16. Bishop, N. J. et al., ''Increased Concentration of Aluminum in the Brain of an Infant,'' *Archives of Disease in Childhood*, 64:1316–1317, 1989.

17. Koo, W. W. K. et al.,''Aluminum in Parenteral Nutrition Solution—Sources and Possible Alternatives,'' *Journal of Parental and Enteral Nutrition*, 10:591–595, 1986.

18. Heyman, M. B. et al., ''Aluminum Does Not Accumulate in Teenagers and Adults on Prolonged Parenteral Nutrition Containing Free Amino Acids,'' *Journal of Parenteral and Enteral Nutrition*, 10:86–87, 1986.

19. Klein, G. L., ''Unusual Sources of Aluminum,'' in *Aluminum and Renal Failure*, edited by M. E. Debroe and J. W. Coburn, Kluwer, Boston, 1989.

20. Bishop, N. J. et al., ''Aluminum Neurotoxicity in Preterm Infants Receiving Intravenous Feeding Solutions,'' *New England Journal of Medicine*, 336:1557–1561, 1997.

21. Eastern Research Group, *Compliance Cost Analysis of a Regulation for Parenteral Drug Products Containing Aluminum*, March 11, 1996.

22. March 3, 1986, Meeting Minutes for the Advisory Committee on Endocrinologic and Metabolic Drug Products.

23. November 6, 1986, Meeting Minutes for Public Workshop on aluminum toxicity in clinical medicine, existing aluminum monitoring, clinical effects of aluminum loading, and methodology for quantitative aluminum determination in parenteral products.

24. June 25 and 26, 1987, Meeting Minutes of the Allergenic Products Advisory Committee—available in Docket No. 84N–0387.

List of Subjects in 21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 201 be amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 357, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. New § 201.323 is added to subpart G to read as follows:

§ 201.323 Aluminum in large and small volume parenterals used in total parenteral nutrition.

(a) The aluminum content of all large volume parenteral (LVP) drug products used in total parenteral nutrition (TPN) therapy shall not exceed 25 micrograms per liter (µg/L).

(b) The package insert of all LVP's used in TPN therapy shall state that the drug product contains no more than 25 µg/L. This information shall be contained in the ''Precautions'' section of the labeling of all LVP's used in TPN therapy.

(c) The maximum level of aluminum present at expiry shall be stated on the immediate container label of all small volume parenteral (SVP) drug products and pharmacy bulk packages used in the preparation of TPN solutions. The aluminum content shall be stated as follows: ''Contains no more than _____ µg/L.'' The immediate container label of all SVP drug products and pharmacy bulk packages that are lyophilized powders used in the preparation of TPN solutions shall contain the following statement: ''When reconstituted in accordance with the package insert instructions, the concentration of aluminum will be no more than _____ µg/L.'' This maximum level of aluminum shall be stated as the highest of:

(1) The highest level for the batches produced during the last 3 years;

(2) The highest level for the latest five batches; or

(3) The maximum historical level, but only until completion of production of the first five batches after this rule takes effect.

(d) The package insert for all LVP's, SVP's, and pharmacy bulk packages shall contain the following warning statement, intended for patients with impaired kidney function and for neonates receiving TPN therapy. This information shall be contained in the ''Warnings'' section of the labeling of all SVP's and LVP's as follows:

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

(e) Applicants and manufacturers shall develop validated assay methods to determine the aluminum content in parenteral drug products. The assay methods shall comply with current good manufacturing practice requirements. Applicants shall submit to the Food and Drug Administration (FDA) both validation of the method used and release data for several batches. Manufacturers of parenteral drug products not subject to an approved application shall make assay methodology available to FDA during inspections. Holders of pending applications shall submit an amendment under § 314.60 or § 314.96 of this chapter.

Dated: December 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–76 Filed 1-2-98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Chapter II

Workshops on The Federal Oil and Gas Royalty Simplification and Fairness Act of 1996 (RSFA)

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of workshop.

SUMMARY: The Minerals Management Service (MMS), Royalty Management Program, is implementing the requirements of the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996. The purpose of this notice is to inform the public of a public workshop session on assessing for chronic erroneous reporting.

DATES: The workshop will be held on Tuesday, January 27, 1998, from 2 p.m. until 4 p.m., Mountain time.

ADDRESSES: The workshop will be held at the Embassy Suites Denver Southeast, 7525 East Hampden Avenue, Denver, Colorado 80231, telephone (303) 696–6644. Mail comments to: David S. Guzy, Chief, Rules and Publications Staff, Royalty Management Program, Minerals Management Service, P.O. Box 25165, MS 3021, Denver, Colorado 80225–0165; courier delivery to building 85, Denver Federal Center, Denver, Colorado 80225; or e-mail David__Guzy@mms.gov.

FOR FURTHER INFORMATION CONTACT: David S. Guzy, Chief, Rules and Publications Staff, telephone (303) 231–3432; Fax (303) 231–3385; e-mail: David__Guzy@mms.gov.

SUPPLEMENTARY INFORMATION: President Clinton signed the Federal Oil and Gas Royalty Simplification and Fairness Act (RSFA) on August 13, 1996, to improve the management of royalties from Federal oil and gas leases. This is the first major legislation affecting royalty management since the Federal Oil and Gas Royalty Management Act of 1982 (FOGRMA) was passed in January 1983.

In our **Federal Register** Notice dated October 30, 1996 (61 FR 55941), MMS listed key issues involved in implementing RSFA. This workshop will focus on assessing for chronic erroneous reporting and will follow and

be held at the same location as the appeals workshop.

In order to accomplish a broad based fact finding on how the requirements of RSFA affect our customers and stakeholders, comments from the public are encouraged. In addition to attendance at this meeting, comments can be made in writing and sent directly to MMS using instructions in the **ADDRESSES** part of this notice.

Dated: December 29, 1997.

Lucy Querques Denett,

Associate Director for Royalty Management.

[FR Doc. 98–121 Filed 1–2–98; 8:45 am]

BILLING CODE 4310–MR–P

PANAMA CANAL COMMISSION

35 CFR Parts 133 and 135

RIN 3207–AA45

Tolls for Use of Canal; Rules for Measurement of Vessels

AGENCY: Panama Canal Commission.

ACTION: Notice of proposed rulemaking; request for comments; notice of hearing.

SUMMARY: The Panama Canal Commission (Commission) proposes to set a fixed, minimum toll rate for certain small vessels transiting the Panama Canal. The Commission has determined an efficient use of existing Canal capacity and resources requires a change in the method of calculating tolls used to meet the transit needs of certain small vessels. A minimum toll for small vessels will ensure the Commission can recover at least part of the resources it expends on this type of transits.

The proposed increase complies with the statutory requirement tolls be set at rates which produce revenues sufficient to cover Canal costs of operation and maintenance, including capital for plant replacement, expansion and improvements, and working capital.

This notice of proposed rulemaking also announces the availability from the Commission of an analysis showing the basis and justification for the proposed change, solicits written data, views or arguments from interested parties, and sets the time and place for a public hearing.

DATES: The agency must receive written comments and requests to present oral testimony on or before February 6, 1998. A public hearing will be held at 9 a.m., February 13, 1998, in the Republic of Panama.

ADDRESSES: Mail comments and requests to testify at the hearing to: John A. Mills, Secretary, Panama Canal Commission, 1825 I Street NW., Suite 1050, Washington, DC 20006–5402; or Department of Financial Management, Panama Canal Commission, Balboa, Ancon, Republic of Panama.

The hearing location is at the Miraflores Visitors Pavilion Theater, Building 6–A, Miraflores Locks, Republic of Panama (accessible from Gaillard Highway).

FOR FURTHER INFORMATION CONTACT: John A. Mills, Telephone: (202) 634–6441, Facsimile: (202) 634–6439, E-mail: pancanalwo@aol.com; or Department of Financial Management, Telephone: 011 (507) 272–3137, Facsimile: 011 (507) 272–3040, E-mail: fmfp@pancanal.com.

SUPPLEMENTARY INFORMATION: Section 1604 of the Panama Canal Act of 1979, as amended, 22 U.S.C. 3794, establishes procedures for proposing toll rate increases and changes in the rules for measurement of vessels. Those procedures have been supplemented by regulations in 35 CFR part 70, which also provides interested parties with instructions for participating in the process governing changes in toll rates and measurement rules. The Commission strongly encourages all interested parties to present in writing, or orally at the hearing, pertinent data, views or arguments, along with other relevant information. Oral presentations should be limited to 20 minutes. Further information governing the content of the notice of appearance or intention to present supplementary data at the hearing appear at 35 CFR 70.8 and 70.10.

Section 1602(b) of the Panama Canal Act of 1979, as amended, 22 U.S.C. 3792(b), requires Canal tolls be prescribed at rates calculated to produce revenues to cover as nearly as practicable all costs of maintaining and operating the Panama Canal and the facilities and appurtenances related thereto. In analyzing the issue of tolls for certain small vessels, it is recognized the primary purpose of the Commission is to provide a safe and efficient transit service to the oceangoing vessels of the world, primarily those engaged in commerce. The waterway, however, also attracts a considerable number of small vessels, such as yachts, fishing craft, and tugboats. Such small vessel transits are incidental to the primary mission of the Canal. They also consume a disproportionately large share of available Canal capacity and resources, creating costly inefficiencies in Canal operations. In addition, and perhaps more importantly, small vessels (especially yachts), impose administrative costs and logistical problems which currently are not offset by the tolls they pay. Consequently, last November, Congress amended section 1602(a) of the Panama Canal Act of 1979, 22 U.S.C. 3792(a) by Pub. L. 105–85 to allow the Commission to set tolls for yachts and other small vessels transiting the Canal based on other than net vessel tons of earning capacity.

The Commission is attempting to reduce the administrative costs and logistical requirements of small vessel transits. It is also trying to improve the scheduling options available for these vessels with the goal of minimizing the negative impact on the Commission's resources and capacity, and, wherever possible, reduce the expenses associated with the transit of these small vessels. All of these steps are taken in order to maintain the transit service offered to these vessels. Even with these measures, however, the Commission's analysis of small vessel transits indicates the cost of providing the service far exceeds the toll charged for the service. To address this issue, the Commission's Board of Directors approved a recommendation to set a fixed, minimum toll for certain small vessels to recover these expenses in a proportionate manner.

The Commission will consider all submissions before publishing the final rule in the **Federal Register**. The final rule, as approved and published by the Commission, will be effective no earlier than 30 days after the date of its publication as final in the **Federal Register**.

The Commission is exempt from Executive Order 12866. Accordingly, provisions of that directive do not apply to this rule. Even if the Order were applicable, this change would not constitute a ''rule'' as that term is defined in the Regulatory Flexibility Act [5 U.S.C. 601(2)] because it concerns ''rates'' and ''practices relating'' thereto.

Furthermore, the Commission has determined implementation of this rule will have no adverse effect on competition, employment, investment, productivity, innovation, or on the ability of the United States based enterprises to compete with foreign based enterprises in domestic or export markets.

The Secretary of the Commission certifies these proposed regulatory changes meet the applicable standards of sections 3(a) and 3(b)(2) of Executive Order No. 12988 of February 7, 1996.

List of Subjects

35 CFR Part 133

Navigation, Panama Canal, Tolls, Vessels.

35 CFR Part 135

Measurement, Vessels.