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Item ID Number	05640 ☐ **Not Scanned**
Author	
Corporate Author	
Report/Article Title	Part V, Veterans Administration: 38 CFR Parts 1 and 3, Adjudication of Claims Based on Exposure to Dioxin or Ionizing Radiation; Proposed Rules
Journal/Book Title	Federal Register
Year	1985
Month/Day	April 22
Color	☐
Number of Images	9
Descripton Notes	

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 1950'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-78-62, 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 hexachlorophene, 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 Chlorocnegens, 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, Environment 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

become 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(e)(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(e)(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 267, 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 (1984). 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 or 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 medical 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 considerations 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 dose, 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)

§ 3.313 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, 1988.

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

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