

§ 103.41 What happens if a lender violates provisions of this part?

In addition to reducing or eliminating payment on a specific claim for loss, BIA may either temporarily suspend, or permanently bar, a lender from making or acquiring loans under the Program if the lender repeatedly fails to abide by the requirements of this part, or if the lender significantly violates the requirements of this part on any single occasion.

§ 103.42 How long must a lender comply with Program requirements?

(a) A lender must comply in general with Program requirements during:

(1) The effective period of its loan guaranty agreement or loan insurance agreement; and

(2) Whatever additional period is necessary to resolve any outstanding loan guaranty or insurance claims or coverage the lender may have.

(b) Except as otherwise required by law, a lender must maintain records with respect to a particular loan for 6 years after either:

(1) The loan is repaid in full; or

(2) The lender accepts payment from BIA for a loss on the loan, pursuant to a guaranty certificate or an insurance agreement.

(c) At any time 2 years or more following one of the events specified in paragraphs (b)(1) or (2) of this section, a lender may convert its records for corresponding loans to any electronic format that is readily retrievable and that provides an accurate, detailed image of the original records. Upon converting its records in this manner, the lender may dispose of its original loan records.

(d) This section does not restrict any claims BIA may have against the lender or any other party arising from the lender's participation in the Program.

§ 103.43 What must the lender do after repayment in full?

The lender must completely and promptly release of record all remaining collateral for a guaranteed or insured loan after the loan has been paid in full. The release must be at the lender's sole cost. In addition, if the loan is prepaid the lender must notify BIA in accordance with § 103.33(f).

Subpart H—Definitions and Miscellaneous Provisions**§ 103.44 What certain terms mean in this part.**

BIA means the Bureau of Indian Affairs within the United States Department of the Interior.

Default means:

(1) The borrower's failure to make a scheduled loan payment when it is due;

(2) The borrower's failure to meet a material condition of the loan agreement;

(3) The borrower's failure to comply with any other condition, covenant or obligation under the terms of the loan agreement within applicable grace or cure periods;

(4) The borrower's failure to remain at least 51 percent Indian owned, as provided in § 103.25(b);

(5) The filing of a voluntary or involuntary petition in bankruptcy listing the borrower as debtor;

(6) The imposition of a Federal, State, local, or tribal government lien on any assets of the borrower or assets otherwise used as collateral for the loan, except real property tax liens imposed by law to secure payments that are not yet due;

(7) Any default defined in the loan agreement, to the extent the definition is not inconsistent with this part.

Equity means the value, after deducting all debt, of the borrower's tangible assets in the business being financed, on which a lender can perfect a first lien security interest. It can include cash, securities, or other cash equivalent instruments, but cannot include the value of contractual options, the right to pay below market rental rates, or similar rights if those rights:

(1) Are unassignable; or

(2) Can expire before maturity of the loan.

Indian means a person who is a member of a tribe as defined in this part.

Loan agreement means the collective terms and conditions under which the lender extends a loan to a borrower, as reflected by the documents that evidence the loan.

Mortgage means a consensual lien on real or personal property in favor of the lender, given by the borrower or a co-maker or guarantor of the loan (other than BIA), to secure loan repayment. The term "mortgage" includes "deed of trust."

NEPA means the National Environmental Policy Act of 1969, 42 U.S.C. 4321 *et seq.*

Person means any individual or distinct legal entity.

Program means the BIA's Loan Guaranty, Insurance, and Interest Subsidy Program, established under 25 U.S.C. 1481 *et seq.*, 25 U.S.C. 1511 *et seq.*, and this part 103.

Reservation means any land that is an Indian reservation, California rancharia, public domain Indian allotment, pueblo, Indian colony, former Indian reservation in Oklahoma, or land held by an Alaska Native corporation under the provisions

of the Alaska Native Claims Settlement Act (85 Stat. 688), as amended.

Secretary means the Secretary of the United States Department of the Interior, or his authorized representative.

Tribe means any Indian or Alaska Native tribe, band, nation, pueblo, rancharia, village, community or corporation that the Secretary acknowledges to exist as an Indian tribe, and that is eligible for services from BIA.

§ 103.45 Information collection.

(a) The information collection requirements of §§ 103.11, 103.12, 103.13, 103.14, 103.17, 103.21, 103.23, 103.26, 103.32, 103.33, 103.34, 103.35, 103.36, 103.37, and 103.38 have been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.*, and assigned approval number 1076-0020. The information will be used to approve and make payments on Federal loan guarantees, insurance agreements, and interest subsidy awards. Response is required to obtain a benefit.

(b) The burden on the public to report this information is estimated to average from 15 minutes to 2 hours per response, including the time for reviewing instructions, gathering and maintaining data, and completing and reviewing the information collection. Direct comments regarding the burden estimate or any other aspect of this information collection to the Information Collection Control Officer, Bureau of Indian Affairs, MS 4613, 1849 C Street, NW., Washington, DC 20240.

Dated: December 28, 2000.

Kevin Gover,

Assistant Secretary—Indian Affairs.

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DEPARTMENT OF TRANSPORTATION**Coast Guard****33 CFR Part 155**

[USCG-1998-3417]

RIN 2115-AF60

Salvage and Marine Firefighting Requirements; Vessel Response Plans for Oil

AGENCY: Coast Guard, DOT.

ACTION: Final rule; partial suspension of regulation.

SUMMARY: Current vessel response plan regulations require the owners or operators of vessels carrying Groups I

through V petroleum oil as a primary cargo to identify in their response plans a salvage company with expertise and equipment, and a company with firefighting capability that can be deployed to a port nearest to the vessel's operating area within 24 hours of notification (Groups I-IV) or a discovery of a discharge (Group V). On February 12, 1998, a notice of suspension was published in the **Federal Register**, suspending the 24-hour requirement scheduled to become effective on February 18, 1998, until February 12, 2001 (63 FR 7069). The Coast Guard has decided to extend this suspension period for another 3 years to allow us to complete the rulemaking that proposes to revise the salvage and marine firefighting requirements. The extension is necessary because the potential impact on small businesses from this new rulemaking requires us to prepare an initial regulatory flexibility analysis under the Small Business Regulatory Enforcement Fairness Act of 1996. This was not determined until a draft regulatory assessment was complete in November 2000. We expect to complete the analysis and publish a notice of proposed rulemaking this year. The extension of the suspension period will continue to relieve the affected industry from complying with the existing 24-hour requirements until the project is complete, and amendments to the salvage and marine firefighting requirements become final.

DATES: This extension is effective as of February 12, 2001. Termination of the suspension will be on February 12, 2004.

ADDRESSES: You may submit comments by one of the following methods:

(1) By mail to the Docket Management Facility, (USCG-1998-3417), U.S. Department of Transportation, room PL-401, 400 Seventh Street SW., Washington, DC 20590-0001.

(2) By hand delivery to room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(3) By fax to the Docket Management Facility at 202-493-2251.

(4) Electronically through the Web site for the Docket Management System at <http://dms.dot.gov>.

The Docket Management Facility maintains the public docket for this rulemaking. Comments and material received from the public will become part of this docket and will be available for inspection or copying at room PL-401 on the Plaza level of the Nassif

Building at the same address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also access this docket on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: For questions on this final rule partial suspension of regulations, call Lieutenant Douglas Lincoln, Office of Response, Response Operations Division, Coast Guard Headquarters, telephone 202-267-0448, or via e-mail: dlincoln@comdt.uscg.mil. For questions on viewing, or submitting material to, the docket, call Dorothy Beard, Chief, Dockets, Department of Transportation, telephone 202-366-9329.

SUPPLEMENTARY INFORMATION:

Background and Regulatory History

Requirements for salvage and marine firefighting resources in vessel response plans have been in place since February 5, 1993 (58 FR 7424). The existing requirements are general. The Coast Guard did not originally develop specific requirements because each salvage and marine firefighting response for an individual vessel is unique, due to the vessel's size, construction, operating area and other variables. The Coast Guard's intent was to rely on the planholder to prudently identify contractor resources to meet their needs. The Coast Guard anticipated that the significant benefits of a quick and effective salvage and marine firefighting response would be sufficient incentive for industry to develop salvage and marine firefighting capability parallel to the development of oil spill removal organizations.

Early in 1997, it became apparent that there was disagreement among planholders, salvage and marine firefighting contractors, maritime associations, public agencies, and other stakeholders as to what constituted adequate salvage and marine firefighting resources. There was also concern as to whether these resources could respond to the port nearest to the vessel's operating area within 24 hours.

On June 24, 1997, a notice of meeting was published in the **Federal Register** (62 FR 34105) announcing a workshop to solicit comments from the public on potential changes to the salvage and marine firefighting requirements currently found in 33 CFR part 155.

A public workshop was held on August 5, 1997, to address issues related to salvage and marine firefighting response capabilities, including the 24-hour response time requirement, which was then scheduled to become effective on February 18, 1998. The participants uniformly identified the following three

issues that they felt the Coast Guard needed to address:

(1) Defining the salvage and marine firefighting capability that is necessary in the plans.

(2) Establishing how quickly these resources must be on-scene.

(3) Determining what constitutes an adequate salvage and marine firefighting company.

Reason for Suspension

On February 12, 1998, a notice of suspension was published in the **Federal Register**, suspending the 24-hour requirement scheduled to become effective on February 18, 1998, until February 12, 2001 (63 FR 7069) so that the Coast Guard could address the issues identified at the public workshop through a rulemaking that would revise the existing salvage and marine firefighting requirements. The Coast Guard has decided to extend the suspension period for another 3 years. The extension is necessary because the potential impact on small businesses from this new rulemaking requires us to prepare an initial regulatory flexibility analysis under the Small Business Regulatory Enforcement Fairness Act of 1996. This was not determined until a draft regulatory assessment was complete in November 2000. We expect to complete the analysis and publish a notice of proposed rulemaking this year. The extension of the suspension period will continue to relieve the affected industry from complying with the existing 24-hour requirements until the project is complete, and amendments to the salvage and marine firefighting requirements become final.

Regulatory Evaluation

Although the final rule published in 1996 was a significant regulatory action under section 3(f) of Executive Order 12866, the Office of Management and Budget (OMB) does not consider this extension as a significant action. As a result, it does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. It is not "significant" under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979).

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this extension will have a significant economic impact on a substantial number of small entities. "Small entities" include small businesses, 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.

This action will not have a significant economic impact on a substantial number of small entities because the original requirements did not have a significant effect on a substantial number of small entities. The extension on the suspension does not change those original requirements. Any future regulatory action on this issue will address any economic impacts, including impacts on small entities.

Therefore, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this extension to a suspension of a final rule will not have a significant economic impact on a substantial number of small entities.

Assistance for Small Entities

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about Federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on the enforcement actions of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

Collection of Information

This action does not provide for a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Federalism

We have analyzed this action under E.O. 13132 and have determined that it does not have implications for federalism under that Order. Because this action extends a suspension of a final rule, it does not preempt any state action.

Unfunded Mandates Reform Act

This action will not result in an unfunded mandate under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538).

Taking of Private Property

This action will not effect a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This action meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this action under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not concern an environmental risk to health or risk to safety that may disproportionately affect children.

Environment

We considered the environmental impact of this proposed rule and concluded that preparation of an Environmental Impact Statement is not necessary. An Environmental Assessment and a Finding of No Significant Impact are available in the docket where indicated under

ADDRESSES.

List of Subjects in 33 CFR Part 155

Hazardous substances, Incorporation by reference, Oil pollution, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 155 as follows:

PART 155—OIL OR HAZARDOUS MATERIAL POLLUTION PREVENTION REGULATIONS FOR VESSELS

1. The authority citation for part 155 continues to read as follows:

Authority: 33 U.S.C. 1231, 1321(j); 46 U.S.C. 3715, 3719; sec. 2, E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; 49 CFR 1.46, 1.46 (iii).

Sections 155.110-155.130, 155.350-155.400, 155.430, 155.440, 155.470, 155.1030(j) and (k), and 155.1065(g) also issued under 33 U.S.C. 1903(b); and §§ 155.1110-155.1150 also issued 33 U.S.C. 2735.

Note: Additional requirements for vessels carrying oil or hazardous materials appear in 46 CFR parts 30 through 36, 150, 151, and 153.

§ 155.1050 [Amended]

2. In § 155.1050, paragraph (k)(3) is suspended until February 12, 2004.

§ 155.1052 [Amended]

3. In § 155.1052, the last sentence in paragraph (f) is suspended until February 12, 2004.

Dated: January 10, 2001.

R.C. North,

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

[FR Doc. 01-1205 Filed 1-11-01; 2:28 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICE

45 CFR Part 46

RIN 0925-AA14

Protection of Human Research Subjects

AGENCY: Department of Health and Human Services (DHHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (DHHS) is amending its human subjects protection regulations. These regulations provide additional protections for pregnant women and human fetuses involved in research and pertains to human in vitro fertilization. The rule continues the special protections for pregnant women and human fetuses that have existed since 1975. The rule enhances the opportunity for participation of pregnant women in research by promoting a policy of presumed inclusion, by permitting the pregnant woman to be the sole decision maker with regard to her participation in research, and by exempting from the regulations six categories of research. The rule also provides a mechanism for the Secretary of HHS to conduct or fund research not otherwise approvable after consultation with an expert panel and public review and comment.

DATES: Effective date: March 19, 2001.

FOR FURTHER INFORMATION CONTACT: Susan Sherman, JD, Office for Human Research Protections (OHRP), 6100 Executive Blvd, Suite 3B01, Rockville, MD 20892-7507. Telephone 301-496-7005. Email: ShermanS@od.nih.gov.

SUPPLEMENTARY INFORMATION:

Background

The Department of Health and Human Services (DHHS) regulates research involving human subjects conducted or supported by the agency through regulations codified at Title 45, part 46, of the Code of Federal Regulations. Subpart B of 45 CFR part 46, promulgated on August 8, 1975, pertains to research involving fetuses, pregnant women, and human in vitro fertilization. The 1975 regulations were jointly published in the **Federal Register** with the report and recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Research on the Fetus (40 FR 33526). Subsequent changes were incorporated January 11, 1978 (43 FR 1758), November 3, 1978 (43 FR 51559), and June 1, 1994 (59 FR