

§ 1.17

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vs. results necessary to support decisions.

(4) *Reliability.* Use of the same research design by others should yield the same findings.

(g) The final program evaluation report will be reviewed for comments and concurrence by relevant organizations within the Department of Veterans Affairs, but in no case should this review unreasonably delay the results of the evaluation. Where disagreement exists, the dissenting organization's position should be summarized for a decision by the Secretary.

(h) The final program evaluation report will be forwarded, with approved recommendations, to the concerned organization. An action plan to accomplish the approved recommendations will be forwarded for evaluation by the evaluating entity.

(i) Program evaluation results should be integrated to the maximum extent possible into Department of Veterans Affairs plans and budget submissions to ensure continuity with other Department of Veterans Affairs management processes.

(Authority: 38 U.S.C. 527)

[47 FR 53735, Nov. 29, 1982, as amended at 54 FR 34980, Aug. 23, 1989]

§ 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 Vet-

erans' 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 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) 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. 501; Pub. L. 98-542)

[54 FR 40391, Oct. 2, 1989; 54 FR 46187, Nov. 1, 1989]

§ 1.18 Guidelines for establishing presumptions of service connection for former prisoners of war.

(a) *Purpose.* The Secretary of Veterans Affairs will establish presumptions of service connection for former prisoners of war when necessary to prevent denials of benefits in significant numbers of meritorious claims.

(b) *Standard.* The Secretary may establish a presumption of service connection for a disease when the Secretary finds that there is at least limited/suggestive evidence that an increased risk of such disease is associated with service involving detention or internment as a prisoner of war and an association between such detention or internment and the disease is biologically plausible.

(1) *Definition.* The phrase "limited/suggestive evidence" refers to evidence of a sound scientific or medical nature that is reasonably suggestive of an association between prisoner-of-war experience and the disease, even though the evidence may be limited because matters such as chance, bias, and confounding could not be ruled out with confidence or because the relatively small size of the affected population restricts the data available for study.

(2) *Examples.* "Limited/suggestive evidence" may be found where one high-quality study detects a statistically significant association between the prisoner-of-war experience and disease, even though other studies may be inconclusive. It also may be satisfied

where several smaller studies detect an association that is consistent in magnitude and direction. These examples are not exhaustive.

(c) *Duration of detention or internment.* In establishing a presumption of service connection under paragraph (b) of this section, the Secretary may, based on sound scientific or medical evidence, specify a minimum duration of detention or internment necessary for application of the presumption.

(d) *Association.* The requirement in paragraph (b) of this section that an increased risk of disease be "associated" with prisoner-of-war service may be satisfied by evidence that demonstrates either a statistical association or a causal association.

(e) *Evidence.* In making determinations under paragraph (b) of this section, the Secretary will consider, to the extent feasible:

(1) Evidence regarding the increased incidence of disease in former prisoners of war;

(2) Evidence regarding the health effects of circumstances or hardships similar to those experienced by prisoners of war (such as malnutrition, torture, physical abuse, or psychological stress);

(3) Evidence regarding the duration of exposure to circumstances or hardships experienced by prisoners of war that is associated with particular health effects; and

(4) Any other sound scientific or medical evidence the Secretary considers relevant.

(f) *Evaluation of studies.* In evaluating any study for the purposes of this section, the Secretary will consider:

(1) The degree to which the study's findings are statistically significant;

(2) The degree to which any conclusions drawn from the study data have withstood peer review;

(3) Whether the methodology used to obtain the data can be replicated;

(4) The degree to which the data may be affected by chance, bias, or confounding factors; and

(5) The degree to which the data may be relevant to the experience of prisoners of war in view of similarities or differences in the circumstances of the study population.