
Room 8C41, Landow Building  
Bethesda, MD 20817  
FTS 496-4947 or (301) 496-4947

Dr. David Rall  
Director, National Institute of Environmental Health Services  
P.O. Box 12233  
Research Triangle Park, NC  
27709  
FTS 629-3201 or (919) 541-3201

OFFICE OF THE PRESIDENT

Dr. Alvin Young  
Senior Policy Analyst  
Office of Science Technology Policy  
New Executive Office Building  
Room 5005  
Washington, D.C. 20500  
FTS 395-3125 or (202) 395-3125

ENVIRONMENTAL PROTECTION AGENCY

Dr. Donald Barnes  
Senior Science Advisor to the  
Assistant Administration for  
Pesticides and Toxic Substances  
U.S. Environmental Protection Agency  
401 M Street, S.W., (TS788)  
Washington, D.C. 20460  
FTS 382-2897 or (202) 382-2897

CONGRESSIONAL OFFICE OF TECHNOLOGY  
ASSESSMENT (OBSERVER)

Ms. Hellen Gelband  
Analyst  
Office of Technology Assessment  
United States Congress  
Washington, D.C. 20510  
(202) 226-2070

DEPARTMENT OF DEFENSE

Colonel George Stebbing, M.D.  
OASD/HA/PA & QA  
The Pentagon, Room 3D372  
Washington, D.C. 20301-1200  
FTS 695-6800 or (202) 695-6800

Dr. Jerome G. Bricker  
6000 Cable Avenue  
Camp Springs, MD 20746-3824  
(301) 423-4821

DEPARTMENT OF AGRICULTURE

Dr. Phillip Kearney  
Chief, Pesticide Degradation Lab  
U.S. Department of Agriculture  
BARC - West  
Building 050 - Room 100  
Beltsville, MD 20705  
(301) 344-3533

DEPARTMENT OF LABOR

Mr. Stephen Mallinger  
Deputy Director for the Director  
of Technical Support  
U.S. Department of Labor  
OSHA  
200 Constitution Avenue, S.W.  
Room N-3651, FPB  
Washington, D.C. 20210  
FTS 523-7047 or (202) 523-7047

VETERANS ADMINISTRATION

Dr. Barclay Shepard (10B/A0)  
Director, Agent Orange Projects  
Office  
VA Central Office  
810 Vermont Avenue, N.W.  
Washington, D.C. 20240  
FTS 373-2751

Dr. Han K. Kang  
Director  
VA Office of Environmental  
Epidemiology (10B/A02)  
Riddell Building  
1730 K Street, N.W. - Suite 401  
Washington, D.C. 20006-3868  
FTS 653-1891 or (202) 653-1891

DEPARTMENT OF STATE

Dr. Charles E. Brodine  
Assistant Medical Director for  
Environmental  
Health and Preventive Medicine  
Office of Medical Services, M/MED  
Department of State, Room 4253  
Washington, D.C. 20520  
FTS 647-5337 or (202) 647-5337