DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 803

Medical Device Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its medical device reporting regulations to reflect a change in address for agency contacts for reporting a public health emergency. This action is editorial in nature and is intended to improve the accuracy of the agency’s regulations.

DATES: This rule is effective January 10, 2006.

FOR FURTHER INFORMATION CONTACT: Howard A. Press, Center for Devices and Radiological Health, Office of Surveillance and Biometrics (HFZ–530), 1350 Piccard Dr., Rockville, MD 20850, 301–827–2983.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in 21 CFR part 803.12(c) to reflect a reorganization affecting the agency contacts for reporting public health emergencies. The current address for reporting a public health emergency to FDA is the FDA Emergency Operations Branch (HFC–162), Office of Regional Operations, at 301–443–1240, followed by the submission of a fax to 301–443–3757. The new contact is the FDA Office of Emergency Operations (HFA–615), Office of Crisis Management, Office of the Commissioner, at 301–443–1240. This report can be followed by an e-mail to emergency.operations@fda.hhs.gov or a fax report sent to 301–827–3333. This document is published as a final rule with the effective date given previously. Because the final rule is an administrative action, FDA has determined that it has no substantive impact on the public. It imposes no costs, and merely updates contact information included in the Code of Federal Regulations (CFR) for the convenience of the public. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary and that this rule may take effect upon publication.

List of Subjects in 21 CFR Part 803

Imports, Medical devices, Medical device reporting, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and underauthority delegated to the Commissioner of Food and Drugs, 21 CFR part 803 is amended as follows:

PART 803—MEDICAL DEVICE REPORTING

1. The authority citation for 21 CFR part 803 continues to read as follows:


2. Section 803.12 is amended by revising paragraph (c) to read as follows:

   § 803.12 Where and how do I submit reports and additional information?
   * * * * *
   (c) If an entity is confronted with a public health emergency, this can be brought to FDA’s attention by contacting the FDA Office of Emergency Operations (HFA–615), Office of Crisis Management, Office of the Commissioner, at 301–443–1240, followed by the submission of an e-mail to emergency.operations@fda.hhs.gov or a fax report to 301–827–3333.
   * * * * *


   Jeffrey Shuren,
   Assistant Commissioner for Policy.
   [FR Doc. 06–172 Filed 1–9–06; 8:45 am]
   BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 946

[VA–122–FOR]

Virginia Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: We are approving an amendment to the Virginia regulatory program under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). The program amendment revises the Virginia Coal Surface Mining Reclamation Regulations. The amendment reflects changes in the renumbering of Virginia Code section references to the Virginia Administrative Process Act; clarification regarding the filing of requests for formal hearing and judicial review; revisions of the Virginia rules to be consistent with amendments to the
Federal rules; regulation changes to implement requirements of Virginia House Bill (HB) 2573 (enacted as emergency legislation); and corrections of typographical errors.

DATES: Effective Date: January 10, 2006.

FOR FURTHER INFORMATION CONTACT: Mr. Robert A. Penn, Director, Big Stone Gap Field Office; Telephone: (276) 523-4303. Internet: rpenn@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Virginia 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 Virginia program on December 15, 1981. You can find background information on the Virginia program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Virginia program in the December 15, 1981, Federal Register (46 FR 61088). You can also find later actions concerning Virginia's program and program amendments at 30 CFR 946.12, 946.13, and 946.15.

II. Submission of the Amendment

By letter dated May 9, 2005 (Administrative Record Number VA–1048), the Virginia Department of Mines, Minerals and Energy (DMME) submitted an amendment to the Virginia program. In its letter, the DMME stated that the program amendment revises Virginia Coal Surface Mining Reclamation Regulations to reflect the changes in renumbering of the Virginia Code section references to the Virginia Administrative Process Act; clarification regarding the filing of requests for formal hearing and judicial review; revisions of the Virginia rules to be consistent with amendments to the Federal rules; revisions to allow approval of natural stream restoration channel design; regulation changes to implement requirements of Virginia HB 2573 (enacted as emergency legislation in Chapter 3 of the 2005 Virginia Acts of Assembly); and correct typographical errors.

We announced receipt of the proposed amendment in the June 17, 2005, Federal Register (70 FR 35199). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the amendment's adequacy. We did not hold a public hearing or meeting because no one requested one. The public comment period ended on July 18, 2005. We received comments from three Federal agencies.

By letter dated Nov. 14, 2005 (Administrative Record Number VA–1055), Virginia withdrew its proposed amendments regarding revisions to allow approval of natural stream restoration channel design. Specifically, Virginia withdrew new Sections 4 VAC 25–130–816.43(d) and 4 VAC 25–130–817.43(d), concerning diversions. In its letter, Virginia stated that it is currently discussing these amendments with the U.S. Army Corps of Engineers and that some changes may be necessary.

By electronic mail dated December 1, 2005 (Administrative Record Number VA–1056), Virginia corrected a reference error in its amendment to 4 VAC 25–130–784.20(a)(3). Specifically, Virginia deleted an incorrect reference to 4 VAC 25–130–817.121(c)(4) and added in its place a reference to section 45.1–258(D) of the Code of Virginia.

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.

1. The amendment revises several subsections of the Virginia Coal Surface Mining Reclamation Regulations (VAC) by changing existing citations of Virginia Code sections to reflect the changes in the renumbering of the Virginia Code section references to the Virginia Administrative Process Act. We are approving the citation changes in the provisions listed below because those amendments reflect codification changes and do not render the program inconsistent with SMCRA or the Federal regulations:

   4 VAC 25–130–700.12(e) Petitions to initiate rule making.
   4 VAC 25–130–773.2(1) Improvidently issued permits: Rescission procedures.
   4 VAC 25–130–775.11(b)(1) Administrative Review.

   4 VAC 25–130–800.51(c)(1) Administrative review of performance bond forfeiture.
   4 VAC 25–130–842.15(d) Review of decision not to inspect or enforce.
   4 VAC 25–130–843.13(b) Suspension or revocation of permits; pattern of violations.
   4 VAC 25–130–845.19(c) Request for hearing.

2. 4 VAC 25–130–775.11 Administrative Review.

   New subsection (d) is added to provide as follows:

   (d) All requests for hearing or appeals for review and reconsideration made under this section shall be filed with the Director, Department of Mines, Minerals and Energy, Post Office Drawer 900, Big Stone Gap, Virginia 24219.

   While this provision has no Federal counterpart, its addition does not render the Virginia program inconsistent with SMCRA or the Federal regulations.

   Therefore, it is approved.

3. 4 VAC 25–130–775.13 Judicial Review.

   New subsection (c) is added to provide as follows:

   (c) All notices of appeal for judicial review of a Hearing Officer's final decision, or the final decision on review and reconsideration, shall be filed with the Director, Department of Mines, Minerals and Energy, Post Office Drawer 900, Big Stone Gap, Virginia 24219.

   While this provision has no Federal counterpart, its addition does not render the Virginia program inconsistent with SMCRA or the Federal regulations.

   Therefore, it is approved.

4. 4 VAC 25–130–784.20 Subsidence Control Plan.

   Subsection (a)(3) is amended by deleting language concerning presubsidence survey requirements. The DMME stated that the provision was amended to delete those requirements that are counterpart to Federal regulations that were suspended effective December 22, 1999 (64 FR 71652). The following language is being deleted: "Condition of all noncommercial buildings or occupied residential dwellings and structures related thereto, that may be materially damaged or for which the reasonably foreseeable use may be diminished by subsidence, within the area encompassed by the applicable angle of draw; as well as a survey of the." In addition, the following language is being deleted: "Premining condition or
value of such noncommercial buildings or occupied residential dwellings and structures related thereto and the.” As revised, subsection (a)(3) provides as follows:

(3) A survey of the quantity and quality of all drinking, domestic and residential water supplies within the permit area and adjacent area that could be contaminated, diminished, or interrupted by subsidence. If the applicant cannot make this survey because the owner will not allow access to the site, the applicant will notify the owner in writing of the effect that denial of access will have, as described in 4 VAC25–130–817.121(c)(4). The applicant must pay for any technical assessment or engineering evaluation used to determine the quantity and quality of drinking, domestic, or residential water supplies. The applicant must provide copies of the survey and any technical assessment or engineering evaluation to the property owner and the division.


While a portion of 30 CFR 784.20(a)(3) was suspended, the remainder of that provision continues in force to the extent that it applies to the EPAct protected water supplies survey and any technical assessments or engineering evaluations necessarily related thereto. With one exception, we find that as amended, 4 VAC25–130–784.20(a)(3) is consistent with and no less effective than the Federal regulations at 30 CFR 784.20(a)(3) as affected by the suspension of December 22, 1999, and can be approved. The one exception can also be approved, but for a different reason. One sentence of this subsection was amended in a subsequent submission dated December 1, 2005. Prior to the latter submission, the sentence stated as follows:

If the applicant cannot make this survey because the owner will not allow access to the site, the applicant will notify the owner in writing of the effect that denial of access will have, as described in 4 VAC25–130–817.121(c)(4).

As amended, this sentence now states that:

If the applicant cannot make this survey because the owner will not allow access to the site, the applicant will notify the owner in writing of the effect that denial of access will have pursuant to section 45.1–256(D) of the Code of Virginia, as amended.

The sentence was changed to correct the erroneous reference to 4 VAC25–130–817.121(c)(4), which pertains to subsidence damage to structures, rather than water supplies, and which is proposed for deletion, in relevant part, in this amendment package. The Code of Virginia subsection now referenced pertains to water replacement, and states as follows:

D. If the Director has ordered replacement under subsection B of this section and the operator subject to the order has failed to provide the map or maps in accordance with subsection C of this section, then the Director’s order shall not be overturned absent clear and convincing evidence to the contrary. Upon conclusion of an investigation, if the Director does not order replacement under the provisions of subsection B of this section and reasonable access for a pre-mining survey was denied, the Director’s determination shall not be overturned absent clear and convincing evidence to the contrary.

When OSM approved this statutory provision on September 24, 1993, it noted that the provision has no Federal counterpart, but "will not render Virginia’s program inconsistent with any requirements of SMCRA or the Federal regulations." 58 FR 49928–9. Likewise, the newly revised sentence in 4 VAC25–130–784.20(a)(3), requiring that landowners be notified of the effect of denial of access to conduct a pre-mining water survey, has no Federal counterpart, but also will not render Virginia’s program inconsistent with any requirements of SMCRA or the Federal regulations.

5. 4 VAC25–130–800.51 Administrative review of performance bond forfeiture. Subsection (e) is amended by clarifying that the “Division of Mined Land Reclamation” is now the “Department of Mines, Minerals and Energy.” As amended, subsection (e) provides as follows:

(e) All requests for hearing, or appeals for review and reconsideration made under this section; and all notices of appeal for judicial review of a Hearing Officer’s final decision, or the final decision on review and reconsideration shall be filed with the Director, Department of Mines, Minerals and Energy, Post Office Drawer 900, Big Stone Gap, Virginia 24219.

We find that the revision of subsection (e) is a nonsubstantive change and can be approved.

6. 4 VAC25–130–816.11 Signs and markers.

Now subsection (a)(4) is added and existing (a)(4) is re-designated as (a)(5). As amended, subsection (a) provides as follows:

(a) Specifications. Signs and markers required under this Part shall:

(1) Be posted, maintained, and removed by the person who conducts the surface mining activities;

(2) Be of a uniform design throughout the operation that can be easily seen and read;

(3) Be made of durable material;

(4) For permit boundary markers on areas that are located on steep slopes above private dwellings or other occupied buildings, be made of or marked with fluorescent or reflective paint or material; and

(5) Conform to local ordinances and codes.

This provision is apparently intended to accommodate the steep slope conditions found in some areas of Virginia. While there is no direct Federal counterpart to the provision, we find that the amendment is not inconsistent with the Federal regulations concerning signs and markers at 30 CFR 816.11(a) and can be approved.

7. 4 VAC25–130–816.64 Use of explosives; blasting schedule.

New subsection (a)(4) concerning seismic monitoring is added and provides as follows:

(4) Seismic monitoring shall be conducted when blasting operations on coal surface mining operations are conducted within 1,000 feet of a private dwelling or other occupied building.

The Federal blasting regulations at 30 CFR 816.67(d)(6) concern seismic monitoring of blasting operations. The Federal provision provides that the regulatory authority may require an operator to conduct seismic monitoring of any or all blasts or may specify the location at which the measurements are taken and the degree of detail necessary in the measurement. We find that the new seismic monitoring requirement is consistent with the Federal seismic monitoring requirements at 30 CFR 816.67(d)(6) and can be approved.

8. 4 VAC25–130–816.105 Backfilling and grading; thick overburden.

This change is intended to revise Virginia’s rule to be consistent with the counterpart Federal regulations at 30 CFR 816.105 concerning backfilling and grading, thick overburden. The Federal regulations concerning thin overburden are located at 30 CFR 816.104. If all Virginia provisions, thin overburden is addressed at 4 VAC25–130–816.104.
Virginia’s 4 VAC 25–130–816.105 is amended as follows: The term “Thin” is deleted and replaced by the term “Thick” in subsection (a); the term “insufficient” is deleted and replaced by “more than sufficient” in subsection (a); the term “less” is deleted and replaced by the term “more” in subsection (a); and the term “thin” is deleted and replaced by the term “thick” in subsection (b). As amended this provision provides as follows:

(a); the term existing subsection (a)(4) is re-

amended as follows: The term

(b) Where thick overburden occurs within

the permit area, the permittee at a minimum shall:

(1) Closely resemble the surface
configuration of the land prior to mining; or
(2) Blend into and complement the drainage pattern of the surrounding terrain.

We find that that as amended, VAC 25–130–816.105 is substantively identical to and no less effective than the Federal regulations concerning thick overburden at 30 CFR 816.105 and can be approved.

9. 4 VAC 25–130–817.11 Signs and markers.

New subsection (a)(4) is added and existing subsection (a)(4) is re-designated as (a)(5). New subsection (a)(4) provides as follows:

(4) For permit boundary markers on areas
that are located on steep slopes above private dwellings or other occupied dwellings, be made of or marked with fluorescent or reflective paint or material; and

This provision is apparently intended to accommodate the steep slope conditions found in some areas of Virginia. While there is no direct Federal counterpart to the provision, we find that the amendment is not inconsistent with the Federal regulations concerning signs and markers at 30 CFR 817.11(a) and can be approved.

10. 4 VAC 25–130–817.64 Use of explosives; general performance standards.

New subsection (d) is added and provides as follows:

(d) Seismic monitoring shall be conducted when blasting operations on coal surface mining operations are conducted within 1,000 feet of a private dwelling or other occupied building.

The Federal blasting regulations at 30 CFR 817.67(d)(6) concern seismic monitoring of blasting operations. The Federal provision provides that the regulatory authority may require an operator to conduct seismic monitoring of any or all blasts and may specify the location at which the measurements are taken and the degree of detail necessary in the measurement. We find that the new seismic monitoring requirement at 4 VAC 25–130–817.64(d) is consistent with the Federal seismic monitoring requirements at 30 CFR 817.67(d)(6) and can be approved.

11. 4 VAC 25–130–817.121 Subsidence control.

This provision is amended by deleting subsections (c)(4)(i)–(iv) and redesignating subsection (c)(4)(v) as subsection (c)(4). The DMME stated that this provision was amended to delete those requirements that are counterpart to Federal regulations that were suspended effective as of December 22, 1999 (64 FR 71652). The deleted provision had created a rebuttable presumption that underground mining caused subsidence where the subsidence damage occurred within the angle of draw. As amended, subsection (c)(4) provides as follows:

(4) Information to be considered in determination of causation. In a determination whether damage to protected structures was caused by subsidence from underground mining, all relevant and reasonably available information will be considered by the division.

On December 22, 1999, OSM suspended the Federal regulations at 30 CFR 817.121(c)(4)(i)–(iv). In the December 22, 1999, Federal Register notice (64 FR 71652–3) that suspended those provisions, OSM explained why the regulations were suspended. On April 27, 1999, the United States Court of Appeals for the District of Columbia Circuit issued a decision vacating certain portions of the regulatory provisions of the Federal subsidence regulations including those at 30 CFR 817.121(c)(4)(i)–(iv). National Mining Association v. Babbitt, supra. OSM subsequently suspended those provisions. Paragraph (v) within 30 CFR 817.121(c)(4) applies generally to the types of information that must be considered in determining the cause of damage to an EPAct protected structure and is not limited to or expanded by the area defined by the angle of draw. Therefore, paragraph (v) was not suspended and remains in force. We find that as amended, 4 VAC 25–130–817.121(c)(4) is no less effective than the Federal regulations at 30 CFR 817.121(c)(4) as affected by the suspension of December 22, 1999, and can be approved.

12. 4 VAC 25–130–843.13 Suspension or revocation of permits; pattern of violations.

Subsection (e) is amended by clarifying that the “Division of Mined Land Reclamation” is now the “Department of Mines, Minerals, and Energy.” As amended, subsection (e) provides as follows:

(e) All requests for hearing, or appeals for review and reconsideration made under this section; and all notices of appeal for judicial review of a Hearing Officer’s final decision, or the final decision on review and reconsideration shall be filed with the Director, Department of Mines, Minerals and Energy, Post Office Drawer 900, Big Stone Gap, Virginia 24219.

We find that the revision of subsection (e) is a nonsubstantive change and can be approved.


Subsection (e) is amended by clarifying that the “Division of Mined Land Reclamation” is now the “Department of Mines, Minerals, and Energy.” As amended, subsection (e) provides as follows:

(e) All requests for hearing before a Hearing Officer, or appeals for review and reconsideration, made under this section, and all notices of appeal for judicial review of a Hearing Officer’s final decision or a final decision on review and reconsideration shall be filed with the Director, Department of Mines, Minerals and Energy, Post Office Drawer 900, Big Stone Gap, Virginia 24219.

We find that the revision of subsection (e) is a nonsubstantive change and can be approved.


Subsections (c)(1) and (d) are amended to correct typographical errors. At subsection (c)(1), the phrase “(a) and (d)” is added immediately before “(b),” and the phrase “and (c)” is deleted. As amended, subsection (c)(1) provides as follows:

(c) Credit for good faith in attempting to achieve compliance.

(1) The division shall deduct from the total points assigned under subsections (a) and (b) points based on the demonstrated good faith of the permittee in attempting to achieve rapid compliance after notification of the
violation. Points shall be deducted as follows.

In the Virginia program, point assignments are located at 4 VAC 25–130–845.13(a) and (b). We find that the revisions to subsections (c)(1) appropriately correct the inadvertent reference to subsection (c). Therefore, we are approving these revisions.

Subsection (d) is amended by adding “(a),” immediately before “(b),” adding “and” immediately following “(b),” and deleting “and” immediately following (c). As amended, the language of subsection (d) provides as follows:

(d) Determination of base penalty.

The division shall determine the base amount of any civil penalty by converting the total number of points calculated under subsections [a], [b], and [c], of this section to a dollar amount, according to the following schedule.

In the Virginia program, point calculations are determined under 4 VAC 25–130–845.13(a), (b), and (c). We find that the revisions to subsection (d) appropriately correct the inadvertent reference to subsection (d) and can be approved.

Subsection (e), concerning credit and additional penalties for previous history is amended at (e)(1) by adding the words “or a violation that resulted in personal injury or fatality to any person.” As amended, subsection (e)(1) provides as follows:

(1) Except for a violation that resulted in personal injury or fatality to any person, the division shall reduce the base penalty determined under subsection (d) by 10% if the permittee has had no violations cited by the division within the preceding 12-month period.

The State has amended this existing provision concerning reduction of the base penalty if the permittee has no violations cited within the preceding 12-month period by adding an exception to the penalty reduction. While there is no direct counterpart to the language, we find that the amendment does not render 4 VAC 25–130–845.13(e) inconsistent with the Federal regulations pertaining to civil penalties at 30 CFR part 845 and can be approved.

Subsection (f), concerning maximum penalty which the division may assess, is amended by adding the words “except that if the violation resulted in a personal injury or fatality to any person, then the civil penalty determined under subsection (d) shall be multiplied by a factor of twenty (20), not to exceed $70,000.” As amended, subsection (f) provides as follows:

(f) The maximum penalty which the division may assess under this section for each cessation order or notice of violation shall be $5,000, except that if the violation resulted in a personal injury or fatality to any person, then the civil penalty determined under subsection (d) shall be multiplied by a factor of twenty (20), not to exceed $70,000.

As provided in 4 VAC 25–130–845.15, each day of continuing violation may be deemed a separate violation for the purpose of assessing penalties.

The State has amended the existing provision concerning the maximum civil penalty that may be assessed, by adding an exception to the maximum penalty limit based on whether the violation resulted in a personal injury or fatality to any person. This provision is more stringent than the Federal regulations. However, SMCRRA section 505(b) provides that any provision of State law or regulation which provides for more stringent land use and environmental controls and regulations than do SMCRRA or the implementing regulations shall not be construed as inconsistent with SMCRRA. Therefore, we are approving this revision.

15. 4 VAC 25–130–845.15 Assessment of separate violations for each day.

Subsection (a) is amended in the last sentence by adding the words “or more” immediately following the words “a violation that resulted in personal injury or fatality to any person.” As amended, subsection (a) provides as follows:

(a) The division shall assess a civil penalty for each day from the date of issuance of the notice of violation or cessation order to the date set for abatement of the violation. In determining whether to make such an assessment, the division shall consider the factors listed in 4 VAC 25–130–845.13 and may consider the extent to which the person to whom the notice or order was issued gained any economic benefit as a result of a failure to comply. For any violation which continues for two or more days and which has been assessed a penalty of $5,000 or more under 4 VAC 25–130–845.13, the division shall assess a penalty for a minimum of two separate days.

We find that as amended, 4 VAC 25–130–845.15 does not render the Virginia program inconsistent with the Federal regulations at 30 CFR 845.15(a) concerning the assessment of separate violations for each day and can be approved.


New subsection (d) is added to provide as follows:

All requests for hearing or appeals for review and reconsideration made under this section shall be filed with the Director, Department of Mines, Minerals and Energy, Post Office Drawer 900, Big Stone Gap, Virginia 24219.

We find that the amendment is consistent with the counterpart Federal regulations at 30 CFR 845.19 concerning request for a hearing and can be approved.

17. 4 VAC 25–130–846.14 Amount of the individual civil penalty.

Subsection (b) is amended in the first sentence by adding new language concerning an exception to the maximum penalty. As amended, subsection (b) provides as follows:

(b) The penalty shall not exceed $5,000 for each violation, except that if the violation resulted in a personal injury or fatality to any person, then the civil penalty determined under 4 VAC 25–130–845.13 shall be multiplied by a factor of twenty (20), not to exceed $70,000. Each day of a continuing violation may be deemed a separate violation and the division may assess a separate individual civil penalty for each day the violation, failure or refusal continues, from the date of service of the underlying notice of violation, cessation order or other order incorporated in a final decision issued by the Director, until abatement or compliance is achieved.

This provision is more stringent than the Federal regulations. However, SMCRRA section 505(b) provides that any provision of State law or regulation which provides for more stringent land use and environmental controls and regulations than do SMCRRA or the implementing regulations shall not be construed as inconsistent with SMCRRA. Therefore, we are approving this revision.

IV. Summary and Disposition of Comments

Public Comments

We asked for public comments on the amendment (Administrative Record Number VA–1053), but did not receive any.

Federal Agency Comments

Under 30 CFR 732.17(b)(11)(i) and section 503(b) of SMCRRA, on May 12, 2005, we requested comments on the amendments from various Federal agencies with an actual or potential interest in the Virginia program (Administrative Record Number VA–1049). By letter dated May 27, 2005, the U.S. Department of Labor, Mine Safety and Health Administration (MSHA) responded and stated that it found no conflict with MSHA rules and regulations (Administrative Record Number VA–1050). By letter dated June 6, 2005, the United States Department of the Interior, Bureau of Land Management responded and stated that the amendment meets their requirements under 43 CFR 3400 and SMCRRA Sec. 522 (Administrative Record Number VA–1051).
Environmental Protection Agency (EPA) Concurrency and Comments

Under 30 CFR 732.17(h)(11)(ii), we are required to get a written concurrence from EPA for those provisions of the program amendment that relate to air or water quality standards issued under the authority of the Clean Water Act (33 U.S.C. 1251 et seq.) or the Clean Air Act (42 U.S.C. 7401 et seq.). None of the revisions that Virginia 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 WV—1049). The EPA responded by letter dated June 20, 2005 (Administrative Record Number VA—1052), and stated that there are no apparent inconsistencies with the Clean Water Act or other statutes or regulations under EPA’s jurisdiction. EPA offered no other comments.

V. OSM’s Decision

Based on the above findings, we are approving the amendment sent to us by Virginia on May 9, 2005, and as amended on November 14, 2005, and December 1, 2005. To implement this decision, we are amending the Federal regulations at 30 CFR part 946, which codify decisions concerning the Virginia 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 regulation effective immediately will expedite that process. SMCRA requires consistency of State and Federal standards.

VI. Procedural Determinations

Executive Order 12630—Takings

The provisions in the rule based on counterpart Federal regulations do not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulations. The revisions made at the initiative of the State that do not have Federal counterparts have also been reviewed and a determination made that they do not have takings implications. This determination is based on the fact that the provisions are administrative and procedural in nature and are not expected to have a substantive effect on the regulated industry.

Executive Order 12866—Regulatory Planning and Review

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

Executive Order 12988—Civil Justice Reform

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

Executive Order 13132—Federalism

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to “establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.” Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be “in accordance with” the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations “consistent with” regulations issued by the Secretary pursuant to SMCRA.

Executive Order 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 Federal regulations 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

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

Paperwork Reduction Act

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

Regulatory Flexibility Act

The Department of the Interior certifies that a portion of the provisions in 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.) because they are based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations. The Department of the Interior also certifies that the provisions in this rule that are not based upon counterpart Federal regulations 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.).
et seq.). This determination is based on the fact that the provisions are administrative and procedural in nature and are not expected to have a substantive effect on the regulated industry.

Small Business Regulatory Enforcement Fairness Act

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

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of $100 million or more in any given year. This determination is based upon the fact that a portion of 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 did not impose an unfunded mandate. For the portion of the State provisions that is not based upon counterpart Federal regulations, this determination is based upon the fact that the State provisions are administrative and procedural in nature and are not expected to have a substantive effect on the regulated industry.

List of Subjects in 30 CFR Part 948

Intergovernmental relations, Surface mining, Underground mining.


Brent Wahlquist,
Regional Director, Appalachian Region.

For the reasons set out in the preamble, 30 CFR part 946 is amended as set forth below:

PART 946—VIRGINIA

1. The authority citation for part 946 continues to read as follows:

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

2. Section 946.15 is amended in the table by adding a new entry in chronological order by “Date of final publication” to read as follows:

§ 946.15 Approval of Virginia regulatory program amendments.

* * * *

<table>
<thead>
<tr>
<th>Original amendment submission date</th>
<th>Date of final publication</th>
<th>Citation/description</th>
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<tbody>
<tr>
<td>May 9, 2005, and as amended on November 14, 2005, and December 1, 2005.</td>
<td>January 10, 2006</td>
<td>4 VAC 25–130–700.12(e); 773.21(c); 775.11(b)(1) and (d); 775.13(c); 784.20(a)(3); 800.51(c)(1); 800.51(e); 816.11(a)(4) and (a)(5); 816.64(a)(4); 816.105(a) and (b); 817.11(a)(4); 817.64(d); 817.121(c)(4); 842.15(d); 843.12(j); 843.13(b); 843.13(e); 843.15(c); 843.16(e); 845.13(c)(1), (d), (e)(1), and (l); 845.15(a); 845.18(b)(1); 845.19(c); 845.19(d); and 846.14(b).</td>
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SUPPLEMENTARY INFORMATION:

Regulatory Information

On December 8, 2005, we published a notice of proposed rulemaking (NPRM) entitled “Drawbridge Operation Regulations”; Housatonic River, Connecticut, in the Federal Register (70 FR 72967). We received no comments in response to the notice of proposed rulemaking. No public hearing was requested and none was held.

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.

The bridge repairs scheduled to begin on January 9, 2006, are vital necessary repairs that must be performed with all due speed to assure the safe operation of the bridge. Any delay in making this rule effective would not be in the best interest of public safety and the marine interests that use the Housatonic River because failure to start the rehabilitation...