

persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the gene expression profiling test system for breast cancer prognosis they intend to market.

## II. What Is the Environmental Impact of This Rule?

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## III. What Is the Economic Impact of This Rule?

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 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 final rule is not a significant regulatory action 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. Because classification of these devices into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect

this final rule to result in any 1-year expenditure that would meet or exceed this amount.

## IV. Does This Final Rule Have Federalism Implications?

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.

## V. How Does This Rule Comply With the Paperwork Reduction Act of 1995?

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## VI. What References Are on Display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Agendia BV, dated January 22, 2007.

## List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

## PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

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

■ 2. Section 866.6040 is added to subpart G to read as follows:

### § 866.6040 Gene expression profiling test system for breast cancer prognosis.

(a) *Identification.* A gene expression profiling test system for breast cancer prognosis is a device that measures the ribonucleic acid (RNA) expression level

of multiple genes and combines this information to yield a signature (pattern or classifier or index) to aid in prognosis of previously diagnosed breast cancer.

(b) *Classification.* Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Gene Expression Profiling Test System for Breast Cancer Prognosis.” See § 866.1(e) for the availability of this guidance document.

Dated: May 1, 2007.

**Linda S. Kahan,**

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

[FR Doc. E7–8871 Filed 5–8–07; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 935

[OH–251–FOR]

#### Ohio Regulatory Program

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

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

**SUMMARY:** We are approving an amendment to the Ohio regulatory program (the “Ohio program”) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). This amendment is intended to remove certain Conflict of Interest provisions from the approved Ohio program that were previously approved by OSM but have not been promulgated by Ohio through their rulemaking process.

**EFFECTIVE DATE:** May 9, 2007.

**FOR FURTHER INFORMATION CONTACT:** Mr. George Rieger, Chief, Pittsburgh Field Division, Telephone: (717) 782–4036. E-mail: [grieger@osmre.gov](mailto:grieger@osmre.gov).

#### SUPPLEMENTARY INFORMATION:

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

#### I. Background on the Ohio 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 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 Ohio program on August 16, 1982. You can find background information on the Ohio program, including the Secretary’s findings, the disposition of comments, and conditions of approval of the Ohio program in the August 16, 1982, **Federal Register** (47 FR 34687). You can also find later actions concerning Ohio’s program and program amendments at 30 CFR 935.11, 935.15, and 935.16.

## II. Submission of the Amendment

By letter dated August 30, 2006, Ohio sent us a proposed amendment to its program (Administrative Record Number OH-2187-00) under SMCRA (30 U.S.C. 1201 *et seq.*). In its letter, Ohio stated that it has reviewed amendments previously proposed by Ohio in Program Amendment #69. Ohio stated that those amendments of program amendment #69 related to Conflict of Interest have not been promulgated by Ohio and are deemed to be no longer necessary. Therefore, Ohio stated, it would like to withdraw the Conflict of Interest amendments from consideration by OSM.

OSM approved the Conflict of Interest amendments that Ohio proposed in program amendment #69 (including the subsequent revisions) in the **Federal Register** on July 17, 1995 (60 FR 36352). Because we had already published our approval of the Conflict of Interest provisions that Ohio has requested be withdrawn from consideration, we were unable to merely withdraw those provisions. Rather, we sought public comment on whether the removal of the Conflict of Interest provisions that we approved in 1995 would render the approved Ohio program less effective than SMCRA and the Federal regulations.

*Background Information:* Ohio program amendment #69 was originally submitted by Ohio by letter dated September 22, 1994 (Administrative Record Number OH-2059). Revisions to amendment #69 were subsequently submitted by letters dated March 8, 1995, and May 3, 1995 (Administrative Record Numbers OH-2099 and OH-2115, respectively). We announced receipt of those proposed amendments, and the two revisions, in the October 21, 1994; March 17, 1995; and May 12, 1995; **Federal Register** (59 FR 53122, 60

FR 14401, and 60 FR 25660, respectively). We approved the amendments in the July 17, 1995, **Federal Register** notice.

We announced receipt of Ohio’s request that we remove the Conflict of Interest provisions from the approved Ohio program in the October 19, 2006, **Federal Register** (71 FR 61695). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the proposed amendment (Administrative Record Number OH-2187-01). We did not hold a hearing or meeting because no one requested one. The public comment period ended on November 20, 2006. We received no comments.

## III. OSM’s Findings

Following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are approving the amendment. Any revisions that we do not specifically discuss below concern nonsubstantive minor wording, editorial, or renumbering of sections changes, and are approved herein without discussion.

### *Restrictions on Financial Interest of Employees. Ohio Administrative Code (OAC) Section 1501:13-1-03*

#### 1. OAC 1501: 13-1-03(D)(2) Definition of “Employee”

In its September 22, 1994, amendment, Ohio proposed to revise the definition of “Employee” at paragraph (D)(2) to provide that members of the Ohio Board (currently “Council”) on Unreclaimed Strip Mined Lands are included under the definition of “employee.” Ohio also proposed to revise this paragraph to provide that, for the purposes of OAC Section 1501:13-1-03, hearing officers for the Ohio Reclamation Board of Review (currently the Reclamation Commission) shall also be included within the definition of “employee.” Ohio also proposed to revise the appeal procedures at paragraphs (L)(1) and (2) to delete separate references to the Reclamation Commission’s hearing officers because those hearing officers are to be included under the definition of “employee” in this rule. We approved these revisions in our July 17, 1995, notice.

In its August 30, 2006, letter to OSM, Ohio requested that the provisions that OSM approved on July 17, 1995, be withdrawn. Under this request, therefore, neither members of the Council nor hearing officers for the Reclamation Commission would be specifically identified as “employees”

under the definition of “employee” at paragraph (D)(2). To approve these deletions from the Ohio provisions that were approved by OSM, we must determine whether the deletions render the Ohio program less effective than the Federal definition of “employee” at 30 CFR 705.5.

The Federal definition of “employee” at 30 CFR 705.5 provides as follows:

Employee. Means (a) any person employed by the State Regulatory Authority who performs any function or duty under the Act, and (b) advisory board or commission members and consultants who perform any function or duty under the Act, if they perform decisionmaking functions for the State Regulatory Authority under the authority of State law or regulations. However, members of advisory boards or commissions established in accordance with State law or regulations to represent multiple interests are not considered to be employees. State officials may through State law or regulations expand this definition to meet their program needs.

The Ohio Revised Code (ORC) at section 1513.29 establishes the Council. Under ORC 1513.29, the Council’s duties involve gathering information on unreclaimed strip mined lands, studying, and making recommendations concerning eroded land within the State, including land affected by strip mining for which no cash is held in the strip mining reclamation fund. In addition, an Ohio Attorney General’s Opinion from 1978 states that the Council “has the authority as a matter of law to fund reclamation projects on private lands pursuant to Chapter 1513 of the Revised Code \* \* \*.” (Ohio Op. Atty Gen No. 78-016) That is, members of the Council perform a function or duty under Chapter 1513 of the Ohio Revised Code, and fall within the definition of “employee” in OAC 1501:13-1-03. We find that the existing Ohio definition of “employee” which does not specifically identify members of the Council as employees does not render the Ohio program less effective than the Federal definition of “employee” at 30 CFR 705.5 and can be approved.

Next, we will consider whether hearing officers for the Reclamation Commission are considered employees under the Federal regulations. The ORC at 1513.05 establishes the Reclamation Commission. That provision also provides that “The commission shall appoint one or more hearing officers who shall be attorneys at law admitted to practice in this state to conduct hearings under this chapter.” Therefore, it is clear that hearing officers for the Reclamation Commission are not members of the Reclamation Commission, but are appointed by the

Reclamation Commission to conduct hearings. It is our understanding that the hearing officer for the Reclamation Commission is an employee of the Ohio Department of Natural Resources and is considered by that department to be an "employee" under the Ohio definition of "employee" at OAC 1501: 13-1-03 and is required to file the appropriate conflict of interest forms under OAC 1501: 13-1-03(I). Therefore, we find that the existing Ohio definition of "employee" which does not specifically identify hearing officers for the Reclamation Commission as employees does not render the Ohio program less effective than the Federal definition of "employee" at 30 CFR 705.5 and can be approved. Our approval is based upon our understanding noted above.

#### 2. OAC 1501: 13-1-03(I)(1) Use of Financial Interest Statement Form by Members of the Ohio Reclamation Commission

In its September 22, 1994, amendment, Ohio proposed to revise paragraph (I)(1) to add that members of the Ohio Reclamation Board of Review (currently Reclamation Commission) shall report all required information concerning employment and financial interests on Form OSM-23. We approved the provisions on July 17, 1995. On August 30, 2006, Ohio requested that its amendments to paragraph (I)(1) that we approved in 1995 be withdrawn. In effect, the phrase "and members of the Reclamation Board of Review" (currently the Reclamation Commission) will be deleted from provision concerning what to file at OAC 1501: 13-1-03(I)(1).

The Federal regulations at 30 CFR 705.11(a) provide that employees and members of advisory boards and commissions established in accordance with State laws or regulations to represent multiple interests, who perform a function or duty under SMCRA, must file a statement of employment and financial interests. The Ohio Reclamation Commission is such a multi-interest advisory board and, therefore, must file a statement of employment and financial interests.

The current Ohio provision at OAC 1501: 13-1-03(F)(1), concerning who shall file, provides that members of the Reclamation Commission are required to file a statement of employment and financial interests. Therefore, despite the fact that OAC 1501: 13-1-03(I)(1) concerning what to file does not specifically mention members of the Reclamation Commission, the Commission members are required to file by Ohio's regulations. Therefore, we find that the existing Ohio provision at

OAC 1501: 13-1-03(I)(1), despite the fact that it does not specifically mention members of the Reclamation Commission definition, does not render the Ohio program less effective than the Federal regulations at 30 CFR 705.11(a) and can be approved.

We note that OAC 1501: 13-1-03(I)(1) provides that the report shall be on "OSM Form 705-1" as provided by OSM. This form number is not correct. The form that OSM will provide for reporting financial interests is OSM "Form 23."

#### 3. OAC 1501: 13-1-03(J)(1) Acceptance of Gifts and Gratuities by Members of the Ohio Reclamation Commission

In its September 22, 1994, amendment, Ohio proposed to revise paragraph (J)(1) to prohibit, with certain exceptions, the solicitation or acceptance of gifts and gratuities by members of the Ohio Reclamation Board of Review (currently Reclamation Commission) from coal companies which are conducting or seeking to conduct regulated activities or which have an interest that may be substantially affected by the performance of the Reclamation Commission members' official duties. We approved the provisions on July 17, 1995.

On August 30, 2006, Ohio requested that its amendments to paragraph (J)(1) that we approved be withdrawn. In effect, the phrase "and members of the Reclamation Board of Review" will be deleted from the approved Ohio program at OAC 1501: 13-1-03(J)(1) concerning gifts and gratuities. Despite the fact that the Ohio provision at OAC 1501: 13-1-03(J)(1) does not prohibit members of the Reclamation Commission from soliciting or accepting gifts or any other thing of monetary value, the Ohio program is not rendered less effective than the Federal regulations at 30 CFR 705.18 concerning gifts and gratuities. Without the language that we approved on July 17, 1995, the State rule at OAC 1501: 13-1-03(J)(1) is substantively identical to the counterpart Federal regulations at 30 CFR 705.18(a) concerning the prohibitions against soliciting or receiving gifts and gratuities. That is, the Federal regulations do not require that members of multi-interest boards such as the Reclamation Commission must comply with the prohibitions against soliciting or receiving gifts and gratuities at 30 CFR 705.18.

The Federal regulations at 30 CFR 705.4(d) do provide, however, that members of multi-interest boards must recuse themselves from proceedings which may affect their direct or indirect

financial interests. The counterpart State provision concerning recusal is OAC 1501: 13-1-03(C). Additionally, the Federal regulations at 30 CFR 705.11(a) provide that members of multi-interest boards must file a statement of employment and financial interests. The counterpart State provision concerning the requirement for members of multi-interest boards to file a statement of employment and financial interests is OAC 1501: 13-1-03(F)(1). Therefore, we find that the removal of the words "and members of the Reclamation Board of Review" from OAC 1501: 13-1-03(J)(1) does not render the Ohio provision less effective than the counterpart Federal regulation at 30 CFR 705.18(a) and can be approved.

#### 4. OAC 1501: 13-1-03(L)(1) Appeal of Remedial Actions

In its September 22, 1994, amendment, Ohio proposed to revise paragraph (L)(1) to add that nothing in OAC Section 1501:13-1-03 modifies any right of appeal that any employee may have under State law of a decision by the Chief of the Division of Natural Resources, on an employee's appeal of remedial action for prohibited financial interests. The State also deleted the words "and such board's hearing officers" from the provision. We approved the provisions on July 17, 1995.

On August 30, 2006, Ohio requested that the amendment to paragraph (L)(1) that we approved be withdrawn. The existing State provision at OAC 1501: 13-1-03(L)(1), without the language that the State has requested be removed from the approved program, provides as follows:

(1) Employees other than the chief of the Division of Mineral Resources Management and members of the reclamation commission and such commission's hearing officers may file their appeal in writing with the chief, who will conduct an informal hearing on the merits.

The counterpart Federal regulations at 30 CFR 705.21(a) concerning appeals procedures provide as follows:

(a) Employees other than the Head of the State Regulatory Authority, may file their appeal, in writing, through established procedures within their particular State.

The Federal regulation at 30 CFR 705.21(a) that is quoted above provides that conflict of interest appeal procedures for employees within a State should be governed by established procedures within the State. That is, the Federal conflict of interest provisions provide that the State has the discretion to establish its own appeal procedures.

Additionally, the Federal regulations at 30 CFR 705.21(a) do not contain a counterpart to the language that Ohio wishes to be deleted from the approved program, which provides that nothing in the rule modifies any right of appeal of the Chief's decision that any employee may have under State law. Therefore, the removal of that language does not render OAC 1501: 13-1-03(L)(1) less effective than the Federal regulations at 30 CFR 705.21(a). Therefore, we find that the existing State provision at OAC 1501: 13-1-03(L)(1) is not inconsistent with the Federal conflict of interest provisions at 30 CFR 705.21 and can be approved.

#### 5. OAC 1501: 13-1-03(L)(2) Appeal of Remedial Actions

In its September 22, 1994, amendment, Ohio proposed to revise paragraph (L)(2) by deleting language so that paragraph (L)(2) provides that only the Chief of the Division of Reclamation (currently the Division of Mineral Resources Management) may appeal a remedial action to the Director of OSM. We approved the proposed deletion of language on July 17, 1995.

On August 30, 2006, Ohio requested that the proposed deletion at paragraph (L)(2) that we approved be withdrawn. As a result, the existing State provision at OAC 1501: 13-1-03(L)(2) provides as follows:

(2) The chief of the Division of Mineral Resources Management and members of the reclamation commission and such commission's hearing officers may file their appeal in writing, with the director of the office of surface mining reclamation and enforcement, who will refer it to the conflict of interest appeals board within the United States Department of the Interior.

Under paragraph (L)(2), therefore, the Chief of the Division of Mineral Resources Management, members of the Reclamation Commission, and the Commission's hearing officers may file their appeals of orders for remedial action under paragraph (K) with OSM.

Under the Federal regulations, appeal procedures for employees are specified at 30 CFR 705.21(a), which provides that employees may file their appeals through established procedures within their respective States. Under the Federal regulations, appeal procedures for the head of the regulatory authority are specified at 30 CFR 705.21(b), which provides that the head of the State regulatory authority may file an appeal with OSM who will refer it to the Conflict of Interest Appeals Board within the Department of the Interior. Insofar as it applies to the Chief of the Division of Mineral Resources Management, who is the head of the

Ohio Regulatory Authority, restored paragraph (L)(2) is substantively identical to, and therefore no less effective than, the Federal regulations at 30 CFR 705.21(b). With respect to Reclamation Commission hearing officers, who are "employees" under Ohio's approved program, restored paragraph (L)(2) is no less effective than 30 CFR 705.21(a), which allows States to establish appeal procedures for all employees except for the head of the regulatory authority. For hearing officers, the "established procedures" in Ohio will be those applicable to the United States Department of the Interior's Conflict of Interest Appeals Board. Finally, there are no specific Federal provisions concerning appeals of conflict of interest decisions by members of multiple interest boards, such as members of Ohio's Reclamation Commission. However, nothing in SMCRA or the Federal regulations prohibits Ohio from allowing these members to appeal these types of decisions. Therefore, restored paragraph (L)(2) is not inconsistent with SMCRA or the Federal regulations insofar as it applies to members of the Reclamation Commission. For all of these reasons, we are approving restored paragraph (L)(2).

#### 6. OAC 1501: 13-1-03(L)(3) Appeal of Remedial Actions

In its September 22, 1994, amendment, Ohio proposed to add new paragraph (L)(3) to provide that members of the Ohio Reclamation Board of Review (currently the Reclamation Commission) may request advisory opinions from the Director of OSM on issues pertaining to an apparent prohibited financial interest. The provision also stated that resolution of conflicts is governed by section 1513.05 and 1513.29 of the Ohio Revised Code. We approved the proposed new language on July 17, 1995.

On August 30, 2006, Ohio requested that the proposed new language at paragraph (L)(3) that we approved be withdrawn. As noted above at Finding 5, the existing Ohio provision at OAC 1501: 13-1-03(L)(2) provides that members of the Reclamation Commission and such Commission's hearing officers may file an appeal in writing, with the Director of OSM. Therefore, the provision that we approved on July 17, 1995, at OAC 1501: 13-1-03(L)(3), which also provides that members of the Commission may request advisory opinions from OSM is not necessary. We find that the removal of paragraph (L)(3) from the approved Ohio program does not render the Ohio program less

effective than the Federal regulations at 30 CFR 705.21 concerning appeal procedures and can be approved. We note that the language at paragraph (L)(3) also provided that resolution of conflicts is governed by section 1513.05 of the Ohio Revised Code. However, the removal of paragraph (L)(3) from the Ohio program does not negate the fact that the provisions at ORC 1513.05 and 1513.29 continue to apply to the Reclamation Commission.

### IV. Summary and Disposition of Comments

#### Public Comments

On October 19, 2006, we published a **Federal Register** notice and asked for public comments of the amendment (Administrative Record Number OH-OH-2187-01). No comments were received.

#### 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 Ohio program (Administrative Record Number OH-2187-02). No comments were received.

#### Environmental Protection Agency (EPA) Concurrence and Comments

Under 30 CFR 732.17(h)(11) (ii), we are required to obtain 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 Ohio proposed to make in this amendment pertain to air or water quality standards. Therefore, we did not ask EPA to concur on the amendment.

Under 30 CFR 732.17(h)(11)(i), we requested comments on the amendment from EPA (Administrative Record Number OH-2187-02). No EPA comments were received.

### V. OSM's Decision

Based on the above findings, we are approving, the program amendment that Ohio sent to us on August 30, 2006.

To implement this decision, we are amending the Federal regulations at 30 CFR part 935, which codify decisions concerning the Ohio 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 the State has the capability of carrying out the provisions of the Act and meeting its purposes. Making this rule effective

immediately will expedite that process. SMCRA requires consistency of State and Federal standards.

## 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 regulations.

### *Executive Order 12866—Regulatory Planning and Review*

This rule is exempted from review by the Office of Management and Budget (OMB) 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, to the extent allowable by law, 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 since each such 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. Section 503(a)(7) requires that State programs contain rules and regulations “consistent with” regulations issued by the Secretary pursuant to SMCRA.

### *Executive Order 13175—Consultation and Coordination With Indian Tribal Governments*

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally-recognized Indian tribes and have determined that the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. The basis for this determination is that our decision is on a State regulatory program and does not involve a Federal program involving Indian lands.

### *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*

Section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that a decision on a proposed State regulatory program provision does not constitute a major Federal action within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)). A determination has been made that such decisions are categorically excluded from the NEPA process (516 DM 8.4.A).

### *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 has determined 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. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. 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, geographic regions, or Federal, State or local governmental agencies; 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, which 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 a cost of \$100 million or more in any given year on any governmental entity or the private sector.

### **List of Subjects in 30 CFR Part 935**

Intergovernmental relations, Surface mining, Underground mining.

Dated: March 15, 2007.

**H. Vann Weaver,**

*Acting Regional Director, Appalachian Region.*

■ For the reasons set out in the preamble, 30 CFR part 935 is amended as set forth below:

### **PART 935—OHIO**

■ 1. The authority citation for part 935 continues to read as follows:

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

■ 2. Section 935.15 is amended by adding a new entry to the table in chronological order by “Date of final publication” to read as follows:

### **§ 935.15 Approval of Ohio regulatory program amendments.**

\* \* \* \* \*

Original amendment submission date	Date of final publication	Citation/description
* August 30, 2006 .....	* May 9, 2007 .....	* OAC 1501:13-1-03(D)(2), (I)(1), (J)(1), (L)(1), (L)(2), and the deletion of (L)(3).

[FR Doc. E7-8867 Filed 5-8-07; 8:45 am]  
BILLING CODE 4310-05-P

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 165**

[COTP San Francisco Bay 07-006]

RIN 1625-AA00

**Safety Zone; KFOG “Kaboom” Fireworks Display, San Francisco Bay, CA**

**AGENCY:** Coast Guard, DHS.  
**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone in the navigable waters of San Francisco Bay for the loading, transport, inactive period, and launching of fireworks used during the KFOG “KaBoom” Fireworks Display to be held on May 12, 2007. This safety zone is intended to prohibit vessels and people from entering into or remaining within the regulated areas in order to ensure the safety of participants and spectators.

**DATES:** This rule is effective from 8 a.m. on May 10, 2007, to 9:30 p.m. on May 12, 2007.

**ADDRESSES:** Documents indicated in this preamble as being available in the docket, are part of docket COTP San Francisco Bay 07-006 and are available for inspection or copying at Coast Guard Sector San Francisco, 1 Yerba Buena Island, San Francisco, California, 94130, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** Ensign Sheral Richardson, U.S. Coast Guard Sector San Francisco, at (415) 556-2950 extension 136.

**SUPPLEMENTARY INFORMATION:**

**Regulatory Information**

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Logistical details surrounding the event were not finalized and presented to the Coast Guard in time to draft and publish an

NPRM. As such, the event would occur before the rulemaking process was complete. Because of the dangers posed by the pyrotechnics used in this fireworks display, safety zones are necessary to provide for the safety of event participants, spectator craft, and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event.

For the same reasons listed in the previous paragraph, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Any delay in the effective date of this rule would expose mariners to the dangers posed by the pyrotechnics used in this fireworks display.

**Background and Purpose**

The San Francisco Radio Station KFOG is sponsoring a brief fireworks display on May 12, 2007 in the waters of San Francisco Bay near Piers 30 and 32. The fireworks display is meant for entertainment purposes in support of KFOG’s annual festival in San Francisco. This safety zone is being issued to establish a temporary regulated area in San Francisco Bay around the fireworks launch barge during the loading of the pyrotechnics, during the transit of the barge to the display location, inactive period, and during the fireworks display. This temporary regulated area around the launch barge is necessary to protect spectators, vessels, and other property from the hazards associated with the pyrotechnics on the fireworks barge. The Coast Guard has granted the event sponsor a marine event permit for the fireworks display.

**Discussion of Rule**

The Coast Guard is establishing a temporary safety zone on specified waters off of the San Francisco waterfront. During the loading of the fireworks barge, while the barge is being towed to the display location, and until the start of the fireworks display, the safety zone will apply to the navigable waters around and under the fireworks barge within a radius of 100 feet. Fifteen minutes prior to and during the twenty-two minute fireworks display, the area to which this safety zone applies to will

increase in size to encompass the navigable waters around and under the fireworks barge within a radius of 1,000 feet. Loading of the pyrotechnics onto the fireworks barge is scheduled to commence at 8 a.m. on May 10, 2007, and will take place at Pier 50 in San Francisco. Towing of the barge from Pier 50 to the display location is scheduled to take place on May 12, 2007. During the fireworks display, scheduled to commence at 9 p.m. on May 12, 2007, the fireworks barge will be located approximately 1,000 feet off of Pier 30 in position 37°47.21’ N, 122°22.86’ W.

The effect of the temporary safety zone will be to restrict general navigation in the vicinity of the fireworks barge while the fireworks are loaded at Pier 50, during the transit of the fireworks barge, and until the conclusion of the scheduled display. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the safety zone. This safety zone is needed to keep spectators and vessels a safe distance away from the fireworks barge to ensure the safety of participants, spectators, and transiting vessels.

**Regulatory Evaluation**

This rule is not a “significant regulatory action” under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order.

Although this rule restricts access to the waters encompassed by the safety zone, the effect of this rule will not be significant because the local waterway users will be notified via public broadcast notice to mariners to ensure the safety zone will result in minimum impact. The entities most likely to be affected are pleasure craft engaged in recreational activities.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term “small entities” comprises small businesses, not-for-profit