§ 814.124 Institutional Review Board requirements.

(a) * * * If, however, a physician in an emergency situation determines that approval from an IRB cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior approval by the IRB located at the facility or by a similarly constituted IRB that has agreed to oversee such use. In such an emergency situation, the physician shall, within 5 days after the use of the device, provide written notification to the chairman of the IRB of such use. Such written notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.

12. Section 814.126 is amended by revising the first sentence in paragraph (a) and by revising paragraph (b) to read as follows:

§ 814.126 Postapproval requirements and reports.

(a) An HDE approved under this subpart shall be subject to the postapproval requirements and reports set forth under subpart E of this part, as applicable, with the exception of § 814.82(a)(7). * * *

(b) In addition to the reports identified in paragraph (a) of this section, the holder of an approved HDE shall prepare and submit the following complete, accurate, and timely reports:

(1) *Annual report.* An HDE applicant is required to submit an annual report on the anniversary date of marketing approval. The annual report shall include:

(i) An update of the information required under § 814.102(a) in a separately bound volume;

(ii) An update of the information required under § 814.102(c)(2), (c)(3), and (c)(5);

(iii) The number of devices that have been shipped or sold since initial marketing approval under this subpart H and, if the number shipped or sold exceeds 4,000, an explanation and estimate of the number of devices used per patient. If a single device is used on multiple patients, the applicant shall submit an estimate of the number of patients treated or diagnosed using the device together with an explanation of the basis for the estimate;

(iv) Information describing the applicant's clinical experience with the device since the HDE was initially approved. This information shall include safety information that is known or reasonably should be known to the applicant, medical device reports made under part 803 of this chapter, any data generated from the postmarketing studies, and information (whether published or unpublished) that is known or reasonably expected to be known by the applicant that may affect an evaluation of the safety of the device or that may affect the statement of contraindications, warnings, precautions, and adverse reactions in the device's labeling; and

(v) A summary of any changes made to the device in accordance with supplements submitted under § 814.108. If information provided in annual reports, or any other information in the possession of FDA, gives the agency reason to believe that a device raises public health concerns or that the criteria for exemption are no longer met, the agency may require the HDE holder to submit additional information to demonstrate continued compliance with the HDE requirements.

(2) *Other.* An HDE holder shall maintain records of the names and addresses of the facilities to which the HUD has been shipped, correspondence with reviewing IRB's, as well as any other information requested by a reviewing IRB or FDA.

Dated: March 31, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–9637 Filed 4–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 160

46 CFR Part 4

[CGD 94–027 and CGD 94–030]

RIN 2115–AE82 and 2115–AE89

Notice of Hazardous Conditions/ Immediate Reporting of Casualties

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is issuing a final rule which amends the rules that describe what marine casualties and hazardous conditions require immediate notice. This rule also clarifies notice procedures. The reason for the change is to provide mechanisms that will help prevent another disaster such as the derailment of a passenger train near Mobile, Alabama, in September 1993. The final rule combines the Notice of Hazardous Conditions and the Immediate Reporting of Casualties interim rules that became effective on August 3, 1994. The Notice of Hazardous Conditions interim rule amending 33 CFR part 160 is adopted as final without change.

DATES: This final rule is effective on May 18, 1998.

ADDRESSES: Documents indicated in this preamble are available for inspection or copying at the office of the Executive Secretary, Marine Safety Council (G–LRA/3406), U.S. Coast Guard Headquarters, 2100 Second Street SW., room 3406, Washington, DC 20593–0001, between 9:30 a.m. and 2 p.m., Monday through Friday, except Federal holidays. The telephone number is 202 267–1477.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth W. Olsen, Project Manager, Office of Investigations and Analysis, (G–MOA–1), U.S. Coast Guard, 2100 Second Street, SW., Washington, DC 20593–0001, telephone (202) 267–1430.

SUPPLEMENTARY INFORMATION:

Regulatory History

On August 3, 1994, the Coast Guard published in the **Federal Register** two interim rules entitled Notice of Hazardous Conditions (59 FR 39458) and Immediate Reporting of Casualties (59 FR 39469). The Notice of Hazardous Conditions interim rule amended 33 CFR part 160, and the Immediate Reporting of Casualties interim rule amended 46 CFR part 4. These rules were published as interim rules because the Coast Guard determined that it would be contrary to the public interest to delay publication of rules, which clarified existing law, imposed no new regulatory requirements, and involved no significant change in policy. The Coast Guard combined the interim rules into a single final rule because both were initiated as a result of the derailment of the Amtrak Sunset Limited passenger train near Mobile, AL. The Coast Guard received 15 letters commenting on the rulemaking for Immediate Reporting of Casualties and two additional letters which presented comments on both the rulemaking for Immediate Reporting of Casualties and the rulemaking for Notice of Hazardous Conditions. No public hearing was requested, and none was held as a result of these comments.

Background and Purpose

The derailment of the Amtrak Sunset Limited, a passenger train, on September 22, 1993, with extensive injury and loss of life, resulted in a study by the Coast Guard entitled Review of Marine Safety Issues Related to Uninspected Towing Vessels. This study provided the Commandant of the Coast Guard with a number of

recommendations to enhance safety in the towing industry.

One of those recommendations called for a regulatory project to improve how information concerning allisions is reported. Another recommendation called for a regulatory project to amend 33 CFR 160.215 to clearly indicate that the required notice of a hazardous condition includes a hazardous condition caused by a vessel or its operation even when the hazardous condition is not on board the vessel.

The Commandant concurred with these and other recommendations and directed the appropriate offices to initiate the regulatory projects.

On March 2, 1994, the Coast Guard published a notice in the **Federal Register** (59 FR 10031) announcing a public meeting to review the study and seek public comment on the recommendations identified in the study. The meeting took place on April 4, 1994, at Coast Guard Headquarters, in Washington, DC. This public meeting, comprised mainly of representatives from the towing industry and the Coast Guard, solicited and elicited detailed comments concerning the recommendations. These comments were considered when the Coast Guard developed the interim rules for the immediate reporting and hazardous condition regulatory projects.

Discussion of Comments and Changes

1. 33 CFR 160.215

Two comments recommended revising the rule to include language to protect vessel personnel from employer retaliation when a hazardous condition or casualty is reported directly to the Coast Guard. An existing law, 46 U.S.C. 2114, prohibits the discharge of or discrimination against a seaman by the owner, charterer, managing operator, agent, master or individual in charge of a vessel when the seaman in good faith reports or is about to report to the Coast Guard a violation of 46 U.S.C. subtitle II or related regulations. This statute clearly expresses that a seaman discharged or discriminated against in violation of 46 U.S.C. 2114 may bring an action in an appropriate district court of the United States. The Coast Guard believes that this statute provides suitable protection and remedy for seamen in such cases.

2. 46 CFR 4.05–1(a)(1)

One comment questioned the use of the term ''allision'' and suggested its removal.

However the Coast Guard considers the term ''allision'' to be appropriate when describing collisions involving vessels and stationary objects and no change was made to the rule as a result of this comment.

3. 46 CFR 4.05–1(a)(1)

One comment expressed the need to include collisions as reportable casualties in 46 CFR subpart 4.05. The Coast Guard does not believe that every collision needs to be reported. Only those collisions that result in the conditions presented in 46 CFR 4.05–1 (a)(4) through (a)(7), or those that are the result of a loss detailed in 46 CFR 4.05–1(a)(3), must be reported.

4. 46 CFR 4.05–1(a)(2)

Another comment suggested that all intended and unintended strikes with bridges should be considered reportable casualties. The Coast Guard does not agree with this suggestion. Intended strikes that do not meet any criterion of 46 CFR subpart 4.05–1 (a)(3) through (a)(7), and that do not create a hazardous condition, a hazard to navigation, the environment, or the safety of a vessel; are considered non-reportable casualties.

5. 46 CFR 4.05–1(a)(3)

Two comments questioned the purpose of requiring immediate reporting of casualties which occur at sea when no other vessel is involved. Additionally, the comments contended that there was no added value in reporting mechanical breakdowns when the breakdowns are rectified by vessel personnel. The Coast Guard disagrees with these comments. The collection of casualty related system and vessel operational data is essential to the Coast Guard's effort in measuring the effectiveness of its marine safety programs. Thus, no change was made to the rule as a result of these comments.

6. 46 CFR 4.05–1(a)(6) and 4.05–10(a)

Two comments expressed concern about the increased workload that may emerge as a result of reporting certain injuries and of reporting injuries on commercial vessels that render crewmen unfit for duty. The rule does not create a substantial workload increase to vessel owners, agents, masters, operators, or persons in charge because it clarifies an existing requirement and does not place any new requirement on the public. This eliminates misunderstanding as to what events require a written report and results in an even greater reduction in workload.

7. 46 CFR 4.05–1 (a) and (b) and 4.05–10(b)

Three comments suggested that the phrase ''filed without delay,'' and the term ''delivered'' used in 46 CFR 4.05–10 required clarification. The Coast Guard has considered these comments and has concluded that no change is necessary and that the phrase ''filed without delay'' and the term ''delivered'' are appropriately used in the rule.

8. 46 CFR 4.05–10(a)

Three comments questioned the use of the phrase ''any marine casualty'' in 46 CFR 4.05–10(a). The Coast Guard recognizes that ''any marine casualty'' could mean those casualties defined by 46 CFR 4.03–1. However, the Coast Guard only requires written reports for casualties reported under 46 CFR 4.05–1(a). Therefore, the rule has been amended to clarify that the term ''marine casualty'' refers only to those defined in § 4.05–1.

9. 46 CFR 4.05–10(a)

One comment had no suggestions regarding the interim rules, but requested better instruction on form CG–2692 (Report of Marine Accident, Injury or Death). The Coast Guard considered this request and determined that making revisions to form CG–2692 is beyond the scope of this rulemaking.

10. 46 CFR 4.05–10(b)

The Coast Guard clarifies this section. The term ''notice'' used in the phrase ''the notice required by paragraph (a) of this section'' is incorrect. The rule has been amended because paragraph (a) of § 4.05–10 requires a written report, not a notice.

Regulatory Evaluation

This final 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 the Order. It has not been reviewed 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 10(e) of the regulatory policies and procedures of DOT is unnecessary. This finding rests on the determination that this rule clarifies existing requirements and does not place any new requirements on the industry.

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'' may include small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard reviewed this rule for potential impact on small entities and has determined that it does not place any new requirements on the public or any small entity, because it only clarifies existing law. Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this final rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

In accordance with section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), the Coast Guard offers to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. Assistance with provisions of this final rule can be obtained by contacting Commandant (G–MOA–1), Office of Investigations and Analysis, 2100 Second Street, SW., Washington, DC 20593–0001, telephone 202–267–1430.

Collection of Information

This final rule contains no new collection-of-information requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Federalism

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

Environment

The Coast Guard considered the environmental impact of this final rule and concluded that, under paragraph 2.B.2 e.(34)(a) of Commandant Instruction M16475.1B, this rule is categorically excluded from further environmental documentation. This rule concerns administrative matters which clearly have no environmental impact. A Categorical Exclusion Determination is available in the docket for inspection or copying where indicated under **ADDRESSES.**

List of Subjects in 33 CFR Part 160

Administrative practice and procedure, Hazardous materials transportation, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Vessels, Waterways.

TITLE 33—NAVIGATION AND NAVIGABLE WATERS

PART 160—PORTS AND WATERWAYS SAFETY–GENERAL

Accordingly, the interim rule amending 33 CFR part 160 which was published at 59 FR 39458 on August 3, 1994, is adopted as a final rule without change.

List of Subjects in 46 CFR Part 4

Administrative practice and procedure, Alcohol abuse, Drug abuse, Drug testing, Investigations, Marine safety, National Transportation Safety Board, Reporting and recordkeeping requirements, Safety, Transportation.

For the reasons discussed in the preamble, the Coast Guard is adopting the interim rule published at 59 FR 39458, August 3, 1994, amending 46 CFR part 4 as final with the following changes:

TITLE 46—SHIPPING

PART 4—MARINE CASUALTIES AND INVESTIGATIONS

1. The authority citation for part 4 continues to read as follows:

Authority: 33 U.S.C. 1231; 43 U.S.C. 1333; 46 U.S.C. 2103, 2306, 6101, 6301, 6305; 50 U.S.C. 198; 49 CFR 1.46, Authority for subpart 4.40: 49 U.S.C. 1903(a)(1)(E); 49 CFR 1.46.

2. Section 4.05–10 is revised to read as follows:

§ 4.05–10 Written report of marine casualty.

(a) The owner, agent, master, operator, or person in charge shall, within five days, file a written report of any marine casualty required to be reported under § 4.05–1. This written report is in addition to the immediate notice required by § 4.05–1. This written report must be delivered to a Coast Guard Marine Safety Office or Marine Inspection Office. It must be provided on Form CG–2692 (Report of Marine Accident, Injury or Death), supplemented as necessary by appended Forms CG–2692A (Barge Addendum) and CG–2692B (Report of Required Chemical Drug and Alcohol Testing Following a Serious Marine Incident).

(b) If filed without delay after the occurrence of the marine casualty, the report required by paragraph (a) of this section suffices as the notice required by § 4.05–1(a).

Dated: April 9, 1998.

R. C. North,

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

[FR Doc. 98–9921 Filed 4–16–98; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–5991–7]

National Oil and Hazardous Substances Pollution Contingency Plan, National Priorities List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of partial deletion of portions of the Celanese Corporation Shelby Fiber Operations superfund site located in Shelby, Cleveland County, North Carolina from the national priorities list.

SUMMARY: The Environmental Protection Agency (EPA) Region 4 announces the deletion of portions of the Celanese Corporation Shelby Fiber Operations Superfund Site from the National Priorities List (NPL) in Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Pollution Contingency Plan (NCP) which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. The only portions of the Site that are being deleted are: the *Outer Tier* groundwater extraction well system and the associated treatment system of Operable Unit #1 (OU#1), and the former source area and remediated creeks of Operable Unit #2 (OU#2). (This partial deletion does NOT include the remaining portions of OU#1 the Inner Tier extraction and treatment system.) EPA and the State of North Carolina Department of Environment, Health, and Natural Resources have determined that all appropriate actions have been implemented to protect public health, welfare and the environment under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). This partial deletion does not preclude future action under Superfund deemed necessary.