

lease or assignment. The Superintendent may cancel and annul your lease without court action or any other proceeding. But the Superintendent must give you at least 30 days' notice to show why your lease shouldn't be canceled and annulled or why you shouldn't receive any other penalty.

**§ 214.19 Under what conditions may I have to pay a fine?**

(a) If you violate any of your lease's terms and conditions or any regulations on leases, the Superintendent may:

(1) Cancel your lease;  
 (2) Fine you no more than \$500 per day for every day you violate the terms of the lease or regulations or don't carry out the Superintendent's orders regarding your lease; or

(3) Fine you and cancel your lease.

(b) You are entitled to notice and a hearing on the terms of the lease or regulations that you have violated. The Superintendent will hold the hearing to reach a final decision. The Superintendent's findings are final, unless you appeal under 25 CFR part 2.

Dated: July 23, 1996.

Ada E. Deer,

*Assistant Secretary—Indian Affairs.*

[FR Doc. 96-19339 Filed 8-7-96; 8:45 am]

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**DEPARTMENT OF VETERANS AFFAIRS**

**38 CFR Part 3**

**RIN 2900-AI35**

**Diseases Associated With Exposure to Certain Herbicide Agents (Prostate Cancer and Acute and Subacute Peripheral Neuropathy)**

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Proposed rule.

**SUMMARY:** The Department of Veterans Affairs (VA) is proposing to amend its adjudication regulations concerning presumptive service connection for certain diseases for which there is no record of the disease during service. This proposed amendment is necessary to implement a decision of the Secretary of Veterans Affairs under the authority granted by the Agent Orange Act of 1991 that there is a positive association between exposure to herbicides used in the Republic of Vietnam during the Vietnam era and the subsequent development of prostate cancer and acute and subacute peripheral neuropathy. The intended effect of this proposed amendment is to establish

presumptive service connection for those conditions based on herbicide exposure.

**DATES:** Comments must be received on or before September 9, 1996.

**ADDRESSES:** Mail or hand deliver written comments to: Director, Office of Regulations Management (02D), Department of Veterans Affairs, 810 Vermont Avenue, NW, Room 1154, Washington DC 20420. Comments should indicate that they are in response to "RIN 2900-AI35." All written comments will be available for public inspection at the above address in the Office of Regulations Management, Room 1158, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays).

**FOR FURTHER INFORMATION CONTACT:** John Bisset, Jr., Consultant, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, 810 Vermont Avenue, NW., Washington, DC 20420, telephone (202) 273-7230.

**SUPPLEMENTARY INFORMATION:** Section 3 of the Agent Orange Act of 1991, Pub. L. 102-4, 105 Stat. 11, directed the Secretary to seek to enter into an agreement with the National Academy of Sciences (NAS) to review and summarize the scientific evidence concerning the association between exposure to herbicides used in support of military operations in the Republic of Vietnam during the Vietnam era and each disease suspected to be associated with such exposure. Congress mandated that NAS determine, to the extent possible: (1) Whether there is a statistical association between the suspect diseases and herbicide exposure, taking into account the strength of the scientific evidence and the appropriateness of the methods used to detect the association; (2) the increased risk of disease among individuals exposed to herbicides during service in the Republic of Vietnam during the Vietnam era; and (3) whether there is a plausible biological mechanism or other evidence of a causal relationship between herbicide exposure and the suspect disease. Section 3 of Pub. L. 102-4 also required that NAS submit reports on its activities every two years (as measured from the date of the first report) for a ten-year period.

Section 1116(b) of 38 U.S.C., which was added by Pub. L. 102-4, provides that whenever the Secretary determines, based on sound medical and scientific evidence, that a positive association exists between exposure of humans to a herbicide agent (i.e., a chemical in a herbicide used in support of the United States and allied military operations in

the Republic of Vietnam during the Vietnam era) and a disease, the Secretary will publish regulations establishing presumptive service connection for that disease. An association is considered "positive" if the credible evidence for the association is equal to or outweighs the credible evidence against the association. In making that determination, the Secretary is to consider the reports received from NAS as well as all other available sound medical and scientific information and analyses.

NAS issued its initial report, entitled "Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam" (VAO), on July 27, 1993. The Secretary subsequently determined that positive associations exist between exposure to herbicides used in the Republic of Vietnam and the subsequent development of Hodgkin's disease, porphyria cutanea tarda, multiple myeloma and certain respiratory cancers. Final regulations were published in the Federal Register on February 3, 1994 (See 59 FR 5106-07) and June 9, 1994 (See 59 FR 29723-24) creating presumptions of service connection for these conditions based on herbicide exposure. Presumptions already existed for chloracne, non-Hodgkin's lymphoma and soft tissue sarcomas.

After reviewing the latest scientific studies and conducting a public meeting, NAS issued a second report, entitled "Veterans and Agent Orange: Update 1996," on March 14, 1996. On the same day, the Secretary announced that VA would review the findings in that second NAS report and pertinent studies to determine whether a positive association exists between herbicide exposure and any condition for which the Secretary has not specifically determined a presumption of service connection is warranted. That review has been completed and the Secretary has concluded that positive associations exist for prostate cancer and acute and subacute peripheral neuropathy.

Prostate cancer is a very common male genitourinary cancer which shows marked increased prevalence with age. The 1993 NAS report assigned prostate cancer to a category labeled limited/suggestive evidence of an association. This is defined as meaning there is evidence suggestive of an association between herbicide exposure and a particular health outcome, but that evidence is limited because chance, bias, and confounding could not be ruled out with confidence. There were statistically significant occupational studies which showed no association between prostate cancer and herbicide

exposure (Ronco G., Costa G., Lynge E., 1992. Cancer risk among Danish and Italian farmers. *British Journal of Industrial Medicine* 49:220-225; and Wiklund K., 1983. Swedish agricultural workers: A group with decreased risk of cancer. *Cancer* 51:566-568). Some occupational studies showed a slight, elevated risk for prostate cancer among farm and forestry workers; a cohort study of farmers found the risk of prostate cancer among farmers increased with the magnitude of potential herbicide exposure. (See 59 FR 342 for study citations.) Upon a review of the evidence then available, the Secretary determined that the credible evidence against an association between prostate cancer and herbicide exposure outweighed the credible evidence for such an association, and he determined that a positive association did not exist.

In its 1996 report NAS, after a thorough review of previously and newly available scientific literature, also assigned prostate cancer to the category labeled limited/suggestive evidence of an association with herbicide exposure, which it defined in the same manner as in the 1993 NAS report (See above). The 1996 NAS report noted several new occupational studies and veteran studies. One large study (Blair A., Mustafa D., Heineman E.F., 1993. Cancer and other causes of death among male and female farmers from twenty-three states. *American Journal of Industrial Medicine* 23:729-742) found a statistically significant, slightly increased proportionate cancer mortality ratio (PCMR) for prostate cancer among farmers in 22 of 23 states. Another cancer mortality study (Bueno de Mesquita H.B., Doornbos G., Van der Kuip D.A., Kogevinas M., Winkelmann R., 1993. Occupational exposure to phenoxy herbicides and chlorophenols and cancer mortality in the Netherlands. *American Journal of Industrial Medicine* 23:289-300) evaluated employees of two Dutch companies which produced chlorophenoxy herbicides. Mortality rates from prostate cancer were increased among the exposed men in this study (standardized mortality rate (SMR) = 2.6, confidence interval (CI) 0.5-7.7), although the results were not statistically significant. A mortality study of chemical workers exposed to an accidental release of TCDD in 1949 (Collins J.J., Strauss M.E., Levinskas G.J., Connor P.C., 1993. The mortality experience of workers exposed to 2,3,7,8-tetrachlorodibenzo-p-dioxin in a trichlorophenol process accident. *Epidemiology* 4:7-13) found an increased risk of prostate cancer death in the exposed workers when compared

to the rates in the local population, although, again, the results were not statistically significant. One recent study of Finnish herbicide workers with a median total duration of exposure of six weeks showed no increased risk of death from prostate cancer (Asp S., Riihimaki V., Hernberg S., Pukkala E., 1994. Mortality and cancer morbidity of Finnish chlorophenoxy herbicide applicators: an 18-year prospective follow-up. *American Journal of Industrial Medicine* 26:243-253). Cancer incidence rates after TCDD exposure in the Seveso, Italy, cohort were re-evaluated (Bertazzi A., Pesatori A.C., Consonni D., Tironi A., Landi M.T., Zocchetti C., 1993. Cancer incidence in a population accidentally exposed to 2,3,7,8-tetrachlorodibenzo-para-dioxin. *Epidemiology* 4:398-406). The cancer risk in the more highly exposed zones was previously reported to be slightly increased (relative risk (RR) = 1.4, CI 0.5-3.9), although not to a statistically significant degree, (Pesatori A.C., Consonni D., Tironi A., Landi M.T., Zocchetti C., Bertazzi P.A., 1992. Cancer morbidity in Seveso area, 1976-1986. *Chemosphere* 25:209-212), but an updated study of the less exposed areas failed to show an increased risk (Bertazzi et al., 1993). A proportionate mortality study of Michigan Vietnam veterans (Visintainer P.F., Barone M., McGee H., Peterson E.L., 1995. Proportionate mortality study of Vietnam-era veterans of Michigan. *Journal of Occupational and Environmental Medicine* 37:423-428), showed a nonsignificant, slightly increased rate of death due to genital cancers. Prostate cancer rates were not reported separately in this study.

The large cohort study of Canadian farmers (Morrison et al., 1993) had been previously reviewed by the 1993 NAS report. Although this study found a decreased risk of prostate cancer for the entire cohort, when the cohort was divided into subsets based on suspected herbicide exposure, the study found an increased risk of prostate cancer among those considered most likely to have been exposed (based on amount of herbicides used on the subjects' farms and the lack of hired help or customary expenses for assisting in work). In addition, the study reported an increasing risk with increasing numbers of acres sprayed. Subsequent to the 1993 report, the authors published a letter to the editor containing a reanalysis of their data which supported the findings of an increased risk of prostate cancer and the previously reported dose-response relationship with herbicide exposure (Morrison et al., 1994. (Letter

to the editor). *American Journal of Epidemiology* 140:1058-1059). Most of the other occupational and environmental studies indicate some elevation in risk of prostate cancer. Considering all of the evidence, the Secretary has determined that the credible evidence for an association is equal to or outweighs the credible evidence against an association and, therefore, there is a positive association between herbicide exposure and prostate cancer. Accordingly, we are proposing to amend 38 CFR 3.309(e) to establish a presumption of service connection based on herbicide exposure for prostate cancer that manifests itself to a degree of 10 percent at any time after exposure. This amendment is proposed to be effective the date of publication of the final rule, in accordance with 38 U.S.C. 1116(c)(2).

Peripheral neuropathy can be induced by many common medical and environmental disorders unrelated to herbicide exposure, such as alcoholism, diabetes, and exposure to other toxic chemicals. The 1993 NAS report assigned peripheral neuropathy to a category labeled inadequate/insufficient evidence to determine whether an association exists, which was defined as meaning that the available studies were of insufficient quality, consistency, or statistical strength to permit a conclusion regarding the presence or absence of an association with herbicide exposure. NAS stated that many case reports suggested that acute or subacute peripheral neuropathy can develop with exposure to dioxin, but that the most rigorously conducted studies argued against a relationship between dioxin or herbicides and chronic peripheral neuropathy. VAO stated that, as a group, the studies on peripheral neuropathy suffered from various methodologic defects, such as not applying consistent methods to define a comparison group, determine exposure, evaluate clinical deficits, use standard definitions of peripheral neuropathy, or eliminate confounding variables. Occupational studies that did not have those methodological problems showed no difference in the incidence of peripheral neuropathy for workers exposed to herbicides and workers not so exposed. Accordingly, the Secretary determined that the credible evidence against an association between peripheral neuropathy and herbicide exposure outweighed the credible evidence for such an association, and he determined that a positive association did not exist. (See 59 FR 343 for study citations.) The Secretary asked, however, that NAS reconsider in detail the relationship

between exposure to herbicides and the development of acute and subacute effects of peripheral neuropathy in the next report.

The 1996 NAS report assigned acute and subacute peripheral neuropathy to the category labeled limited/suggestive evidence of an association with herbicide exposure. However, the 1996 NAS report continued to assign chronic peripheral neuropathy to the category labeled inadequate/insufficient evidence to determine whether an association exists. In response to VA's request to conduct a detailed reconsideration of the relationship between herbicide exposure and the subsequent development of acute and subacute peripheral neuropathy, the 1996 NAS report noted that the methodology used to establish associations between suspected causal agents and persistent chronic peripheral neuropathy relies on epidemiological studies with adequate controls. Such studies can rarely be set in motion with sufficient speed to assess relationships between unexpected chemical exposure and the development of acute or subacute peripheral neuropathy. Because of the transient nature of the conditions, documenting signs and symptoms in association with documented exposures can be difficult to accomplish in a systematic manner. Consequently, greater reliance must be placed on case and less well controlled studies.

Two case studies (Todd R.L., 1962. A case of 2,4-D intoxication. *Journal of the Iowa Medical Society* 52:663-664; and Berkley M.C., Magee K.R., 1963. Neuropathy following exposure to a dimethylamine salt of 2,4-D. *Archives of Internal Medicine* 111:133-134) reported development of peripheral neuropathies within days of exposure to 2,4-D followed by gradual recovery over a period of months. Studies of the Seveso, Italy accident (Boeri R., Bordo B., Crenna P., Filippini G., Massetto M., Zecchini A., 1978. Preliminary results of a neurological investigation of the population exposed to TCDD in the Seveso region. *Rivista di Patologia Nervosa e Mentale* 9:111-128; Pocchiari F., Silano V., Zampieri A., 1979. Human health effects from accidental release of tetrachlorodibenzo-p-dioxin (TCDD) at Seveso, Italy. *Annals of the New York Academy of Science* 320:311-320; and Filippini G., Bordo B., Crenna P., 1981. Relationship between clinical and electrophysiological findings and indicators of heavy exposure to 2,3,7,8-tetrachlorodibenzo-p-dioxin. *Scandinavian Journal of Work, Environment, and Health* 7:257-262) suggested that peripheral nerve

problems were more prevalent in the exposed group. Filippini et al. (1981) demonstrated that those individuals with clinical signs of significant exposure (chloracne or elevated liver enzymes) showed a risk ratio of 2.8. Two subsequent follow-up studies (Barbieri S., Pirovano C., Scarbato G., Tarchini P., Zappa A., Maranzana M., 1988. Long-term effects of 2,3,7,8-tetrachlorodibenzo-p-dioxin on the peripheral nervous system. Clinical and neurophysiological controlled study on subjects with chloracne from the Seveso area. *Neuroepidemiology* 7:29-37; and Assennato G., Cervino D., Emmett E.A., Longo G., Merlo F., 1989. Follow-up of subjects who developed chloracne following TCDD exposure at Seveso. *American Journal of Industrial Medicine* 16:119-125) showed no increased frequency of peripheral neuropathy several years after the accident among the highly exposed group. Environmental studies and case reports suggest that the development of peripheral neuropathy can follow high levels of exposure to herbicides, and that peripheral neuropathy associated with herbicide exposure will manifest very soon after exposure. The trend to recovery in the individual cases reported and the negative findings of many long-term follow up studies of peripheral neuropathy suggest that, if a neuropathy develops, it resolves with time. Considering all of the evidence, the Secretary has determined that the credible evidence for an association is equal to or outweighs the credible evidence against an association and, therefore, there is a positive association between herbicide exposure and acute and subacute peripheral neuropathy that manifests within one year of exposure.

Since the available evidence indicates that herbicide-related acute and subacute peripheral neuropathy develops shortly after exposure, in our judgment a manifestation period of one year following exposure will allow VA to identify all peripheral neuropathies that are associated with herbicide exposure. We are proposing to define the term "acute and subacute peripheral neuropathy" to mean transient peripheral neuropathy that appears within weeks or months of exposure to an herbicide agent and resolves within two years of the date of onset. Most of the toxic diseases of nerve develop subacutely over weeks or months ("Principles of Neurology" Raymond D. Adams, M.D., and Maurice Victor, M.D., fifth ed., 1993). As the 1996 NAS report indicates, neuropathies associated with herbicide exposure are transient and

resolve over several months. In our judgment, requiring that peripheral neuropathy resolve within two years of onset is, therefore, a reasonable method to differentiate transient peripheral neuropathies, for which the Secretary has found a positive association with herbicide exposure, from chronic peripheral neuropathies, for which he has found no such association. We are proposing to amend 38 CFR 3.307(a) and 3.309(e) to establish a presumption of service connection for acute and subacute peripheral neuropathy becoming manifest within one year following exposure to herbicide agents. This amendment is proposed to be effective the date of publication of the final rule, in accordance with 38 U.S.C. 1116(c)(2).

The six-year benefit cost for prostate cancer based on herbicide exposure is \$65.3 million, with an administrative cost of \$959,000. Additionally, the medical care cost over six years is \$38 million. Prostate cancer is a male genitourinary cancer that shows marked increased prevalence with age. Accordingly, costs beyond the six-year period would likely be substantially higher.

For the purposes of this rulemaking, "acute and subacute peripheral neuropathy" means transient peripheral neuropathy that appears within weeks or months of exposure to an herbicide agent and resolves within two years of the date of onset. Consequently, there are no benefit costs associated with this condition.

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

The Secretary has determined that it is not feasible to allow the 60-day comment period referred to in section 6(a)(1) of Executive Order 12866 because a comment period of that length would prevent VA from complying with the statutory requirement to publish a final rule within 90 days of publication of the proposed rule imposed by 38 U.S.C. 1116(c)(2).

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

## List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Veterans, Vietnam.

Approved: July 8, 1996.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR part 3 is proposed to be amended as follows:

**PART 3—ADJUDICATION****Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation**

1. The authority citation for Part 3, subpart A continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

**§ 3.307 [Amended]**

2. In § 3.307, paragraph (a)(6)(ii) is amended by removing “chloracne and” and adding, in its place, “chloracne,”; and by adding “tarda, and acute and subacute peripheral neuropathy” immediately following “cutanea”.

**§ 3.309 [Amended]**

3. In § 3.309, paragraph (e), the listing of diseases is amended by adding “Acute and subacute peripheral neuropathy” between “Non-Hodgkin’s lymphoma” and “Porphyria cutanea tarda”; by adding “Prostate cancer” between “Porphyria cutanea tarda” and “Respiratory cancers (cancer of the lung, bronchus, larynx, or trachea)”.

4. Section 3.309, paragraph (e) is further amended by redesignating the Note as “Note 1.”; and by adding “Note 2.” to read as follows:

**§ 3.309 Disease subject to presumptive service connection.**

\* \* \* \* \*

(e) \* \* \*

Note 2: For purposes of this section, the term *acute and subacute peripheral neuropathy* means transient peripheral neuropathy that appears within weeks or months of exposure to an herbicide agent and resolves within two years of the date of onset.

[FR Doc. 96–20196 Filed 8–7–96; 8:45 am]

BILLING CODE 8320–01–P

**40 CFR Part 52**

[WA47–7120b; FRL–5544–1]

**Clean Air Act Approval and Promulgation of Carbon Monoxide Implementation Plan for the State of Washington: Puget Sound Emission Inventory**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The EPA proposes to approve the 1990 base year and 1995 projected year carbon monoxide emission inventory portion of the Puget Sound carbon monoxide (CO) State Implementation Plan (SIP) submitted on September 30, 1994, by the State of Washington Department of Ecology (Ecology) for the purpose of bringing about the attainment of the national ambient air quality standard (NAAQS) for CO. In the Final Rules Section of this Federal Register, the EPA is approving the State’s SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If the EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this action.

**DATES:** Comments on this proposed rule must be received in writing by September 9, 1996.

**ADDRESSES:** Written comments should be addressed to Montel Livingston, Environmental Protection Specialist (OAQ–107), Office of Air Quality, at the EPA Regional Office listed below. Copies of the documents relevant to this proposed rule are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day. Environmental Protection Agency, Region 10, Office of Air Quality, 1200 6th Avenue, Seattle, WA 98101. Washington State Department of Ecology, 300 Desmond Drive, Olympia, WA 98504.

**FOR FURTHER INFORMATION CONTACT:** Stephanie Cooper, Office of Air Quality

(OAQ–107), EPA, 1200 6th Avenue, Seattle, WA 98101, (206) 553–6917.

**SUPPLEMENTARY INFORMATION:** See the information provided in the Direct Final action which is located in the Rules Section of this Federal Register.

Dated: July 22, 1996.

Randall F. Smith,

Acting Regional Administrator.

[FR Doc. 96–20140 Filed 8–7–96; 8:45 am]

BILLING CODE 6560–50–P

**40 CFR Part 52**

[FRL–5533–3]

**Approval and Promulgation of Implementation Plans; Massachusetts; Emissions Banking, Trading, and Averaging Program Approval**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by Massachusetts. This revision establishes a voluntary emissions banking, trading, and averaging program for eligible sources of volatile organic compounds (VOC), nitrogen oxides (NOx), or carbon monoxide (CO). The goal of these regulations is to encourage the creation, trading, or averaging of surplus emission reductions for facilities to meet new source review offsetting, netting, and reasonably available control technology (RACT) requirements in the most cost-effective manner. The program was adopted as a voluntary Economic Incentive Program, developed pursuant to EPA’s guidance.

In the Final Rules Section of this Federal Register, EPA is approving this rule without prior proposal. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to the direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this action should do so at this time.

**DATES:** Comments on this action must be received by September 9, 1996.

**ADDRESSES:** Comments may be mailed to Susan Studlien, Deputy Director, Office of Ecosystem Protection, U.S. Environmental Protection Agency, Region I, JFK Federal Bldg., Boston, MA