changes, but asked that procedures should be in place to allow the bridge to be opened on short notice.

Copies of the comments were provided to CONRAIL. In its letter of May 6, 1996, a copy of which is in the public docket for this rulemaking, CONRAIL responded to the comments. It contended that the impact of upriver development was speculative, and noted that the State of Maryland did not comment on the proposed changes. It noted that historic data for 1993 and 1994 showed infrequent bridge openings and that under the proposed changes the bridge would continue to be manned and open on demand during periods of most frequent use. It agreed that arrangements are needed to open the bridge for emergency response vessels on short notice, and they will be required to post a sign providing a 24-hour emergency point of contact. CONRAIL advised the Coast Guard that once a request for an emergency opening is received during periods the bridge is unmanned, an opening will occur within 30 minutes of that request. D.C. Fireboats expressed to the Coast Guard that this arrangement is acceptable to them and relieves their concerns.

The Coast Guard believes that the historic data indicates that adoption of the proposed changes will continue to meet the reasonable needs of navigation. The schedule may be further revised as needed to respond to changes in traffic volume. The Coast Guard agrees that timely bridge openings for emergency response vessels must be ensured, and this rulemaking does not change that requirement. To ensure a rapid response, the Coast Guard has added a requirement that CONRAIL post a sign on the bridge providing a 24-hour emergency point of contact to arrange for bridge openings on short notice when the bridge is unmanned.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this final rule will have a significant economic impact on a substantial number of small entities. ''Small entities'' include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as ''small business concerns'' under section 3 of the Small Business Act (15 U.S.C. 632). Because it expects the impact of this rule to be minimal, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612, and it has determined that this rule will not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that under section 2.B.2.e.(32)(e) of Commandant Instruction M16475.1B (as amended, 59 FR 38654, 29 July 1994), this rule is categorically excluded from further environmental documentation. A Categorical Exclusion Determination statement has been prepared and placed in the rulemaking docket.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

In consideration of the foregoing, the Coast Guard is amending Part 117 of Title 33, Code of Federal Regulations to read as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for Part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05–1(g); Section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. In § 117.253, paragraphs (b)(1)(ii) and (iii) are revised, and paragraph (b)(3) is added to read as follows:

§ 117.253 Anacostia River.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(ii) Between 9 a.m. and 12 noon and between 1 p.m. and 6 p.m. from May 15 through September 30.

(iii) Between 6 p.m. and 7 p.m. from May 15 through September 30 if notice is given to the bridgetender not later than 6 p.m. on the day for which the opening is requested.

* * * * *

(2) * * *

(3) The owners of the bridge shall provide and keep in good legible condition signs providing a 24-hour emergency telephone number which may be called to arrange for bridge openings. The signs shall be painted in contrasting colors with letters and numbers not less than six inches high. The signs shall be placed on the bridge so that they are plainly visible to the operator of any vessel approaching the bridge from either upstream or downstream.

Dated: October 18, 1996.

Kent H. Williams,

Vice Admiral, U.S. Coast Guard Commander, Fifth Coast Guard District.

[FR Doc. 96–28651 Filed 11–6–96; 8:45 am]

BILLING CODE 4910–14–M

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: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) adjudication regulations concerning presumptive service connection for certain diseases for which there is no record of the disease during service. This 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 amendment is to establish presumptive

service connection for those conditions based on herbicide exposure.

EFFECTIVE DATE: This amendment is effective November 7, 1996.

FOR FURTHER INFORMATION CONTACT: John Bisset, Jr., Consultant, Regulations Staff, Compensation and Pension Service (213), Veterans Benefits Administration, 810 Vermont Avenue, NW, Washington, DC 20420, telephone (202) 273–7230.

SUPPLEMENTARY INFORMATION: VA published a proposal to amend 38 CFR 3.307(a) and 3.309(e) to establish presumptive service connection for prostate cancer and acute and subacute peripheral neuropathy based on exposure to herbicides in the Federal Register of August 8, 1996 (61 FR 41368–71). Interested persons were invited to submit written comments concerning the proposal on or before September 9, 1996. We received three comments from private individuals; one comment from a veterans' service organization, the Vietnam Veterans of America, Inc.; and one comment from a United States Senator.

The Vietnam Veterans of America, Inc., indicated that it had no reservations with the language of the proposed rule, commended VA's timely response to the 1996 National Academy of Sciences (NAS) report ''Veterans and Agent Orange: Update 1996,'' and urged VA to publish the final regulations as soon as possible in order to afford the earliest possible effective date for compensation benefits based on herbicide-related prostate cancer and acute and subacute peripheral neuropathy.

Two commenters asked that VA defer publishing final regulations until it could study Vietnam veterans suffering from chronic peripheral neuropathy.

38 U.S.C. 1116(c)(1)(A) requires that the Secretary, not later than 60 days after the date on which he receives a report from NAS, determine whether a presumption of service connection is warranted for each disease covered by the report and, if the Secretary determines that a presumption is warranted, issue proposed regulations within 60 days thereafter. 38 U.S.C. 1116(c)(2) requires the Secretary to issue final regulations establishing presumptive service connection for any condition for which he determines there is a positive association with exposure of humans to an herbicide agent not later than 90 days after he has issued proposed regulations. The Secretary is not free to ignore these statutory requirements. For reasons more fully explained in the proposal, the Secretary has concluded that presumptive service connection is warranted for acute and subacute peripheral neuropathy, and VA is, therefore, proceeding with publication of a final rule notwithstanding these comments.

One commenter noted that VA had previously proposed to recognize an association between peripheral neuropathy and exposure to dioxin without excluding chronic peripheral neuropathy and stated it should now recognize chronic peripheral neuropathy as associated with herbicide exposure since the only changed circumstance was VA's subsequent contract with NAS to review, summarize, and assess the scientific evidence concerning the association between herbicide exposure and particular diseases.

In the Federal Register of January 21, 1992 (See 57 FR 2236–38), VA published a proposed rule to recognize an association between peripheral neuropathy and exposure to herbicides containing dioxin; however, a final rule was never published. That proposed rulemaking was initiated to implement a preliminary determination under the provisions of the Veterans' Dioxin and Radiation Exposure Compensation Standards Act, Public Law 98–542, that there was a significant statistical association between exposure to herbicides containing dioxin and the subsequent development of peripheral neuropathy.

The Agent Orange Act of 1991, Public Law 102–4, established different standards governing VA rulemaking than were applicable under Public Law 98–542. Under the Agent Orange Act, VA is required to determine, based on reports from NAS and all other sound medical and scientific information and analyses available to it, whether the credible evidence for an association between herbicide exposure and a disease is equal to or outweighs the credible evidence against an association. NAS reports received by VA in 1993 and 1996 reviewed a broader range of medical and scientific evidence than VA had considered in connection with the 1992 proposed rules, including several studies published since January 21, 1992, and concluded that there was inadequate/insufficient evidence to determine whether an association exists between herbicide exposure and chronic peripheral neuropathy. Pursuant to the standards of the Agent Orange Act, VA has determined that the evidence against an association between herbicide exposure and chronic peripheral neuropathy outweighs the evidence for such an association and has published a notice of that determination, including an explanation of the scientific basis for that determination, in the Federal Register of August 8, 1996 (See 61 FR 41442, 41446–47). Accordingly, because VA's determination is based upon a different, and more comprehensive, body of evidence, and the specific rulemaking requirements of the Agent Orange Act, we take no action based on this comment.

Another commenter urged VA to expand the scope of the proposed rule to include presumptive service connection for chronic peripheral neuropathy because of the lack of uniformity in the scientific literature.

NAS, in its 1996 report, assigned chronic peripheral neuropathy to a category labeled inadequate/insufficient evidence to determine whether an association exists. NAS defined that category as meaning that the available studies are of insufficient quality, consistency, or statistical strength to permit a conclusion regarding the presence or absence of an association with herbicide exposure. The studies reviewed by NAS suggested 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 reported and the negative findings of many long-term followup studies of peripheral neuropathy suggested that if such a neuropathy develops, it resolves with time. These findings are consistent with the findings of other studies that found no evidence of increased occurrence of chronic peripheral neuropathy after TCDD exposure. The Secretary determined that a positive association does not exist between herbicide exposure and the subsequent development of chronic peripheral neuropathy (See 61 FR 41446–47). Accordingly, VA takes no action based on this comment.

One commenter submitted analyses by two individuals contending there is an association between herbicide exposure and chronic peripheral neuropathy and stated that NAS did not consider these analyses.

The first of those analyses is contained in a February 19, 1992, letter from an environmental scientist with the United States Environmental Protection Agency (EPA) commenting on VA's January 1992 proposed rule to recognize an association between herbicide exposure and peripheral neuropathy becoming manifest within 10 years after exposure to herbicides containing dioxin. As noted above, the proposed rule was never finalized. The comment, among other things, disagreed with the proposal to limit the

recognized association to only those peripheral neuropathies becoming manifest within 10 years after exposure. The commenter asserted that neurotoxic damage, such as peripheral neuropathy, may not be clinically detectable for many years and that, therefore, peripheral neuropathy due to herbicide exposure may become manifest more than ten years after exposure. Although NAS apparently did not consider the February 19, 1992, letter to VA in its review of the medical and scientific literature, we note that the author of that letter presented testimony to NAS at the September 9, 1992, public meeting held by NAS prior to the issuance of its initial report. (Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam, 1993, Appendix B, B–10.). To that extent, this author's views have been called to the attention of NAS.

The second analysis submitted by the commenter is contained in a May 26, 1995, letter from a retired consultant in genetic toxicology to an American Legion official discussing the initial NAS report. The author of that letter stated that the methodology and analysis used by NAS was deficient in failing to give proper consideration to studies of toxicological effects in animals, failing to give proper consideration to clinical reports of individual cases involving herbicide exposure and its effects, and failing to address the synergistic effects of exposure to other substances, such as insecticides, disinfectants, solvents, and prescription drugs. The author further stated that peripheral neuropathy is strongly associated with human exposure to components of herbicides used in Vietnam, and that the author was personally aware of published clinical reports of 54 individuals who developed peripheral neuropathy shortly after exposure to 2,4–D.

Based on its review of numerous studies and case reports, NAS concluded that, although some case reports suggested that acute or subacute peripheral neuropathy can develop shortly after exposure to dioxin and related products, the most rigorously conducted studies argued against a relationship between dioxin or herbicides and chronic peripheral neuropathy. In view of the evidence that acute and subacute peripheral neuropathies resolve within a short time and the negative findings of the most rigorous long-term studies of herbicide exposure, VA has concluded that the evidence against an association between chronic peripheral neuropathy and herbicide exposure outweighs the evidence for such an association. The analyses submitted by the commenter do not alter that conclusion.

Although one of the analyses states that the effects of neurotoxic damage, such as peripheral neuropathy, may first become clinically detectable many years after exposure, the studies discussed by NAS, including followup studies conducted 15 and 30 years after exposure, generally showed no significant increase in peripheral neuropathy in the exposed populations. Further, although the other analysis referenced clinical reports of 54 individuals who developed peripheral neuropathy shortly after exposure to 2,4–D, that fact is consistent with the conclusion that acute and subacute peripheral neuropathy may develop shortly after exposure but does not demonstrate that chronic peripheral neuropathy is associated with herbicide exposure. The alleged methodological deficiencies in the 1993 NAS report also do not alter our conclusion. The 1996 NAS report discussed both animal studies and case reports, where relevant, in its review of the available scientific and medical literature. Further, NAS properly focused on the health effects of exposure to herbicides, as required by the Agent Orange Act of 1991, rather than on exposure to other substances.

This same commenter also forwarded a copy of a General Accounting Office (GAO) report concerning (1) the efforts of the Department of Health and Human Services' Centers for Disease Control (CDC) to study the effects of Agent Orange on the health of Vietnam veterans and (2) CDC's contracting and contract administration practices on contracts it awarded for the studies. Since this GAO report does not concern the NAS literature review or its recommendations regarding prostate cancer or peripheral neuropathy, we will not amend the proposed rule based on that report.

Another commenter said that in estimating the five-year benefit cost of this rulemaking, VA should consider that, in the case of retired military personnel, any increase in VA benefit payments is offset by a reduction in military retired pay.

When estimating the cost of a proposed rule, VA is determining the potential cost to VA rather than to the Federal Government as a whole. However, VA recognizes that the cost to the Government of expansion of entitlement to compensation based on herbicide exposure may be offset to some degree by a reduction in military retired pay because retired servicemembers cannot receive both benefits concurrently and must waive retired pay to receive compensation from VA.

The six-year benefit costs 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.

VA appreciates the comments submitted in response to the proposed rule which is now adopted without change; except that amendatory instruction # 2 is changed from the proposal to correct a typographical error.

Pursuant to the provisions of 38 U.S.C. 1116(c)(2), this final rule is made effective on the date of publication in the Federal Register.

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. 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 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: October 29, 1996.

Jesse Brown,

Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR part 3 is 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 '', and acute and subacute peripheral neuropathy'' immediately following ''tarda''.

§ 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:'' immediately following the last entry in note 1 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. 96–28683 Filed 11–6–96; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 70

[NY001; FRL–5646–7]

Clean Air Act Final Interim Approval of Operating Permits Program; New York

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final interim approval.

SUMMARY: The EPA is promulgating final interim approval of the operating permits program that the State of New York (NY) submitted in accordance with Title V of the Clean Air Act (the Act) and its implementing regulations codified at Part 70 of Title 40 of the Code of Federal Regulations (40 CFR Part 70). This approved interim program allows NY to issue operating permits to all major stationary sources, and to certain other sources, for a period of two years, at which time the interim program must be replaced by a fully approved program.

EFFECTIVE DATE: This interim program will be effective December 9, 1996.

ADDRESSES: Copies of NY's submittal and other supporting information used in developing the final interim approval as well as the Technical Support Document are available for inspection, during normal business hours, at the following location: U.S. Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, NY 10007–1866; Attention: Steven C. Riva.

FOR FURTHER INFORMATION CONTACT: Gerald P. DeGaetano, Permitting Section, Air Programs Branch, Division of Environmental Planning and Protection, at the above EPA Office, or at telephone number (212) 637–4020.

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

The Act and its implementing regulations at 40 CFR Part 70 require that States develop and submit operating permit programs to the EPA by November 15, 1993, and that the EPA act to approve or disapprove each program within one year after receiving a complete submittal. The EPA reviews State programs pursuant to Section 502 of the Act and the Part 70 regulations, which together outline the criteria for approval or disapproval. Where a program substantially, but not fully, meets the requirements of 40 CFR Part 70, EPA may grant the program interim approval for a period of up to two years. If a State does not have an approved program by the end of an interim program, EPA must establish and implement a federal operating permits program for that State.

On July 30, 1996, EPA proposed interim approval of the operating permits program submitted by NY (see 61 FR 39617). In that Federal Register document, EPA indicated that NY was in the process of re-proposing Appendix B of Title 6 of the Official Compilation of Codes, Rules and Regulations of the State of New York (6 NYCRR) Part 201 (Appendix B is entitled, ''Transition Plan Application Schedule''), and that such would be finalized prior to EPA's final interim approval of the NY program. Subsequently, Appendix B was adopted by NY on September 11, 1996, and became effective 30-days from that date, on October 11, 1996.

During the 30-day public comment period that ended on August 29, 1996, two comment letters were received on the aforementioned EPA proposal to grant NY interim program approval. One comment letter supported the State program, and the other letter provided a number of comments and concerns and asked that these be addressed. A response to all of the pertinent comments received is included in Section II.B. of this notice. Based upon EPA's review, none of the comments received alters EPA's decision to approve the NY program. Therefore, in this notice, the EPA is taking final action to promulgate interim approval of the NY Operating Permits Program.

II. Final Action and Implications

A. Analysis of State Submission

On July 30, 1996, the EPA proposed interim approval of NY's Title V Operating Permits Program. The program elements discussed in the proposed notice are unchanged, except for Appendix B of 6 NYCRR Part 201, discussed above. EPA's position remains unchanged, in that the NY program substantially meets the requirements of 40 CFR Part 70.

B. Response to Public Comments

1. Comments From the Society of Plastics Industry, Inc.

In this letter, dated August 27, 1996, the commenter supports NY's efforts to implement an operating permits program. In addition, the commenter requested that EPA finalize its August 1994 and August 1995 proposals (to 40 CFR Part 70), to allow the State to quickly receive final program approval.

Response. In the July 30, 1996 Federal Register Notice, EPA listed eight items that NY must correct in order for EPA to grant full (rather than interim) program approval to the State. Under 5 of these 8 items, it was noted that EPA had proposed revisions to 40 CFR Part 70 on August 29, 1994 and August 31, 1995 which, if such revisions were to be promulgated as proposed, would eliminate these 5 issues from being a barrier to full program approval for NY. That is, NY would not have to revise its regulations for these 5 issues to receive full program approval. However, NY will still be required to revise its regulations with respect to the other 3 issues (refer to Section II.C., below, for additional discussion on this matter).

EPA is required to grant or deny Title V program approval based on current requirements. At present, these requirements are those listed in the 40 CFR Part 70 regulations promulgated on July 21, 1992. Unless and until these regulations are revised, the July 21, 1992 version will be applied to determine a State program's approvability. Also, if future revisions to 40 CFR Part 70 do not address the ''Interim Program Approval'' items noted in EPA's July 30, 1996 Federal Register Notice, then New York State must correct those items as described therein, in order to be granted full program approval.

2. Comments From the Consumer Policy Institute

This letter, dated August 29, 1996, provided a number of comments on