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Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

#### List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend 21 CFR part 880 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. Part 880 is amended in subpart G by adding § 880.6310 to read as follows:

##### § 880.6310 Medical Device Data System.

(a) *Identification.* (1) A medical device data system (MDDS) is a device intended to provide one or more of the following uses:

(i) The electronic transfer or exchange of medical device data from a medical device, without altering the function or parameters of any connected devices.

(ii) The electronic storage and retrieval of medical device data from a medical device, without altering the function or parameters of connected devices.

(iii) The electronic display of medical device data from a medical device, without altering the function or parameters of connected devices.

(iv) The electronic conversion of medical device data from one format to another format in accordance with a preset specification.

(2) Medical device data consists of numerical or other information available from a medical device in a form suitable for processing by computer. Medical device data can represent any type of information or knowledge, e.g., clinical values, alarm conditions, error messages. This identification does not include a device that creates diagnostic, decision support, or alarm functions. It also does not include the report-writing functions of a data system that allows for the manual input of data by practitioners. This identification does not include devices with any real time, active, or online patient monitoring.

(b) *Classification.* Class I (general controls). When the device is indicated for use only by a healthcare professional

and does not perform irreversible data compression, it is exempt from the premarket notification procedures in subpart E of part 807, subject to the limitations in § 880.9. When the device is indicated to be prescribed by a healthcare professional for use by a lay user, or performs irreversible data compression, or for over-the-counter use by a lay user, the device requires the submission and clearance of a premarket notification.

Dated: January 25, 2008.

**Daniel G. Schultz,**

*Director, Center for Devices and Radiological Health.*

[FR Doc. E8-2325 Filed 2-7-08; 8:45 am]

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#### DEPARTMENT OF THE TREASURY

##### Internal Revenue Service

##### 26 CFR Part 1

[REG-153589-06]

RIN 1545-BG34

##### Time and Manner for Electing Capital Asset Treatment for Certain Self-Created Musical Works

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking by cross-reference to temporary regulation.

**SUMMARY:** In the Rules and Regulations section of this issue of the **Federal Register**, the IRS is issuing a temporary regulation that provides the time and manner for making an election to treat the sale or exchange of musical compositions or copyrights in musical works created by the taxpayer (or received by the taxpayer from the works' creator in a transferred basis transaction) as the sale or exchange of a capital asset. The temporary regulation reflects changes to the law made by the Tax Increase Prevention and Reconciliation Act of 2005 and the Tax Relief and Health Care Act of 2006. The temporary regulation affects taxpayers making the election under section 1221(b)(3) of the Internal Revenue Code (Code) to treat gain or loss from such a sale or exchange as capital gain or loss. The text of the temporary regulation also serves as the text of this proposed regulation.

**DATES:** Written or electronic comments and requests for a public hearing must be received by May 8, 2008.

**ADDRESSES:** Send submissions to: CC:PA:LPD:PR (REG-153589-06), room

5203, Internal Revenue Service, PO Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG-153589-06), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at [www.regulations.gov](http://www.regulations.gov) (IRS REG-153589-06).

#### FOR FURTHER INFORMATION CONTACT:

Concerning the proposed regulation, Jamie Kim, (202) 622-4950; concerning submission of comments or requesting a hearing, *Richard.A.Hurst@irs.counsel.treas.gov*, (202) 622-7180 (not toll-free numbers).

#### SUPPLEMENTARY INFORMATION:

##### Background and Explanation of Provisions

Temporary regulation in the Rules and Regulations section of this issue of the **Federal Register** amends the Income Tax Regulations (26 CFR part 1) relating to section 1221(b)(3) of the Internal Revenue Code (Code). The temporary regulation provides rules regarding the time and manner for making an election under section 1221(b)(3) to treat the sale or exchange of certain musical compositions or copyrights in musical works as the sale or exchange of a capital asset. The text of the temporary regulation also serves as the text of this proposed regulation. The preamble to the temporary regulation explains the amendments.

##### Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this regulation, and because the regulation does not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Internal Revenue Code, this regulation has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

##### Comments and Requests for a Public Hearing

Before this proposed regulation is adopted as a final regulation, consideration will be given to any

written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department request comments on the clarity of the proposed rules and how they can be made easier to understand. All comments will be available for public inspection and copying. A public hearing will be scheduled if requested in writing by any person that timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

#### Drafting Information

The principal author of these regulations is Jamie Kim of the Office of Associate Chief Counsel (Income Tax & Accounting). However, other personnel from the IRS and Treasury Department participated in their development.

#### List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

#### Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

#### PART 1—INCOME TAXES

**Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

**Authority:** 26 U.S.C. 7805 \* \* \*.

**Par. 2.** Section 1.1221-3 is added to read as follows:

#### § 1.1221-3 Time and manner for electing capital asset treatment for certain self-created musical works.

[The text of proposed § 1.1221-3 is the same as the text of § 1.1221-3T(a) through (d)(1) published elsewhere in this issue of the **Federal Register**.]

**Linda E. Stiff,**

*Deputy Commissioner for Services and Enforcement.*

[FR Doc. E8-2307 Filed 2-7-08; 8:45 am]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA-R01-OAR-2007-1054; A-1-FRL-8524-8]

#### Approval and Promulgation of Air Quality Implementation Plans; Maine; Transportation Conformity

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The EPA is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Maine. This revision establishes transportation conformity criteria and procedures related to interagency consultation and enforceability of certain transportation-related control measures and mitigation measures. The intended effect of this action is to approve State criteria and procedures to govern transportation conformity determinations. This action is being taken in accordance with the Clean Air Act.

**DATES:** Written comments must be received on or before March 10, 2008.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R01-OAR-2007-1054 by one of the following methods:

1. *http://www.regulations.gov*: Follow the on-line instructions for submitting comments.

2. *E-mail*: [arnold.anne@epa.gov](mailto:arnold.anne@epa.gov).

3. *Fax*: (617) 918-0047.

4. *Mail*: "EPA-R01-OAR-2007-1054", Anne Arnold, U.S. Environmental Protection Agency, EPA New England Regional Office, One Congress Street, Suite 1100 (mail code CAQ), Boston, MA 02114-2023.

5. *Hand Delivery or Courier*. Deliver your comments to: Anne Arnold, Manager, Air Quality Planning Unit, Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, One Congress Street, 11th floor, (CAQ), Boston, MA 02114-2023. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding legal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

#### FOR FURTHER INFORMATION CONTACT:

Donald O. Cooke, Air Quality Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, One Congress Street, Suite 1100 (CAQ), Boston, MA 02114-2023, telephone number (617) 918-1668, fax number (617) 918-0668, e-mail [cooke.donald@epa.gov](mailto:cooke.donald@epa.gov).

**SUPPLEMENTARY INFORMATION:** In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial

submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this action rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: January 24, 2008.

**Ira W. Leighton,**

*Acting Regional Administrator, EPA New England.*

[FR Doc. E8-2248 Filed 2-7-08; 8:45 am]

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Parts 52 and 70

[EPA-R07-OAR-2007-0829; FRL-8526-1]

#### Approval and Promulgation of Implementation Plans and Operating Permits Program; State of Kansas

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve a revision to the Kansas State Implementation Plan (SIP) for the purpose of revoking the Sulfur Compound Emissions rule and for the purpose of approving revisions to a Class I major source operating permit annual emissions inventory rule and several Class II minor source operating permits rules. EPA is also proposing to approve additional amendments adopted by KDHE on February 20, 1998 which pertain to the Class II operating permit rules. The rules were primarily revised to align the annual emission inventory reporting date deadline with the June 1 payment of applicable emissions fees. EPA's proposed approval of these amendments would ensure consistency between the state and the Federally-approved rules.