

of Food and Drugs, it is proposed that 21 CFR part 872 be amended as follows:

PART 872—DENTAL DEVICES

■ 1. The authority citation for 21 CFR part 872 continues to read as follows:

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

■ 2. Section 872.3960 is amended by revising paragraph (c) to read as follows:

§ 872.3960 Mandibular condyle prosthesis.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or a notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before March 30, 1999, for any mandibular condyle prosthesis that was in commercial distribution before May 28, 1976, or that has, on or before March 30, 1999, been found to be substantially equivalent to a mandibular condyle prosthesis that was in commercial distribution before May 28, 1976. Any other mandibular condyle prosthesis shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

■ 3. Section 872.4770 is added to subpart E to read as follows:

§ 872.4770 Temporary mandibular condyle reconstruction plate.

(a) *Identification.* A temporary mandibular condyle reconstruction plate is a device that is intended to stabilize mandibular bone and provide for temporary reconstruction of the mandibular condyle until permanent reconstruction is completed in patients who have undergone resective surgical procedures requiring removal of the mandibular condyle and mandibular bone. This device is not intended for treatment of temporomandibular joint disorders.

(b) *Classification.* Class II (special controls). The special controls is FDA's guideline, "Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate." See § 872.1(e) for the availability of this guidance document.

Dated: February 1, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 226

Osage Negotiated Rulemaking Committee

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Meetings.

SUMMARY: In accordance with the requirements of the Federal Advisory Committee Act, the U.S. Department of the Interior, Bureau of Indian Affairs, Osage Negotiated Rulemaking Committee, will meet as indicated in the **DATES** section of this document.

DATES: *Meetings:* The meetings will be held as follows: *February:* Monday, February 25, 2013, from 8 a.m. to 3:30 p.m.; Tuesday, February 26, 2013, from 8 a.m. to 6 p.m.; and Wednesday, February 27, 2013, from 8 a.m. to 6 p.m. *March:* Wednesday, March 13, 2013, from 8 a.m. to 6 p.m. and Thursday, March 14, 2013, from 8 a.m. to 6 p.m.

ADDRESSES: *February Meeting:* Wah Zha Zhi Cultural Center, 1449 W. Main, Pawhuska, Oklahoma 74056; *March Meeting:* Osage Casino Event Center, 951 W. 36 Street North, Tulsa, Oklahoma 74127.

FOR FURTHER INFORMATION CONTACT: Mr. Eddie Streater, Designated Federal Officer, Bureau of Indian Affairs, Wewoka Agency, P.O. Box 1540, Seminole, OK 74818; telephone (405) 257-6250; fax (405) 257-3875; or email osageregneg@bia.gov. Additional Committee information can be found at: <http://www.bia.gov/osageregneg>.

SUPPLEMENTARY INFORMATION: On October 14, 2011, the United States and the Osage Nation (formerly known as the Osage Tribe) signed a Settlement Agreement to resolve litigation regarding alleged mismanagement of the Osage Nation's oil and gas mineral estate, among other claims. As part of the Settlement Agreement, the parties agreed that it would be mutually beneficial "to address means of improving the trust management of the Osage Mineral Estate, the Osage Tribal Trust Account, and Other Osage Accounts." Settlement Agreement, Paragraph 1.i. The parties agreed that a review and revision of the existing regulations is warranted to better assist the Bureau of Indian Affairs (BIA) in managing the Osage Mineral Estate. The parties agreed to engage in a negotiated rulemaking for this purpose. Settlement Agreement, Paragraph 9.b. After the Committee submits its report, BIA will

develop a proposed rule to be published in the **Federal Register**.

Meeting Agenda: February: Present and review specific proposed changes to or additions to 25 CFR part 226 in the following categories: General/Definitions, Rents, Royalties & Reporting, Operations, Surface Issues, Bonds, Penalties & Enforcement. *March:* Follow-up discussions and committee decisions on specific proposed changes to or additions to 25 CFR part 226 in the following categories: General/Definitions, Rents, Royalties & Reporting, Operations, Surface issues, Bonds, Penalties & Enforcement. The final agenda will be posted on www.bia.gov/osageregneg prior to each meeting.

Public Input: All Committee meetings are open to the public. Interested members of the public may present, either orally or through written comments, information for the Committee to consider during the public meeting. Written comments should be submitted, prior to, during, or after the meeting, to Mr. Eddie Streater, Designated Federal Officer, preferably via email, at osageregneg@bia.gov, or by U.S. mail to: Mr. Eddie Streater, Designated Federal Officer, Bureau of Indian Affairs, Wewoka Agency, P.O. Box 1540, Seminole, OK 74818. Due to time constraints during the meeting, the Committee is not able to read written public comments submitted into the record.

Individuals or groups requesting to make oral comments at the public Committee meeting will be limited to 5 minutes per speaker. Speakers who wish to expand their oral statements, or those who had wished to speak, but could not be accommodated during the public comment period, are encouraged to submit their comments in written form to the Committee after the meeting at the address provided above. There will be a sign-up sheet at the meeting for those wishing to speak during the public comment period.

The meeting location is open to the public. Space is limited, however, so we strongly encourage all interested in attending to preregister by submitting your name and contact information via email to Mr. Eddie Streater at osageregneg@bia.gov. Persons with disabilities requiring special services, such as an interpreter for the hearing impaired, should contact Mr. Streater at (405) 257-6250 at least seven calendar days prior to the meeting. We will do our best to accommodate those who are unable to meet this deadline.

Dated: February 4, 2013.

Michael S. Black,

Director, Bureau of Indian Affairs.

[FR Doc. 2013-02871 Filed 2-6-13; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R01-OAR-2012-0951; FRL- 9778-6]

Approval and Promulgation of Air Quality Implementation Plans; Massachusetts; Revisions to Fossil Fuel Utilization and Source Registration Regulations and Boiler Industrial Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing to approve several State Implementation Plan (SIP) revisions submitted by the State of Massachusetts. The revisions add new monitoring, inspection, maintenance and testing requirements for certain fossil fuel utilization facilities, rename and clarify stationary source emission reporting requirements, and establish compliance and certification standards for new boilers. The intended effect of this action is to propose approval of the state's revised fossil fuel utilization facility regulation, source registration regulation, and new industrial performance standards for boilers. This action is being taken under the Clean Air Act.

DATES: Written comments must be received on or before March 11, 2013.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R01-OAR-2012-0951 by one of the following methods:

1. *www.regulations.gov*: Follow the on-line instructions for submitting comments.
2. *Email*: mcdonnell.ida@epa.gov.
3. *Fax*: (617) 918-0653.
4. *Mail*: "Docket Identification Number EPA-R01-OAR-2012-0951", Ida E. McDonnell, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Permits, Toxics and Indoor Programs Unit, 5 Post Office Square—Suite 100, (Mail Code OEP05-2), Boston, MA 02109-3912.
5. *Hand Delivery or Courier*. Deliver your comments to: Ida E. McDonnell, Manager, Air Permits, Toxics, and Indoor Programs Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of

Ecosystem Protection, Air Permits, Toxics and Indoor Programs Unit, 5 Post Office Square—Suite 100, (mail code OEP05-2), Boston, MA 02109-3912. 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.

Instructions: Direct your comments to Docket ID No. EPA-R01-OAR-2012-0951. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through www.regulations.gov, or email, information that you consider to be CBI or otherwise protected. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through www.regulations.gov your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Permits, Toxics and

Indoor Programs, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 to 4:30, excluding legal holidays.

In addition, copies of the state submittal and EPA's technical support document are also available for public inspection during normal business hours, by appointment at the Division of Air Quality Control, Department of Environmental Protection, One Winter Street, 7th Floor, Boston, MA 02108.

FOR FURTHER INFORMATION CONTACT: Brendan McCahill, Air Permits, Toxics and Indoor Programs Unit, Office of Ecosystem Protection, U.S. Environmental Protection Agency Region 1, 5 Post Office Square—Suite 100, (Mail code OEP05-2), Boston, MA 02109-3912, Telephone number (617) 918-1652, Fax number (617) 918-0652, Email McCahill.Brendan@EPA.GOV.

SUPPLEMENTARY INFORMATION: Throughout this document whenever "we," "us," or "our" is used, we mean EPA.

Organization of this document. The following outline is provided to aid in locating information in this preamble.

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 - B. 310 CMR 7.12: U Source Registration
 - C. 310 CMR 7.26(30)–(37) Industrial Performance Standard—U Boilers
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I. What action is EPA proposing in this document?

On June 28, 1990 and July 11, 2001, the Massachusetts Department of Environmental Protection (MassDEP) submitted SIP amendments revising 310 CMR 7.04 "U Fossil Fuel Utilization Facilities." On July 11, 2001, the MassDEP submitted a SIP amendment revising 310 Code of Massachusetts Regulations (CMR) 7.12, "U Source Registration." On September 14, 2006, the MassDEP submitted a SIP amendment adopting 310 CMR 7.26(30)–(37), "Industrial Performance Standard—U Boilers." On February 13, 2008, the MassDEP submitted an additional amendment to revise 310 CMR 7.04 "U Fossil Fuel Utilization