

V. Effective Date and Opportunity for Public Comment

The agency is issuing this amendment as an interim final rule effective December 11, 1995. The establishment of fees necessary to provide, equip, and maintain an adequate certification program for insulin has been mandated by Congress under section 506(b) of the act (21 U.S.C. 356(b)). As certification services are provided to manufacturers directly by FDA, the setting of a fee schedule to pay for these services is a matter particularly within the purview and expertise of the agency. The fees established by this regulation have been based on cost accounting methods using data compiled by the agency. The cost accounting methods used are the same as those used in two previous rulemakings that established fees for insulin certification. FDA invited comment on these rulemakings, but received none addressing either the adequacy of the fees or accuracy of the cost accounting methods used. Moreover, FDA's experience under the 1991 fee schedule indicates that the fees in that fee schedule do exceed the amounts needed to provide for the insulin certification program and are, therefore, in excess of the fees authorized by the act. For the foregoing reasons, FDA finds for good cause that notice and public procedure would be unnecessary, and contrary to the public interest, and, therefore, a public comment period before the establishment of this rule may be dispensed with under 5 U.S.C. 553(b)(B).

FDA believes that it is appropriate to invite and consider public comments on the provisions of this interim final rule, to determine if these provisions should be amended in the future. Therefore, under 21 CFR 10.40(e), interested persons may, on or before February 7, 1996, submit to the Dockets Management Branch (address above) written comments regarding this document. FDA will use any comments received to determine whether this interim final rule should be modified or other administrative actions taken. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 429

Administrative practice and procedure, Drugs, Labeling, Packaging

and containers, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 429 is amended as follows:

PART 429—DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN

1. The authority citation for 21 CFR part 429 continues to read as follows:

Authority: Secs. 502, 506, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352, 356, 371).

2. Section 429.55 is amended by revising paragraph (b) to read as follows:

§ 429.55 Fees.

* * * * *

(b) The fees for requests for certification submitted under § 429.40 are as follows:

(1) \$2,400 for each master lot or mixture of two or more master lots or parts thereof.

(2) \$1,700 for each dosage form batch.

(3) The fees established in this paragraph may increase as Federal salary costs increase. The rate of increase will be no higher than Federal salary increases, commencing with pay raises on or after January 1, 1997. Notification of the exact fees established and adjustments will be communicated directly to the manufacturers of insulin products.

* * * * *

Dated: November 2, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-27714 Filed 11-8-95; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[IN-110, Amendment Number 93-7, Part I]

Indiana Regulatory Program

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

ACTION: Final rule; approval of amendments.

SUMMARY: OSM is approving part of a proposed amendment to the Indiana permanent regulatory program (hereinafter referred to as the Indiana program) under the Surface Mining Control and Reclamation Act of 1977

(SMCRA). The amendment consists of proposed changes to the Indiana Surface Mining Rules provisions concerning OSM Regulatory Reform I, II and III issues, required program amendments, and State initiatives. This final rule notice is addressing the first of three subparts of the original amendment. The primary focus of the amendments in this subpart is on soil capability and restoration standards, individual civil penalties, significant/nonsignificant revisions, coal exploration, and performance bonds. The amendment is intended to resolve outstanding issues that remain present in the approved Indiana program resulting from changes to the Federal program. The amendment would also incorporate changes desired by the State that address various parts of the State rules.

EFFECTIVE DATE: November 9, 1995.

FOR FURTHER INFORMATION CONTACT:

Mr. Roger W. Calhoun, Director, Indianapolis Field Office, Office of Surface Mining Reclamation and Enforcement, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, IN 46204, Telephone (317) 226-6166.

SUPPLEMENTARY INFORMATION:

- I. Background on the Indiana 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 Indiana Program

On July 29, 1982, the Indiana program was made effective by the conditional approval of the Secretary of the Interior. Information pertinent to the general background on the Indiana program, including the Secretary's findings, the disposition of comments, and a detailed explanation of the conditions of approval of the Indiana program can be found in the July 26, 1982 Federal Register (47 FR 32107). Subsequent actions concerning the conditions of approval and program amendments are identified at 30 CFR 914.10, 914.15, and 914.16.

II. Submission of the Amendment

Since July 29, 1982 (the date of conditional approval of the Indiana program), a number of changes have been made to the Federal regulations concerning surface coal mining and reclamation operations. Pursuant to the Federal regulations at 30 CFR 732.17, OSM informed Indiana on May 22, 1985 (Regulatory Reform I), on August 24, 1988 (Regulatory Reform II), and September 20, 1989 (Regulatory Reform III), that a number of Indiana regulations

are less effective than or inconsistent with the revised Federal requirements.

By letter dated December 30, 1993 (Administrative Record No. IND-1322), the Indiana Department of Natural Resources (IDNR) submitted to OSM State program amendment package number 93-7 consisting of revisions to 38 sections of the Indiana rules.

These revisions address changes to the Indiana program that were identified in the three letters referred to above, and certain required program amendments. The State has also proposed additional changes which Indiana believes will further improve the approved State program. The primary focus of the submittal is on soil capability and restoration standards, individual civil penalties, significant/non-significant

revisions, coal exploration, and performance bonds.

OSM announced receipt of the proposed amendment in the January 24, 1994, Federal Register (59 FR 3528), and, in the same notice, opened the public comment period and provided opportunity for a public hearing on the adequacy of the proposed amendment. The comment period closed on February 24, 1994.

By letter dated December 6, 1994 (Administrative Record Number IND-1415), Indiana submitted additional minor changes to amendment 93-7.

By letter dated January 12, 1995 (Administrative Record Number IND-1423), OSM provided Indiana with comments concerning the proposed amendment. Indiana responded by letter

dated January 25, 1995 (Administrative Record Number IND-1419). In that letter, Indiana said that it wishes to separate amendment 93-7 into three subparts, and that the responses being supplied pertain to the first subpart of amendment 93-7. The amendments are being addressed in this notice comprise amendment 93-7, Part I.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the first of three subparts of proposed program amendment 93-7.

A. Revisions to Indiana's Rules That Are Substantively Identical to the Corresponding Federal Regulations

State rule	Subject	Federal counterpart
310 IAC 12-0.5-122.5	Definition of substantially disturb	30 CFR 701.5.
310 IAC 12-3-78	Underground permits; general requirements	30 CFR 784.11.
310 IAC 12-3-82	Underground permits; postmining land use	30 CFR 784.15(b).
310 IAC 12-4-5	Filing bonds; requirements	30 CFR 800.11.
310 IAC 12-5-4	Coal exploration; permits	30 CFR 772.14.
310 IAC 12-6-21	Individual civil penalties; timing for assessment	30 CFR 846.12.
310 IAC 12-6-23	Individual civil penalties; assessment procedures	30 CFR 846.17.
310 IAC 12-6-24	Individual civil penalties; payment of penalty	30 CFR 846.18.
310 IAC 12-7-4	Filing requirements	30 CFR 705.11.
310 IAC 12-7-5	Filing dates	30 CFR 705.13.
310 IAC 12-7-6	Filing locations	30 CFR 705.15.

Because the above proposed revisions are identical in meaning to the corresponding Federal regulations, or contain nonsubstantive wording and paragraph notation changes, the Director finds that Indiana's proposed rules are no less effective than the Federal regulations.

B. Revisions to Indiana's Rules That Are Not Substantively Identical to the Corresponding Federal Regulations

1. 310 IAC 12-0.5-109.5 Definition of Rooting Media

"Rooting media" is defined as a soil material beneath the topsoil consisting of replaced "B" horizon, "B/C" mixture, another suitable soil material as determined by the director of the Indiana Department of Natural Resources (IDNR). While there is no direct counterpart to this definition, the Director finds that the definition is not inconsistent with the Federal definition of "soil horizons" as 30 CFR 701.5.

2. 310 IAC 12-0.5-110.5 Definition of Shadow Area

"Shadow area" is defined as any area beyond the limits of the permit area in which underground mine workings are located. This area includes resources

above and below the coal that are protected by IC 13-4.1 that may be adversely impacted by underground mining operations including impacts of subsidence. While there is no direct Federal counterpart to this definition, the Director finds the definition to be consistent with the Federal definition of "affected area" at 30 CFR 701.5.

3. 310 IAC 12-1-5 Exemption for Coal Extraction Incidental to the Extraction of Other Minerals

This provision is being amended to correct a citation error. Reference to IC 13-4.1-1-4(2) is being deleted and replaced by IC 13-4.1-1-3(12). This amendment satisfies the required program amendment codified at 30 CFR 914.16(bb).

4. 310 IAC 12-3-31 and 310 IAC 12-3-69 Permit Applications; Geology Description

These provisions have been rewritten to be substantively identical to the counterpart Federal provisions at 30 CFR 780.22 and 784.22 with the following exceptions. At 310 IAC 12-2-31(c) and at 12-3-69 (a)(3) and (c), the Indiana language uses the term "rule" rather than the more inclusive term

"article." To no less effective than the counterpart Federal regulations at 30 CFR 780.22(c) and 784.22 (a)(3) and (c), the Indiana language should use the term "article" meaning the entire set of performance standards under 310 IAC 12. In its letter to OSM dated January 25, 1995, Indiana stated that the language has been changed to read "article."

Indiana is amending 310 IAC 12-3-69(d) to clarify that the applicant may request that the director of the IDNR waive in whole or in part certain geologic information if that information is unnecessary because other reliable information is available. The amendments are substantively identical to and no less effective than the counterpart Federal language at 30 CFR 784.22(d) with one exception. The State provision would authorize the waiver of all the requirements of section 310 IAC 12-3-69(b) rather than only the requirements of 310 IAC 12-3-69 (b)(2) and (b)(3) as is authorized by the counterpart Federal provisions at 30 CFR 784.22(d). In its letter to OSM dated January 25, 1995, Indiana stated that the language has been changed to read subsections "69 (b)(2) and (b)(3)."

Therefore, OSM finds the proposed amendments to be no less effective than the counterpart Federal regulations.

5. 310 IAC 12-3-48 Permit Applications; Postmining Land Uses

In addition to nonsubstantive wording changes, Indiana is deleting a reference to 310 IAC 12-5-68 and adding in its place reference to new 310 IAC 12-5-68.5 concerning postmining land use capability. Indiana is also adding new subsection 48(a)(3) to provide that consideration be given to all of the proposed surface mining activities consistent with surface owner plans and applicable State and local land use plans and programs. The new language is substantively identical to counterpart Federal language at 30 CFR 780.23(b)(3). The Director finds that the proposed citation change does not render the provision less effective than 30 CFR 780, and the added language is no less effective than the counterpart Federal language at 30 CFR 780.23(b)(3).

6. 310 IAC 12-3-97 Special Categories of Mining; Approximate Original Contour Variance for Steep Slope Mining; Permits

In addition to various nonsubstantive changes made throughout this section, the following changes are made. At subsection 97(a)(3), Indiana is deleting reference to sections 310 IAC 12-5-68 and 12-5-136 and replacing them with 310 IAC 12-5-68.5 and 12-5-136.5, respectively. The deletion of 310 IAC 12-5-68 and 310 IAC 12-5-136 and their replacement by 310 IAC 12-5-68.5 and 310 IAC 12-5-136.5, respectively is discussed later in this document. The Director finds that the amendments to subsection 97(a)(3) do not render the provision less effective than the counterpart Federal regulations at 30 CFR 816/817.133(d)(2) concerning alternative postmining land use requirements.

New subsection 97(a)(8) is added to require the design and certification of a proposed use by a qualified registered professional engineer. The director finds the proposed language to be substantively identical to counterpart Federal language at 30 CFR 816/817.133(d)(5).

New subsection 97(a)(9) is added to limit the amount of spoil to be placed off the mine bench. The Director finds the proposed language to be substantively identical to 30 CFR 816/817.133(d)(8).

New subsection 97(a)(10) is added to ensure adequate time for public agencies to review and comment on the proposed land use. The Director finds that the proposed language is

substantively identical to the Federal regulations at 30 CFR 816/817.133(d)(10).

7. 310 IAC 12-3-106 Permit Applications; Review, Public Participation, and Approval or Disapproval of Permit Applications; Permit Terms and Conditions; Responsibility

In addition to various nonsubstantive changes made throughout this section, the following changes are made. Subsection 106(a) is being amended to apply to both permit revisions and renewals in addition to initial permit. The amended language is substantively identical to the counterpart Federal language at 30 CFR 733.13(a)(1).

Subsection 106(a) is also being amended by adding the words "at a minimum" to clarify that the list of requirements starting at subsection 106(a)(1) is not an exhaustive list. The amended language is substantively identical to the counterpart language at 30 CFR 773.13(a)(1).

Subsection 106(a)(2) is amended to require a "map or" description that clearly "shows or" describes (at subsection 106(a)(2)(A)) the required information to be included in the newspaper announcement. The amended language is substantively identical to the counterpart Federal language at 30 CFR 773.13(a)(1)(ii).

Subsection 106(a)(2)(B) is amended to provide that if a map is used, it shall indicate the north direction. The added language is substantively identical to the counterpart language at 30 CFR 773.13(a)(1)(ii).

Subsection 106(a)(6) is being amended to provide that all of the requirements of subsection 106(a)(6) pertaining to the relocation of roads will also apply to the closure of roads. The words "approximate timing and" are added immediately preceding the words "duration of the relocation or closure." The amended language is substantively identical to the counterpart Federal provision at 30 CFR 773.13(a)(1)(v).

New subsection 106(a)(7) is added to require that copies of the advertisement be mailed to certain persons. While there is no direct Federal counterpart language, the proposed language is not inconsistent with SMCRA at section 513 concerning public notice and 30 CFR 773.13 concerning public participation.

New subsection 106(a)(8) is added to provide that if the permit application includes a request for an experimental practice under section 94, a statement must be provided that indicates that an experimental practice is requested and identifies the regulatory provisions for which a variance is requested. In its

January 25, 1995, letter to OSM, Indiana stated that the citation of section "94" has been corrected to read "94.1." The Director finds that the proposed language, with the corrected citation is substantively identical to and no less effective than the counterpart Federal language at 30 CFR 773.13(a)(1)(vi).

Subsection 106(a)(9) as a counterpart to 30 CFR 773.13(a)(2) concerning the requirement to make a copy of the permit, revision, or renewal available to the public at the courthouse of the county where the mining is proposed to occur, or an accessible public office approved by the regulatory authority. Indiana language counterpart to the Federal requirement that applicants file changes to the applications at the public office at the same time the change is submitted to the regulatory authority is found at 310 IAC 12-3-106(c). The director finds that the proposed language, along with the language referred to above and found at 310 IAC 12-3-106(c), is substantively identical to the Federal language at 30 CFR 773.13(a)(2). The Director notes that Indiana uses public libraries as the accessible public office where the copies of permits, revisions, and renewals will be filed.

Subsection 106(c) is being amended to change a citation of subsection 106 "(b)" to read 106 "(a)(9)". In addition, the subsection is being amended to provide that any subsequent modification of the application "or permit" be also filed with the library copy of the application or permit. The Director finds these changes to be consistent with the counterpart Federal regulations at 30 CFR 773.13(a)(2).

Subsection 106(d) has several changes. Subsections 106(d)(2), (3), and (4) have been amended to clarify that the library copy of the application or permit may be removed from the library only after all bond has been released from the permit. Subsection 106(d)(4) is amended to add citations of 310 IAC 12-3-17 and 31, concerning application or permit information that may be exempt from public disclosure, to the citation of 310 IAC 12-3-110. The Director finds that these changes are consistent with and no less effective than the Federal regulations at 30 CFR 773.13.

New subsection 106(d)(5) is added to provide that the applicant shall not be responsible for the maintenance of the copy of the application or permit on file with the library. There is no Federal Counterpart to this proposed language. However, since the applicant is required, under subsection 106(d)(1), to pay the library a \$50 dollar nonrefundable fee, it is reasonable to

conclude that the library, upon acceptance of the fee, is responsible for the maintenance of the copy. Therefore, the Director finds the new language does not render the Indiana program less effective.

Subsection 106(e) is amended to add the words "or a revision or renewal of a permit." The added words are substantively identical to the counterpart language at 30 CFR 773.13(a)(3).

Subsection 106(g) is added as a counterpart to 30 CFR 773.12 concerning the coordination of the review and issuance of permits with other agencies to avoid duplication. The director finds the new language to be substantively identical to 30 CFR 773.12.

8. 310 IAC 12-4-7 Period of Liability

Subsection 7(a) is amended to update the citations of the revegetation standards to reflect the most current, approved standards. Language is also added to provide a counterpart to the Federal regulations at 30 CFR 800.13(a)(2) concerning the bonding of specific phases of reclamation. The Director finds that the revised citations do not render the Indiana program less effective and the added language is substantively identical to the counterpart Federal regulations.

Subsection 7(b) is revised by the updating of a citation to the approved revegetation standards. The Director finds that the citation change does not render the Indiana program less effective.

Subsection 7(d) is amended by updating two citations and adding language that mirrors Federal language. The proposed citation changes reflect amendments that were proposed in the original submittal of this amendment package (Amendment 93-7). On January 25, 1995, Indiana requested that Amendment 93-7 be subdivided and reviewed in three parts. The proposed citation changes reflect amendments that are now contained in Part III of Amendment 93-7. The Director is approving the citation changes and notes that the amendments to those provisions will be reviewed in a future Federal Register Notice.

The language in subsection 7(d) that mirrors the Federal language (at 30 CFR 800.13(c)) refers to the applicable five "or ten (10) year" period of liability for revegetation success. The director finds that the added language is substantively identical to and no less effective than the counterpart Federal language.

Subsection 7(e) is amended by deleting language that did not hold the operator responsible for actions by third

parties. The Federal regulations previously contained such a provision, but were amended to eliminate the reference to actions by third parties. Indiana is adding, in place of the deleted language, language that is substantively identical to the counterpart Federal regulations at 30 CFR 800.13(d)(1). The Director finds that with the amendments, the provision is no less effective than the counterpart Federal language.

9. 310 IAC 12-5-3 Coal Exploration; Performance Standards

The introductory paragraph to this section is amended to add language that is substantively identical to and no less effective than the counterpart Federal language at 30 CFR 815.1 concerning the scope and purpose of the performance standards for coal exploration.

New subsection 3(a) is added and is substantively identical to and no less effective than the counterpart Federal regulations at 30 CFR 815.15(a) concerning the protection of certain habitats of unique or unusually high value.

Subsection 3(b)(2) is amended by deleting the existing language and adding in its place language that is substantively identical to and no less effective than the counterpart Federal regulations at 30 CFR 815.15(b) concerning roads and other transportation facilities.

Subsections 3(b)(3) and (4) are deleted. There are no Federal counterparts at 30 CFR 815.15 to the deleted language and the deletion does not render the Indiana program less effective than the Federal regulations.

Subsection 3(e) is amended by deleting and adding language to make the provision substantively identical to and no less effective than the counterpart Federal regulations at 30 CFR 815.15(e) concerning revegetation of areas disturbed by coal exploration.

Subsection 3(f) is amended to change the term "may" to read "shall" to clarify that the requirements of the section are mandatory rather than voluntary. The Director finds the change to be substantively identical to and no less effective than the Federal requirement at 30 CFR 815.15(f) concerning diversions.

Subsection 3(h) is amended by deleting language and adding language that is substantively identical to the Federal regulations at 30 CFR 815.15(i) concerning minimizing disturbances to the hydrologic balance. The Director finds that the amended provision is no less effective than the Federal counterpart.

Subsection 3(i) is amended by deleting and adding language that

makes the provision substantively identical to and no less effective than the counterpart Federal regulations at 30 CFR 815.15(j) concerning acid- or toxic-forming materials.

10. 310 IAC 12-6-20 Individual Civil Penalties; Definitions

This new provision has been renumbered. In the original submittal, this provision was identified as 310 IAC 12-6-19.

This new provision is added to provide a counterpart to the Federal regulations at 30 CFR 846.5. In its January 25, 1995, letter to OSM, Indiana corrected two citation references in subsection (2)(B). Indiana is revising the sentence in subsection (2)(B) to read: "* * * except an order incorporated in a decision issued under IC 13-4.1-12-1." The citation change concerns civil penalties and adds specificity to the Indiana provision that is counterpart to the Federal citation of section 518(b) of SMCRA at 30 CFR 846.5 in the definition of "violation, failure or refusal." The Director finds that the addition is substantively identical to and no less effective than the counterpart Federal regulations.

11. 310 IAC 12-6-22 Individual Civil Penalties; Amount

This new provision has been renumbered. In the original submittal, this provision was identified as 310 IAC 12-6-21. This new provision is added to provide a counterpart to the Federal regulations at 30 CFR 846.14 concerning the amount of individual civil penalties. In its January 25, 1995, submittal to OSM, Indiana made one citation change. In subsection 22(a), Indiana changed "IC 13-4.1" to read "IC 13-4.1-12-1." The change adds appropriate specificity to identify the criteria concerning civil penalties. With the above change, the new language of this subsection is substantively identical to and no less effective than 30 CFR 846.14.

IV. Summary and Disposition of Comments

Federal Agency Comments

Pursuant to section 503(b) of SMCRA and 30 CFR 732.17(h)(1)(i), comments were solicited from various interested Federal agencies. The U.S. Fish and Wildlife Service (FWS) responded (Administrative Record Number IND-1335). The FWS commented that additional information should be added to 310 IAC 12-5-3(a) to state that if wetlands are affected, a permit by the U.S. Army Corps of Engineers may be needed. In response, the Director notes that the counterpart Federal standards at

30 CFR 815.15 do not contain such a provision and that the Indiana provision is substantively identical to the Federal provision so the Indiana provision need not be changed.

Other comments submitted by FWS pertain to amendments that will be addressed later in final rule notices concerning Amendment 93-7 parts II and III.

No other agency comments were received.

Public Comments

A public comment period and opportunity to request a public hearing was announced in the January 24, 1994, Federal Register (59 FR 3528). The comment period closed on February 24, 1994. No one commented and no one requested an opportunity to testify at the scheduled public hearings so no hearing was held.

Environmental Protection Agency (EPA)

Under 30 CFR 732.17(h)(11)(ii), the Director is required to obtain the written concurrence of the Administrator of the EPA with respect to any provisions of a State program amendment that relate to air or water quality standards promulgated 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.*). The Director has determined that these amendments contain no provisions in these categories and that EPA's concurrence is not required.

Pursuant to 732.17(h)(11)(i), OSM solicited comments on the proposed amendments from EPA (Administrative Record No. IND-1330). EPA did not provide any comments concerning this amendment.

V. Director's Decision

Based on the findings above, the Director is approving Indiana's program amendment #93-7 as submitted by Indiana on December 30, 1993, and amended on December 6, 1994, and January 25, 1995.

The Federal regulations at 30 CFR Part 914 codifying decisions concerning the Indiana 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 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 914

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 20, 1995.

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 914—INDIANA

1. The authority citation for part 914 continues to read as follows:

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

2. In section 914.15, paragraph (mmm) is added to read as follows:

§ 914.15 Approval of regulatory program amendments

* * * * *

(mmm) Amendment #93-7, Part I concerning revisions to the following Indiana rules as submitted to OSM on December 30, 1993, and amended on December 6, 1994, and January 25, 1995, is approved effective November 9, 1995.

310 IAC 12-0.5-109.5 concerning the definition of rooting media;

310 IAC 12-0.5-110.5 concerning the definition of shadow area;

310 IAC 12-0.5-122.5 concerning the definition of substantially disturb;

310 IAC 12-1-5 concerning exemption for coal extraction incidental to the extraction of other minerals;

310 IAC 12-3-31 concerning permit applications, geology description;

310 IAC 12-3-48 concerning permit applications, postmining land uses;

310 IAC 12-3-69 concerning permit applications (underground), geology description;

310 IAC 12-3-78 concerning permit applications (underground), general;

310 IAC 12-3-82 concerning permit applications (underground), postmining land use;

310 IAC 12-3-97 concerning special categories of mining, approximate original contour variance for steep slope mining, permits;

310 IAC 12-3-106 concerning permit applications, review, public participation, and approval or disapproval of permit applications, permit terms and conditions, responsibility;

310 IAC 12-4-5 concerning requirements for filing bonds;

310 IAC 12-4-7 concerning period of liability;

- 310 IAC 12-5-3 concerning performance standards for coal exploration;
- 310 IAC 12-5-4 concerning permits for coal exploration;
- 310 IAC 12-6-20 concerning individual civil penalties, definitions;
- 310 IAC 12-6-21 concerning individual civil penalties;
- 310 IAC 12-6-22 concerning the amount of individual civil penalties;
- 310 IAC 12-6-23 concerning assessment procedures for individual civil penalties;
- 310 IAC 12-6-24 concerning payment of individual civil penalties;
- 310 IAC 12-7-4 concerning financial interests, filing requirements;
- 310 IAC 12-7-5 concerning financial interests, filing dates; and
- 310 IAC 12-7-6 concerning financial interests, filing locations.

§ 914.16 [Amended]

3. In Section 914.16, paragraph (bb) is removed and reserved.

[FR Doc. 95-27806 Filed 11-8-95; 8:45 am]

BILLING CODE 4310-05-M

30 CFR Part 920

[MD-038-FOR]

Maryland Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Maryland regulatory program (hereinafter referred to as the "Maryland program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Maryland proposed revisions to its rules and statutes pertaining to the Small Operators Assistance Program (SOAP). The amendment is intended to revise the Maryland program to be consistent with the corresponding Federal regulations.

EFFECTIVE DATE: November 9, 1995.

FOR FURTHER INFORMATION CONTACT: Robert Biggi, Director, Harrisburg Field Office, OSM, Harrisburg Transportation Center, Third Floor, Suite 3C, 4th and Market Streets, Harrisburg, PA 17101. Telephone: (717) 782-4036.

SUPPLEMENTARY INFORMATION:

- I. Background on the Maryland Program
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I. Background on the Maryland Program

On December 1, 1980, the Secretary of the Interior conditionally approved the Maryland program. Background information on the Maryland program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the December 1, 1980, Federal Register (45 FR 79449). Subsequent actions concerning conditions of approval and program amendments can be found at 30 CFR 920.12, 920.15 and 920.16.

II. Submission of the Proposed Amendment

By letter dated June 16, 1995, (Administrative Record No. MD-572.00) Maryland submitted a proposed amendment to its program pursuant to SMCRA at its own initiative. Maryland proposed to revise its SOAP provisions in the Annotated Code of Maryland (Code) to incorporate the provisions of House Bill 945 approved on May 18, 1995, by the Governor of Maryland and in the Code of Maryland Regulations (COMAR). Specifically, the code has been revised to delete the portion of existing section 7-505(c)(4) which refers to SOAP operator eligibility. This provision is proposed to be added to section 7-515. Also, the Code has been revised to delete the provisions of existing section 7-515 which specified alternative permit procedures for coal mining operations of two acres or less. The revised provisions at 7-515 provide that, upon written request of the operator, the Department of Natural Resources (Department) will assume the cost of certain, specified activities for those operations where probable total annual production at all locations will not exceed 300,000 tons. The Department is also required to either provide training to or assume the cost of training coal operators in the preparation of permit applications and compliance requirements. If the operator's annual production of coal

exceeds 300,000 tons, the operator is required to reimburse the Department for any assistance received. The corresponding regulations at COMAR 08.20.16.02A have been revised to specify the services that will be provided by a qualified laboratory and reimbursed by the Department to qualified operators. The eligibility for assistance provisions at COMAR 08.20.16.03A have been revised to increase the total annual coal production limit from 100,000 tons to 300,000 tons. COMAR 08.20.16.02B has been revised to increase the percentage of ownership for production purposes in an operation either by the applicant or others from 5% to 10%. The applicant liability provisions at COMAR 08.20.16.08A have been revised to require that if the operator's annual production of coal during the 12 months immediately following the date on which the operator is issued the permit exceeds 300,000 tons, the operator is required to reimburse the Department for the cost of services specified in section .02A. The same requirement applies if the operator sells, transfers, or assigns the permit to another person and the transferee's total production exceeds 300,000 tons.

OSM announced receipt of the proposed amendment in the July 13, 1995, Federal Register (60 FR 36080) and in the same document opened the public comment period and provided an opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on August 14, 1995.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment.

Revisions not specifically discussed below concern nonsubstantive wording changes, or revised cross-references and paragraph notations to reflect organizational changes resulting from this amendment.

A. Revisions to Maryland's Statutes and Regulations That Are Substantively Identical to the Corresponding Provisions of the Federal Statutes and Federal Regulations

State regulation	Subject	Federal counterpart
COMAR 08.20.16.02A	Program Services	30 CFR 795.9 (a), (b).
COMAR 08.20.16.03A	Eligibility	30 CFR 795.6(a)(2).
COMAR 08.20.16.03B	Eligibility	30 CFR 795.6(a)(2) (i), (ii).
COMAR 08.20.16.08 A, B	Applicant Liability	30 CFR 795.12(a) (2), (3).
Code 7-515(A) (1), (3)-(6)	Operator Assistance	SMCRA 507(c)(1).