

51364) is herein finalized without change.

The contents of records required for regulated transactions are stated in 21 CFR 1310.06. Specifically, 21 CFR 1310.06(a)(5) provides that each record shall include the type of identification used by the purchaser and any unique number on that identification. It is the responsibility of the regulated person who engages in a regulated transaction to identify the other party to the transaction and verify the existence and apparent validity of a business entity ordering a listed chemical in compliance with 21 CFR 1310.07. If the assignment of a company customer identification number is based upon meeting all requirements as specified in 21 CFR 1310.07, and this customer identification number can be cross-referenced with the type of identification used to verify the existence and apparent validity of the purchaser and any unique number on that identification, then a customer identification number will be deemed adequate to meet the requirements of 21 CFR 1310.06(a)(5).

Further, 21 CFR 1310.06(b) states that normal business records shall be considered adequate if they contain the information listed in 21 CFR 1310.06(a) and are readily retrievable from other business records of the regulated person. Thus, if these records are readily retrievable and meet all the requirements of 21 CFR 1310.06(a) then these records shall be deemed adequate. However, it is the responsibility of each regulated person to ensure that all requirements of 21 CFR 1310.06 are adequately met if relying on normal business records to satisfy the recordkeeping requirements of 21 CFR 1310.03.

The products in question are prescription products which are already subject to strict Federal and state controls. This final rule modifies 21 CFR 1310.06(b) to reflect that for purposes of this section, prescription and hospital records kept in the normal course of medical treatment shall be adequate to meet recordkeeping requirements.

This rule has been drafted and reviewed in accordance with Executive Order 12866, Section 1(b), Principles of Regulation. The Deputy Administrator has determined that this rule is not a significant regulatory action under Executive Order 12866 Section 3(f), Regulatory Planning and Review. This action allows relief from regulatory requirements by permitting the use of normal business records for these prescription products rather than requiring the creation of separate

records of transactions. Accordingly, this rule has not been reviewed by the Office of Management and Budget.

The Deputy Administrator in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that the rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1310

Drug traffic control, Reporting and recordkeeping requirements.

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

Accordingly, the interim rule amending 21 CFR part 1310 which was published at 59 FR 51364 on October 11, 1994, is adopted as a final rule without change.

Dated: March 20, 1995.

Stephen H. Greene,

Deputy Administrator, Drug Enforcement Administration.

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[IN-121; Amendment 94-7]

Indiana 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 Indiana regulatory program (hereinafter referred to as the "Indiana program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Indiana proposed revisions to the Indiana Surface Coal Mining rules pertaining to the backfilling and grading of surface coal mining and reclamation operations. The amendment is intended to provide additional safeguards and clarify ambiguities.

EFFECTIVE DATE: April 7, 1995.

FOR FURTHER INFORMATION CONTACT:

Roger W. Calhoun, Director, Indianapolis Field Office, OSM, Minton-Capehart Federal Building, Room 301, Indianapolis, Indiana 46204. Telephone: (317) 232-1547.

SUPPLEMENTARY INFORMATION:

- I. Background on the Indiana Program.
- II. Submission of the Proposed 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 Secretary of the Interior conditionally approved the Indiana program. Background information on the Indiana program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the July 29, 1982, **Federal Register** (47 FR 32071). Subsequent actions concerning conditions of approval and program amendments can be found at 30 CFR 914.10, 914.15, and 914.16.

II. Submission of the Proposed Amendment

By letter dated January 31, 1995, (Administrative Record No. IND-1420) Indiana submitted a proposed amendment to its program pursuant to SMCRA at its own initiative. Indiana proposed to revise 310 IAC 12-5-54.1—Surface Mining: Backfilling and Grading, Timing Limitations.

OSM announced receipt of the proposed amendment in the February 17, 1995, **Federal Register** (60 FR 9313), 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 March 20, 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.

310 IAC 12-5-54.1—Surface Mining: Backfilling and Grading, Timing Limitations

Indiana is revising subsection (a) to make several nonsubstantive wording changes. At subsection (a)(1), Indiana is requiring that backfilling and grading in

mining operations that involve spoil ridges be accomplished in 180 days of deposition, provided that no more than four spoil ridges remain at any one time. The current regulations specify that no more than an average of four spoil ridges by length remain.

Indiana is revising subsection (b) to make two nonsubstantive wording changes and to correct a cross-reference.

Indiana is revising subsection (c) to make two nonsubstantive wording changes and to delete the requirement that requests for an extension of the timing limitation for more than one year be approved by the Natural Resources Commission.

The corresponding Federal regulations at 30 CFR 816.101 were suspended effective August 31, 1992 (57 FR 33875). Therefore, States may adopt backfilling and grading time and distance standards which result in contemporaneous mining and reclamation as required by 30 CFR 816.100. The Director finds the proposed revisions at 310 IAC 12-5-54.1 no less effective than the Federal requirements for contemporaneous reclamation at 30 CFR 816.100 and 817.100.

IV. Summary and Disposition of Comments

Public Comments

The Director solicited public comments and provided an opportunity for a public hearing on the proposed amendment. No public comments were received, and because no one requested an opportunity to speak at a public hearing, no hearing was held.

Federal Agency Comments

Pursuant to 30 CFR 732.17(h)(11)(i), the Director solicited comments on the proposed amendment from various Federal agencies with an actual or potential interests in the Indiana program. No comments were received.

Environmental Protection Agency (EPA)

Pursuant to 30 CFR 732.17(h)(11)(ii), OSM is required to obtain the written concurrence of the EPA with respect to those provisions of the proposed 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.*).

None of the revisions that Indiana proposed to make in this amendment pertain to air or water quality standards. Therefore, OSM did not request EPA's concurrence.

V. Director's Decision

Based on the above finding, the Director approves the proposed amendment as submitted by Indiana on January 31, 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 corresponding 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 corresponding Federal regulations.

List of Subjects in 30 CFR 914

Intergovernmental relations, Surface mining, Underground mining.

Dated: March 30, 1995.

David G. Simpson,

Acting Assistant Director, Eastern Support 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. Section 914.15 is amended by adding paragraph (hhh) to read as follows:

§ 914.15 Approval of regulatory program amendments.

* * * * *

(hhh) The following amendment (Program Amendment Number 94-7) as submitted to OSM on January 31, 1995 is approved effective April 7, 1995: 310 IAC 12-5-54.1 concerning timing limitations for backfilling and grading of surface coal mining and reclamation operations.

[FR Doc. 95-8583 Filed 4-6-95; 8:45 am]

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