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Descripton Notes Assorted minutes, reports, correspondence, and lists related to the VA Advisory Committee on Environmental Hazards. Alvin L. Young filed these materials under the label "VA Advisory Committee on Environmental Hazards."

VETERANS'ADVISORY COMMITTEE ON
ENVIRONMENTAL HAZARDS
SCIENTIFIC COUNCIL
JUNE 24, 1985

The Scientific Council of the Veterans' Advisory Committee on Environmental Hazards convened at 9:10 am. Following brief introductory remarks by Dr. Kurland, the Council received a briefing from Dr. Lathrop on the status of the Ranch Hand Study. Dr. Lathrop reported on the findings of the first morbidity report and on the first mortality report. Enlisted men in both the Ranch Hand group and the controls have a higher mortality than the officers but the mortality rate was still lower than that of the general population. He noted the limitations of the study due particularly to the size of the study population. He reported that the study has thus far revealed no herbicide causality for any particular disease or health problem. The mortality study also revealed no unusual patterns or rates of death. One finding of interest was the absence of any diagnosis of chloracne among the Ranch Hand population. No significant differences in the rate of severe and moderate malformations among offspring of the Ranch Hand group and the controls have been noted. Mild malformations (skin blemishes etc.) were more frequent among the Ranch Hand group but this may reflect greater sensitivity of the Ranch Hand parents in reporting such malformations. Further studies are underway. The Council expressed no criticism of the study's results or of the study's methodology.

Dr. Yanders provided a thorough and balanced overview of several studies relating to soft tissue sarcomas and their possible association with exposure to dioxin.

Dr. Colton reported on two mortality studies which have been reported involving Vietnam veterans. A study of the mortality of Vietnam veterans from Massachusetts revealed a higher than expected incidence of death due to soft tissue sarcoma among veterans who served in Vietnam. There was no attempt to correlate the findings with the amount of exposure to Agent Orange a veteran may have had in Vietnam. The authors of the Massachusetts study have stated the limitations of their study and have not overstated their findings.

Dr. Colton noted that the study legitimately raises some questions concerning the association of soft tissue sarcoma with service in Vietnam. Regarding a similar but negative study conducted in New York state, he noted that the study may have been conducted too soon to reveal any conditions which may have a long latency period. A study from New Zealand was also reviewed and it revealed no significant increase in soft tissue sarcoma among the exposed group.

The conclusion of the Council following discussion was that there is no pursuasive evidence that soft tissue sarcoma occurs with any greater frequency among individuals exposed to dioxin than among those not so exposed. The Council believed that the jury is still out on this issue and that no firm conclusions can be made at this time.

The general consensus, therefore, was that the Veterans Administration's approach as expressed in the proposed regulations is in concert with the current scientific understanding about the health effects of exposure to dioxin.

Mr. Seymour Jablon reported to the Council the results of a recently completed study of individuals who participated in a series of atomic weapons tests. The study revealed no consistent evidence of increased deaths from cancer or other diseases for the veterans overall. The study did reaffirm the observation of an excess of leukemia among one group of veterans and found a slight increase in the number of prostate cancers among another group. Mr. Jablon reported that the investigators concluded that the lack of consistent evidence of increased cancer incidence could have two possible explanations: the observed incidence of leukemia among the Smoky participants is simply a "chance aberration" or the actual radiation exposure of these men was several times the dose recorded at the time.

There was an extensive discussion of the recently released radioepidemiological tables. There was general agreement that the tables reflect the best available information and represent valid

science. Dr. Theissen had presented to the Council the recommendations of the Science Council of the Committee on Interagency Radiation Research and Policy Coordination and noted that there were some uncertainties associated with the Tables. The Council agreed with this analysis yet believed that the Tables may have some applicability to the VA's compensation system. The Council recommended, therefore, that following a determination of exposure and the presence of a radiogenic cancer occurring within the appropriate latency period the tables be used as a starting point in considering claims but should not be the final determinative in granting or denying service connection. The approach recommended by the Council is that the tables be used to determine an estimate and a range of probability that a given cancer was caused by a given exposure to radiation reflecting the uncertainties in the doses and the table values. In addition to the Tables, other factors should be considered such as the individual's family history, his/her exposure to other known carcinogens, and the individual's life-style and occupational history. Expressing the probability of causation as a range rather than as a specific number will convey the basic uncertainty associated with the Tables and will tend to diminish the likelihood of total reliance upon the Tables themselves.

There was also discussion of possible threshold values of probability of causation or dose levels below which it is highly unlikely that the radiation exposure was causative but no formal recommendation was made.

Respectfully submitted,

Frederic L. Conway

Frederic L. Conway
Executive Secretary

Veterans' Advisory Committee on
Environmental Hazards
June 25, 1985

A member of the audience questioned the way in which the regulations characterize the relationship between exposure and diseases. He proposed that the VA articulate a standard for such matters. The Committee referred this comment to the Agency.

The Committee reviewed the various written comments that have been received by the Agency on the proposed regulations governing the adjudication of claims for compensation based upon exposure to dioxin or ionizing radiation. The Committee observed that most of the comments related to policy matters to be addressed by the Agency.

Dr. Taylor provided an overview of chloracne. He described methods and routes of exposure to chloracnegens, the various types of chloracnegens, the clinical aspects of chloracne and the diagnostic criteria for chloracne.

Following Dr. Taylor's presentation, the Committee focused on the proposed regulations governing the adjudication of claims for disability compensation based upon exposure to dioxin. Some concern was expressed about the proposed three month presumptive period for chloracne, the principal concern being whether a veteran's service medical records would accurately reflect the nature of the skin condition a veteran may have received treatment for while in Vietnam, e.g. misdiagnosing a case of chloracne as tropical dermatitis. Dr. Taylor expressed the opinion that chloracne usually manifests itself shortly after exposure, generally within a matter of days, and that the three months presumption appeared to be quite adequate. Dr. Lathrop noted that in the Ranch Hand study, there had been no case of chloracne found, neither by current manifestation, biopsy examination, nor by history. The absence of chloracne among this group of individuals who are believed to have had high exposure to Agent Orange could not be explained and no conclusions could be drawn from this.

The Committee concluded its review of the "dioxin rule" by observing it had no serious objections to the proposed rule and generally endorsed the principles of the regulation. It was suggested that the Agency emphasize to its adjudicators that the diagnosis of chloracne need not have been made within the three month period in order for service connection to be established.

Regarding the proposed regulations governing claims based upon exposure to ionizing radiation, there was some discussion about the proposed latency period of more than two years but less than 30 years for leukemia and bone cancers and more than ten years for all other cancers. The Committee recommended that the minimum latency period for leukemias and bone cancers be reduced to one year and for all other radiogenic cancers to five years. The Committee observed that the open-ended latency period for other cancers is consistent with information currently available.

With respect to the list of radiogenic diseases, the Committee recommended that the Agency adopt the list of cancers used by the Ad Hoc Working group in the radioepidemiological tables developed by them. This would result in the addition of cancer of the esophagus, stomach cancer, colon cancer, cancer of the pancreas, cancer of the kidney and urinary bladder, and salivary gland cancer to the list of radiogenic diseases. The Committee had no objection to the inclusion of skin cancer. It's absence from the list used by the Ad Hoc Working Group was due to the fact that skin cancer is not observed at low doses and not to any suggestion that it is a non-radiogenic disease.

In the regulation pertaining to the evaluation of studies, there was concern expressed about the factor regarding whether a study's findings are statistically significant. It was noted that a study may present statistically significant findings and yet still not be a valid study. When alternative language such as "statistically and epidemiologically valid" was suggested for this regulation, it was noted that the language to which the objection was raised was drawn directly from the statute. On this basis it was questioned whether

the Agency could substitute any other language. Similar language was found in the definition of "sound scientific evidence." Accordingly, the Committee recommended that the language "statistically and epidemiologically valid" be substituted for "statistically significant" in that regulation.

The Committee had no objection to the exclusion of polycythemia vera from the radiation regulation where that regulation pertains to granting service connection on a presumptive basis.

The Committe raised no objections to the procedures set forth in the proposed regulations for handling claims. The Committee endorsed the proposed radiation regulations as a whole with the exceptions noted.

Finally, the Committee asked to be kept informed with respect to whatever additional comments the Agency may receive on its proposed regulations. It also asked that it be provided an opportunity to review whatever changes are made to the proposed regulations in response to the comments reviewed. The Agency agreed to try to accommodate the Committee to the extent that time permits.

Respectfully submitted,

Frederic L. Conway

Frederic L. Conway
Executive Secretary

REPORT OF CONTACT

NOTE: This form must be filled out in ink or on typewriter, as it becomes a permanent record in veterans' folders.

VA OFFICE: DM&S (10X21)

IDENTIFICATION NOS. *(C, XC, SS, XSS, V, K, etc.)*:

LAST NAME—FIRST NAME—MIDDLE NAME OF VETERAN *(Type or print)*:

DATE OF CONTACT: 9/15/86

ADDRESS OF VETERAN: Lt. Col. Alvin L. Young, Ph.D., Senior Policy Analyst
White House Office of Science and Technology Policy

TELEPHONE NO. OF VETERAN: 395-3125

PERSON CONTACTED: Layne A. Drash, Chief, Administrative Support Staff, AOPO

TYPE OF CONTACT *(Check)*: ☒ PERSONAL ☐ TELEPHONE

ADDRESS OF PERSON CONTACTED:

TELEPHONE NO. OF PERSON CONTACTED: 653-5047

BRIEF STATEMENT OF INFORMATION REQUESTED AND GIVEN

I was contacted by Lt. Col. Alvin L. Young on this date regarding the status of the draft monograph Human Exposure to Herbicides prepared by Dr. Terry Lavy in 1982-83 under contract with the VA. Dr. Young stated that he has called Dr. Shepard six times in the very recent past concerning this matter, but that Dr. Shepard did not return any of his calls even though he has made it clear on several occasions that he (i.e., Dr. Young) considered the excessive delay in getting this work published a serious matter. Dr. Young further stated that he had personally initiated this effort in 1982, but that Dr. Shepard, to date, has refused to proceed with its publication. He also noted that Dr. Lavy has repeatedly called Dr. Shepard to request an explanation for the delay, but again, Dr. Shepard did not return those calls. Dr. Young noted that Dr. Lavy has advised him that Dr. Shepard has also not responded to his correspondence inquiries concerning this matter.

In conclusion, Dr. Young said that he is going to prepare a letter to Dr. Earl Brown, Jr. (10X) concerning this matter. He specifically asked me to prepare this Report of Contact stressing that he wishes it to be brought immediately to the attention of responsible Agency staff.

cc: Lt. Col. Alvin L. Young

DIVISION OR SECTION: Administrative Support Staff
AOPO, 10X21

EXECUTED BY *(Signature and title)*: LAYNE A. DRASH
Chief, Administrative Support Staff

VA FORM 119 JUL 1977 EXISTING STOCKS OF VA FORM 119, JUL 1974 WILL BE USED.

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20506

September 19, 1986

Dear Dr. Brown:

The events of the past week prompted me to write to you. Last Friday, 5 September 1986, the Journal of the American Medical Association carried an article that received wide publicity--"Agricultural Herbicide use and Risk of Lymphoma and Soft Tissue Sarcoma". As you and I know, a case-control study, although significant, seldom places into perspective the rarity to which a disease like non-Hodgkin's Lymphoma occurs and the liklihood that some one's handling of 2,4-D would place them at a real risk of developing the disease.

The public, and more especially the medical community, has so few sources of information to which they can turn for factual material. The VA has published the literature reviews on the phenoxy herbicides and dioxin but in 1982 the VA initiated a special program to develop monographs on special topics. I played a role in the selection and initiation of both of those programs. Of the three monographs the VA contracted for and closely followed development of, only two have been published (Birth Defects and Cacodylic Acid). The first monograph submitted to the VA and yet remains to be published is the Monograph on, of all subjects, Human Exposure to the Phenoxy Herbicides. That monograph was twice edited by specialists and has apparently layed dormant in the Agent Orange Projects Office for many, many months. My frustration is that this monograph had a purpose--to inform your VA physicians of human exposure to such herbicides as 2,4-D. The author has written and called me and Dr. Shepard many times over the last couple of years and yet no resolution has occurred.

The second event this past week involved the announcement by the New Jersey Agent Orange Commission of dioxin in the blood and adipose tissue of Vietnam veterans. More than four years ago, the VA took the initiative and lead the scientific community into pursuing this issue. The VA published a preliminary study and followed it up with the design of a major survey of dioxin in human adipose tissue. The program, after the protocol was developed, simply "wilted on the vine". I have now been informed that although it is now underway, we can expect no results until mid-1987.

The VA has so much to be proud of in its response to the needs of the Vietnam Veteran. The Agency organized a credible response to the concerns of Veterans over Agent Orange, and in concert with the Agent Orange Working Group, committed its resources to resolving this difficult issue. At a time when we are finally finding answers and can begin to see an end in sight, we must not weaken the resolve to complete the task. I urge your continued support to see that the monograph effort is completed, the dioxin studies done, and the health studies published.

In my role as an advisor to the Executive Office of the President on this issue of Agent Orange, I can assure you that we are interested in your program and would be pleased to assist you as appropriate.

Sincerely yours,

Al Young

Alvin L. Young, Ph.D.
Senior Policy Analyst
for Life Sciences

Dr. D. Earl Brown, Jr.
ADCMD, Programs, Planning
and Policy Development (10X)
Veterans Administration
810 Vermont Avenue, N.W.
Washington, D.C. 20420

Office of General Counsel Washington D.C. 20420

Veterans Administration

MAR 06 1985

In Reply Refer To: (02C)

Alvin L. Young, Lt. Col., Ph.D.
Senior Policy Analyst
for Life Sciences
Executive Office of the President
Washington, D.C. 20506

Dear ~~Dr. Young~~ Al:

Public Law 98-542 called for the establishment of a Veterans Advisory Committee on Environmental Hazards. The two areas that are of specific concern to the Committee are the health effects of exposure to dioxin and to ionizing radiation as a result of participation in the atomic weapons program or of service with the occupation forces of Hiroshima and Nagasaki, Japan. The first meeting of the Committee is scheduled for April 22 and 23, 1985, at the Veterans Administration Central Office, 810 Vermont Avenue, N.W., Washington. For your information, I am enclosing copies of the Committee's charter and membership roster.

I thought it would be helpful at the outset for the Committee to receive a briefing on the use of herbicides in Vietnam and some of the major iniatives undertaken by the Federal government in response to concerns expressed by Vietnam veterans. I would appreciate it very much if you would be willing to address the Committee on the herbicide issue on Monday afternoon, April 22, 1985. If another time on either of those two days would be better for you, please let me know, as we will be happy to try to accommodate you.

Sincerely yours,

Fred Conway

FREDERIC L. CONWAY III
Executive Secretary
Veterans Advisory Committee
on Environmental Hazards

Enclosures

VETERANS ADMINISTRATION
OFFICE OF GENERAL COUNSEL
WASHINGTON, D. C. 20420

(02C)

Alvin L. Young, Lt. Col., Ph.D.
Senior Policy Analyst
for Life Sciences
Executive Office of the President
Washington, D.C. 20506

Dear Dr. Young:

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Sincerely yours,

FREDERIC L. CONWAY III
Executive Secretary
Veterans Advisory Committee
on Environmental Hazards

Enclosures

Veterans Administration

Memorandum

Date: FEB 20 1985

To: Administrator (00)

From: Special Assistant to the General Counsel (02C)

Subj: Charter for the Veterans' Advisory Committee on Environmental Hazards

Attached for your approval is the charter for the Veterans' Advisory Committee on Environmental Hazards. This Committee is a statutory committee established by section 6 of Pub. L. No. 98-542, the "Veterans' Dioxin and Radiation Exposure Compensation Standards Act."

FREDERIC L. CONWAY III

Att.

Concur: (02)

(10)

Approval: (00) MAR 4 - 1985

(20)

ADMINISTRATOR'S OFFICE
RECEIVED

VA FORM 2105
MAY 1983
☆ U.S. GOVERNMENT PRINTING OFFICE: 1984-421-488/0348

CHARTER

FOR THE

VETERANS' ADVISORY COMMITTEE

ON ENVIRONMENTAL HAZARDS

A. Committee's Official Designation:

Veterans' Advisory Committee on Environmental Hazards

B. Objectives and Scope of the Committee:

The committee is established pursuant to Section 6 of Pub. L. No. 98-542, the Veterans' Dioxin and Radiation Exposure Compensation Standards Act. It will advise the Administrator of Veterans Affairs concerning the scientific and medical evidence of adverse health effects from exposure to herbicides containing dioxin on to ionizing radiation. Public Law No. 98-542 mandates regulations to promote uniformity and consistency in the adjudication of veterans' and survivors' compensation claims based upon disabilities or deaths alleged to result from exposure, in the case of Vietnam veterans, to a herbicide containing dioxin, and in the case of veterans who participated in atmospheric testing of nuclear weapons or the occupation of Hiroshima or Nagasaki, Japan, to ionizing radiation. The Committee will also advise the Administrator concerning these regulations and later amendments.

C. Period of Time Necessary to Carry Out the Committee's Purpose:

As a statutory committee established pursuant to Pub. L. No. 98-542, the Committee will serve for an indefinite period.

D. Agency Official to Whom the Committee Reports:

The Committee will report to the Administrator of Veterans Affairs.

E. Agency Responsible for Providing Necessary Support:

Veterans Administration.

F. Duties and Functions of the Committee:

1. The Committee shall consist of fifteen members appointed by the Administrator after requesting and considering recommendations from veterans service organizations. During the first year, one third of the members will have a one year term, one third will have a two year term and one third will have a three year term. Thereafter, the term of service for each member shall be three years. The Administrator may reappoint any member for additional terms of service. Eleven of the members shall have expertise in biomedical and environmental sciences, including three experts in fields pertinent to understanding the health effects of exposure to dioxin; three experts in fields pertinent to understanding the health effects of exposure to ionizing radiation; and five experts in fields, such as epidemiology and other scientific disciplines, pertinent to determining and assessing the health effects of exposure to dioxin or ionizing radiation in exposed populations. These eleven members shall comprise the Scientific Council of the Committee. The remaining four members shall be individuals from the general public, including a disabled veteran, who have demonstrated an interest in and experience relating to veterans' concerns regarding exposure to dioxin or to radiation. The Chief Medical Director and the Chief Benefits Director are ex officio, non-voting members of the Committee.The Administrator shall appoint the Chairperson of the full Committee and of the Scientific Council.

2. Pub. L. No. 98-542 requires the Administrator to promulgate regulations setting forth the circumstances under which service connection for disabilities resulting from specific diseases may or may not be established. In the case of Vietnam veterans, the diseases include chloracne, porphyria cutanea tarda, and soft tissue sarcomas; in the case of veterans exposed to ionizing radiation as a result of participation in atomic weapons testing or service with the occupation forces of Hiroshima or Nagasaki, Japan, the diseases include most leukemias; cancers of the thyroid, female breast, lung, bone, liver, and skin; and polycythemia vera. Other diseases may be added. Regulations pertaining to these diseases must be based

upon sound medical and scientific evidence. In addition, the Administrator must evaluate the evidence concerning diseases alleged to result from exposure and publish the evaluations in the Federal Register. The regulations must explain how these evaluations are to be used in claims adjudication. In developing these regulations, the Administrator may consult with the Committee. Before the regulations are made final, the Administrator must consult with the Committee and the Scientific Council.

3. The full Committee will submit to the Administrator any recommendations it considers appropriate for administrative or legislative action. Taking into account the advice of the Scientific Council, it will specifically provide advice and recommendations concerning the guidelines and standards and criteria proposed by the Veterans Administration for the resolution of claims for benefits under laws administered by the Veterans' Administration based upon exposure to dioxin or to ionizing radiation.

4. The Scientific Council will consist of two eight-member panels, one focusing on issues relating to exposure to dioxin and the other focusing on issues relating to exposure to ionizing radiation. The Chairperson of the Council shall designate the members of each panel. Each panel will evaluate scientific studies relating to their particular subject matter. The full Council will make findings and evaluations in light of the appraisals of the respective panels regarding pertinent scientific studies and will make periodic reports to the Committee and to the Administrator directly on such findings and evaluations. The Council and the panels will also consider whether there is sound scientific and medical evidence indicating a connection between particular diseases and exposure to dioxin or ionizing radiation and the Council will advise the Administrator of its conclusions in light of the advice of the appropriate panel.

G. Estimated Operating Costs:

The estimated annual cost for operating the Committee is $50,000 and approximately two person years.

H. Number and Frequency of Meetings:

The full Committee will hold at least one meeting per year. The Scientific Council will hold at least one additional meeting per year.

I. Termination Date:

Unless the authorizing statute is repealed by Congressional action, the Committee will have no termination date.

J. Date Charter is Filed:

VETERANS' ADVISORY COMMITTEE
ON ENVIRONMENTAL HAZARDS

RADIATION

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1 Constitution Avenue, N.E.
Washington, D.C. 20002

Honorable Michael D. Zimmerman
Supreme Court of Utah
Room 332
State Capitol Building
Salt Lake City, Utah 84114

federal register

Monday
April 22, 1985

Part V

Veterans Administration

38 CFR Parts 1 and 3

Adjudication of Claims Based on Exposure to Dioxin or Ionizing Radiation; Proposed Rules

VETERANS ADMINISTRATION

38 CFR Parts 1 and 3

Adjudication of Claims Based on Exposure to Dioxin or Ionizing Radiation

AGENCY: Veterans Administration.

ACTION: Proposed rules.

SUMMARY: The Veterans Administration (VA) proposes the following regulations to implement the "Veterans Dioxin and Radiation Exposure Compensation Standards Act." Pub. L. 98-542 (Oct. 24, 1984). The Act requires that the VA conduct rulemaking regarding its guidelines for the adjudication of compensation claims based upon disabilities or deaths of certain veterans who, while in military service, were exposed to ionizing radiation or herbicides containing dioxin. The stated purpose of the Act is to ensure compensation for "veterans who were exposed during service in the Armed Forces in the Republic or Vietnam to a herbicide containing dioxin or to ionizing radiation in connection with atmospheric nuclear tests or in connection with the American occupation of Hiroshima or Nagasaki, Japan, for all disabilities arising after that service that are connected, based on sound scientific and medical evidence, to such service."

DATES: Comments must be received on or before July 22, 1985. It is proposed to make these rules effective thirty days after date of publication of the final rules with the exception of § 3.813 which is proposed to be effective October 1, 1984, as required by law.

ADDRESSES: Interested persons are invited to submit written comments, suggestions, or objections regarding these rules to Administrator of Veterans Affairs (271A), Veterans Administration, 810 Vermont Avenue, NW., Washington, DC 20420. All written comments received will be available for public inspection only at the Veterans Services Unit, room 132, at the above address only between the hours of 8 a.m. and 4:30 p.m. Monday through Friday (except holidays) until August 5, 1985.

FOR FURTHER INFORMATION CONTACT: Robert M. White, Chief, Regulations Staff, Compensation and Pension Service, Department of Veterans Benefits (202) 389-3005.

SUPPLEMENTARY INFORMATION: The VA administers compensation programs for veterans disabled as a result of injuries or diseases incurred or aggravated during military service, and for survivors of veterans whose deaths result from such service connected causes. Monthly benefits are paid at statutory rates which vary with the level of disability or, for survivors, with the military pay grade of the deceased. Nearly two and one-quarter million veterans and 400,000 survivors are currently receiving these payments.

In certain cases, eligibility under these programs may arise if a veteran's disability or death can be traced to exposure, during military service, to ionizing radiation or dioxin. Under Pub. L. 98-542, VA is to set forth, for public comment, "guidelines and (where appropriate) standards and criteria" for its resolution of two categories of such claims: those based on exposure to herbicides containing dioxin (e.g., "Agent Orange") during service in the Republic of Vietnam, and those based on exposure to ionizing radiation in connection with participation in the atmospheric testing of nuclear weapons or the American occupation of Hiroshima or Nagasaki, Japan, at the close of World War II.

Section 5 of the new law specifies that regulations be issued to guide VA adjudication personnel in deciding the merits of these claims. The regulations are to ensure continuation of VA's current policy of granting claimants the benefit of the doubt when there is an approximate balance of positive and negative evidence regarding any material issue. The regulations are also to carry forward current policy of denying claims if the evidence makes clear that disability or death was caused by some post-service occurrence or resulted from the veteran's own willful misconduct.

These rules are to specify whether, and if so under what circumstances, certain diseases are to be recognized as connected to a veteran's exposure. The rules are to be grounded in "sound scientific and medical evidence." With respect to Vietnam veterans exposed to herbicides containing dioxin, the diseases for which rules must be issued are chloracne, porphyria cutanea tarda, and soft tissue sarcoma. For veterans exposed to ionizing radiation under the specified conditions, the diseases for which rules must be issued are leukemias, polycythemia vera, and malignancies of the thyroid, female breast, lung, bone, liver and skin. Additionally, the rules are to indicate how claims will be handled if based upon other diseases for which the Administrator finds there is sound scientific or medical evidence indicating a connection with such exposures.

In addition, the VA is to publish guidelines for its evaluation of studies into the health effects of exposure to ionizing radiation or herbicides containing dioxin, and give notice of these evaluations by publication in the Federal Register.

Section 6 of the Act authorizes a new "Veterans' Advisory Committee on Environmental Hazards." The 15-member committee, composed of an 11-member Scientific Council and 4 lay members, will formally consider these proposed regulations and may recommend changes before final rules are published. The panels of the Scientific Council are also responsible for advising the Administrator as to additional diseases to be covered by the regulations and respecting the study evaluations discussed above.

Finally, these regulations implement Section 9 of the Act, which authorizes "interim benefits" for certain Vietnam veterans.

Section 1.17 Study evaluations.

This section, to be added to Part 1 of 38 CFR Chapter I, relating to General Provisions, provides a formal process for the Agency's evaluations of scientific and medical studies relating to the possible adverse health effects of dioxin or radiation exposure. As contemplated by section 5(b) of the Act, the evaluations would be published from time to time in the "Notices" section of the Federal Register. In addition to statutory criteria—whether the findings are statistically significant, have withstood peer review, and are capable of replication—these evaluations would consider the views of the appropriate panel of the Scientific Council of the Advisory Committee and the significance of the study findings for veterans exposed to dioxin or ionizing radiation during military service.

"Statistical significance" is used by scientists and medical personnel to generalize the results of an investigation of a sample, e.g., laboratory experiment, an opinion poll, or an extensive "head count," to the relevant population. Tests for statistical significance estimate the chance that the investigation's results would have been achieved if the population had particular characteristics. The desired numerical value for statistical significance varies depending upon the information sought and how certain the scientists want to be that the results are not due to chance. Selection of these values depends upon the judgment of expert, qualified scientists, but in the absence of compelling evidence is based upon conventionally accepted numerical values.

"Peer review" is an accepted means of assuring scientific quality. It ordinarily

is performed by a group of a scientist's superiors or peers who review the research when it is completed to determine whether it has been properly conducted and whether the conclusions drawn are justified by the results obtained. Ordinarily the review groups are constituted within the scientist's organization, whether academic, governmental or private, often with participation by outside experts.

Section 3.102 Reasonable doubt policy.

This section of Part 3, Adjudication, is reworded and simplified. Since the 1920's, the purpose of the "reasonable doubt policy" has been to assure the resolution of close issues, material to the claim, in the claimant's favor whenever it is not unreasonable to do so.

Decisions on material issues—usually, issues that must be resolved in the claimant's favor if the benefit is to be granted—are made only after all available evidence has been assembled. If the evidence of record supports the claim and is adequately probative, there is no need for the application of the reasonable doubt policy. Conversely, if the evidence is insufficient to support the claim, the policy should not be applied. Entitlement should never be based on speculation or remote possibility. It sometimes happens, however, that the evidence supporting the claim is counterbalanced by other evidence that creates a reasonable doubt as to the claim's merits. In this type of situation, the reasonable doubt is to be resolved in the claimant's favor.

Section 5(a)(2) of the Act directs the Agency to assure that this policy, reformulated in section 2(13) of the Act, applies to dioxin and radiation exposure claims. Proposed new §§ 3.311a and § 3.311b (below) accordingly refer to § 3.102. To avoid possible confusion from alternative formulations, this regulatory proposal would realign the text of § 3.102 in accordance with the congressional reformulation. No substantive alteration of the "reasonable doubt" policy is intended.

Section 3.311a Dioxin rule.

This section, to be added to 38 CFR Part 3, provides guidelines and criteria for the resolution of veterans' claims based on exposure to a herbicide containing dioxin during military service in the Republic of Vietnam during the Vietnam era.

Background. Beginning in the 1940's, phenoxy herbicides were widely used in the United States and elsewhere by farmers, foresters, and homeowners. Herbicides were used during the Vietnam conflict to defoliate trees, remove ground cover, and destroy crops. Shipped in orange-striped barrels, Agent Orange was a liquid containing two chemicals, one of which, 2,4,5-trichlorophenoxyacetic acid (2,4,5-T), is contaminated during the manufacturing process by 2,3,7,8-tetrachlorodibenzo-p-dioxin, also known as TCDD or, more popularly, dioxin. The contaminant dioxin, first identified in the 1960's, is of special concern because studies have shown it to be highly toxic to certain animal species. More than 2.4 million United States military personnel served in Vietnam. Many were deployed in or near locations where Agent Orange was sprayed, and others—particularly the Ranch Hand group—participated in the spraying operations directly.

According to *The Toxicology, Environmental Fate, and Human Risk of Herbicide Orange and Its Associated Dioxin* (USAF Technical Report No. OEHL TR-78-92, 1978), about 10.6 million gallons of herbicides were sprayed in Vietnam, with a mean dioxin concentration of about 2 parts per million. During the 7-year period of Agent Orange use, about 3 million acres were sprayed at various times. The mean distribution of dioxin per acre is estimated at 0.00013 pounds (0.06 grams). Dioxin is photo-degradable, that is, it decomposes in sunlight. The soil concentration is estimated at 0.016 parts per billion.

There are other sources of human dioxin exposure besides Agent Orange, for example, exposure from industrial accidents, contaminated industrial wastes, farming and ranching herbicide applications, transportation accidents, and hexachloraphene, a germicidal agent widely used in the 1950's and 1960's.

Definitions. The term "dioxin" may refer to one of several chemicals. This section uses dioxin to refer only to 2,3,7,8-tetrachlorodibenzo-p-dioxin, the Agent Orange contaminant. Because some military personnel stationed elsewhere may have been present in the Republic of Vietnam, "service in the Republic of Vietnam" will encompass services elsewhere if the person concerned actually was in the Republic of Vietnam, however briefly.

The law requires these regulations to specify the circumstances under which service connection may be established for disability resulting from chloracne, porphyria cutanea tarda (PCT), or soft tissue sarcoma. These rules are to be based on sound scientific and medical evidence. In this section, "sound scientific evidence" consists of findings that are statistically significant, withstand peer review, and are capable of replication. "Sound medical evidence" means studies consonant with medical knowledge and conclusions on which medical treatment could be prudently based.

Exposure. In view of shifting personnel deployments, absence of on-site measurement of dioxin contamination and other factors, the Agency has adhered to a policy of presuming exposure if the veterans served in Vietnam during the relevant period. This section formalizes that existing policy.

Service connection. At the present time, there is sound scientific and medical evidence that chloracne, a skin disorder, can result from dioxin exposure. *See, e.g.*, Crow, K.D., Significance of Cutaneous Lesions in the Symptomatology of Exposure to Dioxins and Other Chloracnegens, in *Human and Environmental Risks of Chlorinated Dioxins and Related Compounds* (Tucker et al., ed., Plenum Press, 1983). Chloracne may subside spontaneously, but it can be a chronic condition. Industrial accident follow-up studies indicate that chloracne associated with dioxin exposure is manifest within days or weeks. This section provides that a veteran's disabling chloracne may be service connected if the first symptoms appeared within three months of the veteran's departure from the Republic of Vietnam.

PCT. Investigators concerned about the possible deleterious effects of Agent Orange exposure located studies of industrial accidents involving phenoxy chemicals in which some exposed individuals developed porphyria cutanea tarda (PCT). This is a relatively rare liver disorder also found in certain individuals who have a history of alcoholism. Further investigations have revealed that the PCT manifested in the industrial accidents occurred when workers were also exposed to hexachlorobenzene, a known potent cause of PCT. *See, e.g.*, Pazderova, et al., Chronic Intoxication by Chlorinated Hydrocarbons Formed During the Production of Sodium 2,4,5 trichlorophenoxyacetate, 26(9) *Proc. Lek.* 332 (1974), and Jones, R.E., Chelsky, M., Serrone, D.M., and Hillman, D.W., A Reassessment of the Evidence Linking Porphyria Cutanea Tarda to 2,3,7,8 tetrachlorodibenzo-p-dioxin (TCDD) Exposure (Submitted to *Human Pathology* for publication). Sound medical and scientific evidence does not support a causal association between dioxin exposure and the development of PCT. Hence, this section does not provide a basis for service connection, based on dioxin exposure, of a veteran's disabling PCT. *Soft tissue sarcomas.* Malignancies in the soft tissue sarcoma

category are relatively rare. While most of these malignancies are of unknown etiology, prolonged exposure to asbestos fibers is known to be a causative factor in the development of mesothelioma, sometimes classified as one of these sarcomas. Dioxin has not been shown to be a human carcinogen. Studies conducted in Sweden in the 1970's suggest a relationship between exposure to phenoxy herbicides and the subsequent development of soft tissue sarcomas, but studies published elsewhere, including studies in the United States, do not confirm the Swedish studies' hypothesis. See, e.g., Fingerhut et al., An Evaluation of Reports of Dioxin Exposure and Soft Tissue Sarcoma Pathology Among Chemical Workers in the United States, 10 *Scand. J. of Work, Enviroment and Health* 299 (1984), and Riihimaki, V., et al., Mortality of 2,4-D and 2,4,5-T Herbicide Applicators in Finland, 8 *Scand. J. of Work, Environment and Health* 37 (1982). At the present time, sound scientific and medical evidence does not afford a basis for a causal association between dioxin exposure and the development of malignancy of the soft tissue sarcoma group. Hence, this section does not provide for service connection, based on dioxin exposure, of disability resulting from these diseases.

Exceptions. This section provides that chloracne may not be established as service connected if the disability resulted from the veteran's own willful misconduct or there is a supervening, nonservice-connected cause of the disease.

Construction. Nothing in this section is to be construed as preventing the establishment of service connection for a disability that had its origin in military service. For example, a veteran suffering from PCT or a soft tissue sarcoma may establish service connection based on direct evidence that it existed in service or, in the case of a sarcoma, based on symptoms to a compensable degree within the one-year statutory presumptive period following discharge from service (see 38 U.S.C. §§301, 312).

Evaluations. This section provides for the appropriate use of study evaluations published in the "Notices" section of the Federal Register.

Section 3.311b Radiation rule.

This section provides guidelines and criteria for the resolution of claims for service connection of disabilities based on exposure to ionizing radiation as a result of participation in the atmospheric testing of nuclear weapons, the occupation of Hiroshima and Nagasaki, Japan, at the close of World War II, or other service activities. This section would replace existing § 3.311, which would be removed.

Background. Radiation exposures over which veterans have expressed greatest concern are those occurring during atmospheric nuclear testing and the occupation of Hiroshima and Nagasaki. From 1945 through 1962, the U.S. Atomic Energy Commission conducted some 235 atmospheric tests of nuclear weapons, principally in Nevada and the Pacific Ocean. Approximately 203,000 American military personnel participated in one or more of these tests.

To address concerns regarding possible health effects to test participants, the Defense Nuclear Agency (DNA) established the Nuclear Test Personnel Review (NTPR) program in 1977. Among the objectives of this program are identification of personnel involved in testing and compilation of available information on exposure levels. Extensive dose reconstruction has also been undertaken to calculate doses received by participating units and individuals and as a check on recorded dose information from film badges worn by test participants. Research conducted under the NTPR program indicates over 99 percent of atmospheric nuclear test participants reportedly received doses of 5 rem or less. To place this in perspective, 5 rem is the current Federal guideline for allowable annual radiation dose for radiation workers.

The bombings of Hiroshima and Nagasaki occurred in early August 1945. The first American occupation forces arrived in the vicinity of the Hiroshima bombing site 60 days after the bombing. Occupation forces arrived in Nagasaki 45 days after the bombing. Military records show that 11,000 men were billeted for at least a week during 1945-46 inside the city limits of Hiroshima and Nagasaki. Approximately 110,000 personnel spent at least one day within 10 miles of the city limits. An estimated 350,000 personnel were within 100 miles of Hiroshima and Nagasaki.

Substantial knowledge of residual radiation at these locations was derived from on-site surveys conducted shortly after the bombing and from extensive scientific reconstructions. Several factors, including the lapse of time between the bombing and the occupation, heavy rains during this period, the high burst altitude of the bombs used, and the brief duty tours of occupation participants combined to minimize exposure levels of the occupation forces. Analyses performed by the DNA indicate the highest radiation dose any occupation force participant could have received was less than one rem.

Ionizing radiation. Ionizing radiation is radiation having sufficient energy to free electrons from atoms. The resulting ions are capable of causing damage to human tissues. Ionizing radiation includes both electromagnetic radiation, e.g., gamma rays, and particulate radiation, e.g., alpha particles.

Exposure. Shifting personnel deployments, absence of on-site measurement of dioxin contamination and other factors make estimation of the extent of dioxin exposure for a particular veteran extremely difficult. In contrast, radiation exposure generally occurred in clearly defined areas on specific occasions, and measures were taken to monitor exposure levels. Thus, a veteran's in-service radiation dose can generally be estimated with relative precision. The proposed regulations define procedures for estimating radiation dose.

Procedures for service-connection determinations. Proposed § 3.311b is designed to ensure fairness to claimants and consistency and accuracy in the adjudication of radiation exposure claims. Procedures governing development of evidence, provisions presuming exposure in the absence of adequate records, use of outside experts and consultants, and reference to application of the reasonable-doubt standard are among the features of the proposed regulation designed to assure fair treatment of all claimants. Consistency and accuracy will be promoted by specification of minimum standards for extended consideration of claims and by clear definition of factors to be considered at each stage.

Under proposed § 3.311b(b), an initial review of claims based upon radiation exposure would be made in order to identify claims meriting further consideration under § 3.311b(c). The VA believes standards and criteria, *i.e.*, firm rules of decision, are appropriate in connection with this initial review.

Principles governing the disability compensation program preclude establishment of service connection, based upon radiation exposure, unless it can be concluded that exposure occurred as claimed. Further, the VA does not believe a claim merits extended consideration under proposed § 3.311b unless it involves a disease associated with radiation exposure. Proposed § 3.311b(b)(2) specifies those diseases which may be considered to result from radiation exposure. Finally, the proposed rule specifies that further consideration of a claim under § 3.311b is unnecessary if a veteran's disease

became manifest either before or after the period following exposure during which the disease, if related to exposure, would be expected to develop. Under the proposal, if these minimum criteria are met, further consideration of the claim under proposed § 3.311b will be accorded.

Proposed § 3.311b(c)(1) provides that claims meeting the initial review criteria will be referred to the Chief Medical Director. Under the proposed regulation, if the Chief Medical Director is convinced sound scientific and medical evidence supports the conclusion it is at least as likely as not the veteran's disease resulted from radiation exposure in service, the Chief Medical Director will provide the Chief Benefits Director with a written evaluation supporting this conclusion. If the Chief Medical Director determines there is no reasonable possibility the veteran's disease resulted from such exposure, he will so inform the Chief Benefits Director. For purposes of this section, the same definitions of sound scientific and medical evidence stated in proposed § 3.311a, pertaining to dioxin exposure, would apply.

In making determinations under proposed § 3.311b(c), the Chief Medical Director would consider the factors specified in proposed § 3.311b(e). These factors are intended as guidelines, or guidance to the decisionmaker, rather than standards or criteria. The VA considers proper claims resolution to require a balancing of these factors on a case-by-case basis. The factors specified are generally recognized in the medical and scientific literature as influencing the likelihood that a specific type of cancer is radiation induced. See, *e.g.*, Committee on the Biological Effects of Ionizing Radiations, *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation: 1980* (BEIR III report). However, at present, the relative weight of these factors is not susceptible to precise definition.

Proposed § 3.311b(c)(2) provides for referral of a claim to a consultant outside the VA when the Chief Medical Director is unable to determine whether it is at least as likely as not, or that there is no reasonable possibility, the veteran's disease is due to radiation exposure in service. Under proposed § 3.311b(d), the Chief Medical Director would select the consultant after receiving the recommendation of the Director of the National Cancer Institute. The Chief Medical Director would ask the consultant to evaluate the claim using the factors specified in proposed § 3.311b(e) and provide an opinion as to whether it is likely, unlikely, or approximately as likely as not the veteran's disease resulted from exposure to radiation in service. The consultant's opinion would provide valuable evidence for consideration by the Agency.

In all cases, the VA's Department of Veterans Benefits would adjudicate the claim under generally applicable procedures. Adjudication officials would give due consideration to all evidence of record, including any consultant's opinion, and to the policy of resolving reasonable doubt in favor of the claimant. Appeals of adverse decisions could be taken to the Board of Veterans Appeals.

Proposed § 3.311b(a)(2) would provide for referral to the Department of Defense, for a dose estimate, all radiogenic-disease claims based on exposure during atmospheric nuclear weapons testing or during the occupation of Hiroshima and Nagasaki. In other claims where radiation exposure is alleged, the Chief Medical Director would review records bearing on the veteran's radiation dose and apply available methodologies in preparation of a dose estimate.

Under proposed § 3.311b(a)(3), if a claimant submits a radiation dose estimate from a credible source which differs materially from the estimate derived from official sources, an independent expert selected by the Director of the National Institutes of Health will be asked to prepare a separate dose estimate for consideration with all other evidence in adjudication of the claim. To assure this procedure will be invoked only where differing estimates have been prepared by qualified persons having a familiarity with the claim at issue, a dose estimate would be considered from a credible source only if it was prepared by a person or persons certified by an appropriate governing body in the field of nuclear medicine or radiology and was based on analysis of the facts and circumstances of the veteran's exposure.

The difference between a claimant's credible-source estimate and the dose estimate from official sources would ordinarily be considered material and require referral to an independent expert if one estimate is at least double the other. However, the VA intends flexibility in application of this provision based on the circumstances of the individual claim. It is anticipated that, in claims involving high doses, referral to an independent expert may be appropriate in some cases even though one dose estimate is less than double the other. Conversely, when both estimates are very low, referral may not be necessary where, although one estimate is double or more than double the other, the difference is too small to be of significance in adjudication of the claim.

Basis for criteria. The VA considers the proposed criteria for evaluation of radiation claims fully supported by sound scientific and medical evidence and consistent with the policy of resolving reasonable doubt in favor of the claimant. In light of such evidence, the VA has tentatively concluded that service connection based on radiation exposure may be established for each disease referred to in section 2(5) of Pub. L. 98-542, with the exception of polycythemia vera and chronic lymphatic leukemia. The BEIR III report, page 287, Table A-1, indicated chronic lymphatic leukemia has not been observed as resulting from radiation exposure. The VA intends to request the advice of the Veterans' Advisory Committee on Environmental Hazards as to whether sound scientific and medical evidence exists linking these and other diseases to radiation exposure and anticipates that additional diseases may be included in the regulation as radiogenic diseases in the future.

Studies reviewed in the BEIR III report do not suggest a causal connection between skin cancer and low dose levels of ionizing radiation. A connection between skin cancer and radiation exposure at high dose levels is well-established, and skin cancer has, therefore, been included as a radiogenic disease in proposed § 3.311b(b)(2). The VA notes the apparent absence of sound scientific and medical evidence supporting an association between skin cancer and exposure to low levels of ionizing radiation.

The proposed regulations state that sound scientific and medical evidence does not establish a connection between polycythemia vera and radiation exposure. One study (Glyn G. Caldwell, et al., *Polycythemia Vera Among Participants of a Nuclear Weapons Test*, Journal of the American Medical Association, Vol. 252, pp. 662-664 (1984)) of the health and mortality of participants in the "Smoky" atmospheric nuclear test found a greater than expected incidence of polycythemia vera among test participants. However, the lack of other supporting documentation suggests the apparent excess of polycythemia vera cases may have resulted from chance or misdiagnosis. Despite the proposed exclusion of polycythemia vera from the list of radiogenic diseases in § 3.311b(b)(2), service connection may nonetheless be established under generally applicable adjudication

regulations for polycythemia vera becoming manifest during a veteran's period of service.

In order to provide every reasonable consideration to veterans seeking to establish service connection, the VA has proposed use in § 3.311b(b)(4) of the broadest periods of expected incidence supported by sound scientific and medical opinion. In particular, the BEIR III report stated that excess leukemias and bone cancers have been observed within 2 to 4 years after radiation exposure, but that evidence indicates the increased risk of these cancers becomes negligible 25 to 30 years after irradiation. The report goes on to state that, for all other radiation induced cancers reviewed, the minimal latent period is 10 years or more, and there is no indication increased cancer risk eventually declines. See BEIR III report, page 193.

Probability-of-Causation Tables. The Orphan Drug Act, Pub. L. 97-414, 7(b), 96 Stat. 2049, 2060 (1983), directed the Department of Health and Human Services (HHS) to develop and update radioepidemiological tables relating to the probability that certain cancers could result from prior exposure to radiation. The resulting tables have only recently become available.

Because of a lack of data regarding the health effects of low-level radiation exposure, the reliability of any such tables at the lower doses and for certain cancers would be open to some question. In fact, the VA notes that the Ad Hoc Working Group which developed these tables identified many significant sources of uncertainty associated with the tables. *Report of the National Institutes of Health Ad Hoc Working Group to Develop Radioepidemiological Tables* 79-115 (1986). Therefore, the proposed regulations do not adopt the use of the HHS tables, but VA has sought the guidance of the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) of the Federal Coordinating Council for Science, Engineering and Technology (FCCSET) in order to assess the potential utility of employing the tables in some fashion to adjudicate veterans' compensation claims. The Veterans' Advisory Committee on Environmental Hazards will also be asked for its views on this subject.

Section 3.813 Special interim benefits.

This section implements section 9 of the Act. A Vietnam veteran disabled from chloracne or PCT would be eligible for special interim benefits if the disease became manifest within one year of the veteran's departure from Vietnam. Interim benefits would be payable for the two-year period beginning October 1, 1984, at the same rate as compensation for service-connected disability. If the veteran died from the disease, the survivors would be eligible for interim benefits, paid like dependency and indemnity compensation. Interim benefits would not be payable if there is affirmative evidence that the disease was precipitated by a known cause that occurred after the veteran's departure from the Republic of Vietnam. Also, interim benefits would not be payable if the veteran (or survivor) is receiving compensation for disability (or death) resulting from the chloracne of PCT.

Regulatory Evaluations

The Administrator hereby certifies that these proposed regulations do not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, U.S.C. 601-612. Therefore, pursuant to 5 U.S.C. 605(b), these proposed regulations are exempt from the initial and final regulatory flexibility analyses requirements of section 603 and 604. The reason for this certification is that these regulations impose no regulatory burdens on small entities, and only claimants for VA benefits will be directly affected.

In accordance with Executive Order 12291, Federal Regulation, the VA has determined that these proposed regulations are non-major for the following reasons: (1) They will not have an effect on the economy of $100 million or more; (2) They will not cause a major increase in costs or prices; (3) They will not have significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Handicapped, Health care, Pensions, Veterans.

The Catalog of Federal Domestic Assistance program numbers are 64.109 and 64.110.

Approved: April 12, 1985.

Harry N. Walters,

Administrator.

38 CFR Part 1, GENERAL and Part 3, ADJUDICATION, are amended as follows:

PART 1—[AMENDED]

1. Part 1 is amended by adding a new § 1.17 to read as follows:

§ 1.17 Evaluation of studies relating to health effects of dioxin and radiation exposure.

(a) From time to time, the Administrator shall publish evaluations of scientific or medical studies relating to the adverse health effects of exposure to 2,3,7,8 tetrachlorodibenzo-p-dioxin or ionizing radiation in the "Notices" section of the Federal Register.

(b) Factors to be considered in evaluating scientific studies include:

(1) Whether the study's findings are statistically significant and replicable.

(2) Whether the study and its findings have withstood peer review.

(3) Whether the study methodology has been sufficiently described to permit replication of the study.

(4) Whether the study's findings are applicable to the veteran population of interest.

(5) The views of the appropriate panel of the Scientific Council of the Veterans' Advisory Committee on Environmental Hazards.

(Pub. L. 98-542)

PART 3—[AMENDED]

2. Part 3 is amended by revising § 3.102, by removing and reserving § 3.311 and by adding new §§ 3.311a, 3.311b and 3.813 so that the new and revised material reads as follows:

§ 3.102 Sufficiency of the evidence: benefit of reasonable doubt to the claimant.

The policy of the VA in adjudicating claims is to administer the law under a broad interpretation, consistent with the facts shown in each claim. Evidence supporting the claimant's position must be sufficient to justify a belief in a fair and impartial mind that the claim is well grounded. Entitlement to benefits may not be based on pure speculation or remote possibility. When, after consideration of all evidence of record, there is an approximate balance of positive and negative evidence regarding the merits of an issue material to a claim, the benefit of the doubt in resolving that issue shall be given to the claimant.

(38 U.S.C. 210(c))

§ 3.311a Claims based on exposure to herbicides containing dioxin during service in the Republic of Vietnam.

(a) *Definitions.* For purposes of this section:

(1) "Service in the Republic of Vietnam" includes service in the waters

offshore and service in other locations, if the conditions of service involved duty or visitation in the Republic of Vietnam.

(2) "Dioxin" means 2,3,7,8 tetrachlorodibenzo-p-dioxin.

(3) "Sound scientific evidence" means observations, findings, or conclusions which are statistically significant, are capable of replication, and withstand peer review.

(4) "Sound medical evidence" means observations, findings, or conclusions which are consistent with current medical knowledge and are so reasonable and logical as to serve as the basis for management of a medcial condition.

(b) *Presumption of exposure.* A veteran who served in the Republic of Vietnam during the Vietnam era shall be presumed to have been exposed to a herbicide containing dioxin while in Vietnam. The commencement date of any period specified in paragraph (c) of this section shall be the day of the veteran's latest departure from the Republic of Vietnam during such service.

(c) *Service-connection based on dioxin exposure.* Except as provided in paragraph (e) of this section, exposure to dioxin together with the development of the following disease within the period specified is sufficient to establish service-connection for resulting disability: Chloracne manifested not later than three months from the date of exposure.

(d) *Diseases not associated with dioxin exposure.* Sound scientific and medical evidence does not establish a cause and effect relationship between dioxin exposure and the following:

(1) Porphyria cutanea tarda.

(2) Soft tissue sarcomas.

(3) Any other disease not specified in paragraph (c) of this section.

(e) *Exceptions.* Service-connection will not be established if the claimed disease is due to the veteran's own willful misconduct or there is affirmative evidence that establishes a nonservice-related supervening condition or event as the cause of the disease.

(f) *Study evaluations.* In the adjudication of individual claims, due consideration shall be given to the evaluations of study findings published pursuant to § 1.17 of this title.

(g) *Service-connection under other provisions.* Nothing in this section will be construed to prevent the establishment of service-connection for any disease or disorder shown by sound scientific or medical evidence to have been incurred in or aggravated by active service.

(h) *Reasonable doubt doctrine.* With regard to any issue material to the determination of an individual claim, the provisions of § 3.102 of this title shall apply.

(Pub. L. 98-542)

§ 3.311b Claims based on exposure to ionizing radiation.

(a) *Determinations of exposure and dose*—(1) *Dose assessment.* In all claims in which it is established that a radiogenic disease, listed in paragraph (b) (2) of this section, first became manifest after service and was not manifest to a compensable degree within any applicable presumptive period as specified in § 3.307, and it is contended the disease is a result of exposure to ionizing radiation in service, an assessment will be made as to the size and nature of the radiation dose or doses.

(2) *Request for dose information.* Where necessary pursuant to paragraph (a) (1) of this section, dose information will be requested as follows:

(i) *Atmospheric nuclear weapons test-participation claims.* In claims based upon participation in atmospheric nuclear testing, dose data will in all cases be requested from the appropriate office of the Department of Defense.

(ii) *Hiroshima and Nagasaki occupation claims.* In all claims based on participation in the American occupation of Hiroshima or Nagasaki, Japan, prior to July 1, 1946, dose data will be requested from the Department of Defense.

(iii) *Other exposure claims.* In all other claims involving radiation exposure, a request will be made for the veteran's Record of Occupational Exposure to Ionizing Radiation (DD Form 1141), if maintained, service medical records, and other records which may contain information pertaining to the veteran's radiation dose in service. All such records will be forwarded to the Chief Medical Director, who will be responsible for preparation of a dose estimate, to the extent feasible, based on available methodologies.

(3) *Referral to independent expert.* When necessary to reconcile a material difference between an estimate of dose, from a credible source, submitted by or on behalf of a claimant, and dose data derived from official military records, the estimates and supporting documentation shall be referred to an independent expert, selected by the Director of the National Institutes of Health, who shall prepare a separate radiation dose estimate for considerational in adjudication of the claim. For purposes of this paragraph:

(i) The difference between the claimant's estimate and dose data derived from official military records shall ordinarily be considered material if one estimate is at least double the other estimate.

(ii) A dose estimate shall be considered from a "credible source" if prepared by a person or persons certified by an appropriate governing body in the field of nuclear medicine or radiology and if based on analysis of the facts and circumstances of the particular claim.

(4) *Exposure.* In cases described in paragraph (a) (2) (i) and (a) (2) (ii) of this section:

(i) If military records do not establish presence at or absence from a site at which exposure to radiation is claimed to have occurred, the veteran's presence at the site will be conceded.

(ii) Neither the veteran nor the veteran's survivors may be required to produce evidence substantiating exposure if the information in the veteran's service records or other records maintained by the Department of Defense is consistent with the claim that the veteran was present where and when the claimed exposure occurred.

(b) *Initial review of claims.* (1) When it is determined:

(i) A veteran was exposed to ionizing radiation as a result of participation in the atmospheric testing of nuclear weapons; the occupation of Hiroshima or Nagasaki, Japan, from September 1945 until July 1946; or other activities as claimed;

(ii) The veteran subsequently developed a radiogenic disease specified in paragraph (b)(2) of this section; and

(iii) Such disease first became manifest within the period specified in paragraph (b)(4) of this section; before its adjudication the claim will be referred to the Chief Medical Director for further consideration in accordance with paragraph (c) of this section. If any of the foregoing 3 requirements has not been met, it shall not be determined that a disease has resulted from exposure to ionizing radiation under such circumstances. (But see paragraph (h) of this section.)

(2) For purposes of paragraphs (a)(1) and (b)(1) of this section, "radiogenic disease" shall include only the following:

(i) All forms of leukemia except chronic lymphatic leukemia;

(ii) Thyroid cancer;

(iii) Female breast cancer;

(iv) Lung cancer;

(v) Bone cancer;

(vi) Liver cancer; and

(viii) Skin cancer.

(3) For purposes of paragraphs (a)(1) and (b)(1) of this section, "radiogenic disease" shall not include polycythemia vera.

(4) For purposes of paragraph (b)(1) of this section:

(i) Leukemias and bone cancer must become manifest more than 2 years but less than 30 years after exposure;

(ii) Other forms of cancer specified in paragraph (b)(2) of this section must become manifest 10 years or more after exposure.

(c) *Review by Chief Medical Director.* (1) When a claim is forwarded for review pursuant to paragraph (b)(1) of this section, the Chief Medical Director shall consider the claim with reference to the factors specified in paragraph (e) of this section.

(i) If after such consideration the Chief Medical Director is convinced sound scientific and medical evidence supports the conclusion it is at least as likely as not the veteran's disease resulted from exposure to radiation in service, the Chief Medical Director shall so inform the Chief Benefits Director in writing. The Chief Medical Director shall set forth the rationale for this conclusion, including an evaluation of the claim under the applicable factors specified in paragraph (e) of this section.

(ii) If the Chief Medical Director determines there is no reasonable possibility that the veteran's disease resulted from radiation exposure in service, the Chief Medical Director shall so inform the Chief Benefits Director in writing, setting forth the rationale for this conclusion.

(2) If the Chief Medical Director is unable to conclude whether it is at least as likely as not, or that there is no reasonable possibility, the veteran's disease resulted from radiation exposure in service, the Chief Medical Director shall refer the matter to an outside consultant in accordance with paragraph (d) of this section.

(3) For purposes of paragraph (c)(1) of this section, "sound scientific evidence" means observations, findings, or conclusions which are statistically significant, are capable of replication, and withstand peer review, and "sound medical evidence" means observations, findings, or conclusions which are consistent with current medical knowledge and are so reasonable and logical as to serve as the basis of management of a medical condition.

(d) *Referral outside consultants.* (1) Referrals pursuant to paragraph (c) of this section shall be to consultants selected by the Chief Medical Director from outside the VA, upon the recommendation of the Director of the National Cancer Institute. The consultant will be asked to evaluate the claim and provide an opinion as to the likelihood the disease is a result of exposure as claimed.

(2) The request for opinion shall be in writing and shall include a description of:

(i) The disease, including the specific cell type and stage, if known, and when the disease first became manifest;

(ii) The circumstances, including date, of the veteran's exposure;

(iii) The veteran's age, gender, and pertinent family history;

(iv) The veteran's history of exposure to known carcinogens, occupationally or otherwise;

(v) Evidence of any other effects radiation exposure may have had on the veteran; and

(vi) Any other information relevant to determination of causation of the veteran's disease.

The Chief Medical Director shall forward, with the request, copies of pertinent medical records and, where available, dose assessments from official sources, from credible sources as defined in paragraph (a)(3)(ii) of this section, and from an independent expert pursuant to paragraph (a)(3) of this section.

(3) The consultant shall evaluate the claim under the factors specified in paragraph (e) of this section and respond in writing, stating whether it is either likely, unlikely, or approximately as likely as not the veteran's disease resulted from exposure to ionizing radiation in service. The response shall set forth the rationale for the consultant's conclusion, including the consultant's evaluation under the applicable factors specified in paragraph (e) of this section. The Chief Medical Director shall review the consultant's response and transmit it with any comments to the Chief Benefits Director for use in adjudication of the claim.

(e) *Factors for consideration.* Factors to be considered in determining whether a veteran's disease resulted from exposure to ionizing radiation in service include:

(1) The probable dose, in terms of dose type, rate and duration as a factor in inducing the disease, taking into account any known limitations in the dosimetry devices employed in its measurement or the methodologies employed in its estimation;

(2) The relative sensitivity of the involved tissue to induction, by ionizing radiation, of the specific pathology;

(3) The veteran's gender and pertinent family history;

(4) The veteran's age at time of exposure;

(5) The time-lapse between exposure and onset of the disease; and

(6) The extent to which exposure to radiation, or other carcinogens, outside of service may have contributed to development of the disease.

(f) *Adjudication of claim.* The determination of service connection will be made under the generally applicable provisions of this part, giving due consideration to all evidence of record, including any evaluation by the Chief Medical Director or an outside consultant, and to the evaluations published pursuant to § 1.17 of this title. Notwithstanding any determination under paragraph (c)(1) of this section, the Chief Benefits Director may request that the Chief Medical Director refer any claim to an outside consultant. With regard to any issue material to consideration of a claim, the provisions of § 3.102 of this title apply.

(g) *Willful misconduct and supervening cause.* In no case will service connection be established if the disease is due to the veteran's own willful misconduct, or if there is affirmative evidence to establish that a supervening, nonservice-related condition or event is more likely the cause of the disease.

(h) *Service connection otherwise established.* Nothing in this section will be construed to prevent the establishment of service connection for any injury or disease otherwise shown by sound scientific or medical evidence to have been incurred or aggravated as a result of active service.

(Pub. L. 98-542)

§ 3.613 Interim benefits for disability or death due to chloracne or porphyria cutanea tarda.

(a) *Disability benefits.* Except as provided in paragraph (c) of this section, a veteran who served in the active military, naval or air service in the Republic of Vietnam during the Vietnam era, and who suffers from chloracne or porphyria cutanea tarda which became manifest within one year after the date of the veteran's most recent departure from the Republic of Vietnam during such service, shall be paid interim disability benefits under this section in the same manner and to the same extent that compensation would be payable if such disabilities were service-connected.

(b) *Death benefits.* Except as provided in paragraph (c) of this section, if a veteran described in paragraph (a) of this section dies as a result of chloracne or porphyria cutanea tarda, the

veteran's survivors shall be paid interim death benefits under this section based upon the same eligibility requirements and at the same rates that dependency and indemnity compensation would be payable if the death were service-connected.

(c) *Exceptions.* Benefits under this section are not payable for any month for which compensation or dependency and indemnity compensation is payable for the same disability or death, nor are benefits payable under this section (1) when there is affirmative evidence that the disease was not incurred by the veteran during service in the Republic of Vietnam during the Vietnam era, (2) when there is affirmative evidence to establish that an intercurrent injury or disease, which is a recognized cause of the disease for which benefits are being claimed, was suffered by the veteran between the date of the veteran's most recent departure from the Republic of Vietnam during active military, naval or air service and the onset of the claimed disease, or (3) if it is determined, based on evidence in the veteran's service records and other records provided by the Secretary of Defense, that the veteran was not exposed to dioxin during active military, naval or air service in the Republic of Vietnam during the Vietnam era.

(d) *Similarity to service-connected benefits.* For purposes of all laws administered by the VA (except chapters 11 and 13 of Title 38, United States Code), a disease establishing eligibility for disability or death benefits under this section shall be treated as if it were service-connected, and the receipt of disability or death benefits shall be treated as if such benefits were compensation or dependency and indemnity compensation, respectively.

(e) *Effective dates.* Benefits under this section may not be paid for any period prior to October 1, 1984, nor for any period after September 30, 1986.

(Pub. L. 98-542) (Oct. 1, 1984)

[FR Doc. 85-9743 Filed 4-19-85; 8:45 am]
BILLING CODE 8320-01-M

VETERANS' ADVISORY COMMITTEE ON ENVIRONMENTAL HAZARDS

Dioxin Experts

George D. Lathrop, M.D., Ph.D., JRB Associates, San Antonio, Texas
Dr. Lathrop received his medical degree from the University of Illinois in 1962 and his doctorate in epidemiology from the University of California at Berkley in 1968. Formerly the Chief, Epidemiology Division, United States Air Force School of Aerospace Medicine, Dr. Lathrop was the chief investigator for the Air Force "Ranch Hand" study. He is a Fellow of the American College of Preventive Medicine and is certified by the American Board of Preventive Medicine. He is a member of several professional organizations, including the American Public Health Association and the Texas Society of Infectious Diseases.

Walter Melvin, M.D., Professor of Environmental Health Sciences, Colorado State University, Fort Collins, Colorado
Dr. Melvin received his medical degree from the University of Colorado in 1949, a Master of Public Health degree in industrial hygiene from the Harvard University School of Public Health, and a Doctor of Science degree in Environmental Toxicology and Occupational Health from the University of Cincinnati in 1962. He is a founding member of the American College of Toxicology, a Fellow in the American Public Health Association, and a member of a number of other professional associations.

James S. Taylor, M.D., Department of Dermatology, Cleveland Clinic Foundation, Cleveland, Ohio
Dr. Taylor received his medical degree in 1966 from Indiana University and is certified by the American Board of Dermatology. He currently is the head of the section on Industrial Dermatology at the Cleveland Clinic, a post he has held since 1973, and has written several publications on chloracne.

Radiation Experts

James V. Neel, M.D., Ph.D., Professor of Genetics, University of Michigan Medical School, Ann Arbor, Michigan
Dr. Neel received his doctorate in genetics in 1939 and his medical degree in 1944, both from the University of Rochester. He served on the National Research Council's Atomic Bomb Casualty Commission. His membership in professional organizations includes the National Academy of Sciences, the Association of American Physicians, the American Philosophical Society, and the American Society of Naturalists. His principal professional interest is in the area of the genetics of man. He as had extensive experience in the area of the genetic effects of radiation.

Arthur C. Upton, M.D., Institute of Environmental Medicine, New York University Medical Center, New York, New York
Dr. Upton received his medical degree from the University of Michigan in 1946 and is certified by the American Board of Pathology. He has had extensive experience in the area of the effects of radiation exposure with particular interest in the pathology of radiation injury and endocrine glands, cancer, carcinogenesis, experimental leukemia, and aging. He was recently the Director of the National Cancer Institute.

Edward W. Webster, Ph.D., Department of Radiology, Massachusetts General Hospital, Boston, Massachusetts
Dr. Webster received his doctorate in electrical engineering from the University of London in 1946. His particular areas of interest are radiological physics, including radiation dosimetry and protection, in which he is certified by the American Board of Radiology. He is a member of a number of professional associations, including the American Association of Physicists in Medicine, the Health Physics Society and the Society of Nuclear Medicine.

Generalists

Michael Bender, Ph.D., Brookhaven National Laboratory, Upton, New York.
Dr. Bender received his doctorate in biology from the Johns Hopkins University in 1956. He has had experience in the field of radiation and genetics. He is a member of several professional societies, including the American Society for Cell Biology, the Radiation Research Society and the Environmental Mutagen Society.

Theodore Colton, Sc.D., Professor of Public Health, Boston University School of Public Health, Boston, Massachusetts
Dr. Colton received his doctorate from the Johns Hopkins University in 1960. He has had extensive experience in the field of biostatistics and epidemiology. The professional organizations to which he belongs include the Society for Epidemiological Research, the American Public Health Association, and the Biometrics Society. He is a Fellow of the American Statistical Association.

Leonard T. Kurland, M.D., Dr. P.H., M.P.H., Chairman, Department of Medical Statistics and Epidemiology, Mayo Clinic, Rochester, Minnesota
Dr. Kurland received his medical degree from the University of Maryland in 1945, his master's degree in public health from Harvard University in 1948 and his doctorate in public health from the Johns Hopkins University in 1951. He is certified by the American Board of Preventive Medicine. Among his professional interests is the epidemiology of chronic disease. He is a member of the American Epidemiological Society.

Warren K. Sinclair, Ph.D., President, National Council on Radiation Protection and Measurements, Bethesda, Maryland
Dr. Sinclair received his doctorate in physics from the University of London in 1950. His professional interest is in the areas of radiation protection, radiation physics, and radiation biology. His membership in professional organizations includes the Radiation Research Society, the Society of Nuclear Medicine, and the Association of Physicists in Medicine.

Armon F. Yanders, Ph.D., Professor of Biological Sciences and Director, Environmental Trace Substances Research Center, University of Missouri, Columbia, Missouri
Dr. Yanders received his doctorate in zoology from the University of Nebraska in 1953. A geneticist and former Dean of the College of Arts and Sciences of the University of Missouri at Columbia, he is a member of the American Society of Zoologists, and the Genetics Society of America. His research has involved the genetic effects of ionizing radiation and toxic chemicals.

Lay Members

Oliver Meadows, Godley, Texas
Mr. Meadows is a former National Commander of the Disabled American Veterans and former staff director of the House of Representatives' Veterans' Affairs Committee. A disabled veteran of World War II, he currrently serves on the Administrator's Educational Assistance Advisory Committee.

Gerald C. Bender, Jr., Minneapolis, Minnesota
Mr. Bender served in combat in Vietnam and is a disabled veteran. Trained as a lawyer, he currently is the Director of the Agent Orange Information and Assistance Program for the Minnesota Department of Veterans' Affairs.

Hon. Michael Zimmerman, Supreme Court of Utah, Salt Lake City, Utah
Justice Zimmerman was recently appointed to the Supreme Court of Utah. As the Governor of Utah's former representative on the Department of Energy's Offsite Dose Assessment Advisory Committee, he has a demonstrated interest in the issue of radiation-induced illnesses.

Col. Eileen Bonner, Washington, D.C.
Col. Bonner is the current president of the Reserve Officers' Association. A registered nurse, she is a doctoral candidate at Columbia University and a health care administrator.

CENTERS FOR DISEASE CONTROL

CENTER FOR ENVIRONMENTAL HEALTH - AGENT ORANGE PROJECTS

1600 Clifton Road, N. E., Atlanta, Georgia 30333 (404)454-4472

Project Description for:

EPIDEMIOLOGIC STUDY OF THE HEALTH OF VIETNAM VETERANS
The study includes the following three components:

1) Agent Orange Study. (Study of the long-term health effects of exposure to herbicides in Vietnam.)
2) Vietnam Experience Study. (Study of the long-term health effects of military service in Vietnam.)
3) Selected Cancers Study. (Study to determine the risks of specific cancers among Vietnam veterans.)

BACKGROUND: Between August 1965 and February 1971 approximately 11.3 million gallons of the herbicide "Agent Orange" (so named because of the orange markings on the drums in which it was shipped) were sprayed over much of South Vietnam in military operations designed to deprive the enemy of cover and food. A chemical contaminant, 2,3,7,8-tetrachlorodibenzo-p-dioxin, more often called TCDD, or simply dioxin, was created during manufacture of and contained in the Agent Orange which was sprayed. Dioxin has been shown to be a highly toxic substance.

In January 1978 the Veterans' Administration (VA) received the first of what was to become many claims from veterans who felt that their current health problems had resulted from their being exposed to Agent Orange while serving in Vietnam. In January 1979 the U.S. Congress enacted legislation (Public Law 96-151) directing the VA to design and conduct an epidemiologic study to determine if exposure to Agent Orange had caused long-term adverse health effects in Vietnam veterans. In November 1981 the scope of the study was expanded (by Public Law 97-72) to include other factors in the "Vietnam experience," including medications and environmental hazards or conditions.

In January 1983 the responsibility for designing and conducting the investigation was transferred from the VA to the Centers for Disease Control (CDC). In May 1983 CDC scientists completed detailed guidelines (protocols) for the Agent Orange and Vietnam Experience studies, recommending that a third investigation be conducted at the same time to determine the risk of Vietnam veterans developing selected types of cancers.

Public "Notice of Research Project Initiation" was published in the Federal Register on March 13, 1984.

DESCRIPTION: AGENT ORANGE AND VIETNAM EXPERIENCE STUDIES. Although both of these historical, or "retrospective," studies are in some respects similar, each has a separate purpose. The Agent Orange study is designed to find out if troops who were exposed to the herbicide during service in Vietnam have suffered long-term adverse health effects as a result of that exposure. The Vietnam Experience study is designed to demonstrate whether or not there is any difference in the health of veterans of the Vietnam era who served in Vietnam compared to the health of veterans who served in other countries during the same period of time.

The studies require the cooperation of a large number of Vietnam era veterans willing to be interviewed about their health status and experiences before, during, and after those years. With the help of the Department of Defense and other agencies, CDC will identify 30,000 qualified veterans to participate in the studies: 6,000 in each of five separate, specially defined groups or "cohorts." The five cohorts are to be made up of veterans who:

1) Served during 1967-68 in a specified area of Vietnam, and were likely to have been exposed to Agent Orange.

2) Served during 1967-68 in the same area of Vietnam as cohort 1, and were less likely to have been exposed to Agent Orange.

3) Served during 1967-68 in another area of Vietnam than cohorts 1 and 2, and were not likely to have been exposed to Agent Orange.

4) Served in Vietnam during 1966-71. Randomly selected from all areas.

5) Served during 1966-71 in countries other than Vietnam.

Data for the Agent Orange investigation will be gathered from cohorts 1, 2, and 3. Cohorts 4 and 5 will provide data for the Vietnam Experience study.

The interview takes about 45 minutes and will be conducted by telephone. After being interviewed, as many as 2,000 veterans from each cohort will be randomly selected and asked to take comprehensive medical examinations which will take three days to complete. To ensure that standard testing procedures are used, these 10,000 examinations will be conducted at one location: Albuquerque, New Mexico. Veterans' expenses for travel and lodging, etc., will be paid by the government. A stipent ($300) will be paid to each veteran who completes the medical examination.

Veteran interviews in connection with the CDC study began in September, 1984, and will continue until about October, 1987. The medical examinations will be conducted from March, 1985, until about January, 1988.

To ensure statistical accuracy, no volunteers can be included as participants in the studies. Participants will be randomly selected.

To determine whether and to what degree their experiences have affected the health of veterans in the five cohorts, CDC researchers will use computers and complex mathematical analyses to compare the millions of data collected during the study. Non-government research firms, under careful scientific and managerial surveillance by CDC officials, have been contracted to collect some of these data. All personal information collected during the study will be held in complete confidence. Physicians and other health providers working on the CDC studies will not provide any treatment for individuals. If a veteran's medical examination indicates the possible existence of a problem of any sort, the veteran will be advised immediately and encouraged to seek treatment from the VA, private, or other sources of medical services.

DESCRIPTION: SELECTED CANCERS STUDY. There is some scientific evidence that exposure to herbicides may increase the risk of several serious, but relatively rare, cancers in workers in industries which manufacture or use similar products. Because these cancers are so infrequently seen, the 30,000 veterans in the other study cohorts do not offer a large enough sample population upon which to base this investigation. Instead, two other groups will be studied in a "case-control" investigation. The first (case) group will be made up of male patients who have actually had these tumors, and who could have been in the military during the Vietnam conflict. The second (control) group will include men of the same age and from the same current geographic area as the case cohort, but without the tumors.

INVESTIGATION RESULTS: The exact rate of progress of epidemiological studies of this size cannot be forecast. Collection and analysis of the large amounts of data needed for scientifically valid findings takes time; particularly when so many thousands of veterans must be identified, located, interviewed, and examined. CDC will report on each component of the study when it has been completed. Final reports on the Agent Orange and Vietnam Experience components are expected by September 30, 1988. The final report on the Selected Cancers Study component is expected by September 30, 1989.

CDC hopes that these studies will provide answers to many of the important questions being asked about Agent Orange and other factors related to service in Vietnam. But, as in every epidemiologic investigation--no matter how carefully designed and professionally conducted--the possibility exists that definitive answers to some questions may never be found.

AGENT ORANGE EXPOSURE

The claims of a number of veterans who have alleged disabilities due to Agent Orange have been denied because of the lack of evidence showing the existence of a disability attributable to exposure to that chemical. As claims are encountered in which the veteran is claiming exposure to Agent Orange, the information pertaining to availability of hospital examination and treatment is furnished to the veteran.

In those instances where the veteran alleges Agent Orange exposure only, all available service clinical and treatment records are obtained and reviewed by the rating board for any indication of service-connectable disability. Consistent with our reasonable doubt policy, given the considerable uncertainties as to the deposition of defoliants in Southeast Asia and troop positions at pertinent times, we accept, in absence of affirmative evidence to the contrary, a Vietnam veteran's contention of exposure.

A register of Agent Orange claims is being maintained by the VA while studies are being accomplished in the area of Agent Orange.

April 1, 1985

AGENT ORANGE CLAIMS

		NUMBER	PERCENT
A.	Total Number of Claims	24174	100.0%
	Claims with Diagnosis Confirmed	11697	48.4%
	Claims with Diagnosis not Confirmed	6119	25.3%
	Claims with No Disability Alleged	6358	26.3%
B.	Claims with Diagnosis Confirmed	11697	100.0%
	Allowed for Reason Other than Agent Orange	2049*	17.5%
	Denied	9648a	82.5%

a. These 9648 claims having more than one claimed diagnosis fall into the following categories:

Skin condition (acne, alopecia, eczema, keloids and urticaria)	5373
Nervousness, headaches and fatigue (claimed)	2562
Paralysis or numbness and other symptoms of extremities	966
GI and GU conditions	890
Malignancies (leukemia, lymphoma, melanoma, Hodgkin's, etc)	854
Impaired sexual activity (alleged)	341
EENT pathology	481
Lung condition	332
Cardiovascular and hypertension	290
Misc.	162

* Approximately 96.5% or 1981 of the total 2049 claims allowed are service connected for skin condition. Balance of 3.3% or 68 claims were allowed for cancer, psychiatric and neurological conditions and various other miscellaneous disabilities.

IONIZING RADIATION EXPOSURE

Approximately 203,000 veterans participated in atomic tests since Operation Crossroads in Bikini Atoll in 1946. Claims have been received from approximately 4,800 of these veterans alleging exposure to radiation from atmospheric tests, from participating in the clean-up operations in Hiroshima and Nagasaki, from occupational exposure while working with radiation material, and from therapeutic exposure such as x-ray therapy received during treatment.

The best available evidence indicates that the average radiation doses received by veterans from weapons testing and by veterans of the occupation of Hiroshima and Nagasaki were very low. Further, there is little solid scientific evidence to support a causal connection between exposure of the levels involved here and the subsequent development of illnesses.

Over the years, we have received 955 claims in which leukemia and other malignancies have been claimed to be due to exposure received during atmospheric tests. Most claims which have been allowed are for leukemia and other malignancies. To date, no claims have been allowed based on exposure received while participating in the occupation of Hiroshima and Nagasaki.

In evaluating claims for radiation injury or disease, the policy of the VA is that service connection may be established for either the immediate or delayed direct results of ionizing radiation. Our review of diseases or injuries resulting from radiation has always followed detailed development of the facts and circumstances surrounding the exposure unique to each claim. In each claim, we consider the medical characteristics of the disease and the relationship in time between exposure and onset of the disease. We also consider the type, duration and cumulative amount of radiation exposure before arriving at a decision. It has, however, always been our policy that service connection

may be established without regard to the length of time between exposure and disease where the disease or injury is directly traceable to the effects of radiation during military service.

Our liberal approach of resolving all reasonable doubt in favor of the veteran has permitted allowance of a number of cancer claims filed on behalf of former nuclear weapons tests participants, even though their recorded radiation doses were very low and their diseases first appeared many years after service.

When called upon by the VA, the Defense Nuclear Agency will verify the veteran's participation in an A-test and the correctness of film badge readings based upon the individual's activities at each test in which he or she participated. In those instances where there is no record of a film badge reading for an individual, a reconstruction of the extent of his or her exposure together with the highest likely amount of radiation to which the individual may have been exposed while at the test will be furnished.

Under the law, Public Law 97-72, the hospital and medical treatment program of the Veterans Administration is available to all veterans who may be suffering from disease or injury resulting from ionizing radiation. Upon application, the hospital authorities will schedule the veteran for an examination and a professional determination will be made for his or her care. Our hospitals can and do provide the type of care required by the veteran's disability in accordance with his eligibility and entitlement.

Since we maintain a record of all claims for disability allegedly resulting from exposure to ionizing radiation, we are able to reconsider each claim for compensation benefits upon receipt of new and material evidence from any source.

Also, if the results of any of the ongoing epidemiological studies impel a change in our regulations or in the law, those individuals may be assured that their claims will be reviewed under such changes upon the initiative of the VA.

The Hiroshima-Nagasaki study is the only full statistical study on genetic damage in children born of survivors of the nuclear bombings of those cities. The study of the effects of long-term low-level exposure on offsprings is being carried on in the continuation of that study. This is being done by including recently born children of A-bomb survivors in the study and examining them at appropriate intervals; and, to date no evidence has been found of genetic malformation.

April 1, 1985

RADIATION EXPOSURE CLAIMS

		NUMBER	PERCENT
A.	Total Number of Cases in Study	4839	100.0%
	Cases with Diagnosis	3000	62.0%
	Cases no Diagnosis	1839	38.0%
B.	Cases with Diagnosis	3000	100.0%
	Allowed	78	2.6%
	Denied	2922	97.4%
C.	Total Cases in Study	4839	100.0%
	Claimed A-Test	2864	59.2%
	Claimed Other Exposure	1975	40.8%
D.	Those Who Claimed A-Test	2864	100.0%
	Allowed	15	0.5%
	Denied	1811*	63.2%
	No Diagnosis	1038	36.2%
E.	Those Who Claimed Other Exposure	1975**	100.0%
	Allowed	63	3.2%
	Denied	1086	55.0%
	No Diagnosis	826	41.8%

IN SUMMARY

Total Cases	4839	100.0%
Allowed	78	1.6%
Denied	2897	59.9%
No Diagnosis	1864	38.5%

* These 1811 claims have the following 1076 malignant diagnosis:

Histiocytic leukemia - 2	Blood condition - 5	Endocrine cancer - 33
Myelocytic leukemia - 29	Lymphocytic lymphoma - 35	Skin cancer - 151
Hairy cell leukemia - 7	Hodgkin's disease - 17	Brain tumor - 42
Unspecified leukemia- 37	Respiratory cancer - 280	Melanoma - 27
Lymphocytic leukemia- 29	G.U. Cancer - 135	Cancer, musculo-skeletal - 49
Myelogneous leukemia- 20	G.I. Cancer - 178	

** These 1975 claims contain 735 Nagasaki and Hiroshima claims consisting of leukemia and other malignancies 334; Misc. 251 and exposure only 150. None allowed.

Veterans Administration

REFERENCE SLIP

TO (Name or title—Mail routing symbol)	INITIALS—DATE
1. Alvin L. Young, Ph.D.	
2. Senior Policy Analyst for	
3. Life Sciences, OSTP	
4. Washington, D.C. 20506	
5.	

REASON FOR REFERENCE

- [ ] AS REQUESTED
- [ ] FOR YOUR FILES
- [ ] NOTE AND RETURN
- [ ] COMMENTS
- [ ] INFORMATION
- [ ] PER CONVERSATION
- [ ] CONCURRENCE
- [ ] NECESSARY ACTION
- [ ] SIGNATURE

REMARKS

SUBJ: Agenda for 4/22-23/85 Advisory Committee on Environmental Hazards Meeting

The attached agenda is forwarded for your information.

Att.

180,000 AO Reg 18 & CR Exams

FROM
FREDERIC L. CONWAY III (02C)
Special Assistant to
the General Counsel

DATE 4/8/85

TEL. EXT. 3723

VA FORM MAY 1960 3230 EXISTING STOCKS OF VA FORM 3230, AUG 1976, WILL BE USED. ☆ U.S. G.P.O. 1984-709-228

AGENDA

VETERANS' ADVISORY COMMITTEE ON ENVIRONMENTAL HAZARDS

April 22, 1985

9:30	Opening Comments.....	Chair
9:40	Welcome.....	Harry Walters Administrator of Veterans' Affairs Donald Ivers General Counsel Dr. John Ditzler Chief Medical Director John Hagan Acting Chief Benefits Director
10:00	Introductions.....	Frederic L. Conway Executive Secretary
10:10	Committee Organization.....	Chairman
10:30	VA's Disability Compensation Program.....	Gerald Moore, Director, Compensation and Pension Service
10:45	Public Law 98-542.....	John Thompson Deputy Assistant General Counsel
11:15	Discussion	
11:30	Lunch (on own)	

April 22, 1985 (cont.)

1:00	Agent Orange Overview.....	Alvin Young, Lt. Col. USAF, Ph.D. Senior Policy Analyst for Life Sciences, Executive Office of the President
2:15	Break	
2:30	Cabinet Council Agent Orange Working Group.....	Carl Keller, Ph.D, D.V.M. Chair, Science Panel
2:45	VA's Agent Orange Program...	Dr. Barclay Shepard Director, Agent Orange Projects Office
3:15	General Discussion	
4:00	Adjournment	

April 23, 1985

9:30 Atomic Weapons Testing and Hiroshima and Nagasaki, Japan Exposure.....Defense Nuclear Agency

10:30 Discussion

11:15 VA's actions regarding radiation exposure.....Dr. James Smith, Director, Nuclear Medicine Service

11:30 Lunch (on own)

1:00 Committee on Interagency Radiation Research and Policy Coordination.....Dr. Young

1:15 Proposed Regulations.....John Thompson

2:00 Break

2:15 General Discussion

3:00 Concluding Remarks.....Chairman

3:30 Adjournment