cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1995 (Public Law 104-121)), 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 consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review 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. Reclassification of this device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e). Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant impact on any small entity and it may permit small potential competitors to enter the marketplace by lowering costs. The agency, therefore, certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The rule also does not trigger the requirement for a written statement under section 202(a) of the Unfunded Mandates Reform Act because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, or tribal governments in the aggregate, or by the private sector, in any one year. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VI. Paperwork Reduction Act of 1995

FDA has determined that this final rule does not contain any information collection requirements and, therefore, it is not subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995.

List of Subjects in 21 CFR Part 876

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 876 is amended as follows:

PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:


2. Section 876.3630 is revised to read as follows:

§876.3630 Penile rigidity implant.

(a) Identification. A penile rigidity implant is a device that consists of a pair of semi-rigid rods implanted in the corpora cavernosa of the penis to provide rigidity. It is intended to be used in men diagnosed as having erectile dysfunction.

(b) Classification. Class II. The special control for this device is the FDA guidance entitled “Guidance for the Content of Premarket Notifications for Penile Rigidity Implants.”


Linda S. Kahan,
Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00-2148 Filed 2-1-00; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR
Office of Surface Mining Reclamation and Enforcement
30 CFR Part 938

[PA-123-FOR]

Pennsylvania Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendments.

SUMMARY: OSM is approving, with one exception, a proposed amendment to the Pennsylvania permanent regulatory program (Pennsylvania program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment responds to required amendments to the Pennsylvania program that are identified in OSM’s approval of Pennsylvania’s coal refuse disposal amendment on April 22, 1998 (63 FR 19802). The amendment is intended to revise the Pennsylvania program to be consistent with SMCRA and the Federal regulations.


FOR FURTHER INFORMATION CONTACT: Robert J. Biggi, Director, Office of Surface Mining Reclamation and Enforcement, Harrisburg Field Office, Harrisburg Transportation Center, Third Floor, Suite 3C, 4th and Market Streets, Harrisburg, Pennsylvania 17101, Telephone: (717) 782-4036, Internet: bbiggi@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Pennsylvania Program.

II. Submission of the Amendment.

III. Director’s Findings.

IV. Summary and Disposition of Comments.

V. Director’s Decision.

VI. Procedural Determinations.

I. Background on the Pennsylvania Program

On July 31, 1982, the Secretary of the Interior conditionally approved the Pennsylvania Program. You can find background information on the Pennsylvania program including the Secretary’s findings, the disposition of comments, and a detailed explanation of the conditions of approval in the July 30, 1982, Federal Register (47 FR 33050). You can find later actions on conditions of approval and program amendments at 30 CFR 938.11, 938.12, 938.15 and 938.16.

II. Submission of the Amendment

By letter dated September 14, 1995 (Administrative Record Number PA 837.01), Pennsylvania submitted an amendment to the Pennsylvania program. The amending language is contained in Pennsylvania House Bill 1075 and was enacted into Pennsylvania law as Act 1994–114. The amendments changed Pennsylvania’s Coal Refuse Disposal Act (of September 24, 1968 (P.L. 1040, No. 318) and amended on October 10, 1980 (P.L. 807, No. 154)) to provide authorization for refuse disposal in areas previously affected by mining which contain pollutional discharges. We approved the amendments, with certain exceptions, on April 22, 1998 (63 FR 19802–19821). The April 22, 1998, notice contained seven required regulatory program amendments codified at 30 CFR 938.16 paragraphs (vivv) through (bbbb). On June 15, 1998 (63 FR 32615–32616), we corrected an inadvertent omission of a phrase at 30 CFR 938.16 paragraphs (vivv) through (bbbb), concerning the required Pennsylvania regulatory program amendments published in the

By letter dated May 22, 1998 (Administrative Record Number PA 837.72) Pennsylvania responded to the required regulatory program amendments codified at 30 CFR 938.16 (vvv) through (bbbbb) by submitting three items: (1) Written clarifications relating to each of the required regulatory program amendments; (2) The draft text to each of the required regulatory items: (1) Written clarifications relating (vvv) through (bbbb) by submitting three

837.72) Pennsylvania responded to the Administrative Record Number PA 837.72) Pennsylvania responded to the Pennsylvania Bulletin intended to address one of the required amendments; and (3) A legal opinion from the Pennsylvania Department of Environmental Protection (PADEP) legal counsel confirming the PADEP’s authority to implement the necessary change.

By letter dated July 15, 1998 (Administrative Record Number PA 837.74) we responded to PADEP’s May 22, 1998, letter and stated that the clarifications can only be incorporated into the approved Pennsylvania program through formal rulemaking. By letter dated August 17, 1998 (Administrative Record Number PA 837.80), the PADEP requested that we process the PADEP’s May 22, 1998, letter as a program amendment. We opened the 30-day public comment period on August 28, 1998 (63 FR 45973). The comment period closed on September 28, 1998. No one asked to speak at a public hearing, so none was held.

III. Director’s Findings

Following, according to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are our findings concerning the Pennsylvania amendments.

1. Required Amendment Codified at 30 CFR 938.16 (vvv)

This required amendment provides that the State must clarify the meaning of the term “excess soil and related materials” as that term is used in the definition of “coal refuse activities” at section 3(2.1) of the State’s Coal Refuse Disposal Act. In response to the required amendment, the State provided the following clarification.

The meaning of the term “excess soil and related material” as used in the definition “coal refuse disposal activities” in Section 3 of the Coal Refuse Disposal Control Act (CRDCA) is clarified to mean the rock, clay or other materials located immediately above or below a coal seam and which are extracted from a coal mine during the process of mining coal. The term does not include topsoil or subsoil. This clarification will be incorporated in regulations as they are developed.

As explained above by the State, the term “excess soil and related material” is not inconsistent with the intent of the Federal definition of “underground development waste” found in the Federal regulations at 30 CFR 701.5. Therefore, we find that the use of the term “excess soil and related materials” does not render the Pennsylvania program less stringent and can be approved. We will remove the required program amendment when the clarification is incorporated in regulations and those regulations are approved by OSM.

2. Required Amendment Codified at 30 CFR 938.16 (www)

This required amendment concerns the application of the “stream buffer zone rule” at 30 CFR 816/817.57. The State responded and provided its explanation concerning this required amendment. However, OSM is assessing the impact of the stream buffer zone rule. This effort may ultimately result in changes that may affect Pennsylvania’s program amendment. Therefore, we have decided to defer our decision on the State’s proposal until the reassessment of the existing rule is complete.

3. Required Amendments Codified at 30 CFR 938.16 (xxx) and (yyy)

A. The required amendment at 30 CFR 938.16 (xxx) says that the State shall amend the Pennsylvania program to clarify, in the regulations to be developed to implement the provisions of section 6.2 of the State’s Coal Refuse Disposal Act (as is required by Section 3.2(b) of the Coal Refuse Disposal Act), that preexisting discharges that are encountered must be treated to the State effluent standards at Chapter 90, subchapter D at 90.102. In response to the required amendment at 30 CFR 938.16 (xxx), the State provided the following clarification:

The Department clarifies that preexisting discharges which are encountered must be treated to the effluent standards of 25 Pa. Code § 90.102. This clarification will be incorporated in regulations governing Section 6.2 of the CRDCA as they are developed.

We find that the State’s clarification, that subsection 6.2(h) of the CRDCA pertains to preexisting discharges which are encountered, will be consistent with our interpretation of that provision as stated in the April 22, 1996, Federal Register notice.

Therefore, we will remove the required program amendment at 30 CFR 938.16 (yyy) when the clarification is incorporated in regulations and those regulations are approved by OSM.

B. The required amendment at 30 CFR 938.16 (yyy) says that the State shall amend the Pennsylvania program to clarify that subsection 6.2(h) of the Coal Refuse Disposal Act pertains to preexisting discharges that are not encountered.

In the April 22, 1998 Federal Register notice, we said that subsection 6.2(h) could be misinterpreted. Specifically, the language in the first sentence of subsection 6.2(h) which states that “an operator required to treat preexisting discharges under subsection (g) will be allowed to discontinue treating * * *” is unclear. Subsection 6.2(g) pertains to both discharges that are encountered and those that are not encountered, and the treatment standards are different for each. We interpreted the language in the first sentence of section 6.2(h) to pertain only to subsection 6.2(g)(1)(ii), which governs discharges that are not encountered. Therefore, we approved section 6.2(h) to the extent that it provides that an operator may only discontinue treating preexisting discharges that are not encountered when the operator demonstrates that the “baseline” pollution load is no longer being exceeded. Preexisting discharges that are encountered must be treated to the State water quality standards at Chapter 90, subchapter D at 90.102 (63 FR 19810). We also established the required amendment at 30 CFR 938.16 (yyy).

In response to the required amendment at 30 CFR 938.16 (yyy), the State provided the following clarification:

The Department clarifies that subsection 6.2(h) of the CRDCA pertains to preexisting discharges which are not encountered. This clarification will be incorporated in regulations as they are developed.

We find that the State’s clarification, that subsection 6.2(h) of the CRDCA pertains to preexisting discharges which are not encountered, would be consistent with our interpretation of that provision as stated in the April 22, 1996, Federal Register notice.

Therefore, we will remove the required program amendment at 30 CFR 938.16 (yyy) when the clarification is incorporated in regulations governing Section 6.2 of the CRDCA and those regulations are approved by OSM.

4. Required Amendment Codified at 30 CFR 938.16 (zzz)

The required amendment at 30 CFR 938.16 (zzz) says that the State must amend the Pennsylvania program to be no less effective than 30 CFR
by limiting the application of the revegetation standards under subsection 6.2(k) of the CRDCA to areas that were previously disturbed by mining and that were not reclaimed to the State reclamation standards.

In the April 22, 1998, finding on subsection 6.2(k), we said that the State provision lacks a requirement found in 30 CFR §816.6(b)(5). Specifically, subsection 6.2(k) lacks the requirement that, to qualify for the revegetation standards for areas that were previously disturbed by mining, the area that was previously disturbed by mining must not have been reclaimed to the State’s permanent program performance standards. To be no less effective than 30 CFR §816.116(b)(5), the State needs to limit the application of the standards at subsection 6.2(k) to areas that were previously disturbed by mining and that were not reclaimed to the State reclamation standards (63 FR 19811). In addition, we added the required amendment at 30 CFR 938.16(zzz).

In response to the required amendment at 30 CFR 938.16(zzz), the State provided the following clarification:

The Department clarifies that the CRDCA, a special authorization for coal refuse disposal operations will only be granted when such an authorization would result in the site being reclaimed to lesser standards than could be achieved if the monies paid into the Surface Mining Conservation and Reclamation Fund (Fund) must be applied as a credit to the bond required for a special authorization. In the April 22, 1998, Federal Register notice, we said that if any forfeited Fund moneys for a particular site are sufficient to perform all outstanding reclamation obligations for the site, then the site should not be reclaimed to lesser reclamation standards under a special authorization.

Therefore, we approved section 6.2(l) to the extent that the State will not approve a special authorization when the authorization would result in the site being reclaimed to lesser standards than could be achieved if the forfeited bond monies were used to reclaim the site to the standards approved in the original permit under which the bond monies were forfeited (63 FR 19811). We also established the required amendment at 30 CFR 938.16(aaaa).

In response to the required amendment at 30 CFR 938.16(aaaa), the State provided the following clarification:

The Department clarifies that under subsection 6.2(l) of the CRDCA, a special authorization for coal refuse disposal operations will only be granted when such an authorization would result in the site being reclaimed to lesser standards than could be achieved if the monies paid into the Surface Mining Conservation and Reclamation Fund, as a result of a prior forfeiture on the area, were used to reclaim the site to the standards approved in the original permit under which the bond monies were forfeited. This clarification will be incorporated in regulations as they are developed.

We find that, if implemented as the State has indicated above, section 6.2(l) would be consistent with our approval of that provision as stated in the April 22, 1998, Federal Register notice. Therefore, we will remove the required program amendment at 30 CFR 938.16(zzz) when the clarification is incorporated in regulations governing Section 6.2(k) of the CRDCA and those regulations are approved by OSM.

5. Required Amendment Codified at 30 CFR 938.16(aaaa)

The required amendment at 30 CFR 938.16(aaaa) says that the State must amend the Pennsylvania program to clarify that under subsection 6.2(l) of the CRDCA, a special authorization for coal refuse disposal operations will not be granted when such an authorization would result in the site being reclaimed to lesser standards than could be achieved if the moneys paid into the Fund, as a result of a prior forfeiture on the area, were used to reclaim the site to the standards approved in the original permit under which the bond monies were forfeited.

Section 6.2(l) of the CRDCA says that forfeited funds in the Surface Mining Conservation and Reclamation Fund (Fund) must be applied as a credit to the bond required for a special authorization. In the April 22, 1998, Federal Register notice, we said that if any forfeited Fund moneys for a particular site are sufficient to perform all outstanding reclamation obligations for the site, then the site should not be reclaimed to lesser reclamation standards under a special authorization. Therefore, we approved section 6.2(l) to the extent that the State will not approve a special authorization when the authorization would result in the site being reclaimed to lesser standards than could be achieved if the forfeited bond monies were used to reclaim the site to the standards approved in the original permit under which the bond monies were forfeited (63 FR 19811). We also established the required amendment at 30 CFR 938.16(aaaa).

In response to the required amendment at 30 CFR 938.16(aaaa), the State provided the following clarification:

The Department clarifies that under subsection 6.2(l) of the CRDCA, a special authorization for coal refuse disposal operations will only be granted when such an authorization would result in the site being reclaimed to lesser standards than could be achieved if the monies paid into the Surface Mining Conservation and Reclamation Fund, as a result of a prior forfeiture on the area, were used to reclaim the site to the standards approved in the original permit under which the bond monies were forfeited. This clarification will be incorporated in regulations as they are developed.

We find that, if implemented as the State has indicated above, section 6.2(l) would be consistent with our approval of that provision as stated in the April 22, 1998, Federal Register notice. Therefore, we will remove the required program amendment at 30 CFR 938.16(bbbb) when the clarification is incorporated in regulations governing Section 6.2(l) of the CRDCA and those regulations are approved by OSM.

IV. Summary and Disposition of Comments

Federal Agency Comments

Pursuant to 30 CFR §732.17(h)(11)(i), the Director solicited comments on the proposed amendment from various Federal agencies with an actual or potential interest in the Pennsylvania program. The U.S. Department of Labor, Mine Safety and Health Administration (MSHA) responded and stated that the amendment does not conflict with existing MSHA regulations.

The U.S. Department of Agriculture, Natural Resources Conservation Service, and the U.S. Fish and Wildlife Service responded and commented on the State’s required amendment to the Federal Register amendment codified at 30 CFR 938.16(www) concerning stream buffer
zones. As discussed above in Finding 2, we are deferring our decision on this provision. Therefore, we are not responding to these comments at this time. We will fully address the comments from these agencies when we render our final decision on this provision.

**Public and State Agency Comments**

The following comments were received in response to the public comment period that closed on September 28, 1998. Two commenters provided general comments in support of the amendments. In addition, the commenters recommended that OSM reconsider its finding that the term “significant” in the Pennsylvania provision at section 6.1(h)(5) of Act 114 is less effective than the Federal requirements (see Finding 2, above). As discussed above in Finding 2, we are deferring our decision on this provision. Therefore, we are not responding to the comments concerning the required amendment codified at 30 CFR 938.16(www) at this time. We will fully address the comments from these commenters when we render our final decision on this provision.

A commenter stated that OSM’s requirement that the State clarify that preexisting discharges must be treated to effluent standards seems to contradict the advantage to the environment of utilizing previously impacted areas for refuse disposal. The Director disagrees with the commenter’s assertion, because the CRDA does not limit the term “preexisting discharges” to discharges caused by mining which occurred prior to SMCRA’s effective date of August 3, 1977. Preexisting discharges which began after this date, and which are encountered by the present mining operation, must be treated to the effluent standards contained in Chapter 90, subchapter B at 90.102. Therefore, the required amendment at 30 CFR 938.16(www) will remain in place until this clarification is incorporated in the regulations. In addition, the commenter noted that OSM’s decision to change the term “significant” to “preexisting discharges” to discharges caused by mining which occurred prior to SMCRA’s effective date of August 3, 1977, is less effective than the Federal regulations (30 CFR 732.17(h)(11)(ii)).

**V. Director’s Decision**

Based on the above findings, the Director is approving, except as noted below, the proposed amendment as submitted by Pennsylvania on August 17, 1998.

We are deferring our decision on the State’s response to the required amendment codified at 30 CFR 938.16(www).

The Federal regulations at 30 CFR Part 938, codifying decisions concerning the Pennsylvania program, are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to bring their programs into conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

**VI. Procedural Determinations**

**Executive Order 12866**

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

**Executive Order 12988**

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed 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. 1292(d) and 1292(b)) and 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.

**National Environmental Policy Act**

No environmental impact statement is required for this rule since 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 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 submitted this rule is based on the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

**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 938**

Intergovernmental relations, Surface mining, Underground mining.

**Dated:** December 23, 1999.

**Allen D. Klein,**
Regional Director, Appalachian Regional Coordinating Center.

For the reasons set out in the preamble, Title 30, Chapter VII, Subchapter T of the Code of Federal Regulations is amended as set forth below:
PART 938—PENNSYLVANIA

1. The authority citation for Part 938 continues to read as follows:

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

<table>
<thead>
<tr>
<th>Original amendment submission date</th>
<th>Date of final publication</th>
<th>Citation/description</th>
</tr>
</thead>
<tbody>
<tr>
<td>August 17, 1998</td>
<td>February 2, 2000</td>
<td>Letter from Pennsylvania to OSM dated August 17, 1998 (PA–837.80), except a decision on the required amendment at 30 CFR 938.16(www) is deferred.</td>
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DEPARTMENT OF EDUCATION

34 CFR Part 676

Federal Supplemental Educational Opportunity Grant Program

AGENCY: Department of Education.

ACTION: Notice of relief from specific statutory and regulatory provisions.

SUMMARY: We announce relief from specific statutory and regulatory provisions governing the Federal Supplemental Educational Opportunity Grant (FSEOG) Program for the 1999–2000 and 2000–2001 award years. This statutory and regulatory relief applies to additional emergency FSEOG funds provided under recently enacted provisions of the Consolidated Appropriations Act for Fiscal Year 2000. We informed institutions of the means to request these emergency FSEOG funds in an announcement dated January 7, 2000, that was issued on the Information for Financial Aid Professionals (IFAP) Web site (http://ifap.ed.gov).

To facilitate the use of these additional emergency FSEOG funds, the Consolidated Appropriations Act also grants the Secretary authority to waive or modify any statutory or regulatory provisions, applicable to the FSEOG Program, necessary to assist individuals who suffered financial harm resulting from these natural disasters.

We have already provided certain regulatory relief to lenders and guaranty agencies in the Federal Family Education Loan Program under section 432(a)(6) of the HEA and 34 CFR 682.406(b) and 682.413(f). The guaranty agency directors were informed of this relief in a letter dated August 5, 1999 as Disaster Letter 99–28. We have also provided guidance for helping Title IV participants affected by Hurricane Floyd in a Dear Partner letter published in September 1999 as GEN–99–27.

Covered Individuals

This notice is intended to assist individuals who suffered financial harm as a result of Hurricanes Dennis and Floyd in 1999. This notice will apply only to students who, at the time of the disaster, were residing in, employed in, or attending an institution of higher education located in an area designated as a Federally declared natural disaster area (or, in the case of an individual who is a dependent student, whose parent or stepparent suffered financial harm from that disaster, and who resided or was employed in such an area at that time).

A list of those areas designated as a Federally declared natural disaster due to these hurricanes is available by State on the Federal Emergency Management Agency’s (FEMA) Web site (http://www.fema.gov/library/diz99.htm). The nine States that had areas designated as a Federally declared natural disaster due to these hurricanes are Delaware, Florida, Maryland, New Jersey, New York, North Carolina, Pennsylvania, South Carolina, and Virginia.

This notice of statutory and regulatory relief will be applicable only for awards made under the FSEOG Program from the additional emergency appropriation of $10 million during the 1999–2000 and 2000–2001 award years (the periods from July 1, 1999 to June 30, 2000 and July 1, 2000 to June 30, 2001).

For the awarding of the additional emergency appropriation of $10 million in FSEOG funds allocated to institutions under the Consolidated Appropriations Act for Fiscal Year 2000, we provide the following waivers and modifications of specific statutory and regulatory provisions governing the FSEOG Program:

1. Section 413D of the HEA—Allocation of Funds and 34 CFR 673.4 Allocation and Reallocation of FSEOG Funds

To assist affected individuals, the Secretary has decided to modify the applicable statutory and regulatory