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38 CFR Ch. I (7-1-04 Edition)

(2) *Relevancy.* It must deal with issues currently existing within the program, within the Department, and within the environment in which the program operates.

(3) *Validity.* The degree of statistical validity should be assessed within the research design. Alternatives include an assessment of cost of data collection 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 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 subgroup analyses.

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(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]

REFERRALS OF INFORMATION REGARDING CRIMINAL VIOLATIONS

§ 1.200 Purpose.

This subpart establishes a duty upon and sets forth the mechanism for VA employees to report information about actual or possible criminal violations to appropriate law enforcement entities.

(Authority: 5 U.S.C. App. 3, 38 U.S.C. 902)

[68 FR 17550, Apr. 10, 2003]

§ 1.201 Employee's duty to report.

All VA employees with knowledge or information about actual or possible violations of criminal law related to VA programs, operations, facilities, contracts, or information technology systems shall immediately report such knowledge or information to their supervisor, any management official, or directly to the Office of Inspector General.

(Authority: 5 U.S.C. App. 3, 38 U.S.C. 902)

[68 FR 17550, Apr. 10, 2003]

§ 1.203 Information to be reported to VA Police.

Information about actual or possible violations of criminal laws related to VA programs, operations, facilities, or involving VA employees, where the violation of criminal law occurs on VA premises, will be reported by VA management officials to the VA police component with responsibility for the VA station or facility in question. If there is no VA police component with jurisdiction over the offense, the information will be reported to Federal, state or local law enforcement officials, as appropriate.

(Authority: 38 U.S.C. 902)

[68 FR 17550, Apr. 10, 2003]

§ 1.204 Information to be reported to the Office of Inspector General.

Criminal matters involving felonies will also be immediately referred to the Office of Inspector General, Office of Investigations. VA management officials with information about possible criminal matters involving felonies will ensure and be responsible for prompt referrals to the OIG. Examples of felonies include but are not limited to, theft of Government property over \$1000, false claims, false statements, drug offenses, crimes involving information technology systems and serious crimes against the person, *i.e.*, homicides, armed robbery, rape, aggravated assault and serious physical abuse of a VA patient.

(Authority: 5 U.S.C. App. 3)

[68 FR 17550, Apr. 10, 2003]

§ 1.205 Notification to the Attorney General or United States Attorney's Office.

VA police and/or the OIG, whichever has primary responsibility within VA for investigation of the offense in question, will be responsible for notifying the appropriate United States Attorney's Office, pursuant to 28 U.S.C. 535.

(Authority: 5 U.S.C. App. 3, 38 U.S.C. 902)

[68 FR 17550, Apr. 10, 2003]