

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. 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. 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. 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.

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.

DATES: OMB approved the revised collection of information 1625–0105 on November 3, 2003.

FOR FURTHER INFORMATION CONTACT: For information regarding this document, or if you have questions on viewing or submitting material to the docket, write or call Commander (CDR) Jerry Torok or Lieutenant (LT) Kevin Lynn, Project Managers for the Eighth Coast Guard District Commander, Hale Boggs Federal Bldg., 501 Magazine Street, New Orleans, LA 70130, telephone (504) 589–6271.

SUPPLEMENTARY INFORMATION: On October 3, 2003, the Coast Guard published an interim final rule entitled “Regulated Navigation Area; Reporting Requirements for Barges Loaded with Certain Dangerous Cargoes, Inland Rivers, Eighth Coast Guard District” in the **Federal Register** (68 FR 57358). In the preamble of that interim rule, we stated that we would publish a separate notice if and when OMB approved the revised collection of information (1625–0105) contained in the rule (68 FR 57363). On November 3, 2003, OMB announced that they had approved this revised collection of information.

Dated: December 1, 2003.

R.F. Duncan,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 03–30917 Filed 12–15–03; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 65

[Docket No. FEMA–P–7630]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the Base (1% annual-chance) Flood Elevations (BFEs) is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified BFEs for new buildings and their contents.

DATES: These modified BFEs are currently in effect on the dates listed in the table below and revise the Flood Insurance Rate Map(s) in effect prior to this determination for the listed communities.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Mitigation Division Director of the Emergency Preparedness and Response Directorate reconsider the changes. The modified BFEs may be changed during the 90-day period.

ADDRESSES: The modified BFEs for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Doug Bellomo, P.E., Hazard Identification Section, Emergency Preparedness and Response Directorate, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646–2903.

SUPPLEMENTARY INFORMATION: The modified BFEs are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified BFE determinations are available for inspection is provided. Any request for reconsideration must be based on knowledge of changed conditions or new scientific or technical data.

The modifications are made pursuant to Section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR Part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified BFEs are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified BFEs, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any

existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities.

The changes in BFEs are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Mitigation Division Director of the Emergency Preparedness and Response Directorate certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This interim rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and record keeping requirements.

■ Accordingly, 44 CFR Part 65 is amended to read as follows:

PART 65—[AMENDED]

■ 1. The authority citation for Part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

■ 2. The tables published under the authority of § 65.4 are amended as follows: