Regulatory Fairness Act of 1996 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages distributive impacts and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of this device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any 1 year.

XII. Comments

Interested persons may, on or before March 16, 1998 submit to the Dockets Management Branch (address above) written comments regarding this proposal. 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.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 876 be amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

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

2. Section 876.3630 is revised to read as follows:

§ 876.3630 Penile rigidity implant.

(a) *Identification.* A penile rigidity implant is a device that consists of a pair of semi-rigid rods implanted in the corpora cavernosa of the penis to provide rigidity. It is intended to be used in men diagnosed as having erectile dysfunction. (b) *Classification.* Class II (special controls) (premarket notification guidance).

Dated: November 11, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–32809 Filed 12-15-97; 8:45 am]

BILLING CODE 4160–01–F

NATIONAL INDIAN GAMING COMMISSION

25 CFR Part 514

Annual Fees Payable By Indian Gaming Operations

AGENCY: National Indian Gaming Commission.

ACTION: Proposed rule.

SUMMARY: The National Indian Gaming Commission is proposing to amend its fee regulations to add class III gaming revenues to the assessable gross revenue base, increase the total amount of fees that can be imposed, and provide for an exemption for self-regulated tribes such as the Mississippi Band of Choctaw. This action is being taken pursuant to recent amendments to the Indian Gaming Regulatory Act. The primary effect of this action is to increase the funding for the National Indian Gaming Commission.

DATES: Comments must be submitted on or before January 15, 1998.

ADDRESSES: Comments may be mailed to: Fee Regulation Comments, National Indian Gaming Commission, 1441 L Street, N.W., Suite 9100, Washington, DC 20005, delivered to that address between 8:30 a.m. and 5:30 p.m., Monday through Friday, or faxed to 202/632–7066 (this is not a toll-free number). Comments received may be inspected between 9 a.m. and noon, and between 2 p.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: Fred W. Stuckwisch at 202/632–7003; fax 202/632–7066 (these are not toll-free numbers).

SUPPLEMENTARY INFORMATION: The Indian Gaming Regulatory Act (IGRA), enacted on October 17, 1988, established the National Indian Gaming Commission (Commission). The Commission is charged with, among other things, regulating gaming on Indian lands. Pursuant to recent amendments to the IGRA, these fee regulations are being amended to:

(1) Add class III gaming revenues to the assessable gross revenue base,

(2) Increase the total amount of fees that can be imposed, and

(3) Provide an exemption for self-regulated tribes such as the Mississippi Band of Choctaw.

As a result, gaming operations offering only class III games must begin reporting and paying fees, and gaming operations offering both class II and III games must begin reporting and paying fees on their class III revenues.

The Commission has adopted a 30 day comment period for this proposed rule because (1) the basic rule has been in effect for six (6) years, (2) comments were received and considered before the basic rule was adopted, and (3) it is important that the increased funding for the Commission as enacted by Congress be implemented as soon as possible.

The purpose of these regulations is to implement those portions of IGRA that provide for the payment of fees by gaming operations and for the collection and use of such fees by the Commission. Gaming operations are the economic entities that are licensed by a tribe, operate the games, receive the revenues, issue the prizes, and pay the expenses. Gaming operations may be operated by a tribe directly, by a management contractor, or in the case of certain grandfathered class II gaming operations, by an individual owner/operator.

These regulations provide for a system of fee assessment and payment that is self-administered by the gaming operations. Briefly, the Commission adopts and communicates the assessment rates; the gaming operations apply those rates to their revenues, compute the fees to be paid, and report and remit the fees to the Commission on a quarterly basis.

Annual fees are payable quarterly each calendar year based on the previous calendar year's class II and III assessable gross revenues from the gaming operations.

The Commission will adopt preliminary annual fee rate(s) during the first quarter of each calendar year and final annual fee rate(s) for that year during the fourth quarter. Separate rates may be established for assessable gross revenue amounts under $1,500,000 (1st tier) and amounts over $1,500,000 (2nd tier). The rates when adopted will be published in the **Federal Register**.

Under the proposed rule, self-regulated tribes such as the Mississippi Band of Choctaw will be exempt from the payment of fees pursuant to the fiscal year 1998 Interior Appropriations Act. The definitions of self-regulation and self-regulated and the requirements for obtaining a certificate of self-regulation and designation as self-regulated will be developed and added to the regulations in later rulemakings.

Gaming operations are to apply the rates adopted to their assessable gross revenues from the preceding calendar year to determine to amount of fees to be paid. The gaming operations are to report the amounts of assessable gross revenues, the fees to be paid, and their calculations to the Commission when they remit their quarterly payments. Remittances and reports are due no later than March 31, June 30, September 30, and December 31, of each calendar year.

Examples of computations are included in the regulations.

By passing the fees on the previous year's assessable gross revenues, sufficient time is provided to the gaming operations to finalize and submit adjusted numbers before the end of the third quarter of the calendar year. Furthermore, by providing for the adoption of preliminary and final rates by the Commission, it is intended that sufficient time be provided the Commission to ascertain the assessable gross revenue base before finalizing the rates for each calendar year.

These regulations are applicable to all gaming operations under the jurisdiction of the Commission. New gaming operations (with no gaming revenues generated in the previous calendar year) must file reports quarterly even though no fees will be due.

Penalties and interest may be assessed for failures to file quarterly statements and to pay fees when due, and required approvals may be withheld, denied or revoked for failures to pay fees, penalties and interest.

Regulatory Flexibility Act

This proposed rule will not have a significant economic impact on a substantial number of small business entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The additional entities becoming subject to these regulations as a result of the changes now being made are generally larger than those entities presently covered. Furthermore, the fees that will be paid by the entities presently covered will be less than the fees they are presently paying.

National Environmental Policy Act

The Commission has determined that this proposed rule does not constitute a major Federal action significantly affecting the quality of the human environment and that no detailed statement is required pursuant to the National Environmental Policy Act of 1969.

Tadd M. Johnson,

Chairman, National Indian Gaming Commission.

List of Subjects in 25 CFR Part 514

Gambling, Indians-lands, Reporting and recordkeeping requirements.

Accordingly, 25 CFR Part 514 is proposed to be amended as follows:

PART 514—FEES

1. The authority for Part 514 continues to read as follows:

Authority: 25 U.S.C. 2706, 2708, 2710, 2717, 2717a.

2. Section 514.1 is amended by revising paragraphs (a) introductory text, (a)(4), (b) introductory text, (b)(4), (c) introductory text, (c)(1), (c)(2), (c)(5) introductory text, (c)(8), (d) introductory text, and (g) and by adding paragraph (a)(6), to read as follows:

§ 514.1 Annual Fees.

(a) Each gaming operation under the jurisdiction of the Commission shall pay to the Commission annual fees as established by the Commission. The Commission, by a vote of not less than two of its members, shall adopt the rates of fees to be paid.

* * * * *

(4) The rates of fees imposed shall be—

(i) No more than 2.5 percent of the first $1,500,000 (1st tier), and

(ii) No more than 5 percent of amounts in excess of the first $1,500,000 (2nd tier) of the assessable gross revenues from each gaming operation regulated by the Commission.

* * * * *

(6) If a tribe is determined to be self-regulated pursuant to the provisions of 25 U.S.C. 2717(a)(2)(C), no fees shall be imposed.

(b) For purposes of computing fees, assessable gross revenues for each gaming operation are the annual total amount of money wagered on class II and III games, admission fees (including table or card fees), less any amounts paid out as prizes or paid for prizes awarded, and less an allowance for amortization of capital expenditures for structures.

* * * * *

(4) All class II and III revenues from gaming operations are to be included.

(c) Each gaming operation regulated by the Commission shall file with the Commission quarterly a statement showing its assessable gross revenues for the previous calendar year.

(1) These quarterly statements shall show the amounts derived from each type of game, the amounts deducted for prizes, and the amounts deducted for the amortization of structures;

(2) These quarterly statements shall be filed no later than March 31, June 30, September 30, and December 31, of each calendar year the gaming operation is subject to the jurisdiction of the Commission, beginning in September 1991. Any changes or adjustments to the previous year's assessable gross revenue amounts from one quarter to the next shall be explained.

* * * * *

(5) Each gaming operation shall determine the amount of fees to be paid and remit them with the statement required in paragraph (c) of this section. The fees payable shall be computed using—

* * * * *

(8) Quarterly statements, remittances and communications about fees shall be transmitted to the Commission at the following address: Office of Finance, National Indian Gaming Commission, 1441 L Street, N.W., Suite 9100, Washington, DC 20005. Checks should be made payable to the National Indian Gaming Commission (do not remit cash).

* * * * *

(d) The total amount of all fees imposed during any fiscal year shall not exceed $8,000,000. The Commission shall credit pro-rata any fees collected in excess of this amount against amounts otherwise due at the end of the quarter following the quarter during which the Commission makes such determination.

* * * * *

(g) The information collection requirements contained in paragraph (c) of this section have been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.* and assigned clearance number 3200–0011. The information is being collected to determine the assessable gross revenues of each gaming operation and the

aggregate assessable gross revenues of all gaming operations. The information will be used to set and adjust fee rates and to verify the computations of fees paid by each gaming operation. Response is mandatory.

[FR Doc. 97–32662 Filed 12–15–97; 8:45 am]
BILLING CODE 7565–01–M

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 of report.

SUMMARY: This notice announces 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 report, which MSHA received on October 15, 1997, is cumulative evidence concerning the risk to metal and nonmetal miners of noise induced hearing loss (NIHL). The report is relevant to the magnitude of the risk of NIHL among miners. The Agency, therefore, will supplement the rulemaking record with this report and make it available to interested parties upon request.

ADDRESSES: Copies of the report are available from the Office of Standards, Regulations, and Variances, 703–235–1910.

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. In this proposal, MSHA stated that current scientific evidence demonstrates that NIHL constitutes a serious hazard, that evidence exists of continuing harm to miners, and that MSHA standards no longer reflect experience and expert advice. The Agency concluded that regulatory action was necessary to address the continued excess risk of NIHL resulting from mining employment.

MSHA evaluated evidence related to the risk to miners from exposure to harmful levels of noise, and evidence on the level of that risk. MSHA determined that with respect to mine safety and health, any definition of material impairment of hearing should relate to a permanent, measurable loss of hearing which, unchecked, will limit the ability to understand speech, as it is spoken in everyday social (noisy) conditions. This is because speech comprehension is essential for mine safety.

The Agency reviewed the major studies on the level of risk at different noise exposures. The studies consistently indicated that the risk of developing a material impairment became significant over a working lifetime when workplace exposure exceeded average sound levels of 85 dBA. The data further indicated that while lowering exposure from an eight-hour time-weighted average (TWA_8) of 90 dBA to one of 85 dBA did not eliminate the risk, it did reduce the risk by approximately half. MSHA also reviewed a large body of data on the effects of varying industrial sound levels on worker hearing. These studies were supportive of the same conclusion. The Agency also focused on the harm that can occur at lower sound levels by reviewing studies of workers in other countries.

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.

NIOSH has now issued its report to MSHA which analyzes audiometric data on metal and nonmetal miners. This report is entitled ''Prevalence of Hearing Loss For Noise-Exposed Metal/Nonmetal Miners.'' The NIOSH analysis supports the conclusion from earlier scientific studies that miners are losing their hearing sensitivity faster than the general population. It indicates that 49% of the male population of metal and nonmetal miners have a hearing impairment by age 50 as compared with only 9% of the general population.

The report is available to interested members of the public and may be obtained upon request by electronic mail, fax, phone, or mail as follows: (1) Electronic mail: psilvey@msha.gov, (2) Fax: MSHA, Office of Standards, Regulations, and Variances, 703–235–5551, (3) Phone: Patricia W. Silvey, 703–235–1910, and (4) Mail: Mine Safety and Health Administration, Office of Standards, Regulations, and Variances, 4015 Wilson Boulevard, Room 631, Arlington, VA 22203–1984.

Dated: December 9, 1997.

J. Davitt McAteer,

Assistant Secretary for Mine Safety and Health.

[FR Doc. 97–32709 Filed 12–15–97; 8:45 am]
BILLING CODE 4510–43–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 253

[Docket No. 96–6 CARP NCBRA]

Noncommercial Educational Broadcasting Compulsory License

AGENCY: Copyright Office, Library of Congress.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: This document clarifies the dates for filing comments and Notices of Intent to Participate published in the **Federal Register** notice of December 1, 1997, announcing the proposed rulemaking for adjusting the royalty rates for the noncommercial educational broadcasting compulsory license.

FOR FURTHER INFORMATION CONTACT: Tanya M. Sandros, Attorney Advisor, Copyright Arbitration Royalty Panel (CARP), P.O. Box 70977, Southwest Station, Washington, D.C. 20024. Telephone (202) 707–8380. Telefax: (202) 707–8366.

SUPPLEMENTARY INFORMATION: The notice of proposed rulemaking concerning the adjustment of royalty rates for compulsory license governing the use of certain copyrighted works in connection with noncommercial broadcasting contains two dates for filing comments and Notices of Intent to Participate. The correct date, December 29, 1997, is announced in the date caption. The second date, December 31, 1997, stated in the section entitled, Comments and Notices of Intent to Participate, page 63504, second column, first paragraph,