

IV. Paperwork Reduction Act of 1995

FDA concludes that the labeling requirement in this document is not subject to review by the Office of Management and Budget because it does not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the labeling statements are a "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

V. Environmental Impact

FDA has determined under 21 CFR 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

List of Subjects in 21 CFR Part 201

Drugs, Labeling, 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 201 is amended as follows:

PART 201—LABELING

■ 1. The authority citation for 21 CFR part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 2. Section 201.64 is amended by adding paragraph (k) to read as follows:

§ 201.64 Sodium labeling.

* * * * *

(k) The labeling of OTC drug products intended for rectal administration containing dibasic sodium phosphate and/or monobasic sodium phosphate

shall contain the sodium content per delivered dose if the sodium content is 5 milligrams or more. The sodium content shall be expressed in milligrams or grams. If less than 1 gram, milligrams should be used. The sodium content shall be rounded-off to the nearest whole number if expressed in milligrams (or nearest tenth of a gram if expressed in grams). The sodium content per delivered dose shall follow the heading "Other information" as stated in § 201.66(c)(7). Any product subject to this paragraph that contains dibasic sodium phosphate and/or monobasic sodium phosphate as an active ingredient intended for rectal administration and that is not labeled as required by this paragraph and that is initially introduced or initially delivered for introduction into interstate commerce after November 29, 2005, is misbranded under sections 201(n) and 502(a) and (f) of the act.

Dated: November 18, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[Docket No. IN–141–FOR]

Indiana Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: We, the Office of Surface Mining Reclamation and Enforcement (OSM), are approving, with an additional requirement, an amendment to the Indiana regulatory program (Indiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Indiana proposed revisions to and additions of rules about definitions, identification of interests, topsoil, siltation structures, impoundments, refuse piles, prime farmland, lands eligible for re-mining, permitting, performance bond release, surface and ground water monitoring, roads, inspection, and civil penalties. Indiana intends to revise its program to be consistent with the corresponding Federal regulations, clarify ambiguities, and improve operational efficiency.

DATES: Effective: November 29, 2004.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

- I. Background on the Indiana Program
- II. Submission of the Amendment
- III. OSM's Findings
- IV. Summary and Disposition of Comments
- V. OSM's Decision
- VI. Procedural Determinations

I. Background on the Indiana 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 State 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 this Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to this 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 Indiana program effective July 29, 1982. You can find background information on the Indiana program, including the Secretary's findings, the disposition of comments, and the conditions of approval, in the July 26, 1982, **Federal Register** (47 FR 32071). You can also find later actions concerning the Indiana program and program amendments at 30 CFR 914.10, 914.15, 914.16, and 914.17.

II. Submission of the Amendment

By letter dated May 19, 2004 (Administrative Record No. IND–1726), the Indiana Department of Natural Resources, Division of Reclamation (Indiana or IDNR) sent us an amendment to its program under SMCRA (30 U.S.C. 1201 *et seq.*). Indiana sent the amendment in response to a June 17, 1997, letter (Administrative Record No. IND–1575) that we sent to Indiana in accordance with 30 CFR 732.17(c) and in response to the required program amendments at 30 CFR 914.16(f), (s), and (hh) through (mm). The amendment also included changes made at Indiana's own initiative.

We announced receipt of the proposed amendment in the July 19, 2004, **Federal Register** (69 FR 42931). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. We did not hold a public hearing or meeting because no one requested one. The public comment

period ended on August 18, 2004. We received comments from one Federal agency.

During our review of the amendment, we identified concerns about inspection of abandoned sites and several editorial-type errors. We notified Indiana of these concerns by letter dated July 26, 2004, (Administrative Record No. IND-1732).

By letter dated September 14, 2004 (Administrative Record No. IND-1733), Indiana responded to our July 26, 2004, letter. Indiana intends to make changes to its inspection of abandoned sites rule and to correct the editorial-type errors through the errata and program amendment processes at a later date. Therefore, we are proceeding with this final rule **Federal Register** document.

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 with an additional requirement as described below.

A. Minor Revisions to Indiana's Rules

Indiana proposed minor wording, editorial, punctuation, grammatical, and recodification changes to the following previously-approved rules:

312 Indiana Administrative Code (IAC) 25-4-17(a)(1), Surface mining permit applications—identification of interests; 25-4-115(a)(3), Permit approval or denial; 25-4-118(8), Permit

conditions; 25-6-17(b)(2)(I), Surface mining-siltation structures; 25-6-23(a)(2), Surface mining-surface and ground water monitoring; and 25-7-1(a)(1) and (d)(2), Inspections of sites.

Because these changes are minor, we find that they will not make Indiana's rules less effective than the corresponding Federal regulations.

B. Revisions to Indiana's Rules That Have the Same Meaning as the Corresponding Provisions of the Federal Regulations

Indiana's rules listed in the table below contain language that is the same as or similar to the corresponding sections of the Federal regulations.

Topic	State Rule 312 IAC	Federal Regulation 30 CFR
Definition of lands eligible for remining	25-1-75.5	701.5.
Definition of unanticipated event or condition	25-1-155.5	701.5.
Prime farmland	25-4-102(d)(1), (e), (f)	785.17(c)(1), (d)(4), (e).
Performance bond release	25-5-16(b), (c)	800.40(a)(3), (b).
Surface mining and underground mining; hydro- logic balance; siltation structures.	25-6-17(a)(3), (d)(2), (d)(3); 25-6-81(a)(3), (d)(2), (d)(3).	816.46(b)(3), (c)(2); 817.46(b)(3), (c)(2).
Surface mining and underground mining; hydro- logic balance; permanent and temporary im- poundments.	25-6-20(a), (c); 25-6-84(a), (c)	816.49(a), (c); 817.49(a), (c).
Civil penalties; hearing request	25-7-20	845.19(a).

Because the above State rules have the same meaning as the corresponding Federal regulations, we find that they are no less effective than the Federal regulations. We also find that Indiana's revisions at 25-6-20(a)(9)(E) and 25-6-84(a)(9)(E) that change the term "subsection" to the term "clause" in the phrase "the following impoundments shall be exempt from the examination requirements of this subsection" satisfy the required amendment at 30 CFR 914.16(ii)(3), and we are removing it.

C. 312 IAC 25-1-8 Definition of Affected Area

1. 312 IAC 25-1-8(a)(1) through (7). Indiana designated the existing provision as subsection (a) and amended the definition of "affected area" to mean "any land or water surface area that is used to facilitate, or is physically altered by, surface coal mining and reclamation operations." Subdivisions (a)(1) through (7) specify those areas of a permit that will be considered affected areas. At subdivisions (a)(2), (4), and (6), Indiana replaced the terms "an" with the term "any" to refer to areas that would be considered "affected areas." At subdivision (a)(3), Indiana added the word "any" before the word "adjacent." At subdivision (a)(4), Indiana added the language "except as provided in this

section" at the end of the subdivision. Indiana restructured subdivision (a)(5) and changed the words "a site" to "any area." At subdivision (a)(6), Indiana made minor wording revisions by adding the word "property" between the words "other" and "material"; changing the word "incidental" to "incident"; and adding the word "and" after the word "mining." At subdivision (a)(7), Indiana removed the words "of a mine" from the end of the subdivision.

We find that the revised language at subsection (a) is substantively the same as the counterpart language in the Federal definition of "affected area" at 30 CFR 701.5. Therefore, we are approving 312 IAC 25-1-8(a).

2. 312 IAC 25-1-8(b) and (c). Indiana added introductory language at subsection (b) to identify the roads associated with the permit area that are considered affected areas and added subdivisions (b)(1) through (4) to identify the criteria for exemption of those roads that are not considered affected areas. Roads must meet all of the criteria listed in subdivisions (b)(1) through (4) before being considered for exemption. Subsection (b) identifies as affected areas those roads used for the purposes of access to, or for hauling coal to or from, any surface coal mining and reclamation operation unless they meet the criteria in subdivisions (b)(1)

through (4). Subdivision (b)(1) specifies that for a road to be exempt, it must be "designated as a public road pursuant to the laws of the jurisdiction in which it is located." Subdivision (b)(2) specifies that the road must be "maintained with public funds, and constructed in a manner similar to other public roads of the same classification within the jurisdiction." Subdivision (b)(3) provides that the road must have a "substantial (more than incidental) public use." Finally, subdivision (b)(4) specifies that "the extent and the effect of mining-related uses of the road by the permittee must not warrant regulation as part of the surface coal mining and reclamation operations." Indiana added subsection (c) to require the director of the IDNR (director) to determine on a case-by-case basis whether a road satisfies the requirements of subdivision (b)(4) based on the mining related use of the road and consistent with Indiana's definition of "surface coal mining operation."

The language at subsection (b) and subdivisions (b)(1), (b)(2), and (b)(3) is substantively the same as language found in the counterpart Federal definition of "affected area" at 30 CFR 701.5. On November 20, 1986 (51 FR 41952), we suspended the definition of "affected area" at 30 CFR 701.5 insofar as it might limit jurisdiction over roads

covered by the definition of “surface coal mining operations.” Our revised road rules were published on November 8, 1988 (53 FR 45192). In finalizing those rules, we declined to add a reference to “affected area” to the definition of road on the basis that the definition of “affected area” as partially suspended no longer provides additional guidance as to which roads are included in the definition of surface coal mining operations. At the same time, we declined to expressly exclude public roads from the definition of road. In the preamble, we stated that we are concerned that roads constructed to serve mining operations should not avoid compliance with performance standards by being deeded to public entities, but it was not our intent to automatically extend jurisdiction into the existing public road network. Instead, jurisdiction decisions are to be made by the regulatory authorities on a case-by-case basis. Indiana intends to continue to use the definition of “affected area” in determining which roads are subject to jurisdiction. The provisions at 312 IAC 25–1–8(b)(4) and (c) clarify when a public road will be regulated and adequately address the concerns we expressed in the November 8, 1988, preamble (53 FR 45192) regarding public roads. Therefore, we find that Indiana’s definition of “affected area” is no less effective than the Federal regulations concerning jurisdiction over public roads and is consistent with the Federal definition of “affected area.” Based on this finding, we are approving 312 IAC 25–1–8(b) and (c).

D. Recodification Corrections

Indiana’s August 21, 2001, amendment concerned the recodification of its rules to comply with formatting guidelines set forth by the Indiana Legislative Services Agency (Administrative Record No. IND–1712). In recodifying some of its rules, Indiana inadvertently removed previously-approved language. In its May 19, 2004, amendment, Indiana made corrections to the following rules, which were recodified (Administrative Record No. IND–1726).

1. 312 IAC 25–4–17 Surface Mining Permit Applications; Identification of Interests

Indiana’s rule at 312 IAC 25–4–17 specifies the information that must be included in a surface mining permit application for identification of interests. In recodifying 312 IAC 25–4–17(d), (e), and (f), Indiana inadvertently removed language that required an applicant to submit the specified

information with an application. Therefore, in our approval of Indiana’s recodified rule on November 16, 2001 (66 FR 57655), we required Indiana to submit an amendment or otherwise modify its program to clarify that the information specified in 312 IAC 25–4–17(d), (e), and (f) must be submitted with the permit application. We codified this requirement at 30 CFR 914.16(jj). In its May 19, 2004, amendment, Indiana revised 312 IAC 25–4–17 by adding the language “shall be submitted with the application” to the end of subsections (d), (e), and (f).

With the addition of the language that requires the information specified in the subsections to be submitted with the application, we find that Indiana’s rules at 312 IAC 25–4–17(d), (e), and (f) are no less effective than the counterpart Federal regulations at 30 CFR 778.13(a), (b), and (d), respectively. Therefore, we are approving the revisions. We further find that Indiana’s revisions satisfy the required amendment at 30 CFR 914.16(jj), and we are removing it.

2. 312 IAC 25–4–45 Surface Mining Permit Applications; General Requirements for Reclamation Plans

Indiana’s rule at 312 IAC 25–4–45 specifies the information that must be included in the reclamation plan for a surface mining permit. In recodifying 312 IAC 25–4–45(b)(4), Indiana inadvertently removed “total depth” as one of the factors that the operator is to analyze to demonstrate the suitability of topsoil substitutes or supplements. We consider “total depth” to be one of the factors that must be evaluated to demonstrate the suitability of topsoil substitutes or supplements. Therefore, in our approval of Indiana’s recodified rule on November 16, 2001 (66 FR 57655), we required Indiana to submit an amendment or otherwise modify its program to require the demonstration of the suitability of topsoil substitutes or supplements to also be based upon analysis of the “total depth” of the different kinds of soils. We codified this requirement at 30 CFR 914.16(ll). In its May 19, 2004, amendment, Indiana restructured 312 IAC 25–4–45(b)(4) and added “total depth” to the list of factors that must be analyzed to demonstrate the suitability of topsoil substitutes or supplements.

With the addition of “total depth” to the list of factors to be analyzed for the different kinds of soils proposed for topsoil substitutes or supplements, we find that Indiana’s rule at 312 IAC 25–4–45(b)(4) is no less effective than the counterpart Federal regulation at 30 CFR 780.18(b)(4). Therefore, we are approving the revision. We further find

that Indiana’s revision satisfies the required amendment at 30 CFR 914.16(ll), and we are removing it.

3. 312 IAC 25–4–113 Public Availability of Permit Application Information

Indiana’s rule at 312 IAC 25–4–113 provides the exceptions to public availability of permit application information. In recodifying 312 IAC 25–4–113, Indiana inadvertently removed its previously-approved provision that allowed a person to oppose or seek disclosure of confidential information. Indiana also inadvertently removed its previously-approved provision concerning the confidentiality of information on the nature and location of archaeological resources on public and Indian land. Therefore, in our approval of Indiana’s recodified rule on November 16, 2001 (66 FR 57655), we required Indiana to revise 312 IAC 25–4–113 or otherwise modify the Indiana program to allow a person to oppose or seek disclosure of confidential information. We also required Indiana to revise 312 IAC 25–4–113 or otherwise modify the Indiana program to add a provision that classifies information on the nature and location of archeological resources on public land and Indian land as qualified confidential information. We codified these requirements at 30 CFR 914.16(mm)(1) and (2). In its May 19, 2004, amendment, Indiana revised 312 IAC 25–4–113 by adding new subsection (f) to specify that information on the nature and location of archaeological resources on public and Indian land is confidential. Indiana also redesignated existing subsection (f) as subsection (g) and revised the first sentence to allow a person who opposes or seeks disclosure of confidential information to submit a request under 312 IAC 25–4–110.

With the addition of new subsection (f) and the revisions to subsection (g), we find that Indiana’s rules at 312 IAC 25–4–113(f) and (g) are no less effective than the counterpart Federal regulations at 30 CFR 773.6(d)(3) and (d)(3)(iii), and we are approving them. We further find that Indiana’s revisions satisfy the required amendments at 30 CFR 914.16(mm)(1) and (2), and we are removing them.

E. Permit Applications; Reclamation Plan for Siltation Structures, Impoundments, Dams, Embankments, and Refuse Piles

On October 20, 1994 (59 FR 53022), we revised the Federal regulations at 30 CFR 780.25 (Surface Mining) and 784.16 (Underground Mining) concerning

reclamation plan requirements for siltation structures, impoundments, banks, dams, and embankments. On June 17, 1997, we sent Indiana a letter (Administrative Record No. IND-1575) in accordance with 30 CFR 732.17(c). We notified Indiana that it must amend its rules to be no less effective than the revised Federal regulations. Also, in our October 29, 1996 (61 FR 55743), approval of Indiana's September 26, 1994, amendment, as revised on August 16, 1995, we required Indiana to amend 310 IAC 12-3-49 (Surface Mining) and 310 IAC 12-3-83 (Underground Mining) [currently 312 IAC 25-4-49 and 312 IAC 25-4-87, respectively] to add the requirement concerning stability analysis of each structure as is required by 30 CFR 780.25(f) and 784.16(f). We codified this requirement at 30 CFR 914.16(ii)(1). In response to our June 17, 1997, letter and the required amendment at 30 CFR 914.16(ii)(1), Indiana proposed the following revisions to its rules.

1. *312 IAC 25-4-49(a) and 25-4-87(a)*. Indiana revised the first sentence of subsection (a) by requiring an application to include "a general plan and a detailed design plan" instead of "a plan" for each proposed structure within the proposed permit area. Indiana also added "refuse pile" to the list of coal processing waste structures for which a general plan and a detailed design plan were needed.

The counterpart Federal regulations at 30 CFR 780.25(a) and 784.16(a) also require that a permit application include "a general plan and detailed design plan" for each proposed structure. Although the Federal regulations do not include the term "coal processing refuse pile," Indiana's use of the term is equivalent to the Federal term "coal processing waste bank." Therefore, we find that 312 IAC 25-4-49(a) and 25-4-87(a), as revised, are no less effective than the counterpart Federal regulations, and we are approving the revisions.

2. *312 IAC 25-4-49(c) and 25-4-87(c)*. Indiana revised 312 IAC 25-4-49(c) by requiring that permanent and temporary impoundments be designed to comply with the requirements of 312 IAC 25-6-20 and the requirements of the Mine Safety and Health Administration at 30 CFR 77.216-1 and 30 CFR 77.216-2. Indiana revised 312 IAC 25-4-87(c) by requiring that permanent and temporary impoundments be designed to comply with the requirements of 312 IAC 25-6-84 and the requirements of the Mine Safety and Health Administration at 30 CFR 77.216-1 and 30 CFR 77.216-2.

The Federal regulations at 30 CFR 780.25(c) and 784.16(c) contain

substantively the same requirements. Therefore, we find that 312 IAC 25-4-49(c) and 25-4-87(c), as revised, are no less effective than the counterpart Federal regulations, and we are approving the revisions.

3. *312 IAC 25-4-49(d) and 25-4-87(d)*. Indiana added a new subsection (d) to 312 IAC 25-4-49 that requires refuse piles to be designed to comply with 312 IAC 25-6-36 through 312 IAC 25-6-39. Indiana added a new subsection (d) to 312 IAC 25-4-87 that requires refuse piles to be designed to comply with 312 IAC 25-6-98 through 312 IAC 25-6-102. For both rules, Indiana redesignated existing subsection (d) as subsection (e).

The Federal regulations at 30 CFR 780.25(d) and 784.16(d) contain substantively the same requirements. Therefore, we find that Indiana's new rules at 312 IAC 25-4-49(d) and 25-4-87(d) are no less effective than the counterpart Federal regulations, and we are approving them.

4. *312 IAC 25-4-49(f) and 25-4-87(f)*. In response to the required amendment at 30 CFR 914.16(ii)(1), Indiana added new subsection (f). For structures that meet the Class B or C criteria for dams in Technical Release 60 (TR-60) or that meet the size and other criteria of 30 CFR 77.216(a), each reclamation plan under subsections (b), (c), and (e) must include a stability analysis of the structure. The stability analysis must include strength parameters, pore pressures, and long term seepage conditions. The plan must also include a description of each engineering design assumption and calculation.

We find that Indiana's rules at 312 IAC 25-4-49(f) and 25-4-87(f) contain requirements that are substantively the same as the counterpart Federal regulation requirements at 30 CFR 780.25(f) and 784.16(f). Therefore, we are approving them. We further find that Indiana's rules at 312 IAC 25-4-49(f) and 25-4-87(f) satisfy the required amendment at 30 CFR 914.16(ii)(1), and we are removing it.

5. *312 IAC 25-4-49(g) and 25-4-87(g)*. Indiana's rule at subsection (g) requires that applications for specified types of proposed permanent structures that impound water and meet specified criteria must be submitted to the Department of Natural Resources, Division of Water for approval before construction of the structure begins. Indiana redesignated existing subsection (e) as subsection (g) and added introductory language to clarify the types of structures for which applications must be submitted. These structures include proposed permanent siltation structures, water

impoundments, coal processing waste dams, or embankments. Indiana also removed the last sentence from subdivision (g)(3).

There are no Federal counterparts to Indiana's rules at 312 IAC 25-4-49(g) and 25-4-87(g). However, we find that the revisions made to these previously-approved rules will not make the Indiana rules less effective than the Federal regulations or SMCRA.

F. Lands Eligible for Remining

On September 11, 1995, Indiana submitted an amendment concerning statutory requirements for lands eligible for remining (Administrative Record No. IND-1509). After reviewing the amendment, we determined that Indiana's amendment did not include all of the necessary requirements of section 510(e) of SMCRA and the implementing Federal regulations for lands eligible for remining. Therefore, in our approval of Indiana's amendment on April 10, 1996 (61 FR 15891), we required Indiana to amend its program to provide implementing regulations for the statutory requirements. We codified this requirement at 30 CFR 914.16(hh). In response to this requirement, Indiana proposed the following revisions to its rules.

1. 312 IAC 25-4-105.5 Special Categories of Mining; Lands Eligible for Remining

At 312 IAC 25-4-105.5, Indiana added the permitting requirements for lands eligible for remining. An application for a permit must contain an identification of potential environmental and safety problems related to prior mining activity at the site that could be reasonably anticipated to occur. The identification is based on an investigation that includes visual observations, record reviews of past mining, and environmental sampling tailored to the site conditions. An application must also contain descriptions of the mitigative measures that will be taken to ensure the applicable reclamation requirements of the regulatory program can be met. Indiana also provided that the requirements of 312 IAC 25-4-105.5 do not apply after September 30, 2004.

Indiana's September 11, 1995, proposed statute at IC 14-34-4-10.5 did not contain the proviso that the permitting requirements for lands eligible for remining will not apply after September 30, 2004. This proviso is required by section 510(e) of SMCRA and the implementing Federal regulation at 30 CFR 785.25. See 60 FR 58480, November 27, 1995. In our April 10, 1996, approval of Indiana's statute,

we required Indiana to amend its program by adding a counterpart to 30 CFR 785.25 to implement IC 14–34–4–10.5. Indiana added this counterpart at 312 IAC 25–4–105.5 for lands eligible for remining. Indiana’s proposed rule contains requirements that are substantively the same as the counterpart Federal regulation, including the proviso that the requirements do not apply after September 30, 2004. The effective date of our decision in this final rule is after the September 30, 2004, expiration date for these requirements. However, Indiana established the September 30, 2004, date in its rule to clarify that its statute at IC 14–34–4–10.5 and its implementing rule at 312 IAC 25–4–105.5 only apply to permits issued before September 30, 2004. Therefore, we find that 312 IAC 25–4–105.5 is no less effective than the counterpart Federal regulation, and we are approving it.

2. 312 IAC 25–4–114 Review of Permit Applications

At 312 IAC 25–4–114, Indiana added new subsection (d) to require that the prohibitions on the issuance of a permit at subsection (b) do not apply to a violation resulting from an unanticipated event or condition at a surface coal mining operation on lands eligible for remining under a permit held by the applicant. The violation must have occurred after October 24, 1992, and be a result of an unanticipated event or condition on a permit. The permit must have been issued before September 30, 2004, including subsequent renewals, and held by the person making application for a new permit. For a permit issued under 312 IAC 25–4–105.5, concerning lands eligible for remining, an event or condition is presumed to be unanticipated if the event or condition arose after permit issuance, was related to prior mining, and was not identified in the permit.

Indiana’s rule at 312 IAC 25–4–114(d) contains substantively the same requirements as the counterpart Federal regulation at 30 CFR 773.13 concerning unanticipated events or conditions at remining sites. Therefore, we find that 312 IAC 25–4–114(d) is no less effective than the counterpart Federal regulation, and we are approving it.

3. 312 IAC 25–4–115 Permit Approval or Denial—Written Findings

At 312 IAC 25–4–115(a)(13), Indiana added a requirement that the director make a written finding for permits to be issued for lands eligible for remining. For these permits, the director must find

that the permit applications contain: (1) Lands eligible for remining; (2) an identification of any potential environmental and safety problems related to prior mining activity; and (3) mitigation plans to address potential environmental and safety problems.

Indiana’s rule at 312 IAC 25–4–115(a)(13) is substantively the same as the counterpart Federal regulation at 30 CFR 773.15(m), concerning written findings for permits to be issued for lands eligible for remining. Therefore, we find that Indiana’s rule at 312 IAC 25–4–115(a)(13) is no less effective than the counterpart Federal regulation, and we are approving it.

4. 312 IAC 25–5–7 Period of Liability

At 312 IAC 25–5–7(b), Indiana added a provision that allows lands eligible for remining included in permits issued before September 30, 2004, or any renewals thereof, to have a liability period of two years. To the extent that success standards are established by 312 IAC 25–6–59(c)(1) or 25–6–120(c)(1), the lands must equal or exceed the standards during the growing season of the last year of the responsibility period.

Indiana’s new provision at 312 IAC 25–5–7(b) is substantively the same as the counterpart Federal regulation at 30 CFR 816.116(c)(2)(ii), concerning the period of liability for lands eligible for remining. Therefore, we find that the new provision at 312 IAC 25–5–7(b) is no less effective than the counterpart Federal regulation, and we are approving it.

5. Based on the above findings, Indiana’s revisions at 312 IAC 25–4–105.5, 25–4–114, 25–4–115, and 25–5–7(b) satisfy the required amendment at 30 CFR 914.16(hh), and we are removing it.

G. 312 IAC 25–4–118 Permit Conditions

On August 21, 2001 (Administrative Record No. IND–1712), Indiana’s recodified rules included a rule at 312 IAC 25–4–118 that we had not previously approved. This rule specified the conditions under which a permit is issued. In our approval of Indiana’s rule on November 16, 2001 (66 FR 57655), we required Indiana to revise 312 IAC 25–4–118(4) or otherwise modify its program to require permittees to allow authorized representatives of the Secretary of the Interior to have right of entry to surface coal mining and reclamation operations for purposes of inspections, monitoring, and enforcement and to be accompanied by private persons under specified conditions. We codified this requirement at 30 CFR 914.16(kk). In its

May 19, 2004, amendment, Indiana revised 312 IAC 25–4–118(4) by changing the phrase “authorized representatives of the director” to “authorized representatives of the director and the Secretary of the Interior.” With this revision, the permittee must allow the authorized representatives of the director and the Secretary of the Interior, rather than just the director, to have the right of entry to a mine site for the purpose of conducting inspections and to be accompanied by private persons when the inspection is in response to an alleged violation.

Based on the above discussion, we find that Indiana’s rule at 312 IAC 25–4–118(4) is no less effective than the counterpart Federal regulation at 30 CFR 773.17(d), and we are approving it. We further find that Indiana’s revision satisfies the required amendment at 30 CFR 914.16(kk), and we are removing it.

H. 312 IAC 25–6–23 Surface Mining; Hydrologic Balance; Surface and Ground Water Monitoring

On March 26, 1992, as clarified on November 5, 1992, February 1, 1993, and May 19, 1993, Indiana submitted an amendment that included revisions to 310 IAC 12–5–27(a) [currently 312 IAC 25–6–23(a)]. In our August 16, 1993, approval of the revisions (58 FR 43248), we required Indiana to amend 310 IAC 12–5–27(a)(4) [currently 312 IAC 25–6–23(a)(4)] or otherwise amend the Indiana program to be no less effective than 30 CFR 816.41(c)(2), which references and requires compliance with 30 CFR 773.17(e). We codified the required amendment at 30 CFR 914.16(s). In response to this requirement, Indiana proposed to add 312 IAC 25–6–23(a)(4)(C) to require that if the analysis of a ground water sample indicates noncompliance with a permit condition, the permittee must minimize any adverse impact to the environment or public health and safety resulting from the noncompliance, including: (1) Accelerated or additional monitoring to determine the nature and extent of the noncompliance and the results of the noncompliance; (2) immediate implementation of measures necessary to mitigate the noncompliance; and (3) as soon as practicable issue warning to any person whose health and safety is in imminent danger due to the noncompliance.

The counterpart Federal regulation at 30 CFR 816.41(c)(2) references the Federal regulation at 30 CFR 773.17(e), rather than restating its requirements. However, we find that Indiana’s addition of the substantive requirements of 30 CFR 773.17(e) at 312 IAC 25–6–

23(a)(4)(C), rather than referencing its counterpart to 30 CFR 773.17(e), is no less effective than the counterpart Federal regulation at 30 CFR 816.41(c)(2). Therefore, we are approving 312 IAC 25–6–23(a)(4)(C) and removing the required amendment at 30 CFR 914.16(s).

I. 312 IAC 25–6–25 Hydrologic Balance; Water Rights and Replacement

In our August 2, 1991 (56 FR 37013), approval of Indiana's amendment concerning water rights and replacement, we required Indiana to amend 310 IAC 12–5–29 (currently 312 IAC 25–6–25) or otherwise amend the Indiana program to clearly require the replacement of water supplies that are affected by contamination, diminution, or interruption proximately resulting from surface mining activities which do not involve a legitimate water use by a person conducting these surface mining activities. We codified this requirement at 30 CFR 914.16(f). In response to this requirement, Indiana revised 312 IAC 25–6–25 by removing the language "pursuant to a lawful order of an agency or court under IC 14–25–4 or another state water rights law" from the first sentence. Indiana also removed the existing second sentence, which stated that water replacement rights are not determined by the Indiana program. Indiana added a provision that requires the use of baseline hydrologic information to determine the extent of the impact of mining on ground water and surface water, as well as other relevant information.

Indiana's proposed revisions make 312 IAC 25–6–25 substantively identical to the counterpart Federal regulation at 30 CFR 816.41(h). Therefore, we find that 312 IAC 25–6–25 is no less effective than the counterpart Federal regulation, and we are approving the revisions. We further find that Indiana's revisions satisfy the required amendment at 30 CFR 914.16(f), and we are removing it.

J. 312 IAC 25–6–66 (Surface Mining) and 312 IAC 25–6–130 (Underground Mining); Primary Roads

1. On September 26, 1994 (Administrative Record No. IND–1401), as revised on August 16, 1995 (Administrative Record No. IND–1506), Indiana submitted an amendment that included revisions to 310 IAC 12–5–69.5(2) and 12–5–137.5(2) [currently 312 IAC 25–6–66(2) and 25–6–130(2)] concerning primary roads. On October 29, 1996, we approved Indiana's revisions except to the extent that the provisions allowed the use of a maximum slope of 3h:1v without providing engineering design standards

that ensure compliance with the minimum static safety factor of 1.3 (61 FR 55743). We required Indiana to remove the language that we did not approve and notify us when the removal was complete or propose engineering design standards for a slope of 3h:1v that ensures compliance with the 1.3 minimum static safety factor requirements. In response to this requirement, Indiana revised 312 IAC 25–6–66 and 25–6–130 by removing the language that allowed the use of a maximum slope of 3h:1v. We find that with the removal of this language, 312 IAC 25–6–66(2) and 25–6–130(2) are no less effective than the counterpart Federal regulations at 30 CFR 816.151(b) and 817.151(b) for primary roads, and we are approving them.

2. In its May 19, 2004, amendment, Indiana also proposed engineering design standards at 312 IAC 25–6–130(2)(A) through (H) for underground mining primary roads. The design standards allow the use of a maximum slope of 2h:1v as an alternative to the 1.3 static safety factor requirement for primary road embankments.

The Federal regulations at 30 CFR 780.37(c) and 784.24(c) allow regulatory authorities to establish engineering design standards for primary roads in lieu of engineering tests to establish compliance with the minimum static safety factor of 1.3 for primary road embankments. In its September 26, 1994, amendment, Indiana had proposed substantively identical design standards for surface mining primary roads. We conducted a technical review of Indiana's surface mining design standards, found them to be acceptable, and approved them on October 29, 1996. Therefore, we find that Indiana's proposed design standards for underground mining primary roads meet the requirement at 30 CFR 784.24(c), and we are approving them.

K. 312 IAC 25–7–1 Inspections of Sites

On November 28, 1994 (59 FR 60876), we revised the Federal regulations at 30 CFR 840.11 concerning inspection procedures. On June 17, 1997, we sent Indiana a letter (Administrative Record No. IND–1575) in accordance with 30 CFR 732.17(c). We notified Indiana that it must amend its rules to be no less effective than the revised Federal regulations. In response to this requirement, Indiana proposed revisions to its rule at 312 IAC 25–7–1. Indiana removed existing subdivision (a)(2) and redesignated existing subdivisions (a)(3) and (4) as subdivisions (a)(2) and (3). Indiana also redesignated existing subsection (f) as subsection (h) and added new subsections (f) and (g).

1. New subsection (f) provides that in lieu of the inspection frequency established in subsection (a), the regulatory authority must inspect each abandoned site on a set frequency commensurate with the public health and safety and environmental considerations present at each specific site, but in no case will the inspection frequency be set at less than one complete inspection per calendar year. Subdivisions (f)(1) through (3) provide the procedures that the regulatory authority must follow to establish an alternative inspection frequency for abandoned sites.

The requirements of Indiana's new rule at 312 IAC 25–7–1(f) are substantively identical to the counterpart Federal regulation at 30 CFR 840.11(h)(1). Therefore, we find that 312 IAC 25–7–1(f) is no less effective than the counterpart Federal regulation, and we are approving it.

2. New subdivision (g)(1) provides the procedures for publishing a public notice and offering the public an opportunity to comment on the alternative inspection frequency for an abandoned site. New subdivision (g)(2) provides information on the content of a public notice.

The requirements of Indiana's new rule at 312 IAC 25–7–1(g) are substantively identical to the counterpart Federal regulation at 30 CFR 840.11(h)(2). Therefore, we find that 312 IAC 25–7–1(g) is no less effective than the counterpart Federal regulation, and we are approving it.

3. In our June 17, 1997, letter, we notified Indiana that we had revised 30 CFR 840.11(g)(4) to allow a site to be classified as abandoned only in cases where a permit has either expired or been revoked. Previously, 30 CFR 840.11(g)(4) allowed a site to be classified as abandoned on the basis that the permit has expired or been revoked or permit revocation proceedings have been initiated and are being pursued diligently. Indiana did not revise its rule at 312 IAC 25–7–1 to reflect this new requirement of the revised Federal regulation. Therefore, we are requiring Indiana to revise 312 IAC 25–7–1(h)(2)(D)(i) to allow a site to be classified as abandoned only in cases where a permit has expired or been revoked. We are codifying this requirement at 30 CFR 914.16.

IV. Summary and Disposition of Comments

Public Comments

We asked for public comments on the amendment, but did not receive any.

Federal Agency Comments

On June 10, 2004, under 30 CFR 732.17(h)(11)(i) and section 503(b) of SMCRA, we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Indiana program (Administrative Record No. IND-1729).

The U.S. Fish and Wildlife Service (FWS) responded on July 12, 2004 (Administrative Record No. IND-1731), that the amendment contains some items of interest to the FWS related to language concerning prime farmland soils. FWS commented that for conservation of wildlife resources, it is important that pre-mining forest on prime farmland soils can continue to be restored as forest. FWS then stated that it understood from discussions with the IDNR staff that the proposed changes will not adversely affect forest restoration; therefore, it had no specific comments on the amendment.

We agree that the proposed changes to Indiana's prime farmland rule will not adversely affect forest restoration.

Environmental Protection Agency (EPA) Concurrence 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 Indiana proposed to make in this amendment pertain to air or water quality standards. Therefore, we did not ask EPA to concur on the amendment.

On June 10, 2004, under 30 CFR 732.17(h)(11)(i), we requested comments on the amendment from EPA (Administrative Record No. IND-1729). EPA did not respond to our request.

State Historical Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Under 30 CFR 732.17(h)(4), we are required to request comments from the SHPO and ACHP on amendments that may have an effect on historic properties. On June 10, 2004, we requested comments on Indiana's amendment (Administrative Record No. IND-1729), but neither responded to our request.

V. OSM's Decision

Based on the above findings, we approve with an additional requirement the amendment Indiana sent us on May 19, 2004. As discussed in Finding III.K.3, we are requiring Indiana to revise its rule at 312 IAC 25-7-

1(h)(2)(D)(i) to allow a site to be classified as abandoned only in cases where a permit has expired or been revoked.

We approve the rules proposed by Indiana with the provision that they be fully promulgated in identical form to the rules submitted to and reviewed by OSM and the public.

To implement this decision, we are amending the Federal regulations at 30 CFR part 914, which codify decisions concerning the Indiana 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 rule 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 exempted from review by the Office of Management and Budget (OMB) 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. This determination is based on the fact that the Indiana program does not regulate coal exploration and surface coal mining and reclamation operations on Indian lands. Therefore, the Indiana program has no effect on Federally-recognized Indian tribes.

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 part of the 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.*). This determination is based upon 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 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.

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 regulations 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 914

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 14, 2004.

Charles E. Sandberg,

Regional Director, Mid-Continent Regional Coordinating Center.

■ For the reasons set out in the preamble, 30 CFR part 914 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 in the table by adding a new entry in chronological order by "Date of final publication" to read as follows:

§ 914.15 Approval of Indiana regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
May 19, 2004	November 29, 2004	312 IAC 25-1-8; 25-1-75.5; 25-1-155.5; 25-4-17(a)(1), (d), (e), and (f); 25-4-45(b)(4); 25-4-49(a), (c), (d), (f), and (g); 25-4-87(a), (c), (d), (f), and (g); 25-4-102(d)(1), (e), and (f); 25-4-105.5; 25-4-113(f) and (g); 25-4-114(d); 25-4-115(a)(3) and (13); 25-4-118(4) and (8); 25-5-7(b); 25-5-16(b) and (c); 25-6-17(a)(3), (b)(2), (d)(2), and (d)(3); 25-6-20(a) and (c); 25-6-23(a)(2) and (4)(C); 25-6-25; 25-6-66(2); 25-6-81(a)(3), (d)(2) and (3); 25-6-84(a) and (c); 25-6-130(2); 25-7-1(a), (d)(2), (f), and (g); 25-7-20.

■ 3. Section 914.16 is amended by removing and reserving paragraphs (f), (s), (hh), (ii), (jj), (kk), (ll), and (mm) and by adding paragraph (ff) to read as follows:

§ 914.16 Required program amendments.

* * * * *

(ff) By February 28, 2005. Indiana must submit either an amendment or a description of an amendment to be proposed, together with a timetable for adoption of proposed revisions to 312 IAC 25-7-1(h)(2)(D)(i) to allow a site to be classified as abandoned only in cases where a permit has expired or been revoked.

§ 914.25 [Amended]

■ 4. Section 914.25 is amended by:

■ a. Removing the designation "(a)" from paragraph (a); and

■ b. Removing paragraph (b).

[FR Doc. 04-26196 Filed 11-26-04; 8:45 am]

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