

Dated: August 5, 1998.

**Sadye Dunn,**

*Secretary to the Commission.*

[FR Doc. 98-21387 Filed 8-10-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 814

[Docket No. 98N-0168]

#### Medical Devices; 30-Day Notices and 135-Day PMA Supplement Review

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) published, in the **Federal Register** of April 27, 1998 (63 FR 20530), a direct final rule to implement the amendments to the premarket approval provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). The comment period closed on July 13, 1998. FDA is withdrawing the direct final rule because the agency received significant adverse comment.

**DATES:** The direct final rule published at 63 FR 20530, April 27, 1998, is withdrawn on August 11, 1998.

**FOR FURTHER INFORMATION CONTACT:** Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2186.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on April 27, 1998, at 63 FR 20530 is withdrawn.

Dated: August 5, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-21470 Filed 8-10-98; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

### Minerals Management Service

#### 30 CFR Parts 250 and 253

RIN 1010-AC33

#### Oil Spill Financial Responsibility for Offshore Facilities

**AGENCY:** Minerals Management Service (MMS), Interior.

**ACTION:** Final rule.

**SUMMARY:** This final regulation establishes new requirements for demonstrating oil spill financial responsibility (OSFR) for removal costs and damages caused by oil discharges and substantial threats of oil discharges from oil and gas exploration and production facilities and associated pipelines. This rule applies to the Outer Continental Shelf (OCS), State waters seaward of the line of ordinary low water along that portion of the coast that is in direct contact with the open sea, and certain coastal inland waters. This rule implements the authority of the Oil Pollution Act (OPA) of 1990.

**DATES:** This final regulation is effective October 13, 1998. However, the information collection aspects of this rule will not become effective until approved by the Office of Management and Budget (OMB). MMS will publish a document at that time in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Steve Waddell, Adjudication Unit Supervisor, at (504) 736-1710.

**SUPPLEMENTARY INFORMATION:** Title I of OPA (33 U.S.C. 2701 *et seq.*), as amended by section 1125 of the Coast Guard Authorization Act of 1996 (Pub. L. 104-324), provides at section 1016 that parties responsible for offshore facilities must establish and maintain OSFR for those facilities according to methods determined acceptable to the President. Section 1016 supersedes the OSFR provisions of the Outer Continental Shelf Lands Act (OCSLA). The Executive Order (E.O.) implementing OPA (E.O. 12777; October 18, 1991) assigned the OSFR certification function to the Department of the Interior (DOI). The Secretary of the Interior, in turn, delegated this function to MMS.

This regulation replaces the current OSFR regulation at 33 CFR part 135, which was written to implement the OCSLA. The OCSLA regulation is limited to facilities located in the OCS and sets the amount of OSFR that must be demonstrated by responsible parties at \$35 million. The regulation published

today covers both the OCS and certain State waters. The regulation requires responsible parties to demonstrate as much as \$150 million in OSFR if MMS determines that it is justified by the risks from potential oil spills from covered offshore facilities (COFs).

The minimum amount of OSFR that must be demonstrated is \$35 million for COFs located in the OCS and \$10 million for COFs located in State waters. The regulation provides an exemption for persons responsible for facilities having a potential worst case oil-spill discharge of 1,000 barrels (bbls) or less, unless the risks posed by a facility justify a lower threshold volume.

#### Background

The existing OSFR program for offshore facilities was developed under Title III of the OCSLA and initially administered by the U.S. Coast Guard (USCG). OPA replaced and rescinded the OCSLA OSFR requirements. However, section 1016(h) of OPA provides that any regulation relating to OSFR remains in force until superseded by a new regulation issued under OPA. The OSFR regulations for offshore facilities in the OCS (33 CFR part 135) will be phased out according to the timetable specified in § 253.44.

The Secretary of Transportation has authority for vessel oil pollution financial responsibility, and the USCG regulates the oil-spill financial responsibility program for vessels. A mobile offshore drilling unit (MODU) is classified as a vessel. However, a well drilled from a MODU is classified as an offshore facility under this rule.

Upon request from the USCG, MMS will provide available information for any COF involved in an oil pollution incident (i.e., oil-spill discharge or a substantial threat of a discharge) including:

- (1) The lease, permit, or right-of-use and easement (RUE) for the area in which the COF is located;
- (2) The designated applicant and guarantors and their contacts for claims;
- (3) U.S. agents for service of process;
- (4) Amounts indemnified; and
- (5) List of all responsible parties.

#### Analysis of Comments on the Proposed Rule and Changes for the Final Rule

A Notice of Proposed Rulemaking (NPR) was published on March 25, 1997 (62 FR 14052-14079). We received 28 written comments. We also received oral comments during a public workshop on the proposed rule that MMS sponsored in New Orleans, Louisiana, on June 5, 1997. All of the comments were considered in developing this final regulation. The