

continue to evaluate that information. We intend to work as quickly as possible to assess and address the safety issues identified on the Drug Watch, and we will continue to communicate important information about drug risks that are known with greater certainty using traditional means, such as public health advisories. Our goal with the Drug Watch is to share emerging safety information before we have fully determined its significance or taken final regulatory action so that patients and healthcare professionals will have the most current information concerning the potential risks and benefits of marketed drug products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on FDA's Drug Watch for emerging drug safety information. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

### III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: May 4, 2005.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[CGD 17-05-005]

### Prince William Sound Regional Citizens' Advisory Committee Charter Renewal

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of recertification.

**SUMMARY:** The purpose of this notice is to inform the public that the Coast Guard has recertified the Prince William Sound Regional Citizens' Advisory Council (PWSRCAC) as an alternative voluntary advisory group for Prince William Sound, Alaska. This certification allows the PWSRCAC to monitor the activities of terminal facilities and crude oil tankers under the Prince William Sound Program established by statute.

**DATES:** This recertification is effective for the period from March 1, 2005, through February 28, 2006.

**FOR FURTHER INFORMATION CONTACT:** Commander, Seventeenth Coast Guard District, Marine Safety Division, Response Branch by phone at (907) 463-2804, or by mail at P.O. Box 25517; Juneau, Alaska 99802.

### SUPPLEMENTARY INFORMATION:

#### Background and Purpose

As part of the Oil Pollution Act of 1990, Congress passed the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990 (the Act), 33 U.S.C. 2732, to foster a long-term partnership among industry, government, and local communities in overseeing compliance with environmental concerns in the operation of crude oil terminals and oil tankers.

On October 18, 1991, the President delegated his authority under 33 U.S.C. 2732 (o) to the Secretary of Transportation in Executive Order 12777, section 8(g) (see 56 FR 54757; October 22, 1991) for purposes of certifying advisory councils, or groups, subject to the Act. On March 3, 1992, the Secretary redelegated that authority to the Commandant of the USCG (see 57 FR 8582; March 11, 1992). The Commandant redelegated that authority to the Chief, Office of Marine Safety, Security and Environmental Protection (G-M) on March 19, 1992 (letter #5402).

On July 7, 1993, the USCG published a policy statement, 58 FR 36504, to clarify the factors that shall be considered in making the determination as to whether advisory councils, or

groups, should be certified in accordance with the Act.

The Assistant Commandant for Marine Safety and Environmental Protection (G-M), redelegated recertification authority for advisory councils, or groups, to the Commander, Seventeenth Coast Guard District on February 26, 1999 (letter #16450).

On September 16, 2002, the USCG published a policy statement, 67 FR 58440, that changed the recertification procedures such that applicants are required to provide the USCG with comprehensive information every three years (triennially). For each of the two years between the triennial application procedure, applicants submit a letter requesting recertification that includes a description of any substantive changes to the information provided at the previous triennial recertification.

### Discussion of Comments

The January 12, 2005, the USCG published a Notice of Application Submission Deadline; Request for Comments for Recertification of Prince William Sound Regional Citizens' Advisory Council in the **Federal Register** (70 FR 2181). We received 17 letters commenting on the proposed action. No public meeting was requested, and none was held. Of the 17 comments received, 16 were positive. These letters in support of the recertification consistently cited PWSRCAC's broad representation of the respective community's interests, appropriate actions to keep the public informed, improvements to both spill response preparation and spill prevention, and oil spill industry monitoring efforts that combat complacency—as intended by the Act.

The USCG received one comment in opposition to PWSRCAC's recertification. The Native Village of Eyak (NVE) recommended the Coast Guard de-certify the PWSRCAC because it neither represents the NVE, nor can it afford representation to the NVE through membership on the PWSRCAC Board of Directors. The NVE stated that a separate Tribal oversight group should be created. They further stated that advisory group funding should be directed to this Tribal oversight group, and that this group would exist in addition to, not in place of, the PWSRCAC. NVE has twice before voiced this opposition in letters of comment on PWSRCAC's 2001 and 2002 recertification. Commandant, Seventeenth Coast District answered NVE's opposition, with direct responses dated September 7, 2001, and July 11, 2002. For the purpose of public record, those responses are provided here:

The September 7, 2001, U.S. Coast Guard response to the Native Village of Eyak letter dated July 24, 2001, states “[I] have received and reviewed your letter that does not support the recertification of the PWSRCAC. Thank you for your input. Although I understand your position and concerns that the Native Village of Eyak has never been represented by the PWSRCAC and therefore the Native Village of Eyak does not feel the PWSRCAC is broadly representative of the interests and communities in the area, after careful consideration, I do not feel this single issue would justify the U.S. Coast Guard not recertifying the PWSRCAC. In light of your concerns, I have requested, in writing, that the PWSRCAC board contact your Tribal Council and open a dialogue with you to ensure your concerns are reflected in the PWSRCAC’s Activities. Additionally, I recommend that you open a dialog, if you desire, with the PWSRCAC Board of Directors concerning membership on the Board, as membership native villages is consistent with Section 2732(d)(A)(iii) of OPA 90. To respond to your question regarding an investigation into the finances of the RCAC, the Coast Guard is currently conducting a “best practices” audit to assist the PWSRCAC in decreasing their administrative overhead. This audit is still ongoing, and it would be premature for me to further comment on the potential outcome prior to its completion. My staff and I look forward to working with you on our common goal of improving the safe and environmentally sound transport of oil in PWS and surrounding communities.”

The July 11, 2002, U.S. Coast Guard response to the Native Village of Eyak letter dated July 29, 2002, states “I have received and reviewed your letter concerning the recertification of the Regional Citizens’ Advisory Council (RCAC) for Prince William Sound (PWS). The Coast Guard greatly values the important role the Native Village of Eyak Traditional Council (NVETC) plays in the PWS community. Thank you for your input and for this opportunity to consult with you about the PWS RCAC and The Oil Pollution Act of 1990 (OPA 90).”

The history, background, and legal character of the PWS RCAC, along with its funding and responsibilities are unique and worthy of more discussion. The PWS RCAC is an independent, non-profit organization founded in 1989. Though it received Federal oversight like many independent, non-profit organizations, it is not a Federal agency. The PWS RCAC is a local organization that predates the passage of OPA 90.

The existence of the PWS RCAC was specifically recognized in OPA 90 where it is defined as an “alternate voluntary advisory group.”

The Alyeska Pipeline Service Company pays the PWS RCAC \$2 million annually in the form of a long-term contract. In return for this funding, the PWS RCAC must annually show that it “fosters the goals and purposes” of OPA 90 and is “broadly representative of the communities and interests in the vicinity of the terminal facilities and Prince William Sound.” In March 1991, then-President Bush initially certified the PWS RCAC as meeting these broad goals. That certification responsibility was delegated to the Coast Guard in 1991, and for the last ten years the Coast Guard has unconditionally recertified the PWS RCAC annually.

Alyeska funds the PWS RCAC, and the Coast Guard makes sure the PWS RCAC operates in a fashion that is broadly consistent with OPA 90. For example, the PWS RCAC’s responsibilities under OPA 90 are limited to monitoring crude oil terminal and tanker operation in PWS. As such, the PWS RCAC had no role in the response to the F/V WINDY BAY oil spill, which was a diesel fuel oil spill. In such cases, however, the PWS RCAC can and does offer advice based on its local knowledge and in fact facilitated our close cooperation in response to that spill.

In your letter, you made three specific requests. The first was the “the PWS RCAC be decertified on the basis of not broadly representing interests and communities in the area.” I have the authority to grant that request, but cannot grant it. I find that the PWS RCAC does broadly represent the PWS community. The PWS RCAC board includes a broad spectrum of the native and non-native community, the fishing and oil industry, and environmental and recreational organizations as prescribed by OPA 90. Last year after you made similar critical recertification comment, the PWS RCAC invited the NVETC to seek a seat on the board of the RCAC. You decided not to act on that offer. I cannot find your decision not to join the PWS RCAC to be basis for decertification.

Your second request was the “a new group following strict letter of the law in OPA 90 be formed.” Unfortunately, I have neither the authority to grant this request nor the expertise to help you achieve it on your own. The Coast Guard did not create the PWS RCAC and cannot act to create a competing alternative.

Your third request was that “a Tribal oversight group with equal status to the

U.S. government and State of Alaska be created.” Again I have neither the authority nor the expertise to create such an organization. I do encourage you to reconsider your decision not to seek a seat on the PWS RCAC. Though the PWS RCAC is an independent, non-federal, non-profit organization over which I have limited influence, I would ask the PWS RCAC seriously consider a renewed request by you for a seat on the board.

In your letter, you suggested the formation of a Tribal Council of the Native Tribes and Villages in PWS that would exist in addition to PWS RCAC. I appreciate that such a network would facilitate the discussion of mutual issues and concerns. Though the Coast Guard is not empowered to sponsor such an enterprise, I would welcome the information and advice such a group could offer. You may wish to approach the PWS RCAC about such a tribal group.

I would also like to assure you that the Coast Guard recognizes its government-to-government consultative relationship with the Native Village of Eyak. I am grateful for this opportunity to consult with you. I hope to continue to work you on emergent cases like the F/V WINDY BAY case and on any other matters of mutual concern.”

NVE has voiced no new opposition for 2005. The USCG, standing by its direct responses above, likewise offers no new response to NVE’s running opposition.

**Recertification:** By letter dated March 2, 2005, the Commander, Seventeenth Coast Guard certified that the PWSRCAC qualifies as an alternative voluntary advisory group under 33 U.S.C. 2732(o). This recertification terminates on February 28, 2006.

Dated: March 4, 2005.

**James C. Olson,**

*Rear Admiral, U.S. Coast Guard, Commander, Seventeenth Coast Guard District.*

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## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[CGD08-05-020]

### Houston/Galveston Navigation Safety Advisory Committee

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of meetings; change of meeting date and location.

**SUMMARY:** The Houston/Galveston Navigation Safety Advisory Committee