or its elements in accordance with paragraphs (b)(1)(v) and (b)(2)(vi) of this section.

(F) A description of internal and external controls that are recommended or provided and control procedures. The description must identify those control elements that are incorporated into the testing procedure.

(iv) Information demonstrating analytical validity of the device according to analytical performance characteristics, evaluated either specifically for each gene/mutation or, when clinically and practically justified, using a representative approach based on other mutations of the same type, including:

(A) Data that adequately supports the intended specimen type (e.g., formalin-fixed, paraffin-embedded tumor tissue), specimen handling protocol, and nucleic acid purification for specific tumor types or for a pan-tumor claim.

(B) A summary of the empirical evidence obtained to demonstrate how the analytical quality metrics and thresholds were optimized.

(C) Device precision data using clinical samples to adequately evaluate intra-run, inter-run, and total variability. The samples must cover all mutation types tested (both positive and negative samples) and include samples near the limit of detection of the device. Precision must be assessed by agreement within replicates on the assay final result for each representative mutation, as applicable, and also supported by sequencing quality metrics for targeted regions across the panel.

(D) Description of the protocols and/or data adequately demonstrating the interchangeability of reagent lots and multiplexing barcodes.

(E) A description of the nucleic acid assay input concentration range and the evidence to adequately support the range.

(F) A description of the data adequately supporting the limit of detection of the device.

(G) A description of the data to adequately support device accuracy using clinical specimens representing the intended specimen type and range of tumor types, as applicable.

(i) Clinical specimens tested to support device accuracy must adequately represent the list of cancer mutations with evidence of clinical significance to be detected by the device.

(ii) For mutations that are designated as cancer mutations with evidence of clinical significance and that are based on evidence established in the intended specimen type (e.g., tumor tissues) but for a different analyte type (e.g., protein, RNA) and/or a measurement (e.g., incorporating a score or copy number) and/or with an alternative technology (e.g., IHC, RT-qPCR, FISH), evidence of accuracy must include clinically adequate concordance between results for the mutation and the medically established biomarker test (e.g., evidence generated from an appropriately sized method comparison study using clinical specimens from the target population).

(3) For qualitative DNA mutations not described in paragraph (b)(1)(iv)(G) of this section, accuracy studies must include both mutation-positive and wild-type results.

(H) Adequate device stability information.

(v) Information that adequately supports the clinical significance of the panel must include:

(A) Criteria established on what types and levels of evidence will clinically validate a mutation as a cancer mutation with evidence of clinical significance versus a cancer mutation with potential clinical significance.

(B) For representative mutations of those designated as cancer mutations with evidence of clinical significance, a description of the clinical evidence associated with such mutations, such as clinical evidence presented in professional guidelines, as appropriate, with method comparison performance data as described in paragraph (b)(1)(iv)(G) of this section.

(C) For all other mutations designated as cancer mutations with potential clinical significance, a description of the rationale for reporting.

(2) The 21 CFR 809.10 compliant labeling and any product information and test report generated, must include the following, as applicable:

(i) The intended use statement must specify the following:

(A) The test is indicated for previously diagnosed cancer patients.

(B) The intended specimen type(s) and matrix (e.g., formalin-fixed, paraffin-embedded tumor tissue).

(C) The mutation types (e.g., single nucleotide variant, insertion, deletion, copy number variation or gene rearrangement) for which validation data has been provided.

(D) The name of the testing facility or facilities, as applicable.

(ii) A description of the device and summary of the results of the performance studies performed in accordance with paragraphs (b)(1)(iii), (b)(1)(iv), and (b)(1)(v) of this section.

(iii) A description of applicable test limitations, including, for device specific mutations validated with method comparison data to a medically established test in the same intended specimen type, appropriate description of the level of evidence and/or the differences between next generation sequencing results and results from the medically established test (e.g., as described in professional guidelines).

(iv) A listing of all somatic mutations that are intended to be detected by the device and that are reported in the test results under the following two categories or equivalent designations, as appropriate: “cancer mutations panel with evidence of clinical significance” or “cancer mutations panel with potential clinical significance.”

(v) For mutations reported under the category of “cancer mutations panel with potential clinical significance,” a limiting statement that states “For the mutations listed in [cancer mutations panel with potential clinical significance or equivalent designation], the clinical significance has not been demonstrated (with adequate clinical evidence [e.g., by professional guidelines] in accordance with paragraph (b)(1)(v) of this section) or with this test.”

(vi) For mutations under the category of “cancer mutations panel with evidence of clinical significance,” or equivalent designation, link(s) for physicians to access internal or external information concerning decision rules or conclusions about the level of evidence for clinical significance that is associated with the marker in accordance with paragraph (b)(1)(v) of this section.

Dated: June 18, 2018.

Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2018–13406 Filed 6–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR
Office of Surface Mining Reclamation and Enforcement

30 CFR Part 901

[FR Doc. 2018–13406 Filed 6–21–18; 8:45 am]

Alabama Abandoned Mine Land Reclamation Plan

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
(OSMRE), are approving an amendment to the Alabama Abandoned Mine Land Reclamation (AMLR) Plan (hereinafter, the Plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Alabama proposed updates to their Plan with changes required by the 2006 Amendments to SMCRA.

DATES: The effective date is July 23, 2018.


SUPPLEMENTARY INFORMATION:
I. Background on the Alabama Plan
The Abandoned Mine Land Reclamation Program was established by Title IV of the Act. (30 U.S.C. 1201 et seq.) in response to concerns over extensive environmental damage caused by past coal mining activities. The program is funded by a reclamation fee collected on each ton of coal that is produced. The money collected is used to finance the reclamation of abandoned coal mines and for other authorized activities. Section 405 of the Act allows States and Indian tribes to assume responsibility for reclamation activity within the State or on Indian lands if they develop and submit to the Secretary of the Interior for approval, a program (often referred to as a plan) for the reclamation of abandoned coal mines. Background information on the Alabama Plan, including the Secretary’s findings, the disposition of comments, and the approval of the Plan, are found in the May 20, 1982, Federal Register (47 FR 22057). Later actions concerning the Alabama Plan and amendments to the Plan, are found at 30 CFR 901.20 and 901.25.

II. Submission of the Amendment
By letter dated June 7, 2016 (Administrative Record No. AL–0670), Alabama sent OSMRE an amendment to its Plan under SMCRA (30 U.S.C. 1201 et seq.) at its own initiative. We announced receipt of the proposed amendment in the April 7, 2017, Federal Register (82 FR 16975). 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 amendment. We did not hold a public hearing or meeting because no one requested one. The public comment period ended on May 8, 2017. We did not receive any public comments.

During OSMRE’s review, several minor deficiencies were noted, including section numbering inconsistencies and the lien language in the “Reclamation of Private Land” section. By letter dated July 17, 2017 (Administrative Record No. AL–0670–02), OSMRE requested that Alabama address these minor deficiencies. Because these requested changes were minor, Alabama was given the option to either incorporate the changes or withdraw the amendment and resubmit the Plan amendment at a later date. By letter dated July 28, 2017 (Administrative Record No. AL–0670–03), Alabama returned a revised Plan amendment correcting the deficiencies and the amendment process resumed.

III. OSMRE’s Findings
We are approving the amendment as described below. The following are the findings we made concerning Alabama’s amendment under SMCRA and the Federal regulations at 30 CFR 884.14 and 884.15. Any revisions that we do not specifically discuss below concerning non-substantive wording or editorial changes can be found in the full text of the Plan amendment available at www.regulations.gov.

Alabama Reclamation Plan
1. Governor’s Letter of Designation [30 CFR 884.13(a)(1)]
   Alabama included a 1979 letter from the Governor designating the Alabama Department of Industrial Relations, now known as the Alabama Department of Labor (ADOL), as the agency responsible for the abandoned mine lands reclamation program in the state of Alabama. This letter was submitted and approved as part of the original proposed reclamation plan and is consistent with the Federal requirements of 30 CFR 884.13(a)(2).
   Therefore, we are approving its inclusion.

2. Legal Opinion [30 CFR 884.13(a)(2)]
   Alabama included a 1981 legal opinion from the Attorney General of Alabama authorizing the Alabama Department of Industrial Relations, under the legal authority of Alabama law, to conduct its reclamation program in accordance with amendments of Title IV of the Act. This legal opinion was submitted and approved as part of the original proposed reclamation plan and is consistent with the Federal requirements of 30 CFR 884.13(a)(2).
   Therefore, we are approving its inclusion.

3. Purpose, Goals and Objectives [30 CFR 884.13(a)(3)(ii)]
   Alabama, in section 884.13(a)(3)(ii) of the Plan, stated that the goal of its AMLR Plan is to amend those adverse effects of past coal mining conducted prior to August 3, 1977, which impact public health, safety, or general welfare, and cause environmental degradation. The stated objectives of the AMLR Plan are to identify and prioritize these adverse impacts, provide planning procedures, and affect their ultimate reclamation. Alabama also stated that, although the primary purpose of the program is the reclamation of coal mine lands, any non-coal AML issues will be dealt with in accordance with OSMRE policies. ADOL elected to set aside up to the maximum amount allowed by OSMRE of each year’s allocation of AML funds into a separate fund for the abatement of the causes and treatment of the effects of acid mine drainage. These funds are used in accordance with all applicable State and Federal regulations and are used to achieve the priorities of SMCRA. The program purpose, goals, and objectives are consistent with the Federal requirements of 30 CFR 884.13(a)(3)(i).
   Therefore, we are approving their inclusion.

   Alabama, in section 884.13(a)(3)(iii) of the Plan, described the priority system and the specific criteria for identifying and ranking all sites eligible for reclamation under Title IV of the Act. Examples of eligible site problems include: Open and unprotected mine entries; open shafts; hazardous highwalls and other steep embankments; hazardous mine structures; underground mine subsidence; trash dumps on mine lands; water bodies adversely affected by coal mine drainage; dangerous impoundments; and any other mine related danger. The sites given highest priority are those exhibiting extreme danger to public health, safety, and property from adverse effects of coal mining practices. The sites given the second highest priority are those exhibiting adverse effects of coal mining practices that may impact public health and safety. The sites given third priority for restoration are those land and water resources previously degraded by...

Alabama Reclamation Plan
1. Governor’s Letter of Designation [30 CFR 884.13(a)(1)]
   Alabama included a 1979 letter from the Governor designating the Alabama Department of Industrial Relations, now known as the Alabama Department of Labor (ADOL), as the agency responsible for the abandoned mine lands reclamation program in the state of Alabama. This letter was submitted and approved as part of the original proposed reclamation plan and is consistent with the Federal requirements of 30 CFR 884.13(a)(2).
   Therefore, we are approving its inclusion.

3. Purpose, Goals and Objectives [30 CFR 884.13(a)(3)(ii)]
   Alabama, in section 884.13(a)(3)(ii) of the Plan, stated that the goal of its AMLR Plan is to amend those adverse effects of past coal mining conducted prior to August 3, 1977, which impact public health, safety, or general welfare, and cause environmental degradation. The stated objectives of the AMLR Plan are to identify and prioritize these adverse impacts, provide planning procedures, and affect their ultimate reclamation. Alabama also stated that, although the primary purpose of the program is the reclamation of coal mine lands, any non-coal AML issues will be dealt with in accordance with OSMRE policies. ADOL elected to set aside up to the maximum amount allowed by OSMRE of each year’s allocation of AML funds into a separate fund for the abatement of the causes and treatment of the effects of acid mine drainage. These funds are used in accordance with all applicable State and Federal regulations and are used to achieve the priorities of SMCRA. The program purpose, goals, and objectives are consistent with the Federal requirements of 30 CFR 884.13(a)(3)(i).
   Therefore, we are approving their inclusion.

   Alabama, in section 884.13(a)(3)(iii) of the Plan, described the priority system and the specific criteria for identifying and ranking all sites eligible for reclamation under Title IV of the Act. Examples of eligible site problems include: Open and unprotected mine entries; open shafts; hazardous highwalls and other steep embankments; hazardous mine structures; underground mine subsidence; trash dumps on mine lands; water bodies adversely affected by coal mine drainage; dangerous impoundments; and any other mine related danger. The sites given highest priority are those exhibiting extreme danger to public health, safety, and property from adverse effects of coal mining practices. The sites given the second highest priority are those exhibiting adverse effects of coal mining practices that may impact public health and safety. The sites given third priority for restoration are those land and water resources previously degraded by...
adverse effects of coal mining, including measures for the conservation and development of soil, water, woodland, fish and wildlife, recreational resources, and agricultural productivity. The three priority categories described are consistent with Section 403(a) of SMCRA. Alabama also describes ADOL’s data acquisition procedures in determining site eligibility, which include the review of past mining records (available in the OSMRE’s Abandoned Mine Land Inventory System (e-AMLIS)), site inventories, field investigations, and public input. Alabama states that site priority will be determined for all eligible sites, regardless of resource recovery potential, and that any resource recovery will be undertaken in accordance with Federal rules. Any remined sites will remain eligible for AML reclamation. These descriptions are consistent with the Federal requirements of 30 CFR 884.13(a)(3)(ii). Therefore, we are approving their inclusion.

5. Coordination With Other Programs [30 CFR 884.13(a)(3)(iii)]

Alabama, in section 884.13(a)(3)(iii) of the Plan, described ADOL’s coordination with other agencies. The ADOL AML Program coordinates with other State divisions such as the Alabama Department of Environmental Management (ADEM), the State Historic Preservation Office (SHPO), and the Alabama Department of Conservation and Natural Resources (ADCNR), to review proposed reclamation projects, provide assistance, and offer expertise to ensure that reclamation activities restore adversely impacted land and water to a productive state while protecting natural and historic/cultural resources. ADOL maintains an annual cooperative agreement with a non-profit organization, the Walker County Soil and Water Conservation District Board (WCB), which funds and oversees a reclamation group that performs reclamation and maintenance on AML sites and responds to AML emergencies. Historically, several major and minor tribes occupied Alabama; however, no tribal reservations were historically or are currently located in the areas where AML reclamation presently takes place within the Alabama Coal Region. Consultations concerning potential cultural resource impacts are conducted through the SHPO’s Alabama Historical Commission through the NEPA review process. Alabama also describes the purpose of its AML Emergency Program, which is to stabilize the emergency aspects of an AML problem by eliminating the immediate danger to public health, safety, or general welfare. The AML Emergency Program is discussed further in Section 8, “Rights of Entry.” This description of agency coordination is consistent with the Federal requirements of 30 CFR 884.13(a)(3)(iii). Therefore, we are approving its inclusion.


Alabama, in section 884.13(a)(3)(iv) of the Plan, stated that ADOL may acquire, manage, and dispose of lands that have been adversely affected by coal mining activity, if deemed necessary, pursuant to Section 407 of SMCRA, 30 U.S.C. 1237, and Code of Alabama Section 9–16–127. These acquisition, management, and disposition policies and procedures are consistent with the Federal requirements of 30 CFR 884.13(a)(3)(iv). Therefore, we are approving their inclusion.


Alabama, in section 884.13(a)(3)(v) of the Plan, described its policies and procedures for reclamation on private land. Under its Plan, the ADOL State Programs Administrator has the authority to place or waive a lien against private property if the owner has consented to, participated in, or exercised control over the mining operation, and if reclamation will result in a significant increase in property value. If an initial evaluation suggests an increase in property value of $25,000 or more, the land appraisal may be conducted by an independent appraiser. The Administrator will determine whether to place or waive a lien based on both the independent appraisal findings and other relevant facts, in accordance with Code of Alabama Section 9–16–129. During OSMRE’s review, it was noted that this section of the Plan, as well as the referenced Alabama state law (Code of Alabama Section 9–16–129), fails to address the full requirements of 30 CFR 882.13(b) in regard to notifying the landowner of the proposed lien and allowing the landowner a reasonable time to pay that amount in lieu of filing the lien. On July 17, 2017 (Administrative Record No. AL–0670–02), OSMRE requested that Alabama add this lien language to its proposed Plan. On July 28, 2017, Alabama returned a revised Plan which incorporated the additional lien language. These revised policies and procedures are consistent with the Federal requirements of 30 CFR 884.13(a)(3)(v) and 882.13(b). Therefore, we are approving this inclusion.


Alabama, in section 884.13(a)(3)(vi) and (iii) of the Plan, stated its policies and procedures regarding rights of entry to lands or property. Pursuant to Code of Alabama Section 9–16–126, ADOL will take all reasonable actions to obtain advance written consent from the property owner for the purposes of reclamation. In the event that permission cannot be obtained on properties where reclamation is needed and there is an immediate danger to public health, safety, or general welfare, police power entry is authorized under the AML Emergency Program. If police power entry is necessary, a written notice must be mailed to the property owner at least 30 days prior to entry. If the property owner’s address is not known, the notice must be posted on the property and advertised in the newspaper. These policies and procedures are consistent with the Federal requirements of 30 CFR 884.13(a)(3)(vi). Therefore, we are approving their inclusion.


Alabama, in section 884.13(a)(3)(vii) of the Plan, described its public participation policies in the development and operation of its Plan. The ADOL encourages the public to contact its office with any questions or concerns regarding mining related problems or the AML program, or to visit the ADOL Inspections Division Abandoned Mine Lands Program Office. For future projects, ADOL distributes notifications to Federal, State, and local elected officials, and publishes public notices to news outlets within the county where the proposed activity is located. If sufficient public response is received, a public meeting may be scheduled to provide information on proposed activities and address the concerns of the citizens. Additional public involvement in the preparation of any revisions or amendments to the AML Plan will be coordinated and executed by OSMRE during the public comment and review period. These policies and procedures are consistent with the Federal requirements of 30 CFR 884.13(a)(3)(vii). Therefore, we are approving their inclusion.


Alabama, in section 884.13(a)(4)(i) of the Plan, described the organization of ADOL and its relationship to other State organizations that may become involved in its reclamation program. ADOL also
attached an updated organizational chart. The Inspections Division of ADOL reports to the Commissioner, via the State Programs Administrator. The Commissioner for ADOL reports directly to the Governor. The ADOL AML Program also coordinates with other State divisions such as the ADDEM, SHPO, and the ADCNR to review proposed reclamation projects, provide assistance, and offer expertise to ensure that reclamation activities restore adversely impacted land and water to a productive state while protecting natural and historic/cultural resources. This description of agency organization is consistent with the Federal requirements of 30 CFR 884.13(a)(4)(i). Therefore, we are approving its inclusion.


Alabama, in section 884.13(a)(4)(i) of the Plan, described the personnel staffing policies that will govern the assignment of personnel to its reclamation program. The program’s staff is selected on the basis of applicable academic and professional experience. ADOL will be responsible for complying with all pertinent Federal and State laws. This description of agency personnel policies is consistent with the Federal requirements of 30 CFR 884.13(a)(4)(i). Therefore, we are approving its inclusion.


Alabama, in section 884.13(a)(4)(ii) of the Plan, stated that the purchasing and procurement systems used by ADOL will be in accordance with the requirements of Office of Management and Budget (OMB) Circular A–102, Attachment 0. Purchasing and procurement program staff is trained in all applicable State and Federal regulations and larger transactions are reviewed, if necessary, by the Alabama Department of Finance, the State Attorney General, the Alabama Department of Examiners of Public Accounts, and the State Auditor. Alabama also described its AML Applicant/Violator System (AVS), which ensures that no company owners, directors, or major shareholders bidding on AML Federally funded projects have any Federal coal mining violations or state cessation orders that would render them ineligible. Emergency program contractors are also required to meet AVS clearance requirements, unless an overriding need to proceed is determined. These systems are consistent with the Federal requirements of 30 CFR 884.13(a)(4)(i).

Therefore, we are approving their inclusion.


Alabama, in section 884.13(a)(4)(iv) of the Plan, described the ADOL’s accounting system, including procedures for the operation of the State Abandoned Mine Reclamation Fund. The ADOL Finance Division is responsible for the proper accounting of Federal draws, income, and expenses, including the maintenance of records for annual audits conducted by the Alabama Department of Examiners of Public Accounts. AML projects, including administrative, operational, and construction costs, are grant-funded and detailed financial records are maintained for auditing purposes, in accordance with 30 CFR part 886 and OMB Circular A–102, Attachment 0. This system description is consistent with the Federal requirements of 30 CFR 884.13(a)(4)(iv). Therefore, we are approving its inclusion.


Alabama, in section 884.13(a)(5) and (a)(5)(i) of the Plan, included a list of documents and data sources offering general descriptions of known or suspected eligible lands and waters within the State of Alabama which potentially required reclamation at the time of publication. Alabama also included a list of counties, in order of significance which have either reported coal mining prior to 1978, currently have conditions associated with past surface mining practices, or currently have physical hazards or environmental conditions associated with past underground mining practices. Alabama also included a mine map repository showing the general location of known or suspected eligible lands and waters within the State which require reclamation. These descriptions are consistent with the Federal requirements of 30 CFR 884.13(a)(5) and (a)(5)(i). Therefore, we are approving their inclusion.


Alabama, in section 884.13(a)(5) through (a)(5)(iii) of the Plan, described the problems occurring on known or suspected lands and waters which require reclamation, including a table expressing the percentage of total abandoned mine lands affected by each problem. Examples of such problems include: Open shafts and portals; subsidence; highwalls; abandoned structures and equipment; insect or vermin vectors; water impoundments; waste banks; mine-related fires; landslide and flood hazards; pollution of domestic water supplies; erosion; sedimentation; reduced land potential; and aesthetic disamenities. Reclamation techniques to restore the site to an environmentally stable condition will be based on ADOL’s site specific assessments, current industry construction standards, and the reclamation cost estimate procedures outlined in OSMRE Directive AML–1. These descriptions are consistent with the Federal requirements of 30 CFR 884.13(a)(5)(ii) and (iii). Therefore, we are approving their inclusion.

16. The Economic Base [30 CFR 884.13(a)(6)(i)]

Alabama, in section 884.13(a)(6)(i) of the Plan, described the economic base for the state’s primary coal producing region, including population size, market accessibility, current industry activities, such as agricultural products and manufacturing, and available mining resources. This description is consistent with the Federal requirements of 30 CFR 884.13(a)(6)(i). Therefore, we are approving its inclusion.

17. Significant Aesthetic, Historic, and Recreational Values [30 CFR 884.13(a)(6)(ii)]

Alabama, in section 884.13(a)(6)(ii) of the Plan, described the aesthetic, historic, and recreational values of Alabama. Alabama stated that, to ensure that all potential impacts of the reclamation process are mitigated, ADOL’s Planning and Maintenance Branch will consult with the SHPO’s Alabama Historical Commission. This statement is consistent with the Federal requirements of 30 CFR 884.13(a)(6)(ii). Therefore, we are approving its inclusion.


Alabama, in section 884.13(a)(6)(iii) of the Plan, stated that, during the planning stages of proposed AML reclamation projects, evaluations are conducted by the Planning and Maintenance Branch to determine the presence of wetlands, endangered species, and other environmental concerns. Recommendations are provided to enhance or improve wildlife habitat, and to preserve wetlands and other critical wildlife habitat during construction. During this process, ADOL consults with the U.S. Fish and Wildlife Service.
Service to determine whether the project will adversely affect any Federally-listed threatened or endangered species and to develop appropriate mitigation measures and minimize disturbance, if necessary. ADOL also coordinates with the ADCNR and reviews the Outdoor Alabama Watchable Wildlife database to determine whether any important natural features are recorded at or near the proposed reclamation project. These descriptions are consistent with the Federal requirements of 30 CFR 884.13(a)(6)(iii). Therefore, we are approving their inclusion.

IV. Summary and Disposition of Comments

Public Comments

We asked for public comments on the amendment but did not receive any.

Federal Agency Comments

On June 27, 2016, under 30 CFR 884.14(a), we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Alabama plan (Administrative Record No. AL–0670). We did not receive any comments.

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

Under 30 CFR 884.14(a)(2), we are required to request comments from the SHPO and ACHP on amendments that may have an effect on historic properties. On June 27, 2016, we requested comments on Alabama’s amendment (Administrative Record No. AL–0670), but neither the SHPO nor ACHP responded to our request.

V. OSMRE’s Decision

Based on the above findings, we approve the revised amendment Alabama sent us on July 28, 2017 (Administrative Record No. AL–0670–03).

To implement this decision, we are amending the Federal regulations at 30 CFR part 901, that codify decisions concerning the Alabama Plan. In accordance with the Administrative Procedure Act, this rule will take effect 30 days after the date of publication. Section 405 of SMCRA requires that each state with an abandoned mine reclamation program must have an approved State regulatory program pursuant to Section 503 of the Act. Section 503(a) of the Act 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. SMCRA requires consistency of State and Federal standards.

VI. Procedural Determinations

Executive Order 12630—Takings

This rulemaking 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

Pursuant to Office of Management and Budget (OMB) guidance, dated October 12, 1993, the approval of state program amendments is exempted from OMB review under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has reviewed this rule as required by Section 3 of Executive Order 12988. The Department determined that this Federal Register document meets the criteria of Section 3 of Executive Order 12988, which is intended to ensure that the agency reviews its legislation and proposed regulations to eliminate drafting errors and ambiguity, that the agency write its legislation and regulations to minimize litigation, and that the agency’s legislation and regulations provide a clear legal standard for affected conduct rather than a general standard, and promote simplification and burden reduction. Because Section 3 focuses on the quality of Federal legislation and regulations, the Department limited its review under this Executive Order to the quality of this Federal Register document and to changes to the Federal regulations. The review under this Executive Order did not extend to the language of the State AML program or to the Plan amendment that the State of Alabama drafted.

Executive Order 13132—Federalism

This rule is not a “[p]olicy that [has] Federalism implications” as defined by Section 1(a) of Executive Order 13132 because it does not 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.” Instead, this rule approves an amendment to the Alabama Plan submitted and drafted by that State. OSMRE reviewed the submission with fundamental federalism principles in mind as set forth in Sections 2 and 3 of the Executive Order and with the principles of cooperative federalism as set forth in SMCRA. See, e.g., 30 U.S.C. 1201(f). As such, pursuant to Section 503(a)(1) and (7) (30 U.S.C. 1253(a)(1) and (7)), OSMRE reviewed the plan amendment to ensure that it is "in accordance with," the requirements of SMCRA and "consistent with" the 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 rulemaking on Federally-recognized Indian tribes and have determined that the rulemaking 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 AML program and does not involve Federal regulations involving Indian lands.

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

Executive Order 13211 of May 18, 2001, requires agencies to prepare a Statement of Energy Effects for a rulemaking 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 rulemaking does not require an environmental impact statement because it falls within a categorical exclusion within the meaning of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)). It is documented in the DOI Departmental Manual, 516 DM 13.5(B)(29), that agency decisions on approval of state reclamation plans for abandoned mine lands do not constitute major Federal Actions.
**Regulatory Flexibility Act**

The Department of the Interior certifies that this rulemaking 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, which is the subject of this rulemaking, 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 rulemaking 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 rulemaking is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rulemaking: (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, which is the subject of this rulemaking, 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 rulemaking.

**Unfunded Mandates**

This rulemaking will not impose an unfunded mandate on State, local, or tribal governments or the private sector. This determination is based upon the fact that the State submittal, which is the subject of this rulemaking, 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 rulemaking.

**Delegation of Authority**

This final rule removes 33 CFR 117.05–10. The Department of the Interior, acting regionally, now has the authority to remove an abandoned land reclamation plan from the Code of Federal Regulations.

**List of Subjects in 32 CFR Part 736**

Security, Surplus property, Surplus Government property, Surplus real property, Strategic materials, Surface mining, Underground mining, Unfunded Mandates.