Uploaded to the VFC Website

2020

This Document has been provided to you courtesy of Veterans-For-Change!

Feel free to pass to any veteran who might be able to use this information!

For thousands more files like this and hundreds of links to useful information, and hundreds of "Frequently Asked Questions, please go to:

Veterans-For-Change

If Veterans don't help Veterans, who will?

Note: VFC is not liable for source information in this document, it is merely provided as a courtesy to our members & subscribers.

AO

Final Regulation
Proposed Regulation
Minutes - June 26, 1989
" - Sept 8, 1989
Transcripts - June 26, 1989 VA Comm on Env Hazards
Transcript - Sept 8, 1989

Contents

revegetated area prior to bond release for Reclamation Phase II work.

Paragraph (I) has been modified to require that bond release applications include proof of advertisement by the permittee of his filing of the release application. The MDDNR is granted discretionary authority to waive its inspection of the completed reclamation work if it has not received any objections or requests for an informal conference; and it has conducted an inspection of the area within a four month period prior to receiving the bond release application and the inspection did not identify any reason for denying bond release.

Paragraph (K) has been modified to allow the MDDNR to recover from the permittee all costs of reclamation in excess of the amount forfeited should the forfeited bond be insufficient to pay the full cost of reclamation.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(b), OSMRE is now seeking comments on whether the amendments proposed by Maryland satisfy the applicable program approval criteria of 30 CFR 732.15.

If the amendments are deemed adequate, they will become part of the Maryland program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking and include explanations in support of the commentor's recommendations. Comments received after the time indicated under "DATES" or at locations other than the OSMRE Charleston Field Office will not necessarily be considered and included in the Administrative Record for the final rulemaking.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under "FOR FURTHER INFORMATION CONTACT" by 4:00 p.m. on August 2, 1989. If no one requests an opportunity to comment at a public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSMRE officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to comment, and who wish to do so, will be heard following those scheduled. The hearing will end after all persons scheduled to comment have been heard.

Public Meeting

If only one person requests an opportunity to comment at a hearing, a public meeting rather than a public hearing, may be held. Persons wishing to meet with OSMRE representatives to discuss the proposed amendments may request a meeting at the OSMRE office listed under "ADDRESSES" by contacting the person listed under "FOR FURTHER INFORMATION CONTACT." All such meetings will be open to the public and, if possible, notices of meetings will be posted at the location under "ADDRESSES." A written summary of each meeting will be made a part of the Administrative Record.

List of Subjects in 30 CFR Part 920

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Date: July 10, 1989.

Carl C. Close,

Assistant Director, Eastern Field Operations.

[FR Doc. 89-16774 Filed 7-17-89; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900-AE09

Evaluation of Studies Relating to Health Effects of Dioxin and Radiation Exposure

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its regulation on scientific and medical study evaluations to establish criteria for determining when a significant statistical association exists between exposure to dioxin or ionizing radiation and specific diseases. This change is necessary because of a recent court decision. This change will require reassessment of the importance of scientific and medical studies on the health effects of exposure to dioxin or ionizing radiation.

DATES: Comments must be received on or before August 17, 1989. Comments will be available for public inspection until August 28, 1989. This change is proposed to be effective the date of publication of the final rule.

ADDRESSES: Interested persons are invited to submit written comments, suggestions, or objections regarding this change to Secretary of Veterans Affairs (271A), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420. All written comments received will be available for public inspection only in the Veterans Services Unit, Room 132, at the above address between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays), until August 28, 1989.

FOR FURTHER INFORMATION CONTACT: Robert M. White, Chief, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, (202) 233-3005.

SUPPLEMENTARY INFORMATION: On May 2, 1989, the U.S. District Court for the Northern District of California issued an order in the case of Nehmer, et al., v. United States Veterans' Administration, et al., interpreting the rulemaking requirements of the Dioxin and Radiation Exposure Compensation Standards Act, Pub. L. No. 98-542. The court found Congress intended that VA predicate service connection upon a finding of significant statistical association between exposure and disease. The court also found that VA was required to apply its benefit-of-the-doubt policy to the aggregate rulemaking determination as to which diseases were associated with dioxin exposure.

To implement this court decision we propose to amend 38 CFR 1.17 concerning study evaluation criteria. Paragraphs (a) and (b) of that section have always applied to the evaluation of individual scientific or medical studies and are being retained in their entirety with the exception of technical amendments to paragraph (a) changing "Administrator" to "Secretary" in accordance with VA's elevation to Cabinet status and including clarifying language to more closely track the statutory charge to evaluate studies involving exposure to herbicides containing dioxin rather than exposure to dioxin alone. New paragraphs are being added to establish that service connection will be predicated upon determinations of significant statistical association between dioxin or radiation exposure and various diseases as shown by scientific and medical studies.

Paragraph (c) provides that the guidelines for establishing service connection based on dioxin or radiation exposure (38 CFR 3.311a and 3.311b) will be amended whenever the Secretary determines that a significant statistical association exists between such exposure and any disease. These

determinations will be based on the evaluation of scientific and medical studies and on the advice of the Veterans Advisory Committee on Environmental Hazards.

Paragraph (d)(1) sets forth the general proposition that a significant statistical association shall be deemed to exist when the relative weights of valid positive and negative studies permit the Secretary to conclude that it is at least as likely as not that the purported relationship between expocure and disease exists. This conclusion will be based on a balancing test considering the relative strengths and weaknesses of valid studies whose findings relate to the existence of the relationship under consideration. This balancing test incorporates VA's "reasonable doubt" doctrine with respect to this evaluation process. The criteria for determining whether a study is valid and whether it is positive or negative with respect to the issue under consideration are set forth in paragraphs (d)(2) through (d)(4).

There are three criteria which must be satisfied in order for a study to be considered valid for purposes of determining whether a significant statistical association exists. First, the study design and the methods of data collection, verification and analysis must be adequately described. Such descriptions are necessary for reviewers to properly assess study results.

Second, the study must be reasonably free of biases which would cause serious doubt to be cast on the study's findings and conclusions. While all biases which can affect a study's results are not listed, selection, observation and participation of subjects are included as examples of some of the biases investigators must clearly avoid.

The third criterion for a valid study is a satisfactory accounting for known confounding factors which, if not identified and corrected for, could skew the study results. For example, a study involving lung cancer and dioxin or radiation exposure would have to satisfactorily account for the effects of cigarette smoking or asbestos exposure in the study populations and correct for those factors.

In addition to satisfying the criteria for a valid study, findings of a valid *positive* study must also be statistically significant at a probability level of .05 or less and must properly account for multiple comparison and subgroup analyses. Statistical significance at a probability level of .05 or less means that it must be statistically demonstrated that the likelihood is only one in twenty, or less, that the results of the study are due to chance alone. This is to be accomplished using a standard epidemiological tool for determining with a high degree of confidence that the observed association is real and not a chance occurence. Additionaly, it is recognized that multiple comparisons within a study population or division of a study population into numerous subgroups can, upon analysis of the data, produce results which may be meaningful or may be due to chance. It is through proper analysis of the multiple comparisons and subgroup divisions by the investigators that the possibility of attributing undue importance to chance findings may be avoided.

In order to be considered a valid *negative* study, the criteria for a valid study would have to be satisfied, and, in addition, the study would have to have sufficient statistical power to detect the association of interest if it existed. This means that the study would have to include a sufficient number of subjects in both the exposed group and the comparison group to provide an opportunity for the purported association to appear if, in fact, it were there to be detected.

While satisfaction of the criteria in paragraph (d) will require a determination of "significant statistical association", paragraph (e) is being added to give the Secretary latitude to find that such an association exists on the basis of other scientific or medical evidence which may not satisfy the requirements of paragraph (d) in all respects. The Secretary must have the freedom to act positively on behalf of the veteran population in those instances where the results of one or more studies are so compelling that it is unnecessary to insist on complete satisfaction of the criteria in paragraph (d) before making a finding of significant statistical association.

This change establishes specific criteria which would require further amendment of adjudication regulations, however nothing in this regulatory proposal should be construed as in any way limiting or diminishing the Secretary's rulemaking authority under 38 U.S.C. 210(c).

The Secretary hereby certifies that this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The reason for this certification is that this amendment would not directly affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

In accordance with Executive Order 12291, Federal Regulation, the Secretary has determined that this regulatory amendment is non-major for the following reasons.

(1) It will not have an annual effect on the economy of $100 million or more.

(2) It will not cause a major increase in costs or prices.

(3) It 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.

The Catalog of Federal Domestic Assistance program numbers are 64.104, 64.105, 64.109, and 64.110.

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, claims.

Approved: July 12, 1989.

Edward J. Derwinski,

Secretary.

38 CFR Part 1, GENERAL PROVISIONS, is proposed to be amended by revising § 1.17 to read as follows:

PART 1—GENERAL PROVISIONS

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

(a) From time to time, the Secretary shall publish evaluations of scientific or medical studies relating to the adverse health effects of exposure to a herbicide containing 2,3,7,8 tetrachlorodibenzo-p-dioxin (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.

(c) When the Secretary determines, based on the evaluation of scientific or medical studies and after receiving the advice of the Veterans' Advisory Committee on Environmental Hazards,

that a significant statistical association exists between any disease and exposure to a herbicide containing dioxin or exposure to ionizing radiation, § 3.311a or § 3.311b of this title, as appropriate, shall be amended to provide guidelines for the establishment of service connection.

(d)(1) For purposes of paragraph (c) of this section a "significant statistical association" shall be deemed to exist when the relative weights of valid positive and negative studies permit the conclusion that it is at least as likely as not that the purported relationship between a particular type of exposure and a specific adverse health effect exists.

(2) For purposes of this paragraph a valid study is one which:

(i) Has adequately described the study design and methods of data collection, verification and analysis;

(ii) Is reasonably free of biases, such as selection, observation and participation biases; and

(iii) Has satisfactorily accounted for known confounding factors.

(3) For purposes of this paragraph a valid positive study is one which satisfies the criteria in paragraph (d)(2) of this section and whose findings are statistically significant at a probability level of .05 or less with proper accounting for multiple comparisons and subgroup analyses.

(4) For purposes of this paragraph a valid negative study is one which satisfies the criteria in paragraph (d)(2) of this section and has sufficient statistical power to detect an association between a particular type of exposure and a specific adverse health effect if such an association were to exist.

(e) Notwithstanding the provisions of paragraph (d) of this section, a "significant statistical association" may be deemed to exist between a particular exposure and a specific disease if, in the Secretary's judgment, scientific and medical evidence on the whole supports such a decision.

(Authority: 38 U.S.C. 210(c); Pub. L. 98-542)

[FR Doc. 89-16825 Filed 7-14-89; 1:25 pm]

BILLING CODE

DEPARTMENT OF DEFENSE

48 CFR Part 219

Department of Defense Federal Acquisition Regulation Supplement; DFARS Small Business and Small Disadvantaged Business Concerns

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule and request for comment.

SUMMARY: The Defense Acquisition Regulatory (DAR) Council is proposing a revision to the Defense Federal Acquisition Regulation Supplement Subpart 219.8 to conform to proposed FAR revisions published at 54 FR 27310, June 28, 1989.

DATE: Comments concerning the proposed rule must be received by August 17, 1989 to be considered in formulating a final rule. Please cite DAR Case 88-325 in all correspondence related to this issue.

ADDRESS: Interested parties should submit written comments to: Defense Acquisition Regulatory Council, ATTN: Charles W. Lloyd, Executive Secretary, DAR Council, ODASD (P)/DARS, c/o OASD(P&L) (M&RS), Room 3D139, The Pentagon, Washington, DC 20301-3062.

FOR FURTHER INFORMATION CONTACT: Mr. Charles W. Lloyd, Executive Secretary, DAR Council, telephone (202) 697-7266.

SUPPLEMENTARY INFORMATION:

A. Background

Section 303(b) of the "Business Opportunity Development Reform Act of 1988" requires that acquisitions offered for award pursuant to Section 8(a) of the Small Business Act be awarded on the basis of competition restricted to eligible program participants if (a) there is a reasonable expectation that at least two eligible program participants will submit offers and that award can be made at a fair market price, and (b) the anticipated award price of the contract (including options) will exceed $5,000,000 in the case of a contract opportunity assigned a standard industrial classification code for manufacturing and $3,000,000 (including options) in the case of all other contract opportunities. Section 303(d) amends the current appeal authority of the Small Business Administration to permit appeals as to whether a requirement should be offered to the Section 8(a) program and as to whether the estimated fair market price as determined by the contracting agency is correct.

B. Regulatory Flexibility Act

The requirements of the Act are being addressed by the Small Business Administration in development of its regulations implementing the "Business Opportunity Development Reform Act of 1988," Pub. L. 100-656. (FR 12054, March 23, 1989).

C. Paperwork Reduction Act

The requirements of the Paperwork Reduction Act are being addressed by the Small Business Administration in development of its regulations implementing the "Business Opportunity Development Reform Act of 1988", Public Law 100-656. (FR 12054, March 23, 1989)

List of Subjects in 48 CFR Part 219

Government procurement

Charles Lloyd

Executive Secretary, Defense Acquisition Regulatory Council.

Therefore, it is proposed that 48 CFR Part 219 be amended as follows:

1. The authority citation for 48 CFR Part 219 continues to read as follows:

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, and DoD FAR Supplement 201.301.

PART 219—SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS CONCERNS

219.803 [Amended]

2. Section 219.803 is amended by redesignating paragraph (a) as paragraph (c); by changing the reference in the redesignated paragraph (c) to read "19.803(c)" in lieu of "19.803(a); by redesignating (c) (S-71) as paragraph (b); and by removing (c)(S-70) (i) and (ii);

3. Section 219.804-4 is added to read as follows:

219.804-4 Repetitive acquisition.

(a) When the SBA requests that a requirement be reserved for award of a contract (follow-on our otherwise) under the 8(a) Program, the request shall be honored, if otherwise appropriate, and the total SDB set-aside procedure shall not be used.

(b) An SBA request that a new requirement be reserved for the 8(a) Program need not be honored and a contracting officer may proceed with a total SDB set-aside if the SBA request is received after publication of a synopsis pursuant to 205.207(d)(S-72) or (S-73).

[FR Doc. 89-16779 Filed 7-17-89; 8:45 am]

BILLING CODE

48 CFR Part 246

Department of Defense Federal Acquisition Regulation Supplement; DFARS Warranties

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule (extension of comment period).

SUMMARY: The Defense Acquisition Regulatory (DAR) Council published a proposed rule with request for public

DEPARTMENT OF EDUCATION

34 CFR Part 600

Institutional Eligibility Under the Higher Education Act of 1965, as Amended

AGENCY: Department of Education.

ACTION: Suspension of rule.

SUMMARY: In the Federal Register of April 6, 1988 (53 FR 11208–11222), the Secretary issued final regulations governing institutional eligibility under the Higher Education Act of 1965, as amended (HEA). These regulations were codified in 34 CFR part 600.

Section 600.3(d) of the regulations was scheduled to go into effect on July 1, 1988. However, in the Federal Register of July 7, 1988, 53 FR 25469, the Secretary voluntarily suspended the effective date of § 600.3(d) until July 1, 1989, and on July 18, 1988, Public Law 100–369 also suspended the effective date of § 600.3(d) until July 1, 1989.

Under § 600.3(d) of the regulations governing Institutional Eligibility under the Higher Education Act of 1965, as amended, an institution of higher education or a vocational school is legally authorized only to provide its educational programs in clock hours if it must measure those programs in clock hours in its application to receive a State license. In April of 1989, the Department of Education's Office of Postsecondary Education (OPE) notified all the recognized accrediting agencies that the Secretary was going to implement § 600.3(d) on July 1, 1989, and in May of 1989, OPE similarly notified State agencies of that date.

On July 28, 1989, OPE notified postsecondary educational institutions of: (1) The specific procedural steps that they must follow to comply with the requirements of § 600.3(d); and (2) the related student financial assistance rules that they must apply in the awarding of student financial assistance for the 1989–90 award year. So that institutions may put these procedures into effect before the implementation of § 600.3(d), the Secretary suspends paragraph (d) of § 600.3 of the Institutional Eligibility regulations until October 1, 1989.

Waiver of rulemaking. Section 600.3(d) is currently in effect. However, the Department of Education did not provide specific instructions to institutions concerning the requirements of § 600.3(d), with regard to institutional eligibility and the awarding of student financial assistance for the 1989–90 award year, until July 28, 1989. Thus, many institutions may not be in compliance with that provision. The Secretary wishes to suspend § 600.3(d) until October 1, 1989 to permit institutions sufficient time to comply with the July 28, 1989 instructions. Therefore, the Secretary finds, in accordance with 5 U.S.C. 553(b)(B), that solicitation of public comments on this change would be impracticable and contrary to the public interest.

EFFECTIVE DATE: This suspension of § 600.3(d) takes effect 45 days after publication in the Federal Register or later if the Congress takes certain adjournments. Thus, when the suspension is effective, § 600.3(d) will apply as of October 1, 1989.

FOR FURTHER INFORMATION CONTACT: Virginia G. Re, U.S. Department of Education, Office of Postsecondary Education, 400 Maryland Avenue SW. (Regional Office Building 3, Room 3030), Washington, DC 20202. Telephone number (202) 732–4906.

Dated: September 27, 1989.

Lauro F. Cavazos,

Secretary of Education.

[FR Doc. 89–23225 Filed 9–28–89; 9:55 am]

BILLING CODE 4000–01–M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900–AE09

Evaluation of Studies Relating to Health Effects of Dioxin and Radiation Exposure

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) has amended its regulation on scientific and medical study evaluations to establish criteria for determining when a significant statistical association exists between exposure to dioxin or ionizing radiation and specific diseases. This change is necessary because of a recent court decision. This change will require reassessment of the importance of particular scientific and medical studies on the health effects of exposure to dioxin or ionizing radiation.

EFFECTIVE DATE: This change is effective November 1, 1989.

FOR FURTHER INFORMATION CONTACT: Robert M. White, Chief Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 233–3005.

SUPPLEMENTARY INFORMATION: On pages 30099–30101 of the Federal Register of July 18, 1989, VA published proposed amendments to 38 CFR 1.17. Interested persons were invited to submit comments, suggestions or objections by August 17, 1989. Comments were received from nineteen individuals and organizations. Commenters included the senior Senator from New York, the junior Senator from South Dakota, the American Legion, the Veterans of Foreign Wars of the United States, the Disabled American Veterans, the National Veterans Legal Services Project, Inc., representing the Vietnam Veterans of America, the National Vietnam Veterans Coalition, the Oklahoma Agent Orange Foundation, the State of Minnesota Department of Veterans Affairs and ten members of the general public.

In addition, a special session of the Veterans' Advisory Committee on Environmental Hazards was convened on September 8, 1989. The Committee received an oral presentation by four individuals representing the views of the American Legion. (The Committee has received oral presentations from a number of individuals and organizations in the past and will continue to do so so long as adequate advance notice is provided for scheduling purposes.) The Committee also reviewed all of the comments received and offered their views on them. The Committee made a number of recommendations, some in response to the oral presentation made at this meeting by representatives of the American Legion and others in response to the written comments that were reviewed. The comments are summarized below together with VA's response and any indicated amendatory action.

Five commenters from Des Moines, Iowa, requested an extension of the time limit for submitting comments on the proposed changes asserting that the established 30-day period was insufficient. Thirty days is a typical length of time for a comment period in the rulemaking process, especially where rules governing veterans' benfits are concerned. In addition, a significant number of comments were received within the comment period. Further, VA desires to move as swiftly as possible to establish new study evaluation criteria, review the scientific literature and determine whether there currently exists sound scientific and medical evidence that demonstrates a significant statistical association between dioxin or radiation exposure and any diseases.

We decline, therefore, to extend the comment period.

Many commenters addressed issues that were clearly outside the scope of this rulemaking proceeding. Such issues included the composition, membership and alleged bias of the Veterans' Advisory Committee on Environmental Hazards, various comments concerning 38 CFR 1.17(b) and 3.311a for which no changes were proposed, the frequency of VA's publication of study evaluations, consideration of defoliants other than those containing dioxin, objection to the decision not to appeal the court ruling which prompted this rulemaking, assertion that all veterans exposed to Agent Orange should receive some payment from VA and comments concerning claims of specific individuals. Some of these comments could be addressed through administrative procedures while others would require legislative action, but all are outside the scope of the original proposal. Consequently, these will not be addressed in this rulemaking proceeding.

Three veterans' organizations and one individual suggested that the proposed criteria for defining the term "significant statistical association" were too strict or that VA should adopt the criteria already developed by the Environmental Protection Agency (EPA) or the International Agency for Research on Cancer (IARC) as indicative of such an association. The criteria set forth by the EPA (Guidelines for Carcinogen Risk Assessment, (51 FR 33992–34003 (1986)) and the IARC (IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Supplement 4 (1982) and Supplement 7 (1987)) are designed to assess the carcinogenic potential of a particular agent. This process of risk assessment attempts to determine the likelihood that exposure to a specific agent will result in the future development of a certain adverse health effect. The identification of a possible adverse health consequence through the use of either or both human and animal models is the goal of the risk assessment matrix. Its purpose is to serve as the basis for the elimination or lessening of the possible adverse health effect. VA, on the other hand, is attempting to determine the likelihood that a presently existing disease is associated with a prior exposure to a specific agent. In doing so, it is concerned with more than a mere possibility that an effect is associated with a past exposure. Rather, it must determine whether it is at least as likely not that a significant statistical association exists. Consequently, it would not be appropriate to rely upon an approach designed to identify merely possible risks; a different standard must be employed to accomplish VA's task. As described below, VA has looked to the models cited in its attempt to draft a scientifically valid and acceptable standard and utilized them where appropriate.

Further, certain of these commenters suggest VA should adopt the standard articulated by IARC that, in the absence of adequate human data, if studies show evidence of a particular agent's carcinogenicity in animal species, it is prudent to regard such agents "as if they presented a carcinogenic risk to humans." The Advisory Committee had previously considered the applicability of animal data to human experience and did so extensively at its September 8, 1989, meeting. The Committee has noted the widespread variations in observed effects in animals both within the same species and among different species. Other factors such as the dose of exposure and the methods and durations of exposure employed in animal models also play a role in judging the true applicability of animal results. For these reasons, VA does not believe it would be appropriate to adopt the IARC model, especially those portions which would apply "in the absence of adequate human data." As will be discussed later, however, the Committee has articulated what it considers to be a proper role for animal data to play in VA's attempt to determine the human's response to exposure.

The proposed criteria have been criticized as being too strict because their language is similar to that employed by IARC for determining a causual association.[1] VA's advisory committee commented, however, that the criteria set forth are those which are generally accepted by the scientific community in evaluating any study. That is, the Committee advised that there are certain minimal standards which must be met for any scientific study to be considered valid. These standards are the same whether a study purports to establish a causual association or a statistical association. Furthermore, VA notes that a complete reading of the cited IARC monograph page shows that much more is generally needed to infer causal association. The additional factors listed were the existence of several concordant studies which show an association, a showing of strong association, a dose-response relationship, and a reduction of cancer incidence with a reduction in exposure. None of these additional criteria are required for a finding of significant statistical association under VA's proposed rule. Additionally, it should be noted that the application of these criteria, when met, must result in the finding of a significant statistical association. Moreover, the benefit of the doubt rule will be applied by the Secretary to the evaluation of the weight of the scientific evidence. Thus, if there is an approximate balance of positive and negative evidence regarding the association between dioxin and an illness or condition, the benefit of the doubt will be given to the conclusion that the association exists. Studies that do not satisfy these threshold criteria may still contribute to the body of scientific and medical evidence which, in the Secretary's judgment (under proposed paragraph (e)), may warrant a finding of significant statistical association. When read together, VA does not believe that proposed paragraphs (d) and (e) constitute a standard which is too strict.

One commenter suggested that VA was introducing a "null hypothesis" whereby "it is assumed that the relationship does not exist unless there is enough scientific evidence to satisfy a rigorous standard that it does exist." To the extent that this comment suggests that a significant statistical association should be assumed to exist regardless of whether there are any studies which adequately support such a relationship, VA disagrees. First, and foremost, VA does not start with any presumption concerning a disease's association with exposure. Rather, it begins from a neutral position and then seeks to determine the existence of valid positive and valid negative studies. The relative weights of the valid positive and valid negative studies, with the application of the reasonable doubt doctrine, will determine the eventual conclusion. Thus, the regulation does not establish an overly rigorous standard but properly requires that a significant statistical association be established consistent with Public Law 98–542.

Two veterans' organizations asserted that VA should review the results of dioxin studies involving laboratory animals and not confine itself to reviewing studies on the adverse health effects of dioxin exposure in humans. The issue of the value of animal studies

[1] The IARC monograph states: "Three criteria must be met before a causual association can be inferred between exposure and cancer in humans:

1. Three is no identified bias which could explain the association.

2. The possibility of confounding has been considered and ruled out as explaining the association.

3. The association is unlikely to be due to chance."

was also raised by one of the organizations in support of an objection to the proposed change to paragraph (a). That commenter suggested that limiting the studies reviewed to those involving only herbicide exposure would be too restrictive and would be an additional basis for not reviewing studies on laboratory animals. At the same time, an individual commenter supported this change to paragraph (a) indicating that exposure to the herbicide, and not just one of its components or contaminants, was the key issue.

Valid epidemiologic studies constitute that most direct and convincing evidence regarding exposure to some agent and association with adverse human health effects. Animal and mechanistic studies provide less direct evidence in determining the likelihood that a presently existing disease is associated with past exposure to a specific agent, but may provide supportive and supplemental information in evaluation of the weight of evidence of association with adverse human health effects.

To assure that relevant scientific information on any specific issue is considered, we are adding a new paragraph (e) to the proposed rule setting forth the additional types of studies which may contain supportive or supplemental information and which may be considered in assessing the relative weight to be accorded the various valid studies being reviewed. The types of evidence to be considered under new paragraph (e) would include case series (reports of individual cases unrelated to a specific scientific study), correlational studies (studies showing that a temporal or other association between two events is present), studies with insufficient power, animal studies and mechanistic studies (studies of the cellular or molecular response to an exposure).

In response to the comments concerning the revision to paragraph (a), VA notes that the purpose of the proposal was simply to track more closely the statutory charge in Public Law 98-542, the Veterans' Dioxin and Radiation Exposure Compensation Standards Act. Section 5 of that law, which sets forth the requirement for and content of regulations, clearly speaks in terms of "guidelines governing the evaluation of the findings of scientific studies relating to the possible increased risk of adverse health effects of exposure to herbicides containing dioxin * * *." Thus the language of the regulation is faithful to the language of the law. For purposes of grammatical accuracy, however, we are substituting the words "and/or exposure to" for the word "or" immediately following the parenthetical "(dioxin)" in paragraph (a). The change is not intended to restrict the scope of studies to be reviewed and evaluated concerning the issue of adverse health effects related to exposure to herbicides containing dioxin.

Two veterans' organizations and one legislator expressed support for proposed paragraph (e) (redesignated as (f)), but one suggested it could be strengthened by permitting consideration of animal studies. Because the formulation of that paragraph is such as to permit consideration of *any* relevant scientific and medical evidence, we perceive no benefit in referencing one particular type of evidence. Further, as noted above with respect to new paragraph (e), animal studies as well as other relevant studies may be considered in conjunction with valid scientific studies as defined in paragraph (d).

One veterans' organization and one legislator suggested with regard to proposed paragraph (d)(2)(ii) that study biases should not be assumed in the absence of specific evidence of their presence or that they should be permitted to exist if they are satisfactorily accounted for. Neither the presence nor the absence of a bias is assumed. Further, the proposed language only requires that a study be reasonably free of biases and that if biases are found to exist, the investigator acknowledge them and explain how they were taken into account in arriving at the study's conclusions. Reviewers should not be prohibited from suggesting that a particular study methodology may have introduced a bias not accounted for by the investigator. However, we agree that where bias is identified, it should not invalidate a study if it can be shown that the bias did not affect the study's conclusions. To accommodate this suggestion we have amended paragraph (d)(2)(ii), with the concurrence of the Advisory Committee, to read as follows: "Is reasonably free of biases, such as selection, observation and participation biases; however, if biases exist, the investigator has acknowledged them and so stated the study's conclusions that the biases do not intrude upon those conclusions; and".

Two veterans' organizations sought clarification of the terms "positive" and "negative" with reference to the scientific studies being reviewed. One of those commenters suggested that studies which contain misleading statements or which depart from established scientific standards should be eliminated from consideration even before they are designated as "positive" or "negative". The terms "positive" and "negative" with regard to studies are well-understood by scientific investigators and represent general characterizations of studies depending on their findings or lack of findings. A study is "positive" if it finds a correlation the study was designed to detect. A study is "negative" if it did not find a correlation the study was designed to detect. The screening factors suggested by the commenter could be considered in assessing the validity of a study, but not whether the study should be considered at all.

One State veterans' organization conceded that the study evaluation process was ultimately subjective in nature and did not lend itself to complete objectivity but suggested that the process might be more open if additional factors were considered during the study evaluation process and some terms were clarified. The commenter suggested four terms for clarification. Three of those terms (peer review, replicability and the veteran population of interest) are contained in paragraph (b) of the rule which is not a subject of this rulemaking proceeding. The fourth term (relative weights of studies) is a term which cannot be quantified but which relies heavily on the subjective consideration of experienced scientific investigators.

Several of the additional factors suggested for consideration during the process of evaluating epidemiological findings were already included in proposed paragraph (d), i.e., statistical significance, study design and bias. Other suggested factors such as dose-response relationships, the consistency and reproducibility of results, the strength and specificity of the association and its biological significance, that relate to the determination of causality in epidemiology, are not required or determinative for finding significant statistical association, but may be considered in evaluating the relative weights of studies.

One veterans' organization and one legislator addressed the requirement in proposed paragraph (d)(3) that positive studies be statistically significant at a probability level of .05 or less. They indicated that this requirement should not "pre-eliminate" studies, should apply equally to negative studies and, in any event, should probably be raised to .10 or less. While this requirement could prevent a study from being considered as a valid positive study for purposes of paragraph (d), it would not preclude or

"pre-eliminate" it from consideration under paragraph (e) or (f) together with other scientific and medical evidence on the same subject. This requirement is applicable to negative studies because it requires that there be a one-in-twenty chance or less that an apparent positive association is due to chance alone. It is not, therefore, calculated with respect to negative findings. Finally, our Advisory Committee has advised that .05 is the most accepted probability value with or without a prior hypothesis. For these reasons we find no basis for changing the proposal.

One individual commeter suggested that "significant statistical association" was a straightforward mathematical calculation. We believe the commenter was confusing that term with the term "statistical significance" which is a mathematical calculation and which is considered under paragraph (d)(3).

One veterans' organization suggested a mathematical formula for weighting positive and negative studies and suggested its inclusion in paragraph (d)(4). We agree that the statistical power of negative studies should be used in balancing them with positive studies, but use of the mathematical equation proposed is only applicable when two or more studies are identical, or nearly so, with at least one being positive and one being negative. Such an equation would be useful for evaluating laboratory studies, but epidemiological studies unfortunately lack such uniformity.

One veterans' organization suggested that proposed paragraph (c) be amended by adding the phrase "it is at least as likely as not that" before the phrase "a significant statistical association exists * * *" We cannot agree. The language suggested for addition is the key language used in applying the reasonable doubt doctrine. As reflected in proposed paragrapb (c), that doctrine is applied in determining the existence of a significant statistical association under the provisions of proposed paragraph (d)(1), and that is where that reasonable doubt language should and does appear.

The same commenter suggested that some high risk subgroups might be unethically excluded from consideration in a study's conclusions because such things as the possibility of synergistic disease-provoking mechanisms or impairment of the immune system might be viewed as confounding factors for which the investigator had to "correct." We do not agree. The proposed rule does not require correction for possible confounders but rather a satisfactory accounting for known confounders. Under this more liberal construction a valid study is permitted to include confounding factors if they are noted and satisfactorily explained in relation to the study's conclusions.

The interest expressed by both individual and organizational commenters is appreciated. Except as noted herein, the amendments to 38 CFR 1.17 are adopted as proposed.

The Secretary hereby certifies that this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The reason for this certification is that this amendment would not directly affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

In accordance with Executive Order 12291, Federal Regulation, the Secretary has determined that this regulatory amendment is non-major for the following reasons.

(1) It will not have an annual effect on the economy of $100 million or more.

(2) It will not cause a major increase in costs or prices.

(3) It 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.

(The Catalog of Federal Domestic Assistance program numbers are 64.104, 64.105, 64.109, and 64.110)

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, claims.

Approved: September 27, 1989.

Edward J. Derwinski,

Secretary of Veterans Affairs.

PART 1—[AMENDED]

38 CFR Part 1, GENERAL, is amended by revising § 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 Secretary shall publish evaluations of scientific or medical studies relating to the adverse health effects of exposure to a herbicide containing 2, 3, 7, 8 tetrachlorodibenzo-p-dioxin (dioxin) and/or exposure to 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.

(c) When the Secretary determines, based on the evaluation of scientific or medical studies and after receiving the advice of the Veterans' Advisory Committee on Environmental Hazards and applying the reasonable doubt doctrine as set forth in paragraph (d)(1) of this section, that a significant statistical association exists between any disease and exposure to a herbicide containing dioxin or exposure to ionizing radiation, §§ 3.311a or 3.311b of this title, as appropriate, shall be amended to provide guidelines for the establishment of service connection.

(d)(1) For purposes of paragraph (c) of this section a "significant statistical association" shall be deemed to exist when the relative weights of valid positive and negative studies permit the conclusion that it is at least as likely as not that the purported relationship between a particular type of exposure and a specific adverse health effect exists.

(2) For purposes of this paragraph a valid study is one which:

(i) Has adequately described the study design and methods of data collection, verification and analysis;

(ii) Is reasonably free of biases, such as selection, observation and participation biases; however, if biases exist, the investigator has acknowledged them and so stated the study's conclusions that the biases do not intrude upon those conclusions; and

(iii) Has satisfactorily accounted for known confounding factors.

(3) For purposes of this paragraph a valid positive study is one which satisfies the criteria in paragraph (d)(2) of this section and whose findings are statistically significant at a probability level of .05 or less with proper accounting for multiple comparisons and subgroups analyses.

(4) For purposes of this paragraph a valid negative study is one which satisfies the criteria in paragraph (d)(2) of this section and has sufficient statistical power to detect an

association between a particular type of exposure and a specific adverse health effect if such an association were to exist.

(e) For purposes of assessing the relative weights of valid positive and negative studies, other studies affecting epidemiological assessments including case series, correlational studies and studies with insufficient statistical power as well as key mechanistic and animal studies which are found to have particular relevance to an effect on human organ systems may also be considered.

(f) Notwithstanding the provisions of paragraph (d) of this section, a "significant statistical association" may be deemed to exist between a particular exposure and a specific disease if, in the Secretary's judgment, scientific and medical evidence on the whole supports such a decision.

(Authority: 38 U.S.C. 210(c); Pub. L. 98-542)

[FR Doc. 89-23175 Filed 9-29-89; 8:45 am]
BILLING CODE 8320-01-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[DA 89-1143]

Administrative Practice and Procedure

AGENCY: Federal Communications Commission.

ACTION: Final rule; technical amendment.

SUMMARY: This order amends § 1.115(d) to reflect when replies to an opposition to an application for review may be filed. Further the Order reorganized § 1.115(f) and also split that provision into two subsections in order to separate those requirements governing the initial filings relative to an application for review from those requirements governing briefs and reply briefs that may be requested after the Commission grants review of a Review Board final decision. This amendment provides better clarification and organization of existing rules.

EFFECTIVE DATE: October 2, 1989.

ADDRESSES: Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Joe McBride, Office of General Counsel, (202) 254-6530.

SUPPLEMENTARY INFORMATION: The Managing Director adopted on September 13, 1989, and released on September 22, 1989, an Order amending § 1.115 (d) and (f) of the Commission's rules. 47 CFR 1.115 (d) and (f). This amendment provides better clarification and organization of existing rules.

Order

Adopted: September 13, 1989.
Released: September 22, 1989.

By the Managing Director:

1. In *Ronald F. Trinchitella*,[1] the Commission recently clarified that § 1.115(f)'s prohibition on the filing of replies in response to oppositions to applications for review except when requested by the Commission only applies to replies to oppositions to applications for review of final decisions of the Review Board. The Commission noted that the decision adopting the language in question expressly indicated that the prohibition only applied "to Review Board final decisions."[2] The Commission also noted that § 1.115(d) authorizes the filing of reply pleadings.[3] This *Order* amends § 1.115 (d) and (f) to reflect more clearly the Commission's intent when it promulgated those provisions.

2. Section 1.115(d) is being amended to reflect when replies may be filed. Section 1.115(f), as modified, will only contain the technical requirements for applications for review and related pleadings, such as page length, service of copies, and where to file them. Furthermore, § 1.115(f) is being slightly restructured to distinguish between the requirements governing the initial filings relative to an application for review and the subsequent requirements governing briefs and reply briefs that may be requested after the Commission grants review of a Review Board final decision.

3. Accordingly, *It is ordered*, That § 1.115 (d) and (f) of the Commission's rules are amended, as provided in the appendix, pursuant to the authority contained in § 0.231(d) of the Commission's rules.

4. A notice and comment proceeding is not required in this instance because § 1.115 (d) and (f) are rules of agency procedure and practice. See 5 U.S.C. 553(b)(A).

5. This amendment will be effective upon publication in the Federal Register. See 5 U.S.C. 553(d).

Alan R. McKie,
Acting Managing Director.

Rule change

47 CFR part 1 is amended as follows:

[1] *Ronald F. Trinchitella*, FCC 89-270, released August 16, 1989 at n.4.

[2] *Id.* (quoting *Amendments to parts 0 and 1 of the Commission's Rules with respect to Adjudicatory Re-Regulation Proposals*, 58 FCC 2d 865, 876 (1976)).

[3] *Id.*

PART 1—[AMENDED]

1. The authority citation for part 1 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303; Implement, 5 U.S.C. 552, unless otherwise noted.

2. 47 CFR 1.115 (d) and (f) are revised to read as follows.

§ 1.115 Application for review of action taken pursuant to delegated authority.

* * * * *

(d) Except as provided in paragraph (e) of this section, the application for review and any supplement thereto shall be filed within 30 days from the date of public notice of such action, as that date is defined in § 1.4(b) of these rules. Oppositions to the application shall be filed within 15 days after the application for review is filed. When permitted, replies to oppositions shall be filed within 10 days after the opposition is filed and shall be limited to matters raised in the opposition. Replies to oppositions to applications for review of final decisions of the Review Board may be filed only if the Commission requests a reply; except as provided in § 1.115(e)(3), replies to oppositions to all other applications for review are permissible.

* * * * *

(f)(1) Applications for review, oppositions, and replies shall conform to the requirements of §§ 1.49, 1.51, and 1.52, and shall be submitted to the Secretary, Federal Communications Commission, Washington, DC 20554. Except as provided below, applications for review and oppositions thereto shall not exceed 25 double-spaced typewritten pages. Applications for review of final decisions of the Review Board and oppositions thereto shall not exceed 10 double-spaced typewritten pages. Applications for review of interlocutory actions in hearing proceedings (including designation orders) and oppositions thereto shall not exceed 5 double-spaced typewritten pages. When permitted (see § 1.115(d)), reply pleadings shall not exceed 5 double-spaced typewritten pages. The application for review shall be served upon the parties to the proceeding. Oppositions to the application for review shall be served on the person seeking review and on parties to the proceeding. When permitted (see § 1.115(d)), replies to the opposition(s) to the application for review shall be served on the person(s) opposing the application for review and on parties to the proceeding.

(2) If the Commission grants review of a Review Board final decision and

revegetated area prior to bond release for Reclamation Phase II work.

Paragraph (I) has been modified to require that bond release applications include proof of advertisement by the permittee of his filing of the release application. The MDDNR is granted discretionary authority to waive its inspection of the completed reclamation work if it has not received any objections or requests for an informal conference; and it has conducted an inspection of the area within a four month period prior to receiving the bond release application and the inspection did not identify any reason for denying bond release.

Paragraph (K) has been modified to allow the MDDNR to recover from the permittee all costs of reclamation in excess of the amount forfeited should the forfeited bond be insufficient to pay the full cost of reclamation.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(b), OSMRE is now seeking comments on whether the amendments proposed by Maryland satisfy the applicable program approval criteria of 30 CFR 732.15.

If the amendments are deemed adequate, they will become part of the Maryland program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking and include explanations in support of the commentor's recommendations. Comments received after the time indicated under "**DATES**" or at locations other than the OSMRE Charleston Field Office will not necessarily be considered and included in the Administrative Record for the final rulemaking.

Public Hearing

Persons wishing to comment at the public hearing should contact the person listed under "**FOR FURTHER INFORMATION CONTACT**" by 4:00 p.m. on August 2, 1989. If no one requests an opportunity to comment at a public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSMRE officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to comment, and who wish to do so, will be heard following those scheduled. The hearing will end after all persons scheduled to comment have been heard.

Public Meeting

If only one person requests an opportunity to comment at a hearing, a public meeting rather than a public hearing, may be held. Persons wishing to meet with OSMRE representatives to discuss the proposed amendments may request a meeting at the OSMRE office listed under "**ADDRESSES**" by contacting the person listed under "**FOR FURTHER INFORMATION CONTACT.**" All such meetings will be open to the public and, if possible, notices of meetings will be posted at the location under "**ADDRESSES.**" A written summary of each meeting will be made a part of the Administrative Record.

List of Subjects in 30 CFR Part 928

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

Date: July 10, 1989.

Carl C. Close,

Assistant Director, Eastern Field Operations.

[FR Doc. 89-16774 Filed 7-17-89; 8:45 am]

BILLING CODE 4310-05-M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900-AE09

Evaluation of Studies Relating to Health Effects of Dioxin and Radiation Exposure

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its regulation on scientific and medical study evaluations to establish criteria for determining when a significant statistical association exists between exposure to dioxin or ionizing radiation and specific diseases. This change is necessary because of a recent court decision. This change will require reassessment of the importance of scientific and medical studies on the health effects of exposure to dioxin or ionizing radiation.

DATES: Comments must be received on or before August 17, 1989. Comments will be available for public inspection until August 28, 1989. This change is proposed to be effective the date of publication of the final rule.

ADDRESSES: Interested persons are invited to submit written comments, suggestions, or objections regarding this change to Secretary of Veterans Affairs (271A), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420. All written comments received will be available for public inspection only in the Veterans Services Unit, Room 132, at the above address between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays), until August 28, 1989.

FOR FURTHER INFORMATION CONTACT: Robert M. White, Chief, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, (202) 233-3005.

SUPPLEMENTARY INFORMATION: On May 2, 1989, the U.S. District Court for the Northern District of California issued an order in the case of Nehmer, et al., v. United States Veterans' Administration, et al., interpreting the rulemaking requirements of the Dioxin and Radiation Exposure Compensation Standards Act, Pub. L. No. 98-542. The court found Congress intended that VA predicate service connection upon a finding of significant statistical association between exposure and disease. The court also found that VA was required to apply its benefit-of-the-doubt policy to the aggregate rulemaking determination as to which diseases were associated with dioxin exposure.

To implement this court decision we propose to amend 38 CFR 1.17 concerning study evaluation criteria. Paragraphs (a) and (b) of that section have always applied to the evaluation of individual scientific or medical studies and are being retained in their entirety with the exception of technical amendments to paragraph (a) changing "Administrator" to "Secretary" in accordance with VA's elevation to Cabinet status and including clarifying language to more closely track the statutory charge to evaluate studies involving exposure to herbicides containing dioxin rather than exposure to dioxin alone. New paragraphs are being added to establish that service connection will be predicated upon determinations of significant statistical association between dioxin or radiation exposure and various diseases as shown by scientific and medical studies.

Paragraph (c) provides that the guidelines for establishing service connection based on dioxin or radiation exposure (38 CFR 3.311a and 3.311b) will be amended whenever the Secretary determines that a significant statistical association exists between such exposure and any disease. These

determinations will be based on the evaluation of scientific and medical studies and on the advice of the Veterans Advisory Committee on Environmental Hazards.

Paragraph (d)(1) sets forth the general proposition that a significant statistical association shall be deemed to exist when the relative weights of valid positive and negative studies permit the Secretary to conclude that it is at least as likely as not that the purported relationship between exposure and disease exists. This conclusion will be based on a balancing test considering the relative strengths and weaknesses of valid studies whose findings relate to the existence of the relationship under consideration. This balancing test incorporates VA's "reasonable doubt" doctrine with respect to this evaluation process. The criteria for determining whether a study is valid and whether it is positive or negative with respect to the issue under consideration are set forth in paragraphs (d)(2) through (d)(4).

There are three criteria which must be satisfied in order for a study to be considered valid for purposes of determining whether a significant statistical association exists. First, the study design and the methods of data collection, verification and analysis must be adequately described. Such descriptions are necessary for reviewers to properly assess study results.

Second, the study must be reasonably free of biases which would cause serious doubt to be cast on the study's findings and conclusions. While all biases which can affect a study's results are not listed, selection, observation and participation of subjects are included as examples of some of the biases investigators must clearly avoid.

The third criterion for a valid study is a satisfactory accounting for known confounding factors which, if not identified and corrected for, could skew the study results. For example, a study involving lung cancer and dioxin or radiation exposure would have to satisfactorily account for the effects of cigarette smoking or asbestos exposure in the study populations and correct for those factors.

In addition to satisfying the criteria for a valid study, findings of a valid *positive* study must also be statistically significant at a probability level of .05 or less and must properly account for multiple comparison and subgroup analyses. Statistical significance at a probability level of .05 or less means that it must be statistically demonstrated that the likelihood is only one in twenty, or less, that the results of the study are due to chance alone. This can be accomplished using a standard epidemiological tool for determining with a high degree of confidence that the observed association is real and not a chance occurence. Additionaly, it is recognized that multiple comparisons within a study population or division of a study population into numerous subgroups can, upon analysis of the data, produce results which may be meaningful or may be due to chance. It is through proper analysis of the multiple comparisons and subgroup divisions by the investigators that the possibility of attributing undue importance to chance findings may be avoided.

In order to be considered a valid *negative* study, the criteria for a valid study would have to be satisfied, and, in addition, the study would have to have sufficient statistical power to detect the association of interest if it existed. This means that the study would have to include a sufficient number of subjects in both the exposed group and the comparison group to provide an opportunity for the purported association to appear if, in fact, it were there to be detected.

While satisfaction of the criteria in paragraph (d) will require a determination of "significant statistical association", paragraph (e) is being added to give the Secretary latitude to find that such an association exists on the basis of other scientific or medical evidence which may not satisfy the requirements of paragraph (d) in all respects. The Secretary must have the freedom to act positively on behalf of the veteran population in those instances where the results of one or more studies are so compelling that it is unnecessary to insist on complete satisfaction of the criteria in paragraph (d) before making a finding of significant statistical association.

This change establishes specific criteria which would require further amendment of adjudication regulations, however nothing in this regulatory proposal should be construed as in any way limiting or diminishing the Secretary's rulemaking authority under 38 U.S.C. 210(c).

The Secretary hereby certifies that this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The reason for this certification is that this amendment would not directly affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

In accordance with Executive Order 12291, Federal Regulation, the Secretary has determined that this regulatory amendment is non-major for the following reasons.

(1) It will not have an annual effect on the economy of $100 million or more.

(2) It will not cause a major increase in costs or prices.

(3) It 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.

The Catalog of Federal Domestic Assistance program numbers are 64.104, 64.105, 64.109, and 64.110.

List of Subjects in 38 CFR Part 1

Administrative practice and procedure, claims.

Approved: July 12, 1989.

Edward J. Derwinski,

Secretary.

38 CFR Part 1, GENERAL PROVISIONS, is proposed to be amended by revising § 1.17 to read as follows:

PART 1—GENERAL PROVISIONS

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

(a) From time to time, the Secretary shall publish evaluations of scientific or medical studies relating to the adverse health effects of exposure to a herbicide containing 2,3,7,8 tetrachlorodibenzo-p-dioxin (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.

(c) When the Secretary determines, based on the evaluation of scientific or medical studies and after receiving the advice of the Veterans' Advisory Committee on Environmental Hazards,

that a significant statistical association exists between any disease and exposure to a herbicide containing dioxin or exposure to ionizing radiation, § 3.311a or § 3.311b of this title, as appropriate, shall be amended to provide guidelines for the establishment of service connection.

(d)(1) For purposes of paragraph (c) of this section a "significant statistical association" shall be deemed to exist when the relative weights of valid positive and negative studies permit the conclusion that it is at least as likely as not that the purported relationship between a particular type of exposure and a specific adverse health effect exists.

(2) For purposes of this paragraph a valid study is one which:

(i) Has adequately described the study design and methods of data collection, verification and analysis;

(ii) Is reasonably free of biases, such as selection, observation and participation biases; and

(iii) Has satisfactorily accounted for known confounding factors.

(3) For purposes of this paragraph a valid positive study is one which satisfies the criteria in paragraph (d)(2) of this section and whose findings are statistically significant at a probability level of .05 or less with proper accounting for multiple comparisons and subgroup analyses.

(4) For purposes of this paragraph a valid negative study is one which satisfies the criteria in paragraph (d)(2) of this section and has sufficient statistical power to detect an association between a particular type of exposure and a specific adverse health effect if such an association were to exist.

(e) Notwithstanding the provisions of paragraph (d) of this section, a "significant statistical association" may be deemed to exist between a particular exposure and a specific disease if, in the Secretary's judgment, scientific and medical evidence on the whole supports such a decision.

(Authority: 38 U.S.C. 210(c); Pub. L. 98-542)

[FR Doc. 89-16925 Filed 7-14-89; 1:25 pm]

BILLING CODE

DEPARTMENT OF DEFENSE

48 CFR Part 219

Department of Defense Federal Acquisition Regulation Supplement; DFARS Small Business and Small Disadvantaged Business Concerns

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule and request for comment.

SUMMARY: The Defense Acquisition Regulatory (DAR) Council is proposing a revision to the Defense Federal Acquisition Regulation Supplement Subpart 219.8 to conform to proposed FAR revisions published at 54 FR 27310, June 28, 1989.

DATE: Comments concerning the proposed rule must be received by August 17, 1989 to be considered in formulating a final rule. Please cite DAR Case 88-325 in all correspondence related to this issue.

ADDRESS: Interested parties should submit written comments to: Defense Acquisition Regulatory Council, ATTN: Charles W. Lloyd, Executive Secretary, DAR Council, ODASD (P)/DARS, c/o OASD(P&L) (M&RS), Room 3D139, The Pentagon, Washington, DC 20301-3062.

FOR FURTHER INFORMATION CONTACT: Mr. Charles W. Lloyd, Executive Secretary, DAR Council, telephone (202) 697-7266.

SUPPLEMENTARY INFORMATION:

A. Background

Section 303(b) of the "Business Opportunity Development Reform Act of 1988" requires that acquisitions offered for award pursuant to Section 8(a) of the Small Business Act be awarded on the basis of competition restricted to eligible program participants if (a) there is a reasonable expectation that at least two eligible program participants will submit offers and that award can be made at a fair market price, and (b) the anticipated award price of the contract (including options) will exceed $5,000,000 in the case of a contract opportunity assigned a standard industrial classification code for manufacturing and $3,000,000 (including options) in the case of all other contract opportunities. Section 303(d) amends the current appeal authority of the Small Business Administration to permit appeals as to whether a requirement should be offered to the Section 8(a) program and as to whether the estimated fair market price as determined by the contracting agency is correct.

B. Regulatory Flexibility Act

The requirements of the Act are being addressed by the Small Business Administration in development of its regulations implementing the "Business Opportunity Development Reform Act of 1988." Pub. L. 100-656. (FR 12054, March 23, 1989).

C. Paperwork Reduction Act

The requirements of the Paperwork Reduction Act are being addressed by the Small Business Administration in development of its regulations implementing the "Business Opportunity Development Reform Act of 1988", Public Law 100-656. (FR 12054, March 23, 1989)

List of Subjects in 48 CFR Part 219

Government procurement

Charles Lloyd

Executive Secretary, Defense Acquisition Regulatory Council.

Therefore, it is proposed that 48 CFR Part 219 be amended as follows:

1. The authority citation for 48 CFR Part 219 continues to read as follows:

Authority: 5 U.S.C. 301, 10 U.S.C. 2202, DoD Directive 5000.35, and DoD FAR Supplement 201.301.

PART 219—SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS CONCERNS

219.803 [Amended]

2. Section 219.803 is amended by redesignating paragraph (a) as paragraph (c); by changing the reference in the redesignated paragraph (c) to read "19.803(c)" in lieu of "19.803(a); by redesignating (c) (S-71) as paragraph (b); and by removing (c)(S-70) (i) and (ii);

3. Section 219.804-4 is added to read as follows:

219.804-4 Repetitive acquisition.

(a) When the SBA requests that a requirement be reserved for award of a contract (follow-on our otherwise) under the 8(a) Program, the request shall be honored, if otherwise appropriate, and the total SDB set-aside procedure shall not be used.

(b) An SBA request that a new requirement be reserved for the 8(a) Program need not be honored and a contracting officer may proceed with a total SDB set-aside if the SBA request is received after publication of a synopsis pursuant to 205.207(d)(S-72) or (S-73).

[FR Doc. 89-16779 Filed 7-17-89; 8:45 am]

BILLING CODE

---

48 CFR Part 246

Department of Defense Federal Acquisition Regulation Supplement; DFARS Warranties

AGENCY: Department of Defense (DoD).

ACTION: Proposed rule (extension of comment period).

SUMMARY: The Defense Acquisition Regulatory (DAR) Council published a proposed rule with request for public

Minutes

Veterans Advisory Committee on
Environmental Hazards

June 26, 1989

Mr. Meadows opened the meeting with a brief description of the charge to the special task force of the Committee. He noted that the Committee had been asked to review a regulatory proposal designed to implement the decision of the court in Nehmer, et al. v. U.S. Veterans Administration, et al.

Mr. White of the Veterans Benefits Administration provided a summary of the court's holding in the Nehmer case. He stated that the court ruled that VA in using a cause and effect standard in determining what diseases, if any, were associated with exposure to Agent Orange employed a stricter standard than had been intended by the Congress in enacting Pub. Law 98-542. The court stated that Congress intended a less strict standard of "significant statistical association" in attempting to relate a disease to exposure. Accordingly, the Department was directed to consider the scientific literature in light of this standard.

Mr. White advised the task force of the Committee that a draft proposed rule setting forth the criteria by which to judge when a significant statistical association may be said to exist had been prepared for the Committee's consideration. He noted, however, that the Committee should not feel bound by anything contained in the proposal as it was being offered to present a framework for discussion.

Mr. White then summarized key provisions of the draft proposal. He noted that the proposal contained a trigger mechanism whereby a significant statistical association must be found when certain criteria were satisfied: when two or more studies which were favorably evaluated individually have adequate statistical power to detect a 25 percent increased incidence for the disease under consideration; have satisfactorily accounted for confounders; have sufficiently described their methodology and data to allow validation; are statistically significant at a probability of 0.05 or better; and outweigh the results of negative studies on the same subject, it must be concluded that a significant statistical association had been established. He noted that the last criterion, the balancing test of the negative and the positive studies, constituted the required application of the reasonable doubt doctrine to the study evaluation process.

Mr. Conway commented that after the Committee's meeting, the recommendation of the Committee would be presented to the Veterans Benefits Administration for its consideration in drafting a final proposed rule which would be published for public comment in mid-July. Following the public comment period, the Department will consider the comments received, make whatever changes it deems appropriate, and respond to the comments that it did not accept. The Committee would then meet again to consider the comments, the Department's response, and the proposed final regulation. The Department, following receipt of recommendations by the Committee, would then publish final regulations in October. In November, the Committee would convene again to apply the standard to the literature and make whatever recommendations it deems appropriate to the Secretary. The Secretary would then consider that advice and announce any changes to the Department's policy concerning compensation for Agent Orange related diseases in January.

Dr. Whitlock asked for clarification of what was intended by the adequacy of statistical power to detect an increased incidence of 25 percent or more. Mr. Conway responded that based upon consultations with various individuals, it was thought that more was required than a statement that adequate statistical power to detect a disease was necessary; that there should be some threshold number by which to judge the adequacy. There then followed a discussion of this provision of the proposal.

Dr. Colton suggested that it may be better to speak in terms of relative risk, that is that a study must have adequate statistical power to detect an increased risk of 25 percent or greater. Dr. Lathrop asked for the rationale for selecting an increased relative risk of 25 percent, commenting that it is only in very, very large studies that one would have adequate power to detect an increase of 25 percent. Dr. Colton asked what purpose was served by having such a requirement. He noted that if a study did not have adequate statistical power, then it would not be likely to find a statistically significant difference.

Dr. Kurland expressed concern that the issue of multiple comparisons did not appear to be addressed. He also commented that too much emphasis may be given to positive studies because of the tendency of investigators and journals to publish only papers in which there was a positive report.

Dr. Lathrop expressed the belief that the proposed regulation needed to address the issues of selection and participation bias. He agreed with Dr. Kurland and questioned whether sub-sub-group findings were really meaningful. He also commented that in applying the standard to be developed, certain studies were deserving of more weight than others and he gave the example of hypothesis-generating studies versus hypothesis-testing ones.

Dr. Upton commented on the phraseology of "25 percent or more." He offered for consideration the language that a study have adequate statistical power to detect an increase of 25 percent or more in the incidence of the disease under consideration. Having suggested that language, he then questioned whether 25 percent was the proper magnitude of increase. He also cautioned against considering all studies as being equally valid. He noted that in evaluating the scientific literature, there ought to be thoughtful weighting of the strength of the evidence presented.

Dr. Colton commented that there are certain criteria that ought to be employed in determining whether a study's findings are valid. He suggested that the draft regulation should be reorganized such that the first item to be considered is whether the author has adequately described his methodology and his data collection. Then the question to be asked is whether the study is reasonably free from bias, that is selection bias, observation bias and so forth. Next, has the study's author(s) satisfactorily accounted for the presence and correction of known confounding factors or variables. Finally, he would discuss whether the study had adequate statistical power.

In discussing the statistical power needed for a study's findings to be considered valid, Committee members considered whether a one- or a two-tailed test should be employed. Some members thought that a one-tailed test was appropriate because one was not looking for beneficial effects of exposure; others thought that the two-tailed test was more appropriate because a one-tailed test would allow a better opportunity for chance associations to emerge.

Dr. Colton raised a series of questions about the types of studies that would be subjected to the regulatory analysis commenting that hypothesis-testing studies would be of more assistance than hypothesis-generating studies. He also raised the question of the definition of a study: are review papers studies; are several papers by the same authors arising out of the same event separate studies or a single study with different reporting dates?

Dr. Whitlock raised a question on how to balance the positive studies against the negative studies. Dr. Colton commented that this would be an assessment of what the totality of the evidence in published reports was. Mr. Conway explained that a balancing of the evidence would occur when there is an approximate balance of the weight of the evidence; if it is clearly one way or the other, then balancing would not be called for. A concern was expressed that balancing of the scientific evidence was a very subjective test. Several members questioned whether it would be appropriate to consider negative studies at all, especially if the intent was to be liberal so as to allow compensation to be paid. This led to a discussion of how best to consider negative studies. One proposal was to simply disregard them and speak in terms only of positive studies; another suggestion was to consider them the negative studies in determining the probative value of the positive studies.

Mr. Clark, the nominee for Assistant Secretary for Veterans Liaison and Program Coordination for the Department of Veterans Affairs, joined the Committee's deliberations. A discussion then followed of the process to be employed by the Committee and the Department in assessing the scientific literature. It was agreed that further discussion of that issue would have to wait until after the standards to be employed have been agreed upon and finalized.

Dr. Michael Gough, the Chairman of the Veterans Advisory Committee on the Health Related Effects of Herbicides, addressed the issue of the consideration to be given to negative studies and to criticisms that have been expressed about some positive studies. He suggested that there ought to be a way for the Committee to be able to consider these.

Mr. Conway read from the court's opinion wherein it addressed the balancing question. The court stated that the Committee and the Secretary would be required to carefully examine the methodology of each study and determine whether the findings are statistically significant, capable of replication, and withstand peer review. The court went on to state that the Committee and the Secretary would still be required to weigh the scientific evidence cumulatively to avoid giving undue weight to a particular study.

Dr. Colton suggested that if there were one positive study, that should put the members in an alert mode. Dr. Lathrop commented that when there is a positive association, it should trigger the weighing process and if it turns out that the Committee's assessment is that the association is as probable as not, then the recommendation should be made to the Secretary that he should compensate.

The Committee engaged in some discussion about how the matrix for evaluating studies would be applied and by whom. It was suggested that it may be appropriate to apply the proposed framework to the studies already evaluated by the Committee and see what would happen. It was agreed that this ought not be done before a final regulation was in place because it might create the appearance that the criteria were selected on the basis of the outcome that would result instead of on their own merits.

The Committee agreed to the reordering of the paragraphs of the proposed regulation along the lines suggested earlier by Dr. Colton. The first criterion agreed upon was that there be two or more studies which have adequately described the study's design and methodology of data collection to allow validation.

The second criterion would be that the studies were reasonably free of bias. Several members suggested that the types of bias of concern be described. These were selection, response and participation biases.

The third criterion would be that the authors satisfactorily accounted for the presence and correction of known confounding factors.

The Committee then discussed the issue of the statistical power of a study to detect an association. Several members thought it important to be able to properly evaluate a negative study. Among the approaches discussed was to require that a study have adequate statistical power to detect a two-fold increase. Concern was expressed that this may be too strict a standard and may result in disregarding otherwise valid studies. Dr. Upton suggested language to the effect that a study must have adequate statistical power to detect an increase in the disease of interest. Dr. Yanders suggested additional language to the effect that the study's findings be statistically significant at a probability of 0.05 or better. It was noted in the discussion of this suggestion that the problem has not been with invalid negative studies but rather with invalid positive studies. The suggestion was made that the criteria for evaluating a negative study be different from those for evaluating a positive study.

A brief discussion was had on the issue of how to advise the Secretary of the Committee's recommendation. It was noted that generally there would be relatively few studies on a subject, that is two or three rather than a hundred or so. If the break out was that two studies were positive and one was negative, should the Committee make a favorable recommendation to the Secretary? Mr. White suggested that if the studies met all the criteria that would be outlined in the regulation, then, applying the balancing test, the Committee should make a favorable recommendation.

The Committee then adjourned for lunch.

When the Committee reconvened, it considered a draft of the regulation based upon the morning's discussions. (The draft as presented to the Committee is in Appendix I to the minutes.) The Committee focused first on the numbered subparagraphs to paragraph (d) of the proposed regulation. In subparagraph 2, the word applicable was deleted because it was thought to be unnecessary. Subparagraph 3 was accepted with the change of deleting the words "the presence and correction of." Subparagraph 4 was modified to insert the phrase "two-tailed test" to describe the probability level of 0.05. Subparagraph 5 was modified to delete the words "in fact;" concern was expressed that those words might suggest that causal relationship was being sought and not a statistical relationship. In subparagraph 1, it was agreed to delete the phrase "to allow validation" and substitute the words "verification and analysis" in its place. In subparagraph 5, Dr. Kurland suggested that the wording "dealing with the same subject" might be confusing. Different phraseology was suggested and discussed with agreement being reached on "that deal with the same adverse health effect." A similar change was made in the preamble to the regulation in paragraph (d). The Committee then restructured the ordering of the regulation so that it first spoke of the criteria applicable for determining whether a study was valid, then the criteria applicable to a valid positive study and then a valid negative study. The Committee discussed the propriety of requiring two or more positive studies as suggested in the beginning of paragraph (d). It was suggested that the words "relative weight of valid positive and negative studies" be substituted, for this better conveyed the notion of weighing the relative merits of the studies in the decision process. A revision of the draft language was prepared during a short break of the Committee. (The language of the revised draft regulation is set forth in Appendix II.)

Following the break, the Committee discussed the revised proposal. Consideration focused on the criteria for a valid negative study. The Committee's final recommendation is found at Appendix III.

The Committee was advised of the proposed time schedule for the publication of the regulation for public comment, the Department's review of the comments, the Committee's review of the Department's proposed final regulation, and the publication of the final regulation. The Committee then adjourned until September 8.

Respectfully Submitted:

Frederic L. Conway

Frederic L. Conway
Executive Secretary

Approved:

Oliver E. Meadows

Oliver E. Meadows
Chairman

Members in Attendance

Dr. Colton
Dr. Kurland
Dr. Lathrop
Mr. Meadows
Dr. Upton
Dr. Whitlock
Dr. Yanders

Agency Personnel in Attendance

Ms. Sylvia Chavez-Long, Deputy Assistant Secretary for Program Coordination and Evaluation
Mr. Layne Drash, Office of Environmental Medicine
Ms. Bonnie Marinelli, Board of Veterans Appeals
Mr. Herbert Mars, Compensation and Pension Service
Mr. Joel Drembus, Compensation and Pension Service
Mr. Gary Hickman, Compensation and Pension Service
Ms. Sylvia Arrington, Office of the General Counsel
Mr. Tom Roberts, Office of the General Counsel
Ms. Donna St. John, Office of Public Affairs
Dr. Han Kang, Office of Environmental Epidemiology

Members of the Public in Attendance: 11

Appendix I

Revised Paragraph (d)

(d) For purposes of paragraph (c) of this section a "significant statistical association" shall be deemed to exist when two or more scientific or medical studies which have been favorable evaluated under the factors set forth in paragraph (b) of this section, and which purport to establish a relationship between a particular type of exposure and a specific disease,

(1) Have adequately described the study design and methods of data collection to allow validation,

(2) Are reasonably free of applicable biases, such as selection, observation and participation biases,

(3) Have satisfactorily accounted for the presence and correction of known confounding factors,

(4) Are statistically significant at a probability of .05 or less, with proper accounting for multiple comparisons and subgroup analysis, and

(5) When considered in conjunction with negative studies of adequate statistical power dealing with the same subject, are of sufficient relative weight to permit the conclusion that it is at least as likely as not that the purported relationship exists in fact.

(d)(1) For purposes of paragraph (c) of this section a "significant statistical association" shall be deemed to exist when the relative weight of valid positive and negative studies as defined below permit the conclusion that it is at least as likely as not that the purported relationship exists between a particular type of exposure and a specific adverse health effect.

(2) A valid positive study is one which:

(i) Has adequately described the study design, methods of data collection verification and analysis to allow validation;

(ii) is reasonably free of biases, such as selection, observation and participation biases;

(iii) has satisfactorily accounted for known confounding factors; and

(iv) is statistically significant at a probability of .05 or less (two-tailed test), with proper accounting for multiple comparisons and subgroup analyses.

(3) A valid negative study is one which has sufficient statistical power to detect an association between exposure and a specific adverse health effect if such an association in fact exists.

(d)(1) For purposes of paragraph (c) of this section a "significant statistical association" shall be deemed to exist when the relative weight of valid positive and negative studies as defined below permit the conclusion that it is at least as likely as not that the purported relationship exists between a particular type of exposure and a specific adverse health effect.

(2) A valid study is one which:

(i) Has adequately described the study design, methods of data collection verification and analysis;,

(ii) is reasonably free of biases, such as selection, observation and participation biases; and

(iii) has satisfactorily accounted for known confounding factors.

(3) A valid positive study is one which is statistically significant at a probability of .05 or less (two-tailed test), with proper accounting for multiple comparisons and subgroup analyses.

(4) A valid negative study is one that does not meet the criteria in (3) above and has sufficient statistical power to detect an association between exposure and a specific adverse health effect if such an association were to exist.

Minutes of the
Veterans Advisory Committee on
Environmental Hazards

September 8, 1989

Mr. Meadows briefly described the purpose of the day's meeting: to review the public comments that had been received during the comment period for the proposed regulation setting forth the criteria for determining when a significant statistical association exists between exposure to a herbicide containing dioxin and subsequently developing disease.

A panel representing the American Legion had asked for and was given an opportunity to present the views of the American Legion on the make-up of the Committee and the content of the proposed rules. Mr. John Sommer, Director of Veterans Affairs and Rehabilitation for the American Legion, stated that it was the Legion's position that the Federal government had not lived up to its responsibility with respect to the long tern health effects of dioxin exposure. He introduced the members of the panel who accompanied him: Richard Christian, Deputy Director of Veterans Affairs and Rehabilitation, Dr. Ellen Silbergeld and Mr. Ron Simon, an attorney representing the Legion.

Mr. Simon briefly summarized his interpretation of the court's decision in Nehmer v. Veterans Administration. He stated the Legion's position that the proposed rules were worse rather than better than the prior rules. He then criticized the composition of the Committee and particularly focused on Dr. Colton's membership. He stated that it was unacceptable to the Legion that an individual who has testified on behalf of companies that "manufactured dioxin" should participate in a review of the literature. He contended that the viewpoint which had previously been expressed by the Committee was not that shared by most of the scientific community, citing particularly the Environmental Protection Agency (EPA) and the International Agency for Research on Cancer (IARC). He criticized VA for only seeking the advice of scientists "who have been paid to testify against" veterans and none who have taken the side of veterans. He also criticized VA for appearing to adopt the position which had been expressed by chemical companies, that is, that no one can be injured by a chemical unless it can be proved to a scientific certainty that that's true.

Dr. Kurland took exception to the charge of Mr. Simon that VA had solicited advice only from those who had been paid to testify for a point of view. He stated that he had never been in such a position and asked Mr. Simon to defend his statement. Mr. Simon contended that Dr.. Kurland had misrepresented what he had said. He attempted to clarify his position by stating that the Committee only had individuals on it who had testified on behalf of chemical companies and had no individual who had testified on behalf of veterans.
Dr. Colton challenged the accusation that he had been paid to testify against veterans. He stated that he had been asked to give his honest opinion concern-

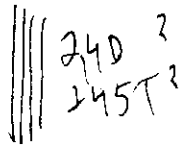
ing the weight of scientific evidence and that he did so in a deposition taken at the request of attorneys representing a chemical company. He also stated that he had checked with VA concerning the propriety of this action and was advised that so long as he expressed his honestly held opinion he could express that opinion anywhere he liked. He further stated that he resented the insinuation that he was a paid professional who testified against veterans. Mr. Simon then examined Dr. Colton concerning his participation in litigation activities. Dr. Lathrop objected to this stating that the Dioxin Panel was not on trial. Mr. Meadows challenged Mr. Simon's assertion that he had not impugned the motives or the integrity of the Committee. He then read from a letter addressed to the Secretary of Veterans' Affairs from the National Commander of the American Legion in which it was stated, "The Committee is engaged in a vulgar and disreputable effort to discredit all of the scientific evidence that supports veterans and to attack any scientist or organization that stands up for veterans." Mr. Simon responded that he only took exception to the word "all" in that he believed that the Committee had only looked at a limited amount of data; with respect to the American Legion study, however, he believed that the Committee did undertake to discredit it.

Mr. Christian stated that there was a perception among Vietnam veterans and the American Legion that the Committee was biased. He stated that he felt that the Committee had insulted the American Legion scientists in the minutes of the Committee's April 25, 1989, meeting.

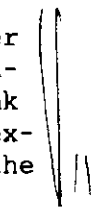
Dr. Silbergeld, in her introductory comments, noted that she was not familiar with the past workings of the Committee nor of its members. She stated that she was going to focus on the adequacy of the approach taken by the Committee in the past and that which was being proposed to take in the future. The first point she made was to urge the Committee have as broad a scope of inquiry as possible. She stated that she was concerned by what she had read in various proposals of the Committee and the comments of the Committee to the Department which she believed recommended a very narrow circumscription of the literature and the information available to be reviewed. She commented that the Committee ought to consider information generated by experimental and animal studies as well as clinical and case reports and epidemiologic studies of all types. She noted that some studies may not rise to a sufficient statistical criterion but that does not mean that they should be considered as negative studies. Rather, she urged that the Committee consider the techniques that have been employed by EPA and IARC to expand and combine data sets in a critical fashion.

Dr. Silbergeld next urged that the Committee take a broad view of what is relevant human experience. She commented that she had heard that the definition of relevance was exposure of military personnel to herbicides. She stated that she thought this to be very wrong-headed. She urged that the Committee consider other forms of exposure such as occupational and environmental exposures. Along

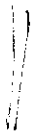
the same line, she also urged that the Committee not restrict itself to herbicides containing dioxin but to keep in mind the three major components, that is trichlorinated phenoxy acetic acid, the dichlorinated phenoxy acetic acids and the range of chlorinated dioxins and dibenzofurans, all of which would provide important information.



She also expressed an opinion concerning her understanding of the proposal to evaluate and weigh the scientific evidence. She stated that it appeared to her that a check-off system in which so-called positive studies and so-called negative studies which cancel each other out was being proposed. She did not think that was an appropriate way to weigh and evaluate any large body of human or experimental evidence. She urged the Committee to adopt the approach taken by the EPA in its development of its risk assessment guidelines.



She then urged the Committee to pay heed to mechanistic studies which she believed was a relatively rich area in the field of dioxin research. She cited two examples of how this type of research could be helpful: mechanistic studies would help to bring understanding of the role of genetic constituents in determining response to dioxin and, second, the impact of various structural changes in the dioxin or dibenzofuran molecule upon the toxic response of humans or others to this class of chemicals.



She next commented on the value of animal studies. She noted that much has been made of wide variation of species response to dioxin exposure. She stated that this rested on the differences in the acute lethal response to dioxin which she stated was clearly very species specific and not of concern to anyone considering human risk. She stated, however, that there when considering low dose response, there was less species diversity. Therefore, she argued, the differences that may exist between animal and human exposure consequences would be quantitative and not qualitative.

Dr. Silbergeld also expressed her opinion that a current review of the literature has led her to conclude that there is found a consistently high degree of potential human risk from exposure to dioxin and related molecules and that these risks include carcinogenic, teratogenic, immunologic, neurologic, dermatologic, and hepatotoxic risks. She commented that the Committee ought to use the highest principles of science in reaching its conclusions and making its recommendations to the Department, which she felt that the Committee had not done in the past.

Dr. Colton said that he agreed with her comments concerning statistical power and thought that they were consistent with what the Committee had done at its previous meeting. He also asked Dr. Silbergeld if she had read the Committee's critique of the American Legion studies. She responded that she had not. He then asked her for her scientific opinion of that work. She described the major

conclusion that she arrived at was that the studies were a demonstration that it was possible to determine with greater certainty who was exposed and that would make it possible to re-examine the veteran cohort in a much more critical way. She felt that the studies appeared to make valid use of the military records and that it may be the only way to study exposure among Vietnam veterans. She noted that their exposure was rapidly receding into the past and that there remained considerable uncertainty as to the pharmacokinetics of the substances of interest making it questionable to totally rely upon blood studies to determine their exposure.

Dr. Kurland, in response to Dr. Silbergeld's advice to review as broad a spectrum of the literature as possible, noted that the Committee had examined and reviewed reports of exposed populations in addition to the Vietnam veterans and that it was his view that the Committee had gone out of its way to find and review anything that could be relevant. He also made reference to the report by the Universities Associated for Research and Education in Pathology which had examined the issue the health aspects of environmental exposure to polychlorinated dibenzodioxins and polychlorinated dibenzofurans and noted that it had reached many of the same conclusions that had been arrived at by the Committee.

Dr. Silbergeld stated that she thought that there was a significant body of epidemiologic and clinical literature concerning related chemicals and circumstances that did not involve 2,4,5-T and 2,4-D which she believed the Committee had not paid adequate attention to. Dr. Kurland disagreed with her conclusion and invited her to review the minutes of the Committee's meetings.

Dr. Lathrop commented that Dr. Silbergeld had examined the literature from the point of view of one interested in toxicology and mechanisms of action. He stated that that perspective consistently overlooked the fact that while certain molecules and compounds may have devastating effects in experimental animals, the ultimate proving ground is the human population. He noted that the Committee had never made a conscious effort to overlook mechanistic studies or animal studies. He noted that individual members would try to keep the Committee informed if there were any break-throughs in these types of studies and whether there were any research results that might be applicable to humans. He expressed his opinion that none were forthcoming to the point that they might yield clinical end points. Dr. Lathrop also took exception to the comment that the Committee had not used the highest principles of science. He stated that the only bias exhibited by the Committee has been for the truth.

Dr. Whitlock stated that in a general sense he agreed with Dr. Silbergeld. He stated that the Committee has tried to define exposure as broadly as possible. He did not think it was yet possible to extrapolate from animal or mechanistic studies to what happens to humans at low doses. In this regard, there has to be dependence upon human epidemiology.

Dr. Yanders agreed with Dr. Whitlock and stated that many of the Committee's members have a strong appreciation for the animal and mechanistic studies and that they have not been disregarded in the Committee's consideration of the human studies.

Dr. Colton responded to some of the criticisms that had been expressed by Mr. Simon. He stated that while he may personally believe that Vietnam veterans are deserving of compensation because they had been mistreated upon their return from Vietnam, his views as a scientist are quite different. He stated his professional opinion that there is insufficient epidemiologic evidence to support a conclusion that Vietnam veterans are deserving of compensation. He indicated that he would express that expert opinion to the Committee and, if asked, to a court as well.

Mr. Christian commented that in his view, the minutes of the April 25, 1989, meeting failed to show that the Committee has done anything to help the Vietnam veteran. He also stated that the information the Committee had received concerning the service HERBS tapes was totally incorrect. He referred to a study by the National Academy of Sciences which validated the information recorded on the tapes. In response to a question by Dr. Lathrop, Mr. Christian reported that the study had examined the tapes of 114 missions, that it was not a study of the entire Ranch Hand HERBS tapes. He expressed the opinion that the tapes were very accurate in detailing the spraying missions.

Mr. Simon stated that his earlier remarks were not designed to call into question the integrity of any Committee member. Rather, he took exception to some of the views expressed by the Committee. He cited as an example, a statement by Dr. Kurland that animal studies had little relevance to human reaction. He stated that he believed that Dr. Kurland honestly held that opinion but that opinion was wrong and that it was not shared by the rest of the scientific community. He stated that the Committee had not reflected the views of anybody but themselves on this debated issue.

Mr. Simon also took exception with Dr. Colton's opinion that there is no firm statistical, human epidemiological evidence. He stated that the Committee has failed to consider or to give sufficient credence to other types of human data such as clinical and other non-epidemiological studies. Mr. Simon also took exception to the Committee's favorable reliance upon the Centers for Disease Control's (CDC) work as a basis for its conclusions. He referred to recent criticism of the CDC as bungling in its handling of the Agent Orange exposure study when it concluded it could not find enough Vietnam veterans exposed to Agent Orange to do a credible study. He also stated that he thought the Committee's position was one that was inconsistent with the obligation of the Department of Veterans Affairs to resolve reasonable doubt in the veteran's favor. He stated

that the Committee's orientation was to find evidence to support a conclusion with a high degree of confidence. This, he stated, was contrary to the law.

Dr. Colton reiterated that he thought Mr. Simon's remarks were calling into question his integrity. He also stated that claimed no expertise beyond his own professional capabilities and training. He looks to epidemiological evidence because that is where his expertise is; he did not mean to suggest that the Committee should, therefore, restrict its investigation only to epidemiologic evidence.

Mr. Simon attempted to clarify his remarks. He stated that he did not question that Dr. Colton honestly arrived at the views he had expressed. Rather, he felt that Dr. Colton represented only one side of a hotly debated issue and that the contrary point of view was not being expressed. When Dr. Colton stated that he was not taking a side, Mr. Simon took issue with that. He analogized the situation to a judge who owned stock in a company presiding in a trial involving that company. He stated that in such a situation the judge would recuse himself. However, when Dr. Colton testified on behalf of chemical companies, he declared a position on one side of the issue and for him to continue to participate on the Committee without the other side being represented was, in Mr. Simon's view, unfair.

Dr. Colton took exception to the characterization that he had taken sides. He stated that he was asked to give his personal opinion, that is what he did. He stated that he reviewed the Stellman papers with an open mind and concluded that it had certain limitations and certain strengths. The same is true of many of the studies that had been reviewed by the Committee. He further stated that no one on the Committee had taken sides on this issue.

Mr. Simon stated it was his opinion that the decisions made by the Committee did indicate that it had taken a side. He again commented that someone who has testified on behalf of one party in a litigation is not one who is considered to have an open mind. Dr. Colton asked if Dr. Silbergeld's opinions should be discredited because she had testified on many occasions on behalf of plaintiffs. Mr. Simon stated that he did not discredit Dr. Colton's opinion only that his was one point of view and that the other point of view was not represented on this Committee. Mr. Meadows asked if Mr. Simon had been paid by the American Legion; he responded that he had. Mr. Meadows then asked if Mr. Simon was biased. Mr. Simon stated that he was absolutely biased. When Mr. Meadows asked if the Committee should spend its time listening to a biased presentation, Mr. Simon declined to comment.

Dr. Silbergeld commented that she had testified as an expert witness. She stated that the issue was not whether one was biased or not but rather it was one of perception. She urged the Committee to consider the issue of broad rep-

resentation of scientific and other opinions on issues of controversy such as this.

Dr. Kurland remarked that he had been impressed when he first come to the Committee that VA staff had stressed the importance of resolving reasonable doubt whenever possible in favor of the veteran. He took exception to the implication that he or anyone else on the Committee was anti-veteran. He also noted that Mr. Simon had taken his comment regarding the strength of animal studies out of context. He stated that he regarded animal work and clinical work to be very important. What he stated was important was the relevance of that work to human experience.

Mr. Meadows, in closing this portion of the meeting, noted that the Committee had searched for materials to be reviewed and that they had reviewed materials upon request by the Administrator, other officials within VA, and members and committees of the congress. He did not recall the American Legion being an active participant in the proceedings of the Committee either by attendance or by suggesting materials for review. He extended an invitation to the Legion to refer materials to the Committee which the Legion thought were pertinent and should be looked at. He concluded by saying that he thought the criticism expressed by the National Commander to the Secretary was unfair and that he took it personally. He asked that these views be conveyed personally to him.

The Committee then took a short break. Upon return, Dr. Lathrop commented that he neglected to state that the HERBS tapes were truly inaccurate. He briefly noted the circumstances under which most Ranch Hand operations were conducted.

Dr. Yanders then proposed a method for the Committee to address the comments that had been received as part of the rule-making process. He suggested that Mr. Conway lead the discussion by briefly summarizing the individual comments and seeing what the Committee's views on the comments were. The Committee would then review the proposed regulation.

First, Dr. Yanders asked if their were any general comments. Dr. Colton stated that some were useful but others were totally off base. Dr. Lathrop commented that some of the views fell under the category of advocacy. Dr. Whitlock thought the comments were reasonable and improved the process. Dr. Yanders agreed with these general comments and then asked Mr. Conway to lead the discussion of each of the comments individually.

Mr. Conway stated that the order of the comments simply reflected the order in which they appeared in his folder. The first comments discussed were those of the State of Minnesota, Department of Veterans Affairs. The comments noted that the proposed rules did not and could not eliminate subjectivity from the evaluative process. It was suggested that the subjectivity be as open to public scru-

tiny as possible. Offered for consideration were the factors suggested by the Office of Technology Policy in its 1985 report, "Chemical Carcinogens: A Review of the Science and Its Associated Principles."[1].

Dr. Lathrop noted that the elements cited are those required for establishing causality in epidemiology. He raised the question as to whether the Committee was permitted to use these in light of the court's ruling in Nehmer.

Dr. Colton commented that he had reviewed the language employed by the IARC which had been suggested as a model and thought that the language proposed by the Committee was very similar to that used by the IARC with regard to epidemiologic evidence. Dr. Whitlock and Dr. Yanders concurred.

Mr. Conway then noted that the comments of the State of Minnesota requested that clarification of various terms be provided. It was noted that these comments were outside the scope of the proposed rule-making. Nevertheless, the Committee did address some of the comments raised. First, there was the comment that the phrase "withstand peer review" should be clarified to explain what are the criteria for peer review. It was agreed that for an article to be capable of withstanding peer review it need only have been reviewed by experts in the field and it did not necessarily have to have appeared in a peer reviewed journal.

The next suggestion commented upon concerned the phrase "relative weights of studies." The question was raised as to how do various factors relate to this in the evaluation process. Dr. Lathrop observed that this is not a quantifiable item but rather is a thought process that one engages in. Dr. Whitlock recalled that EPA had a good statement addressing this issue.

Dr. Lathrop then thought that the comment relating to the phrase "veteran population of interest", i.e., how narrowly is this defined, was a good one. Dr. Lathrop observed that the Committee would not ignore any study of a civilian population that demonstrated a significant effect in assessing the evidence with respect to veterans. Rather, the obligation would be on the Committee to weigh the different kinds of exposure that may have been involved and then determine whether the differences in exposure may have an impact on effects among veterans.

---

1. "In interpreting epidemiological findings, one is guided by the magnitude of the risk estimates, their statistical significance and the rigor of the study design to avoid various kinds of bias... A determination of causality in epidemiology is bolstered by dose-response relationships, the consistency and reproducibility of results, the strength and specificity of the association, its biological significance and other considerations." (At p. 59.)

Dr. Yanders noted that the phrase was fairly well understood among Committee members. Dr. Whitlock asked why was the phrase in there at all and Mr. Conway stated that the language was intended to indicate that radiation studies would be applicable to radiation-exposed veterans and herbicide studies to Vietnam veterans.

Mr. White again raised the issue of whether these comments were germane to the rule-making before the Committee. After some discussion, it was agreed to focus on those comments that were related to the proposed changes in the regulation and defer until a later time discussion of those comments that address other parts of the regulation.

Dr. Kurland noted that there were some comments concerning the use of the phrase "herbicide containing dioxin." He asked whether this word "dioxin" should be in the plural as there are many dioxins. Mr. Conway responded that the phrasing was taken directly from the law and that the Congress intended that the issue of exposure to the 2,3,7,8-TCDD isomer be addressed in the regulation. Dr. Lathrop then asked if the Committee should look at 2,4-D and 2,4,5-T as independent chemicals with possible adverse health effects being associated with each of them alone. Mr. Conway stated that a broad interpretation of the phrase "herbicide containing dioxin" would include Agent Orange and all of its components. This would permit consideration of studies relating to 2,4-D, a component of Agent Orange, which strictly speaking would not be a herbicide containing dioxin.

The Committee next considered the comments of the National Veterans Legal Services Project, Inc., submitted on behalf of the Vietnam Veterans of America (VVA). First, they criticized the proposed regulation as being too rigorous in the setting forth the criteria for determining whether a study satisfies the threshold validity requirement. Calling the criteria "gold star" prerequisites, they argued that the criteria relating to study design, data collection, verification and analysis, freedom from bias and accounting for confounders were designed to make it as difficult as possible for any disease to be recognized as few papers would pass through this test.

Dr. Colton commented that he regarded the criteria criticized as being "gold star" standards as being minimal standards for any reasonable study. Dr. Whitlock and Dr. Kurland expressed agreement with Dr. Colton's remarks.

VVA next criticized the proposed changes as, in effect, setting forth a cause and effect standard. They noted a similarity between the wording of the criteria for a valid study and the criteria set forth by the IARC for inferring a causal association between exposure to a chemical and cancer in humans. Dr. Yanders thought this comment to be unjustified because the criteria articulated by VA and IARC are the standards by which one would judge any scientific paper

without regard to whether one is seeking to establish a causal association or a statistical association. Dr. Colton noted that he had read the IARC monograph and commented that the language used by the IARC was entirely consistent with what the Committee had recommended. He stated that the criteria described related to the evaluation of the quality of the study not to whether the study demonstrated causality. Dr. Yanders agreed with this.

VVA then commented that VA's proposed standards were more appropriate for prospective, experimental models rather than more realistic observational models. They stated that VA should have a rule which would apply to four models of study which they described as controlled comparative clinical trials, purposive sampling, naturalistic or cross-sectional sampling, and case reports.

Dr. Colton thought that there might be some merit to this criticism. He noted that language in the preamble might be construed to apply only to cohort studies. He suggested wording that would make it applicable to al types of study design.

VVA then made specific comments about particular provisions of the proposed rule. First, they argued that the change to the scope of the relevant studies from dioxin to herbicide containing dioxin was constraining and may lead to not using information pertaining to possible damage from dioxin exposure - whether in a herbicide, pesticide, or in an accidental emission. The Committee discussed the change in wording and considered whether it was restrictive. It was noted that the proposed wording was reflective of the statutory language employed by the Congress. It was also pointed out that the new language was intended to be more liberal; for example, under the current wording, studies that addressed only the issue of the effects of 2,4-D would not be considered since 2,4-D was not dioxin. It was the intent of the drafters of this change to liberalize the scope of studies to be considered.

Dr. Whitlock suggested that perhaps the discussion of what was meant by the weight of the evidence could be expanded to make it clear that the Committee will consider a range of studies, including epidemiology studies, studies of animals and studies of cells in culture and mechanistic studies. Dr. Lathrop commented that the Committee had always considered it appropriate to consider any mechanistic study or animal study that had a major bearing from a clinical perspective. He noted that Mr. Conway had requested the Committee to submit papers for possible review and gave wide latitude to the Committee in this regard. Dr. Yanders suggested that the regulatory language remain as proposed and that the preamble be amplified to reflect the Committee's discussion.

The next comment of the VVA concerned the proposed language setting forth the factors to be considered in evaluating scientific studies. Specifically, they argued that the language "whether the study's findings are statistically sig-

nificant and replicable" would preclude consideration of accidentally exposed populations because the circumstances of exposure could not be replicated. Dr. Colton stated that his interpretation of that wording was that an investigator should provide sufficient information such that a different investigator could use the same methodology and data and arrive at the same findings.

VVA also commented that there was great detail provided in describing the criteria for a positive study but that similar detail was lacking for a negative study. Dr. Colton suggested language to the effect that any study which is not a positive study is a negative study. Dr. Lathrop expressed concern that this may permit a single positive finding out of 300 end points being measured making a study which is otherwise negative a positive study. Committee members discussed whether the proposed language would permit pooling of studies. Dr. Lathrop stated that he would like the Committee to be able to make an assessment of small negative or positive studies and the comments of an author who attempts to pool those studies.

Dr. Colton noted that a definition of valid negative study and of valid positive study is provided. He asked whether studies that were neither negative nor positive would be considered in evaluating the weight of the evidence. Mr. White explained that as the regulation was currently structured, when there was an approximate balance in the valid negative and valid positive studies, then the ~~Secretary shall find~~ that a significant statistical association exists. Studies which did not rise to the level of valid positive or negative studies would be considered under the paragraph providing the Secretary with discretion to make such a finding if in his judgment the evidence as a whole warrants such a conclusion.

Dr. Colton suggested adding a paragraph that would address these types of studies. For guidance, he recommended the language employed by the IARC. Dr. Whitlock suggested that it should be made clear that while human epidemiology is the only way to definitively show an association between exposure and adverse health effects the Committee will consider animal studies and mechanistic studies. The Committee agreed to consider language suggested by Dr. Kurland and Dr. Whitlock later in the meeting.

The VVA next questioned how the criteria suggested in the proposed rule would take into account possible synergistic effects of exposure. Dr. Colton stated that would be a very difficult issue to assess in terms of epidemiologic studies.

The next comment of VVA concerned the establishment of a probability value of 0.05. It was suggested that this would pre-eliminate studies and argued for a value of 0.10 or less as this would better detect small effects. Dr. Colton noted that P value is dependent upon two things: the strength of the association

and the sample size. He stated that 0.05 was the standard used by investigators and to adopt a different standard would require a reanalysis of the data. Dr. Whitlock and Dr. Lathrop agreed that the more generally accepted scientific method should be retained.

VVA then suggested that the concept of power should be clarified and offered a mathematical formulation for weighing positive and negative studies. Dr. Colton thought that the Committee should avoid coming up with any mathematical formulation. He stated that there is a very subjective element in analyzing the scientific evidence, for example, in assessing the strengths and limitations of each of the studies, and that this did not lend itself to mathematical formulas.

Finally, VVA suggested that the provision of the rule concerning the Secretary's discretion should be expanded so as to allow consideration of animal studies. It was noted by Dr. Yanders that the Committee had essentially agreed with this and would recommend language to address it.

The Committee then adjourned for lunch.

The Committee then took up the comments of the Veterans of Foreign Wars. That organization suggested that wording be added which would state at the beginning of the rule to the effect that the discovery of any "significant statistical association" would serve to incriminate dioxin exposure as the causative factor in the claimed disability. The Committee had no comment with respect to this suggestion.

The Disabled American Veterans comments were not related to the proposed language in the regulation and consequently were not addressed by the Committee.

Senator Daschle described the proposed regulation as reasonable but he expressed concern about the apparent reliance upon the Committee. He stated that he had serious reservations about the Committee's ability to make informed, independent, unbiased judgments regarding the validity of significance of some of the scientific studies and evidence related to dioxin or radiation exposure. Dr. Colton stated that he was concerned by this letter because it demonstrated, in his opinion, that Senator Daschle had some misconceptions about the way the Committee had been operating. He asked whether there was some way to provide the Senator with information about the Committee. Dr. Yanders noted that Senator Daschle had been present at hearings when he and the Chairman had given testimony on the Committee's actions.

Senator Daschle next suggested that the publication of the evaluation of the scientific literature should be placed on a regular schedule. The Committee did not address this suggestion as it was outside the scope of the rule-making.

He then commented that additional language should be placed in the section dealing with the types of biases that should be accounted for. Dr. Colton noted that the Committee had considered and adopted language that would cover Senator Daschle's concern. The Committee agreed with Dr. Colton.

Finally, Senator Daschle suggested that parallel language be inserted in the section concerning valid negative studies as exists with respect to the probability necessary for a valid positive study. The Committee did not believe that this was necessary and thought that the wording of the proposed regulation was appropriate.

The Committee next addressed the comments of Wayne Soule who suggested that VA needs to apply the benefit of the doubt in evaluating the scientific literature and asked why VA's criteria differed from those of EPA. It was noted that the Committee had essentially agreed with the application of reasonable doubt in evaluating the weight of the scientific evidence. It was also commented that the missions of the EPA and VA were different so that the criteria would necessarily be different.

Mr. Richard Schwanz commented that the number of scientific and other bodies that VA consults with prior to issuing new regulations should be expanded. It was determined that this comment was outside the scope of the rule-making.

Senator Moynihan suggested that the regulation provide for the consideration of other herbicides that were used in Vietnam. The Committee noted that the law was specific as to what herbicides it was to consider. Further, it was observed that the preamble would make it clear that it was the intent of the Department to conduct as broad a review as possible.

Dr. Clapp supported the proposed change in the language identifying the scope of the issue (herbicide containing dioxin). He questioned whether it would be possible to determine retrospectively who was exposed to dioxin. Finally, he suggested that the concepts of significant statistical association and as likely as not do not necessarily relate to one another. The first is a relatively straightforward mathematical calculation and the second involves judgments about the validity of studies. Dr. Colton commented that the Committee was hampered by what the Congress and the judge in Nehmer determined was the appropriate standard. Dr. Yanders thought that the definition was sufficiently broad to cover both the legal and the scientific requirements.

The National Vietnam Veterans Coalition commented that the proposed rule would be used to disqualify credible studies. They also urged that the Advisory Committee be reconstituted. They offered no specific criticism nor proposed any alternative language. A similar commentary was received from the Oklahoma Agent Orange Foundation.

The American Legion in its written comments stated that the proposed rule was inconsistent with criteria expressed by other agencies or organizations such as EPA and IARC. They believe that it is not necessary for VA to make de novo assessments regarding the health effects of exposure to dioxin or to radiation but rather should adopt the assessments of these other bodies. They also commented that VA should consider the results of animal studies in its deliberations. The Committee noted that similar comments were expressed by the American Legion representatives earlier in the day and that the Committee had already addressed these comments.

The Committee then debated the contents of an addition to the proposed regulation that they believed met some of the criticisms that had been expressed in the comments. First, they recommended that a new section be added that would address the consideration of scientific evidence that did not meet the criteria of valid positive or valid negative studies. The discussion centered on the appropriate weight to give to mechanistic and animal studies. Committee members felt that some of the comments that had been made had some validity and sought to accomodate them. After discussion, the Committee agreed upon the following addition to the preamble:

> Valid epidemiologic studies constitute the most direct and convincing evidence regarding exposure to some agent and association with adverse human health effects. Animal and mechanistic studies provide less direct evidence in determining the likelihood that a presently existing disease is associated with past exposure to a specific agent, but may provide supportive and supplemental information in evaluation of the weight of evidence of association with adverse human health effects.

The Committee then offered language for inclusion in the regulation that would set forth how studies not meeting the criteria of valid positive or valid negative studies should be considered:

> For purposes of assessing the relative weights of valid positive and valid negative studies, other studies affecting epidemiological assessments including case series, correlational studies, and studies with insufficient statistical power as well as key mechanistic and animal studies which are found to have particular relevance to an effect on human organ systems may also be considered.

Mr. Conway then explained the sequence of events that would follow this meeting. He stated that the recommendations of the Committee would be considered by the

Veterans Benefits Administration in drafting a final regulation. It would then be submitted to the Office of Management and Budget (OMB) for their review. Upon clearance from OMB, it would be sent to the Federal Register for publication. In November, the Committee would meet to apply the criteria in determining whether there exists a significant statistical association between exposure to Agent Orange and some adverse health effect.

The Committee next discussed the procedures to be employed at the November meeting. Among the options discussed were inviting experts to address the Committee, extending the length of the meeting to more than the usual two days, devoting an entire meeting to the question of the effects of Agent Orange exposure, and focusing on several diseases to permit greater opportunity for more in depth discussion of the literature. The Committee agreed that the proper approach would be to go disease by disease and have Committee members individually state their opinion at the conclusion of the discussions. Dr. Whitlock was asked to assume the responsibility of assessing mechanistic studies and advising the Committee of those studies that he thought were particularly pertinent. The first condition that they would assess would be non-Hodgkin's lymphoma.

Dr. Colton asked if the Secretary had reacted at all to the criticism that had been directed towards the Committee. Mr. Conway indicated that the Secretary had the intention to do what is in the best interests of the Vietnam veteran community. Dr. Colton suggested that should mean compensation for veterans for all diseases regardless of the scientific evidence. Dr. Kurland stated that the goal should be to compensate the veteran consistent with the appropriate scientific evidence.

Whereupon, the meeting concluded.

Approved: Oliver E Meadows
Oliver Meadows, Chairman

Agency personnel in attendance:

Robert Epley
Gary Hickman, Director, Compensation and Pension Service, Veterans Benefits Administration
Robert White, Regulations Staff Chief, Compensation and Pension Service, Veterans Benefits Administration
Quentin Kinderman, Assistant Director, Compensation and Pension Service,Veterans Benefits Administration
Robert Schloendorn, Associate Director, Office of Deputy Chief Benefits Director for Field Operations, Veterans Benefits Administration
Thomas Roberts, Office of General Counsel
Sylvia Arrington, Office of General Counsel
Frederic Conway, Deputy Assistant General Counsel
Donna St. John, Public Affairs Specialist
Han Kang, Ph.D., Director, Office of Environmental Epidemiology, Veterans Health Services and Research Administration
Lawrence Hobson, M.D., Ph.D., Director, Office of Environmental Medicine, Veterans Health Services and Research Administration
Donald Rosenblum, Office of Environmental Medicine, Veterans Health Services and Research Administration
Allan Sinclair, Office of the Secretary of Veterans Affairs
Laurence Christman, Executive Assistant to the Deputy Assistant Secretary for Program Coordination and Evaluation

Public in attendance: 10