

be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www/cfsan.fda.gov/guidance.html>.

Dated: December 11, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-31038 Filed 12-12-03; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 1

[USCG-2003-16628]

#### Notice of Violation Program

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of revised agency policy.

**SUMMARY:** The Coast Guard is expanding the scope of its Notice of Violation (NOV) program for resolving civil penalty cases as provided for in 33 CFR part 1, subpart 1.07. The Coast Guard will issue a revised policy expanding use of the NOV program to all statutory penalty provisions that the Coast Guard is authorized to enforce, and raising the maximum for proposed penalties under the NOV program to \$10,000.

**DATES:** This revised policy is effective on January 5, 2004.

**FOR FURTHER INFORMATION CONTACT:** For further information on the use of the NOV program contact one of the persons listed below. For general questions, contact LCDR Scott Budka (G-MOA) U.S. Coast Guard by telephone at (202) 267-2026 or by electronic mail at [sbudka@comdt.uscg.mil](mailto:sbudka@comdt.uscg.mil). For questions on application of the NOV program to U.S. vessels, contact LCDR Martin Walker (G-MOC) U.S. Coast Guard by telephone at (202) 267-1047 or by electronic mail at [mwalker@comdt.uscg.mil](mailto:mwalker@comdt.uscg.mil). For questions on application of the NOV program to facilities, contact LCDR Phil Perry (G-MOC) U.S. Coast Guard by telephone at (202) 267-6700 or by electronic mail at [pperry@comdt.uscg.mil](mailto:pperry@comdt.uscg.mil). For questions on the application of the NOV program to outer continental shelf facilities, contact LCDR Eric Walters (G-MOC) U.S. Coast Guard by telephone at (202)

267-0499 or by electronic mail at [ewalters@comdt.uscg.mil](mailto:ewalters@comdt.uscg.mil).

**SUPPLEMENTARY INFORMATION:** The Notice of Violation (NOV) program was implemented in 1995 to address the Coast Guard's concern that the civil penalty assessment process was too lengthy when applied to small (under 100 gallons) oil discharges and minor pollution prevention regulation violations (33 CFR parts 154, 155 and 156). The lengthy process time meant that a party frequently would have additional violations before being notified by a Hearing Officer of the initiation of action for the first violation. Early resolution of these minor violations saved time and reduced costs of internal reviews, improved deterrence, and facilitated corrective action by providing a party with earlier notice of violations.

In the Final Rule implementing the NOV program (59 FR 66482, Dec 27, 1994) we stated, "The NOV option can be used by other Coast Guard programs that use the civil penalty process. Any program that implements use of the NOV option will do so by internal policy with prior notification to the public in the **Federal Register**." We are now publishing this notice to inform the public that we are expanding the NOV program by internal policy.

Since the NOV program's implementation, the Coast Guard has issued on average 2,300 NOV's annually for small oil spills and minor pollution prevention regulation violations. 95 percent of those NOV's were accepted by the responsible party, paid and the case closed. Because of the success of the initial limited NOV program, it is being expanded to include oil spills of 1,000 gallons or less and to include violations of other laws and regulations that the Coast Guard enforces.

An NOV may not be issued when the total proposed penalty for a violation exceeds \$10,000. All laws and regulations that the Coast Guard enforces which contain a civil penalty provision are eligible for inclusion in the NOV program. Coast Guard issuing officers will issue a Notice of Violation with a proposed penalty only in clear-cut cases as determined by applying specific written guidance contained in a Commandant Directive, an internal Coast Guard policy document. A penalty schedule based on objective criteria will form an enclosure to the above Commandant Directive. Any case in which aggravating or extenuating circumstances are evidenced, or which concern violations not included in specific guidance documents, may be referred to the Hearing Officer for

processing under the Coast Guard's current procedures as detailed in 33 CFR part 1, subpart 1.07.

This expansion will not change the alleged violator's options concerning the NOV as detailed in 33 CFR 1.07-11. The party has the option of paying the proposed penalty and closing the case or declining the NOV. If the NOV is declined, the case is processed as a Class I Administrative Civil Penalty and adjudicated by the Coast Guard Hearing Office. If the party fails to pay or decline the NOV within 45 days of receipt, the NOV is considered in default, the proposed penalty is considered assessed, and the case is forwarded to Commander, Maintenance & Logistics Command Pacific, Claims and Litigations (Collections) for collection of the penalty.

The NOV process does not preclude the Coast Guard from exercising its authority to utilize any other penalty, enforcement, control, or compliance measures authorized by law.

Dated: December 9, 2003.

T.H. Gilmour,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Marine Safety, Security and Environmental Protection.

[FR Doc. 03-30916 Filed 12-15-03; 8:45 am]

BILLING CODE 4910-15-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 165

[CGD08-03-029]

RIN 1625-AA11

#### Regulated Navigation Area; Reporting Requirements for Barges Loaded With Certain Dangerous Cargoes, Inland Rivers, Eighth Coast Guard District

**AGENCY:** Coast Guard, DHS.

**ACTION:** Interim final rule; notice of approval of revised collection of information.

**SUMMARY:** On October 3, 2003, the Coast Guard published an interim final rule in the **Federal Register** that established a regulated navigation area (RNA) within all inland rivers of the Eighth Coast Guard District and contained reporting requirements for barges loaded with certain dangerous cargoes. This document provides notice that the Office of Management and Budget (OMB) has approved the revised collection of information contained in that interim rule.