

of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 880.5965 is added to subpart F to read as follows:

§ 880.5965 Subcutaneous, implanted, intravascular infusion port and catheter.

(a) *Identification.* A subcutaneous, implanted, intravascular infusion port and catheter is a device that consists of a subcutaneous, implanted reservoir that connects to a long-term intravascular catheter. The device allows for repeated access to the vascular system for the infusion of fluids and medications and the sampling of blood. The device consists of a portal body with a resealable septum and outlet made of metal, plastic, or combination of these materials and a long-term intravascular catheter is either preattached to the port or attached to the port at the time of device placement. The device is available in various profiles and sizes and can be of a single or multiple lumen design.

(b) *Classification.* Class II (special controls) Guidance Document: "Guidance on 510(k) Submissions for Implanted Infusion Ports," FDA October 1990.

3. Section 880.5970 is added to subpart F to read as follows:

§ 880.5970 Percutaneous, implanted, long-term intravascular catheter.

(a) *Identification.* A percutaneous, implanted, long-term intravascular catheter is a device that consists of a slender tube and any necessary connecting fittings, such as luer hubs, and accessories that facilitate the placement of the device. The device allows for repeated access to the vascular system for long-term use of 30 days or more, and it is intended for administration of fluids, medications, and nutrients; the sampling of blood; and monitoring blood pressure and temperature. The device may be constructed of metal, rubber, plastic, composite materials, or any combination of these materials and may be of single or multiple lumen design.

(b) *Classification.* Class II (special controls) Guidance Document: "Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters."

Dated: May 23, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 206

RIN 1010-AC09

Approved Publications and Tables for Use in Applying Revised Royalty Valuation Regulations for Federal Oil

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of approved publications.

SUMMARY: As required by revised Federal oil valuation regulations, the Minerals Management Service (MMS) has approved three spot price publications that royalty payors should use to value oil produced from Federal leases not sold at arm's length.

EFFECTIVE DATE: June 1, 2000.

ADDRESSES: See **FOR FURTHER INFORMATION CONTACT** section below.

FOR FURTHER INFORMATION CONTACT: David Domagala, Royalty Valuation Division, Royalty Management Program, Minerals Management Service, P.O. Box 25165, Mail Stop 3151, Denver, Colorado 80225, telephone number (303) 275-7255 or fax number (303) 275-7227.

SUPPLEMENTARY INFORMATION: MMS published its revised regulations establishing oil value for royalty due on Federal leases in the **Federal Register** on March 15, 2000 (65 FR 14022), effective June 1, 2000. The primary changes in the revised regulations affect Federal lessees who value oil not sold at arm's length. The rule provides that the primary means of valuing crude oil not sold at arm's length is an adjusted spot price, except in the Rocky Mountain Region, where use of an adjusted spot price for valuation purposes is the third valuation benchmark (30 CFR 206.103(b)(4)) (65 FR 14091). The applicable spot price is the one for the oil most closely representing the lease production in terms of physical proximity and quality parameters. The lessee may select the spot price from any MMS-approved publication; however, once the lessee selects a publication for a geographical area (California/Alaska, the Rocky Mountain Region, or the rest of the

country), it must continue to use that same publication for 2 years in that area.

In § 206.104 of the final rule (65 FR 14092) for establishing oil value for royalty due on Federal leases, MMS explained that "approved publications" must be:

- (1) Publications buyers and sellers frequently use;
- (2) Publications frequently mentioned in purchase or sales contracts;
- (3) Publications that use adequate survey techniques, including development of spot price estimates based on daily surveys of buyers and sellers of Alaska North Slope (ANS) and other crude oil; and
- (4) Publications independent from MMS, other lessors, and lessees.

Additionally, MMS established that:

- (1) Any publication may petition MMS to be added to the published list of acceptable publications.
- (2) MMS will reference the tables a lessee must use in the approved publications to determine the associated index prices.
- (3) MMS may revoke its approval of a particular publication if it determines that the prices published in the publication do not accurately represent spot market values.

MMS has verified that the publications listed below meet approval criteria based on input from staff of the publication itself, as well as information from marketers, auditors and industry consultants. MMS also examined and compared historical published spot prices from all three of the approved publications to ensure comparability and consistency. The approved publications and applicable tables are as follows:

- *Platt's Oilgram Price Report* (The same spot prices appear in *Platt's Global Alert*, *Platt's Crude Oil Marketwire*, and the soon-to-be-published *Platt's U.S. Crudewire*.) Use the spot prices found in the "Crude Price Assessments" section.

- *Petroleum Argus Americas Crude* (The same spot prices appear in *Argus Crude*, *Argus Americas Crude Datafile*, *Argus Crude Datafile*.) Use the spot prices found in the "WTI Cushing," "US Gulf Coast," "US Midcontinent," and "US West Coast" sections.

- *Bloomberg Oil Buyers Guide Petroleum Price Supplement* (The same spot prices appear on the *Bloomberg Energy Web Site*, and in *Bloomberg Professional*.) Use the spot prices found in the "Worldwide Crude Price Snapshot" section.

If any of these entities use identical spot price quotes in other of their publications or distributions (such as electronic bulletin boards, newsletters, etc.), they are also approved. MMS will

monitor these three publications to ensure that they continue to meet the approval criteria.

Representatives of any other publication who wish to obtain MMS approval of their publication may contact MMS at the address shown above in the **FOR FURTHER INFORMATION CONTACT** section.

Dated: June 6, 2000.

Lucy Querques Denett,

Associate Director for Royalty Management.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD05-00-016]

RIN 2115-AA97

Safety Zone; Chickahominy River, VA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the Two Rivers Yacht Club fireworks display to be held at Barret's Point at the mouth of the Chickahominy River, Williamsburg, Virginia. This action will restrict vessel traffic on the Chickahominy River within a 500-foot radius of the fireworks display, which will be fired from shore. The safety zone is necessary to protect mariners and spectators from the hazards associated with the fireworks display.

DATES: This rule is effective from 8 p.m. until 11:30 p.m. on July 4, 2000.

ADDRESSES: You may mail comments and related material to USCG Marine Safety Office Hampton Roads, 200 Granby Street, Norfolk, VA, or deliver them to the same address between 8 a.m. and 4 p.m., Monday through Friday, except Federal Holidays. USCG Marine Safety Office Hampton Roads maintains the public docket for this rulemaking. Comments and materials received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at the above address between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Chief Petty Officer Roddy Corr, project officer, USCG Marine Safety Office Hampton Roads, telephone number (757) 441-3290.

SUPPLEMENTARY INFORMATION:

Request for Comments

Although this rule is being published as a temporary final rule without prior notice, an opportunity for public comment is nevertheless desirable to ensure the rule is both reasonable and workable. Accordingly, we encourage you to submit comments and related material. If you do so, please include your name and address, identify the docket number (CGD05-00-016), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8.5 by 11 inches, suitable for copying. If you would like to know if they reached us, please enclose a stamped, self-addressed postcard or envelope.

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. We were not notified of the event with sufficient time to publish an NPRM, allow for comments, and publish a final rule in sufficient time to allow notice to the public for the fireworks display. In previous years, this event and similar ones have been held without incident and without comment from the public regarding the Coast Guard's establishment of limited safety zones around fireworks displays.

Background and Purpose

The Coast Guard is establishing a temporary safety zone for the Two Rivers Yacht Club fireworks display to be held at Barret's Point, at the mouth of the Chickahominy River, Williamsburg, Virginia. The safety zone will restrict vessel traffic on the Chickahominy River within a 500-foot radius of the fireworks display, which will be fired from shore, in approximate position 37° 14.51' N, 076° 52.10' W. The safety zone is necessary to protect mariners and spectators from the hazards associated with the fireworks display.

The safety zone is effective from 8 p.m. until 11:30 p.m. on July 4, 2000. Additional public notifications will be made prior to the event via marine information broadcasts.

Regulatory Evaluation

This 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 that Order. The Office of Management and Budget has not reviewed it 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). This temporary final rule only affects a limited area for three and a half hours, alternative routes exist for maritime traffic, and advance notification via marine information broadcasts will enable mariners to plan their transit to avoid entering the restricted area. 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 the DOT is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises 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.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which might be small entities: the owners or operators of vessels intending to operate or anchor in portions of the Chickahominy River within 500 feet of a shoreside fireworks display at Barret's Point, located at the mouth of the Chickahominy River in approximate position 37° 14.51' N, 076° 52.10' W.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: This temporary final rule only affects a limited area for three and a half hours, alternative routes exist for maritime traffic, and advance notification via marine information broadcasts will enable mariners to plan their transit to avoid entering the restricted area.

Collection of Information

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

Federalism

We have analyzed this rule under Executive Order 13132 and have