

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification requirements in part 807, subpart E of this chapter if it is sold, distributed, and used in accordance with the restrictions set forth in § 809.40 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.198, with respect to complaint files.

Dated: September 25, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 98-5521 Filed 3-3-98; 8:45 am]

BILLING CODE 4160-01-F

NATIONAL INDIAN GAMING COMMISSION

25 CFR Chapter III

Minimum Internal Control Standards for Gaming Operations for Indian Lands

AGENCY: National Indian Gaming Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This document announces the initiation of the rulemaking process and requests information relevant to implementing regulations governing minimum internal control standards for gaming operations operated on Indian lands. The Commission has determined that minimum internal control standards are needed to ensure the integrity of gaming on Indian lands and to safeguard this source of tribal revenues.

DATES: Comments in response to this advance notice must be submitted by April 5, 1998. The Commission will be holding a hearing on this matter on April 1, 1998, in Portland, Oregon.

ADDRESSES: Commentors may submit their comment by mail, facsimile, or delivery to: Minimum Internal Control Rule Comments, National Indian Gaming Commission, Suite 9100, 1441 L Street N.W., Washington, DC 20005. Fax number: 202-632-7066 (not a toll-free number). Public comments may be delivered or inspected from 9 a.m. until noon and from 2 p.m. to 5 p.m. Monday through Friday.

The public hearing will be held at the Doubletree Hotel at Lloyd Center, Portland, Oregon.

FOR FURTHER INFORMATION CONTACT: Mia Dinh at 202-632-7003, or by facsimile at 202-632-7066 (not toll-free numbers.)

SUPPLEMENTARY INFORMATION:

1. Introduction

The Indian Gaming Regulatory Act (IGRA, or the Act), 25 U.S.C. 2701 *et seq.*, was signed into law on October 17, 1988. The Act established the National Indian Gaming Commission (the Commission). The IGRA was enacted for several purposes, primary among them was to provide a statutory basis for the operation of gaming by Indian tribes as a means of promoting economic development self-sufficiency and strong tribal governments, as well as to provide for the regulation of gaming by Indian tribes adequate to shield them from organized crime. The Commission has determined that minimum internal control standards are needed to ensure the integrity of gaming on Indian lands and to safeguard this source of tribal revenues.

The IGRA expressly authorizes the Commission to "promulgate such regulations and guidelines as it deems appropriate to implement the provision of this [Act]." 25 U.S.C. 2706(b)(10).

2. Advance Notice of Proposed Rulemaking

After consideration of this issue, the NIGC has determined that the appropriate course of action is to publish an Advance Notice of Proposed Rulemaking to collect further information.

Before the NIGC proceeds in this area, it intends to have the benefit of a full airing of the issues through the public comment process.

3. Request for Comments

Public comment is requested to assist the NIGC in the drafting of minimum internal control regulations. Comment is requested on the following issues:

(a) Should standards be tiered based on the physical size of the operation, the amount of the gross revenues derived from gaming, or some other criteria? Please explain.

(b) If yes, what tiers should be adopted. Please explain.

(c) What standards should apply to all operations and what standards should apply to only one or two tiers and not the others?

(d) What are the major internal control issues/problems that Indian gaming operations face?

(e) How long should the Commission allow the tribes to implement internal controls that would comply with the regulations?

The Commission solicits any additional suggestions and/or interpretations regarding the issues raised in this Advance Notice of Proposed Rulemaking.

4. Public Participation

Interested parties are invited to submit comments on any or all of these and other pertinent issues related to minimum internal control regulations by April 5, 1998, in triplicate to Minimum Internal Control Rule Comments, National Indian Gaming Commission, Suite 9100, 1441 L Street N.W., Washington, DC 20005. Fax number: 202-632-7066 (not a toll-free number). All written comments submitted in response to this notice will be available for inspection and copying in the NIGC office from 9 a.m. until noon and from 2 p.m. to 5 p.m. Monday through Friday. All timely written submissions will be considered in determining the nature of any proposal.

Authority and Signature

This Advance Notice of Proposed Rulemaking was prepared under the direction of Larry Rosenthal, Chief of Staff, National Indian Gaming Commission, 1441 L St. N.W., Suite 9100, Washington, DC 20005.

Signed at Washington, D.C. this 27th day of February, 1998.

Larry Rosenthal,

Chief of Staff, National Indian Gaming Commission.

[FR Doc. 98-5656 Filed 3-4-98; 8:45 am]

BILLING CODE 7565-01-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG-209276-87]

RIN 1545-AV32

Abatement of Interest; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains a correction to REG-209276-87, which was published in the **Federal Register** on Thursday, January 8, 1998 (63 FR 1086), relating to the abatement of interest attributable to unreasonable errors or delays by an officer or employee of the IRS.

FOR FURTHER INFORMATION CONTACT: David Auclair, (202) 622-4910 (not a toll-free number).

SUPPLEMENTARY INFORMATION:**Background**

The notice of proposed rulemaking that is the subject of this correction is under section 6404 of the Internal Revenue Code.

Need for Correction

As published, REG-209276-87 contains an error which may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication of the notice of proposed rulemaking (REG-209276-87), which is the subject of FR Doc. 98-19, is corrected as follows:

On page 1087, column 3, in the preamble under the paragraph reading "Explanation of Provisions", the first full paragraph in the column is corrected to read:

The provisions of the regulations are proposed to apply to interest accruing with respect to deficiencies or payments of any tax described in section 6212(a) for taxable years beginning after July 30, 1996.

Cynthia E. Grigsby,

Chief, Regulations Unit, Assistant Chief Counsel (Corporate).

[FR Doc. 98-5641 Filed 3-4-98; 8:45 am]

BILLING CODE 4830-01-P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 131**

[FRL-OW-5974-3]

RIN 2040-AC65

Water Quality Standards for Alabama

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA is proposing water quality standards that would be applicable to certain waters of the United States in the State of Alabama. If promulgated as final standards, they will supersede use designations for nine stream segments that EPA disapproved in 1986 and 1991 and which have not been revised by the State. EPA is taking this action because it believes these disapproved State water quality standards are inconsistent with the Clean Water Act and EPA's implementing regulations. Specifically, EPA is proposing new use designations for waters of the State whose current use designations under State law do not meet applicable requirements of the Clean Water Act.

DATES: EPA will accept public comments on this rulemaking until May 4, 1998. Comments postmarked after this date may not be considered. A public hearing will be held in Montgomery, Alabama, on April 22, 1998. Both oral and written comments will be accepted at the hearing.

ADDRESSES: An original plus 2 copies, and if possible an electronic version of comments either in WordPerfect or ASCII format, should be addressed to Fritz Wagener, Water Quality Standards Coordinator, U.S. EPA Region 4, Water Management Division, Atlanta Federal Center, 61 Forsyth Street S.W., Atlanta, Georgia, 30303-3104. A public hearing will be held at the Holiday Inn Hotel and Suites, 120 Madison Avenue, Montgomery, Alabama, 36104 (334-264-2231) from 1-5 p.m. and 6-10 p.m. on April 22, 1998. The administrative record for today's proposed rule is available for public inspection at U.S. EPA Region 4, Water Management Division, 15th Floor, Atlanta Federal Center, 61 Forsyth Street S.W., Atlanta, Georgia, 30303-3104, between 8:00 a.m. to 4:30 p.m. Copies of all or portions of the record will be made available for a charge of 20¢ per page.

FOR FURTHER INFORMATION CONTACT: Fritz Wagener, Water Quality Standards Coordinator, U.S. EPA Region 4, Water Management Division, Atlanta Federal Center, 61 Forsyth Street S.W., Atlanta, Georgia, 30303-3104 (telephone: 404-562-9267).

SUPPLEMENTARY INFORMATION: This Supplementary Information Section is organized as follows:

- I. Potentially Affected Entities
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 - A. Statutory and Regulatory Background
 - B. Rebuttable Presumption of Section 101(a) Uses
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 - A. Overview
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 - C. Request for Comment and Data
- IV. Alternative Regulatory Approaches and Implementation Mechanisms
 - A. Designating Uses
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 - C. Variances
 - D. Total Maximum Daily Loads (TMDLs)
 - V. Regulatory Impact Analysis

- A. Evaluation of Possible Pollutant Reduction Responsibilities
- B. Overview of Methodology to Estimate Potential Costs Related to New Use Designations
- C. Results for Stream Segments with Federal Use Designations
- VI. Executive Order 12866
- VII. Regulatory Flexibility Act as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996
- VIII. Unfunded Mandates Reform Act
- IX. Paperwork Reduction Act
- X. Executive Order 12875
- XI. Endangered Species Act
- XII. National Technology Transfer and Advancement Act

I. Potentially Affected Entities

Citizens concerned with water quality in Alabama may be interested in this rulemaking. Entities discharging pollutants to certain waters of the United States in Alabama could be indirectly affected by this rulemaking since water quality standards are used in determining National Pollutant Discharge Elimination System (NPDES) permit limits. Potentially affected entities include:

Category	Examples of affected potentially entities
Industry	Industries discharging pollutants to Alabama surface waters listed in section 131.34 of this proposed rule.
Municipalities.	Publicly-owned treatment works discharging pollutants to Alabama surface waters listed in section 131.34 of this proposed rule.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding NPDES regulated entities likely to be affected by this action. This table lists the types of entities that EPA is now aware could potentially be affected by this action. Other types of entities not listed in the table could also be regulated. To determine whether your facility, company or business may be affected by this proposed action, you should carefully examine the list of waters identified in § 131.34 of today's proposed rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the proceeding "For Further Information Contact" Section.

II. Background**A. Statutory and Regulatory Background**

Section 303 (33 U.S.C. 1313) of the Clean Water Act (CWA or "the Act") directs States, with oversight by EPA, to adopt water quality standards to protect the public health and welfare, enhance