

device's performance or safety specifications or intended uses.

(1) Has FDA appropriately defined the terms, "refurbisher," "as is" remarketers, and "servicers"? If not, what changes to these definitions should be made?

(2) What evidence exists regarding actual problems with the safety and/or performance of remarketed devices that are the result of the remarketing? Specific examples should be submitted.

(3) What is the appropriate level of regulatory controls that should be applied to persons who remarket devices?

(4) Should refurbishers, "as is" remarketers, and servicers be subject to the same or different regulatory requirements?

In addition, FDA is specifically considering whether to propose rulemaking regarding modified registration, listing, and CGMP requirements for these types of remarketers, or whether to make some or all of these three controls voluntary. For example, the agency could propose that refurbishers and/or servicers be required to register and list with FDA (part 807), and comply with certain CGMP requirements, such as quality system requirements (part 820, subpart B), production and process controls (part 820, subpart G), acceptance activities (part 820, subpart H), corrective and preventive action (part 820, subpart J), labeling and packaging control (part 820, subpart K), and records (part 820, subpart M). Alternatively, the agency could propose that refurbishers and/or servicers be required to register and list, but comply only with CGMP requirements for maintaining complaint files (§ 820.198(a)) and conducting failure analyses (§ 820.198(b) and (c)). In making comments relating to the regulatory approaches, comments should indicate whether their comments relate to refurbishers, "as is" remarketers, and/or servicers, as described in section IV of this document. Other regulatory approaches may be proposed by the agency or by the comments which, if implemented, would require the issuance of new guidance documents, or consist of changes to current regulations or changes to existing guidances CPG 7124.28 and CPG 7133.20.

VI. Comments

The agency will consider any comments submitted in response to this ANPR, or comments relating to the reevaluation of agency guidances, including CPG's 7124.28 and 7133.20. FDA will consider the record of any public meetings or any advisory

committee meetings, along with comments, proposals and other information received, when deciding whether to issue or revise agency guidance or modify any existing regulations.

Interested persons may, on or before March 23, 1998 submit to Dockets Management Branch (address above) written comments regarding this ANPR. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA does not anticipate granting requests for extension to this 90-day comment period.

Dated: December 3, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 52

[PS-158-86]

RIN 1545-AJ23

Petroleum Tax Imposed on Natural Gasoline

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Withdrawal of notice of proposed rulemaking.

SUMMARY: This document withdraws a proposed regulation relating to the petroleum tax imposed on natural gasoline. The withdrawal affects persons that produce natural gasoline at fractionation facilities or receive natural gasoline produced at those facilities.

FOR FURTHER INFORMATION CONTACT: Ruth Hoffman, (202) 622-3130 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 4611 imposed a tax on crude oil (including natural gasoline) received at a United States refinery. On April 26, 1993, a notice of proposed rulemaking (PS-158-86) relating to this tax was published in the **Federal Register** (58 FR 21963). The proposed regulation treats any facility that produces natural gasoline by fractionation or similar operation as a United States refinery. Under this rule, tax would be imposed

on natural gasoline when it is produced from natural gas liquids at a fractionation facility.

Since the publication of the proposed regulation, the tax imposed by section 4611 has expired. Because tax is not currently imposed under section 4611, the proposed regulation is being withdrawn. For purposes of section 4611 prior to its expiration, the IRS will follow the result in *Enron Gas Processing Co. v. United States*, 96-1 USTC ¶ 70,058 (S.D. Tex. 1996), in all cases involving substantially similar facts. In *Enron*, the U.S. District Court for the Southern District of Texas held that fractionation facilities are not United States refineries.

List of Subjects in 26 CFR Part 52

Chemicals, Excise taxes, Reporting and recordkeeping requirements.

Withdrawal of Notice of Proposed Rulemaking

Accordingly, under the authority of 26 U.S.C. 7805, the notice of proposed rulemaking that was published in the **Federal Register** on April 26, 1993 (58 FR 21963) is withdrawn.

Michael P. Dolan,

Deputy Commissioner of Internal Revenue.

[FR Doc. 97-33250 Filed 12-22-97; 8:45 am]

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 56, 57, 62, 70, and 71

RIN AA53

Health Standards for Occupational Noise Exposure in Coal, Metal and Nonmetal Mines

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Proposed rule; availability; request for comments.

SUMMARY: On December 16, 1997, MSHA published a notice in the **Federal Register** (62 FR 65777) announcing the availability of a report from the National Institute for Occupational Safety and Health (NIOSH) entitled "Prevalence of Hearing Loss For Noise-Exposed Metal/Nonmetal Miners." The Agency further stated its intent to supplement the rulemaking record with this report and to make it available to interested parties upon request.

MSHA received several requests from the mining community that they be provided an opportunity to comment on

the report. The Agency has determined that it is in the public interest to allow interested parties an opportunity to comment. MSHA is reopening the rulemaking record for limited comment on the report.

DATES: Submit written comments on the report on or before January 22, 1998.

ADDRESSES: Comments on the report may be transmitted by electronic mail, fax, or mail. Comments by electronic mail must be clearly identified as such and sent to: psilvey@msha.gov.

Comments by fax must be clearly identified as such and sent to: MSHA, Office of Standards, Regulations, and Variances, 703-235-5551. Send mail comments to: Mine Safety and Health Administration, Office of Standards, Regulations, and Variances, 4015 Wilson Boulevard, Room 631, Arlington, VA 22203-1984. Interested persons are encouraged to supplement written comments with computer files or disks.

FOR FURTHER INFORMATION CONTACT: Patricia W. Silvey, Director, MSHA, Office of Standards, Regulations, and Variances, 703-235-1910.

SUPPLEMENTARY INFORMATION: On December 17, 1996, MSHA published a proposed rule in the **Federal Register** (61 FR 66348) revising its health standards for occupational noise exposure in coal and metal and nonmetal mines.

To confirm the magnitude of the risks of NIHL among miners, MSHA examined evidence of reported hearing loss among miners from a variety of sources—audiometric data bases tracking hearing acuity among coal miners, individual commenter data, hearing loss data reported to MSHA, and workers' compensation data. MSHA also asked NIOSH to examine a body of audiometric data which tracked hearing acuity among coal miners and one which tracked hearing acuity among metal and nonmetal miners. NIOSH completed its analysis of the audiometric data on coal miners and issued a report to MSHA entitled "Analysis of Audiograms for a Large Cohort of Noise-Exposed Miners," (Franks, 1996) which is a part of the existing rulemaking record.

On December 16, 1997, MSHA published a notice in the **Federal Register** (62 FR 65777) announcing the availability of a report from the National Institute for Occupational Safety and Health (NIOSH) entitled "Prevalence of Hearing Loss For Noise-Exposed Metal/Nonmetal Miners." The Agency further stated its intent to supplement the rulemaking record with this report and

to make it available to interested parties upon request.

MSHA received several requests from the mining community that they be provided an opportunity to comment on the report. MSHA has evaluated these requests and believes that a 30 day comment period will provide sufficient time for all interested parties to review the report and comment. All interested members of the mining community are encouraged to submit comments prior to January 22, 1998.

Dated: December 17, 1997.

J. Davitt McAteer,

Assistant Secretary for Mine Safety and Health.

[FR Doc. 97-33447 Filed 12-22-97; 8:45 am]

BILLING CODE 4510-43-P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 913

[SPATS No. IL 089-FOR]

Illinois Regulatory Program Amendment

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; reopening and extension of public comment period on proposed amendment.

SUMMARY: OSM is announcing receipt of a request and additional explanatory information for its reconsideration of two regulations disapproved in a previously proposed amendment to the Illinois regulatory program (hereinafter referred to as the "Illinois program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The disapproved regulations concern the determination of revegetation success for non-contiguous surface disturbance areas less than or equal to four acres. The additional explanatory information is intended to clarify the regulations by specifying procedures and evaluation criteria that would be used in the implementation of the regulations.

DATES: Written comments must be received by 4:00 p.m., e.s.t., January 7, 1998.

ADDRESSES: Written comments should be mailed or hand delivered to Andrew R. Gilmore, Director, Indianapolis Field Office at the address listed below.

Copies of the Illinois program, the proposed amendment, the additional explanatory information, and all written comments received in response to this

document will be available for public review at the at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Indianapolis Field Office.

Andrew R. Gilmore, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, Indiana, 46204-1521, Telephone: (317) 226-6700. Illinois Department of Natural Resources, Office of Mines and Minerals, 524 South Second Street, Springfield, Illinois, 62701-1787, Telephone: (217) 782-4970.

FOR FURTHER INFORMATION CONTACT: Andrew R. Gilmore, Director, Indianapolis Field Office, Telephone: (317) 226-6700.

SUPPLEMENTARY INFORMATION:

- I. Background on the Illinois Program
- II. Discussion of the Proposed Amendment
- III. Public Comment Procedures
- IV. Procedural Determinations

I. Background on the Illinois Program

On June 1, 1982, the Secretary of the Interior conditionally approved the Illinois program. Background information on the Illinois program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the June 1, 1982, **Federal Register** (47 FR 23883). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 913.15, 913.16, and 913.17.

By letter dated February 3, 1995 (Administrative Record No. IL-1615), Illinois submitted a proposed amendment to its program pursuant to SMCRA. Illinois submitted the proposed amendment in response to an August 5, 1993, letter (Administrative Record No. IL-1400) that OSM sent to Illinois in accordance with 30 CFR 732.17(c), in response to required program amendments at 30 CFR 913.16 and at its own initiative. OSM announced receipt of the proposed amendment in the February 27, 1995, **Federal Register** (60 FR 19522), and invited public comment on its adequacy. The public comment period ended March 29, 1995. A public hearing was requested, and it was held on March 24, 1995, as scheduled. OSM identified concerns relating to the proposed amendment, and notified Illinois of these concerns by letters dated April 28 and August 3, 1995 (Administrative Record Nos. IL-1649 and IL-1660, respectively). By letter