$100 million or more on either the private sector or State, local, or tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

**V. Federalism**

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

**VI. Paperwork Reduction Act of 1995**

FDA concludes that this final rule does not contain information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

**List of Subjects in 21 CFR Part 888**

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 888 be amended as follows:

## PART 888—ORTHOPEDIC DEVICES

1. The authority citation for 21 CFR part 888 continues to read as follows:

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

2. Section 888.3310 is revised to read as follows:

**§ 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.**

(a) *Identification.* A hip joint metal/polymer constrained cemented or uncemented prosthesis is a device intended to be implanted to replace a hip joint. The device prevents dislocation in more than one anatomic plane and has components that are linked together. This generic type of device includes prostheses that have a femoral component made of alloys, such as cobalt-chromium-molybdenum, and an acetabular component made of ultra-high-molecular-weight polyethylene with or without a metal shell, made of alloys, such as cobalt-chromium-molybdenum and titanium alloys. This generic type of device is intended for use with or without bone cement (§ 888.3027).

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance: Hip Joint Metal/Polymer Constrained Cemented or Uncemented Prosthesis.''

Dated: April 15, 2002.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 02–10509 Filed 4–29–02; 8:45 am]

BILLING CODE 4160–01–S

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## DEPARTMENT OF THE INTERIOR

## Office of Surface Mining Reclamation and Enforcement

## 30 CFR Part 917

**[KY–225–FOR]**

## Kentucky Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Final rule; approval of amendment.

**SUMMARY:** We, the Office of Surface Mining Reclamation and Enforcement (OSM), are approving an amendment to the Kentucky regulatory program (the ''Kentucky program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Kentucky is proposing revisions to the Kentucky Revised Statute (KRS) 350.085(6) to reaffirm, with some modifications, the circumstances under which the regulatory authority may not issue a permit, based upon ownership and control of an operation with an unabated violation. This rule addresses the permit block provisions. The remaining provision will be addressed in a future rulemaking (KY–234–FOR).

**EFFECTIVE DATE:** April 30, 2002.

**FOR FURTHER INFORMATION CONTACT:** William J. Kovacic, Field Office Director; Telephone: (859) 260–8400; E-mail: *bkovacic@osmre.gov*.

**SUPPLEMENTARY INFORMATION:**

I. Background on the Kentucky Program
II. Submission of the Proposed Amendment
III. OSM's Findings
IV. Summary and Disposition of Comments
V. OSM's Decision
VI. Procedural Determinations

**I. Background on the Kentucky Program**

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, ''a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act ***; and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Kentucky program on May 18, 1982. You can find background information on the Kentucky program, including the Secretary's findings, the disposition of comments, and conditions of approval in the May 18, 1982 **Federal Register** (47 FR 21404). You can also find later actions concerning Kentucky's program and program amendments at 30 CFR 917.11, 917.12, 917.13, 917.15, 917.16, and 917.17.

**II. Submission of the Proposed Amendment**

By letter dated May 9, 2000 (administrative record no. KY–1473), Kentucky sent us an amendment to its approved SMCRA regulatory program. The amendment, which includes only changes that the Commonwealth is making on its own initiative, concerns permit blocking, easements of necessity, and revisions to KRS 350.445(3) to address roads above highwalls.

In this rulemaking, we are addressing only the permit block provisions. We announced our decision on the easement of necessity provision in a rule published on June 20, 2001 (66 FR 33020). The provision concerning roads above highwalls will be addressed in a future rulemaking.

We announced receipt of the proposed amendment in the May 31, 2000, **Federal Register** (65 FR 34625). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the amendment's adequacy. We did not hold a public hearing or meeting because no one requested one. The public comment period ended on June 30, 2000. We received several comments from industry groups addressing various parts of the amendment, but only one commenter representing an environmental council addressed the ownership and control provisions.

**III. OSM's Findings**

As discussed below, we find that the amendment is approvable under the criteria in 30 CFR 732.15 and 732.17, with the proviso that the Commonwealth needs to make certain additional changes in a future rulemaking. Any amendment provisions that we do not specifically discuss below concern nonsubstantive wording or editorial changes.

*Revisions to Kentucky's Statutes That Are Not the Same As the Corresponding Provisions of the Federal Regulations*

*House Bill 502.* Part IX, Item 36(b), provides that the permit block provisions of KRS 350.085(6) apply to either the applicant or any person who owns or controls the applicant who is currently in violation. It requires the Kentucky Natural Resources and Environment Protection Cabinet (cabinet) to continue in effect the current administrative regulations on ownership and control, provided that a due process hearing is afforded at the time the cabinet makes a preliminary determination to impose a permit block. It also requires the cabinet to conditionally issue a permit, permit renewal, or authorization to conduct surface coal mining and reclamation operations if it finds that a direct administrative or judicial appeal is presently being pursued in good faith to contest the validity of the determination of ownership and control linkage. The cabinet must conditionally issue permits if the applicant submits proof, including a settlement agreement, that the violation is being abated to the satisfaction of the issuing State or Federal agency. If the initial judicial appeal affirms the ownership and control linkage, the applicant has 30 days to submit proof that the violation has been or is in the process of being corrected. Finally, it provides that nothing within this new provision shall preclude the applicant from seeking further judicial relief.

The first sentence in Item 36(b)states that ''the permit block provisions of KRS 350.085(6) apply to either the applicant or any person who owns or controls the applicant who is currently in violation.'' In *National Mining Ass'n.* v. *U.S. Dep't. of Interior*, 105 F.3d 691, 693 (D.C. Cir. 1997), the United States Court of Appeals for the District of Columbia Circuit struck down the Federal ownership and control regulations that required ''upstream'' blocking of applicants because of violations incurred by the applicant's owners or controllers. However, section 505(b) of SMCRA allows States to enact laws or regulations that provide for ''more stringent land use and environmental controls and regulations of surface coal mining and reclamation operations'' than are provided for in SMCRA or the implementing Federal regulations. Therefore, to the extent that the Kentucky provision may be read as authorizing upstream permit blocking, it is not inconsistent with SMCRA. For this reason, we are approving the first sentence of Item 36(b) in Part IX of H.B. 502 as submitted by Kentucky.

Because we previously approved Kentucky's current ownership and control regulations, we also are approving the first portion of the second sentence of Item 36(b), which requires the cabinet to ''continue in effect the current administrative regulations on ownership and control.'' However, as discussed in Part VIII of the preamble to the rule that we published on December 19, 2000 (see 65 FR 79658), at some point in the future, we will evaluate Kentucky's regulations to determine whether any changes are needed for those regulations to remain no less effective than the Federal regulations as revised on December 19, 2000. If we determine that program amendments are necessary, we will notify Kentucky in accordance with 30 CFR 732.17(d).

H.B. 502 conditions the continuation of the current regulations on provision of an opportunity for a due process hearing at the time that the cabinet makes a preliminary determination to impose a permit block. As published on December 19, 2000, the Federal regulations provide that ''[a]ny person who receives a written decision [on a challenge a finding of ownership or control] ***, and who wishes to appeal that decision, must exhaust administrative remedies under the procedures at 43 CFR. 4.1380 through 4.1387 or, when a state is the regulatory authority, the State regulatory authority counterparts, before seeking judicial review.'' 30 CFR 773.28(e);65 FR 79582, 79666, December 19, 2000. Included in a right to appeal is a right to a due process hearing. However, the appeal must be taken from a final, rather than a preliminary decision.

H.B. 502 allows for an additional, earlier due process hearing after a preliminary determination to impose a permit block. This ''pre-deprivation'' hearing is presumably desired because the Kentucky program does not allow for the issuance of a provisional or conditional permit while a preliminary permit block determination is being challenged internally, i.e., prior to any administrative review of a final decision by the regulatory authority. The new Federal ''ownership and control regulations'' do allow for ''provisional'' permit issuances to applicants who are pursuing good faith challenges to all pertinent ownership and control findings. 30 CFR 773.14(b)(3)(i). These challenges include those that are before OSM itself, after an initial OSM determination of an ownership and control link, and prior to a final OSM decision that would be subject to administrative review. It has been our longstanding position that ownership and control challenge procedures provide due process even without allowing for the issuance of a provisional permit. *See* 59 FR 54306, 54312–16 (1994) (Preamble to OSM's Applicant/Violator System Procedures Rule, or ''AVS Procedures Rule''). The AVS Procedures Rule, which contained the previous ownership or control challenge procedures, was upheld in court against all due process challenges. *National Mining Assoc.* v. *Babbitt,* 43 Env't Rep. Cas. (BNA) 1097, 1111–17, (D.D.C. 1996), *appeal docketed,* No. 96–5274 (D.C. Cir.). Nevertheless, OSM chose to allow issuance of provisional permits even during internal agency challenges. Regulatory authorities are not obligated to provide for the issuance of provisional permits, however. Indeed, Kentucky has chosen not to issue provisional permits at the time of a preliminary determination to impose a permit block, but to offer instead the opportunity for a hearing. This hearing should serve to protect the applicant's interest in much the same manner as would the issuance of a provisional permit. Therefore, we find that Kentucky's allowance of a hearing prior to a preliminary permit block determination is no less effective than the Federal requirement to issue a provisional permit during the pendency of an internal challenge of a positive determination of ownership and control. Accordingly, we are approving this provision.

H.B. 502 also requires the cabinet to conditionally issue a permit, permit renewal, or authorization to conduct surface coal mining and reclamation operations if it finds that a direct administrative or judicial appeal is presently being pursued in good faith to contest the validity of the determination of ownership and control linkage. These circumstances are substantively identical to the circumstances under which the Federal regulations at 30 CFR 773.14(b)(3)(ii) require provisional issuance of a permit. Therefore, we are approving this portion of H.B. 502, although we may require further changes at a later date as a result of the evaluation discussed in Part VIII of the

preamble to the Federal rules published on December 19, 2000.

Next, H.B. 502 provides that ''[t]he cabinet shall conditionally issue permits where the applicant submits proof, including a settlement agreement, that the violation is being abated to the satisfaction of the issuing State or Federal agency.'' These circumstances are substantively identical to the circumstances under which the Federal regulations at 30 CFR 773.14(b)(1) require provisional issuance of a permit. Therefore, we are approving this portion of H.B. 502, although we may require further changes at a later date as a result of the evaluation discussed in Part VIII of the preamble to the Federal rules published on December 19, 2000.

H.B. 502 also provides that if the initial judicial appeal affirms the ownership and control linkage, the applicant has 30 days to submit proof that the violation has been or is in the process of being corrected. Nothing in the Federal regulations at 30 CFR part 773 precludes allowance of a 30-day period for an applicant to submit proof that a violation has been or is in the process of being corrected. Therefore, we are approving this section of H.B. 502 because it is not inconsistent with the Federal regulations.

However, the Federal regulations at 30 CFR 773.14(c)(4) require the initiation of proceedings to suspend or rescind an improvidently issued permit where the initial judicial review decision affirms the validity of the violation or the ownership or control listing or finding. Therefore, we may require further changes at a later date as a result of the evaluation discussed in Part VIII of the preamble to the Federal rules published on December 19, 2000. If we determine that program amendments are necessary, we will notify Kentucky in accordance with 30 CFR 732.17(d).

Finally, we find that the portion of H.B. 502 that states that ''nothing within this new provision shall preclude the applicant from seeking further judicial relief'' is not inconsistent with any provision of SMCRA or the Federal regulations. Therefore, we are approving it.

## IV. Summary and Disposition of Comments

*Public Comments*

We asked for public comments on the amendment (administrative record no. KY–1469), and received several from industry groups. None pertained to HB 502, however. The National Citizens' Coal Law Project, an environmental group, submitted a letter dated June 30, 2000 (administrative record no. KY–1483), supporting the approval of the provisions of HB 502.

*Federal Agency Comments*

Under 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Kentucky program (administrative record no.KY–1469). We received no comments.

*Environmental Protection Agency (EPA) Concurrence and Comments*

Under 30 CFR 732.17(h)(11)(i) and (ii), we are required to get a written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). None of the revisions that Kentucky proposed to make in this amendment pertain to air or water quality standards. Therefore, we did not ask EPA to concur on the amendment.

*State Historic Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)*

Under 30 CFR 732.17(h)(4), we are required to request comments from the SHPO and ACHP on amendments that may have an effect on historic properties. Because none of the proposed amendment provisions relates to historic properties, we did not ask the SHPO and ACHP to comment.

## V. OSM's Decision

As discussed in section III of this preamble, we are approving House Bill 502, Part IX, Item 36(b) concerning permit block provisions.

To implement this decision, we are amending the Federal regulations at 30 CFR Part 917, which codify decisions concerning the Kentucky program. We find that good cause exists under 5 U.S.C. 553(d)(3) to make this final rule effective immediately.

Section 503(a) of SMCRA requires that the State's program demonstrate that it has the capability of carrying out the provisions of the Act and meeting its purposes. Making this regulation effective immediately will expedite that process. SMCRA requires consistency of State and Federal standards.

*Effect of OSM's Decision*

Section 503 of SMCRA provides that a State may not exercise jurisdiction under SMCRA unless the State program is approved by the Secretary. Similarly, 30 CFR 732.17(a) requires that any change of an approved State program be submitted to OSM for review as a program amendment. The Federal regulations at 30 CFR 732.17(g) prohibit any changes to approved State programs that are not approved by OSM. In the oversight of the Kentucky program, we will recognize only the statutes, regulations, and other materials we have approved, together with any consistent implementing policies, directives, and other materials. We will only require Kentucky to enforce approved provisions.

## VI. Procedural Determinations

*Executive Order 12630—Takings*

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

*Executive Order 12866—Regulatory Planning and Review*

This rule is exempt from review by the Office of Management and Budget under Executive Order 12866.

*Executive Order 12988—Civil Justice Reform*

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments because each program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR parts 730, 731, and 732 have been met.

*Executive Order 13132—Federalism*

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to ''establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.'' Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be ''in

accordance with'' the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations ''consistent with'' regulations issued by the Secretary pursuant to SMCRA.

*Executive Order 13211—Regulations That Significantly Affect The Supply, Distribution, or Use of Energy*

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) Considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

*National Environmental Policy Act*

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

*Paperwork Reduction Act*

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

*Regulatory Flexibility Act*

The Department of the Interior certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal that is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

*Small Business Regulatory Enforcement Fairness Act*

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of $100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the fact that the State submittal that is the subject of this rule is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

*Unfunded Mandates*

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of $100 million or more in any given year. This determination is based upon the fact that the State submittal that is the subject of this rule is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.

**List of Subjects in 30 CFR Part 917**

Intergovernmental relations, Surface mining, Underground mining.

Dated: March 11, 2002.

**Allen D. Klein,**

*Regional Director, Appalachian Regional Coordinating Center.*

For the reasons set out in the preamble, 30 CFR part 917 is amended as set forth below:

## PART 917—KENTUCKY

1. The authority citation for part 917 continues to read as follows:

**Authority:** 30 U.S.C. 1201 *et seq.*

2. Section 917.15 is amended by adding a new entry to the table in chronological order to read as follows:

**§ 917.15 Approval of Kentucky regulatory program amendments.**

* * * * *

| Original amendment submission date | Date of final publication | Citation/description |
|---|---|---|
| * | * | * * * * * |
| May 9, 2000 ..... | April 30, 2002 ..... | House Bill 502, Part IX, Subsection 36(b), KRS 350.085(6). |

[FR Doc. 02–10517 Filed 4–29–02; 8:45 am]

**BILLING CODE 4310–05–P**

## LIBRARY OF CONGRESS

## Copyright Office

## 37 CFR Parts 252 and 257

**[Docket No. 2002–5 CARP]**

## Filing of Claims for Cable and Satellite Royalties

**AGENCY:** Copyright Office, Library of Congress.

**ACTION:** Waiver of regulation.

**SUMMARY:** Due to the continued disruption in the delivery of mail, the Copyright Office of the Library of Congress is announcing alternative methods for the filing of claims to the cable and satellite royalty funds for the year 2001. In order to ensure that their claims are timely received, claimants are encouraged to file their cable and satellite claims electronically, utilizing the special procedures described in this document.

**EFFECTIVE DATE:** April 30, 2002.

**ADDRESSES:** If hand delivered, an original and two copies of each claim should be brought to: Office of the Copyright General Counsel, James Madison Memorial Building, Room 403, First and Independence Avenue, SE, Washington, DC 20540 from July 1, 2002 through July 31, 2002. Submissions by electronic mail should be made to the following: for cable claims ''*cableclaims @loc.gov*'' ; for satellite claims ''*satclaims@loc.gov*'' . See **SUPPLEMENTARY INFORMATION** for information about on-line electronic filing through the Copyright Office website. If sent by mail, an original and two copies of each claim should be addressed to: Copyright Arbitration Royalty Panel (CARP), P.O. Box 70977, Southwest Station, Washington, DC. 20024.