

(3) Amphetamines (amphetamine, dextroamphetamine, and their salts, and levamfetamine and its salts) for human use.

(4) Camphorated oil drug products.

(5) Certain halogenated salicylanilides (tribromsalan (TBS, 3,4',5-tribromosalicylanilide), dibromsalan (DBS, 4', 5-dibromosalicylanilide), metabromsalan (MBS, 3, 5-dibromosalicylanilide), and 3,3', 4,5'-tetrachlorosalicylanilide (TC-SA)) as an ingredient in drug products.

(6) Chloroform used as an ingredient (active or inactive) in drug products.

(7) Cobalt preparations intended for use by man.

(8) Intrauterine devices for human use for the purpose of contraception that incorporate heavy metals, drugs, or other active substances.

(9) Oral prenatal drugs containing fluorides intended for human use.

(10) Parenteral drug products in plastic containers.

(11) Sterilization of drugs by irradiation.

(12) Sweet spirits of nitre drug products.

(13) Thorium dioxide for drug use.

(14) Timed release dosage forms.

(15) Vinyl chloride as an ingredient, including propellant, in aerosol drug products.

(b) Any drug listed in paragraph (a) of this section, when composed wholly or partly of any antibiotic drug, must be certified under section 507 of the act or exempted from certification under section 507 of the act for marketing.

§ 310.504 [Removed]

9. Section 310.504 *Amphetamines (amphetamine, dextroamphetamine, and their salts and levamfetamine and its salts) for human use* is removed.

§ 310.506 [Removed]

10. Section 310.506 *Use of vinyl chloride as an ingredient, including propellant, of aerosol drug products* is removed.

§ 310.507 [Removed]

11. Section 310.507 *Aerosol drug products for human use containing 1,1,1-trichloroethane* is removed.

§ 310.508 [Removed]

12. Section 310.508 *Use of certain halogenated salicylanilides as an inactive ingredient in drug products* is removed.

13. Section 310.509 is revised to read as follows:

§ 310.509 Parenteral drug products in plastic containers.

(a) Any parenteral drug product packaged in a plastic immediate

container is not generally recognized as safe and effective, is a new drug within the meaning of section 201(p) of the act, and requires an approved new drug application as a condition for marketing. An "Investigational New Drug Application" set forth in part 312 of this chapter is required for clinical investigations designed to obtain evidence of safety and effectiveness.

(b) As used in this section, the term "large volume parenteral drug product" means a terminally sterilized aqueous drug product packaged in a single-dose container with a capacity of 100 milliliters or more and intended to be administered or used intravenously in a human.

(c) Until the results of compatibility studies are evaluated, a large volume parenteral drug product for intravenous use in humans that is packaged in a plastic immediate container on or after April 16, 1979, is misbranded unless its labeling contains a warning that includes the following information:

(1) A statement that additives may be incompatible.

(2) A statement that, if additive drugs are introduced into the parenteral system, aseptic techniques should be used and the solution should be thoroughly mixed.

(3) A statement that a solution containing an additive drug should not be stored.

(d) This section does not apply to a biological product licensed under the Public Health Service Act of July 1, 1944 (42 U.S.C. 201).

§ 310.510 [Removed]

14. Section 310.510 *Use of aerosol drug products containing zirconium* is removed.

§ 310.513 [Removed]

15. Section 310.513 *Chloroform, use as an ingredient (active or inactive) in drug products* is removed.

§ 310.525 [Removed]

16. Section 310.525 *Sweet spirits of nitre drug products* is removed.

§ 310.526 [Removed]

17. Section 310.526 *Camphorated oil drug products* is removed.

Dated: June 5, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96-14706 Filed 6-6-96; 11:50 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 935

[OH-237-FOR, #71]

Ohio Regulatory Program

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

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: OSM is announcing receipt of a proposed amendment to the Ohio regulatory program (hereinafter the "Ohio program") under the surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of changes to provisions of the Ohio rules pertaining to inspections. The amendment is intended to revise the Ohio program to be consistent with the corresponding Federal regulations.

DATES: Written comments must be received by 4:00 p.m., [E.D.T.] July 11, 1996. If requested, a public hearing on the proposed amendment will be held on July 8, 1996. Requests to speak at the hearing must be received by 4:00 p.m., [E.D.T.], on June 26, 1996.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to George Rieger, Field Branch chief, at the address listed below.

Copies of the Ohio program, the proposed amendment, a listing of any scheduled public hearings, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Appalachian Regional Coordinating Center.

George Rieger, Field Branch Chief,
Appalachian Regional Coordinating
Center, Office of Surface Mining
Reclamation and Enforcement, 3
Parkway Center, Pittsburgh, PA
15220, Telephone: (412) 937-2153
Ohio Division of Mines and
Reclamation, 1855 Fountain Square
Court, Columbus, Ohio 43224,
Telephone: (614) 265-1076.

FOR FURTHER INFORMATION CONTACT:
George Rieger, Field Branch Chief,
Appalachian Regional Coordinating
Center, Telephone: (412) 937-2153.

SUPPLEMENTARY INFORMATION:**I. Background on the Ohio Program**

On August 16, 1982, the Secretary of the Interior conditionally approved the Ohio program. Background information on the Ohio program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the August 10, 1982, Federal Register (42 FR 34688). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 935.11, 935.15, and 935.16.

II. Description of the Proposed Amendment

By letter dated May 17, 1996, (Administrative Record No. OH-2165-00) Ohio submitted a proposed amendment to its program pursuant to SMCRA at its own initiative. The provisions of the Ohio Administrative Code (OAC) that Ohio proposes to amend are: OAC 1501:13-14-01—Inspections.

Specifically, in its definition of "inactive coal mining and reclamation operation," Ohio proposes to clarify that only the completion of Phase II reclamation is necessary for a site to be considered inactive for the purpose of inspection frequency by deleting the reference to bond reduction. Ohio also proposes to add language that specifies that those portions of an active operation on which Phase II reclamation is complete will be considered inactive for the purpose of inspection frequency. Finally, Ohio proposes to delete an outdated reference to permits other than permanent program "D" permits.

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Ohio program.

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Appalachian Regional Coordinating Center will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to speak at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., [E.D.T.] on June 26, 1996. The location and time of the hearing will be arranged with those persons requesting the hearing. If no one requests an opportunity to speak at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advances of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to speak have been heard. Persons in the audience who have not been scheduled to speak, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to speak and persons present in the audience who wish to speak have been heard.

Any disabled individual who has need for a special accommodation to attend a public hearing should contact the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Public Meeting

If only one person requests an opportunity to speak at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under **ADDRESSES**. A written summary of each meeting will be made a part of the Administrative Record.

IV. 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 12778

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (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. 1253 and 1255) 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 submittal which is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic impact, the Department relied upon the data and assumptions for the counterpart Federal regulations.

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Dated: May 31, 1996.

Allen D. Klein,

Regional Director, Appalachian Regional Coordinating Center.

[FR Doc. 96-14606 Filed 6-10-96; 8:45 am]

BILLING CODE 4310-05-M

30 CFR Part 946

[VA-106-FOR]

Virginia Regulatory Program

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

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: OSM is announcing receipt of a proposed amendment to the Virginia regulatory program (hereinafter referred to as the Virginia program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of regulatory changes to implement the standards of the Federal Energy Policy Act of 1992, and the Code of Virginia as amended in 1993. The amendment is intended to revise the State program to be consistent with the Federal regulations as amended on March 31, 1995 (60 FR 16772).

DATES: Written comments must be received by 4:00 p.m., on July 11, 1996. If requested, a public hearing on the proposed amendment will be held on July 8, 1996. Requests to speak at the hearing must be received by 4:00 p.m., on June 26, 1996.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to Mr. Robert A. Penn, Director, Big Stone Gap Field Office at the first address listed below.

Copies of the Virginia program, the proposed amendment, a listing of any scheduled public hearings, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requestor may receive one free copy of the proposed amendment by contacting OSM's Big Stone Gap Field Office.

Office of Surface Mining Reclamation and Enforcement, Big Stone Gap Field Office, 1941 Neeley Road, Suite 201, Compartment 116, Big Stone Gap, Virginia 24219, Telephone: (703) 523-4303

Virginia Division of Mined Land Reclamation, P.O. Drawer 900, Big

Stone Gap, Virginia 24219,
Telephone: (703) 523-8100.

FOR FURTHER INFORMATION CONTACT:

Mr. Robert A. Penn, Director, Big Stone Gap Field Office, Telephone: (703) 523-4303.

SUPPLEMENTARY INFORMATION:

I. Background on the Virginia Program

On December 15, 1981, the Secretary of the Interior conditionally approved the Virginia program. Background information on the Virginia program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the December 15, 1981, Federal Register (46 FR 61085-61115). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 946.12, 946.13, 946.15 and 946.16.

II. Discussion of the Proposed Amendment

By letter dated May 21, 1996 (Administrative Record No. VA-882), Virginia submitted amendments to the Virginia program concerning subsidence damage. The amendments are intended to make the Virginia program consistent with the Federal regulations as amended on March 31, 1995 (60 FR 16722). Virginia stated that the proposed amendments implement the standards of the Federal Energy Policy Act of 1992, and sections 45.1-243 and 45.1-258 of the Code of Virginia.

Virginia also noted that the State has adopted a revised system for numbering the Virginia regulations. For the Virginia program, the prefix "480-03-19" has been replaced with "4 VAC 25-130-." The part of the existing Virginia numbering system that corresponds to the Federal number remains the same. For example, old "480-03-19.700.5" has been "4 VAC 25-130-700.5." The Virginia Division of Mines, Minerals and Energy (DMME) will be reprinting the Virginia program regulations to incorporate the new prefix, both in the numbering of the regulations and in references contained in the regulations. However, the DMME is continuing to use the "480-03-19." prefix pending the reprint.

The proposed amendments are as follows:

1. § 480-03-19.700.5 Definitions

(a) "Drinking, domestic or residential water supply" has been added to mean water received from a well or spring and any appurtenant delivery system that provides water for direct human consumption or household use. Wells and springs that serve only agricultural,

commercial or industrial enterprises are not included except to the extent the water supply is for direct human consumption or human sanitation, or domestic use.

(b) "Material damage, in the context of §§ 480-03-19.784.20 and 480-03-19.817.121" of this chapter has been added to mean:

(a) Any functional impairment of surface lands, features, structures or facilities;

(b) Any physical change that has a significant adverse impact on the affected land's capability to support any current or reasonably foreseeable uses or causes significant loss in production or income; or

(c) Any significant change in the condition, appearance or utility of any structure or facility from its presubsidence condition.

(c) "Non-commercial building" has been added to mean any building, other than an occupied residential dwelling, that, at the time the subsidence occurs, is used on a regular or temporary basis as a public building or community or institutional building as those terms are defined in § 480-03-19.700.5 of this chapter. Any building used only for commercial agricultural, industrial, retail or other commercial enterprises is excluded.

(d) "Occupied residential dwelling and structures related thereto" has been added to mean, for purposes of §§ 480-03-19.784.20 and 480-03-19.817.121, any building or other structures that, at the time the subsidence occurs, is used either temporally, occasionally, seasonally, or permanently for human habitation. This term also includes any building, structure or facility installed on, above or below, or a combination thereof, the land surface if that building, structure or facility is adjunct to or used in connection with an occupied dwelling. Examples of such structures include, but are not limited to, garages; storage sheds and barns; greenhouses and related buildings, utilities and cables, fences and other enclosures; retaining walls; paved or improved patios, walks and driveways; septic treatment facilities; and lot drainage and lawn and garden irrigation systems. Any structure used only for commercial agricultural, industrial, retail or other commercial purposes is excluded.

(e) "Replacement of water supply" has been added to mean, with respect to protected water supplies contaminated, diminished, or interrupted by coal mining operations, provision of water supply on both a temporary and permanent basis equivalent to premining quantity and quality. Replacement includes provision of an