accessed at http://www.fda.gov/cdrh/gmp/gmp.html.

Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by June 11, 1998. No telephone requests will be accepted. You will be notified by fax to tell whether your presentation will be included and your time limitation. If you cannot be reached by fax, please note that in your request.

Due to space limitations, interested parties are encouraged to register early. Depending on the number of requests, registration may be limited to one representative per firm or organization. If special accommodations are needed due to a disability, please contact Timothy R. Wells, at least 7 days in advance.

Dated: May 19, 1998.

Linda S. Kahan,

Acting Deputy Director for Regulations Policy, Center for Devices and Radiological Health. [FR Doc. 98–14049 Filed 5–28–98; 8:45 am] BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 914

[SPATS No. IN-144-FOR]

Indiana Regulatory Program

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

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

SUMMARY: OSM is announcing receipt of a proposed amendment to the Indiana regulatory program (hereinafter the "Indiana program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of revisions to and additions of statutes pertaining to definitions, permit conditions, and permit revisions. The amendment is intended to revise the Indiana program to improve operational efficiency.

This document sets forth the times and locations that the Indiana program and proposed amendment to that program are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and the procedures that

will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received by 4:00 p.m., e.s.t., June 29, 1998. If requested, a public hearing on the proposed amendment will be held on June 23, 1998. Requests to speak at the hearing must be received by 4:00 p.m., e.s.t. on June 15, 1998.

ADDRESSES: Written comments and requests to speak at the hearing should be mailed or hand delivered to Andrew R. Gilmore, Director, Indianapolis Field Office, at the address listed below

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

Andrew R. Gilmore, 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) 226–6700.

Indiana Department of Natural Resources, 402 West Washington Street, Room C256, Indianapolis, Indiana 46204, Telephone: (317) 232–1547.

FOR FURTHER INFORMATION CONTACT:

Andrew R. Gilmore, Director, Indianapolis Field Office, Telephone: (317) 226–6700.

SUPPLEMENTARY INFORMATION:

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 26, 1982, **Federal Register** (47 FR 32107). Subsequent actions concerning the conditions of approval and program amendments can be found at 30 CFR 914.10, 194.15, and 194.15.

II. Description of the Proposed Amendment

By letter dated May 14, 1998 (Administrative Record No. IND–1606), Indiana submitted a proposed amendment to its program pursuant to SMCRA. Indiana submitted the proposed amendment at its own initiative. The amendment pertains to revisions of and additions to the Indiana Code (IC) made by House Enrolled Act

(HEA) No. 1074. HEA No. 1074 was passed through the Indiana Legislature and signed by the Governor of Indiana on March 12, 1998. Only those portions of HEA No. 1074 that pertain to Articles 14–8 and 14–34 are being considered in this document. The full text of the proposed program amendment submitted by Indiana is available for public inspection at the locations listed above under ADDRESSES. A discussion of the proposed amendment is presented below.

1. IC 14-8-2-117.3, Definition for "Governmental Entity"

Indiana proposes the following definition: "Governmental entity, for the purposes of IC 14-22-10-2 and IC 14-22-10.2.5, has the meaning set forth in IC 14-22-10-2(a)."

2. IC 14-34-4-18, Permit Conditions

Indiana identified the existing provision as subsection (a) and added the following new provision at subsection (b):

The director may issue a permit subject to the condition that the permittee obtain or maintain in force other licenses or permits required for the surface coal mining and reclamation operation. However, the imposition of a condition under this subsection does not authorize or require the director to administer or enforce the requirements of any federal law or of any state law other than this article.

3. IC 14-34-5-7, Permit Revisions

The existing provisions in subsections (a) and (b) were removed and the following new provisions were added:

(a) A change in mining or reclamation operations from the approved mining and reclamation plans that would adversely affect the permittee's compliance with this article is a permit revision subject to review and approval as provided in this section and sections 8 through 8.4 of this chapter.

(b) A permit revision is either: (1) A significant revision subject to sections 8 and 8.1 of this chapter; (2) a nonsignificant revision subject to sections 8.2 and 8.3 of this chapter; or (3) a minor field revision subject to section 8.4 of this chapter.

(c) Permit revisions may be approved by: (1) The director; or (2) the director's designated representative.

(d) A permit revision may not be approved unless the permittee demonstrates and the director or the director's designated representative finds the following:

(1) That reclamation as required by this article and by the rules adopted by the commission under IC 14–34–2–1 can be accomplished.

(2) That applicable requirements of IC 14–34–4–7 that are pertinent to the permit revision are met.

(3) That the permit revision complies with all applicable requirements of this article and the rules adopted by the commission under IC 14–34–2–1.

4. IC 14-34-5-8, Permit Revisions

Indiana proposes to remove the language "as defined in the rules adopted under section 6 of this chapter" and to add the language "or minor field revisions" after the phrase "based only on nonsignificant revisions."

5. IC 14–34–5–8.1, Significant Permit Revisions

Indiana proposes to add a new section that defines significant permit revisions. A proposed revision of a permit is significant if any of eight conditions exists. The conditions include: adverse impacts affecting cultural resources, blasting operations, water supply, handling of toxic forming or acid forming materials, and fish and wildlife; the addition of a coal processing facility or a permanent support facility; the changes will cause a new or an updated probable hydrologic consequences determination or cumulative hydrologic impact analysis; or a postmining land use will be changed to a residential land use, a commercial or industrial land use, a recreational land use, or developed water resources.

6. IC 14–34–5–8.2, Nonsignificant Permit Revisions

Indiana proposes to add a new section that defines nonsignificant permit revisions. A proposed revision of a permit is nonsignificant if any of five conditions exist. The conditions include: (1) For surface mines, changes in the direction of mining or location of mining equipment; (2) substitution of mining equipment designed for the same purpose; (3) for underground mines, any change in the direction or location of mining within the permit area or shadow area in response to unanticipated events; (4) a postmining land use other than a change described in section 8.1; or (5) any other change in the mining or reclamation plan that will not have a significant effect on achievement of final reclamation plans, on subsidence control plans, and on the surrounding area, that does not involve significant delay in achieving final reclamation or significant change in the land use, or that is necessitated by unanticipated and unusually adverse weather conditions, other acts of God, strikes, or other cause beyond the reasonable control of the permittee.

7. IC-14-34-5-8.3, Nonsignificant Permit Revisions

Indiana proposes to require that a nonsignificant revision in a mining or reclamation plan must be reviewed and approved in writing by the director before it may be implemented.

8. IC 14-34-5-8.4, Minor Field Revisions

Indiana's proposed new section adds provisions for approval of minor field revisions by an inspector in the field. Subsection (a) defines minor field revisions as those that do not require technical review or design analysis and are capable of being evaluated in the field by the director's designated delegate for compliance with section 14–34–5–7(d). Subsection (b) allows a minor field revision to be approved by a field inspector in an inspection report or on a form signed in the field. Subsection (c) provides examples of the types of minor field revisions allowed, including soil stockpile location and configuration, as-built pond certifications, minor transportation facility changes, pond depth, shape, and orientation, an area for temporary drainage control or temporary water storage, equipment changes, explosive storage areas, minor mine management or support facility locations, adding **United States Natural Resources** Conservation Service conservation practices, methods of erosion protection on diversions, temporary cessation of mining, and minor diversion location changes.

9. IC 14–34–5–8.5, Permit Area Extensions

Indiana's proposed statute provides that an extension of the area covered by a permit, except for an incidental boundary revision, must be made by applying for a new permit.

10. IC-14-34-5-8.6, Incidental Boundary Revisions

This proposed statute addresses the requirements for incidental boundary revisions. Subsection (a) provides that five conditions must apply before an extension is considered an incidental boundary revision: (1) The extension may not constitute a significant revision to the method of conduct of mining or reclamation operations; (2) the extension must be required for the orderly and continuous mining and reclamation operation; (3) the extension must adjoin the permit or shadow area acreage; (4) the extended area must be mined and reclaimed in conformity with the approved permit plans; and (5) the area of the extension may not exceed the lesser of 10 percent of the area originally covered by the permit or 20 acres.

Subsection (b) requires that the aggregate of all incidental boundary revisions of a permit may not exceed the area originally covered by the permit by more than 15 percent, unless the director finds that all other provisions of

this section are met and the interests of the public are not adversely affected.

Subsection (c) provides that the aggregate of all incidental boundary revisions of a permit that involve coal removal may not exceed the area originally covered by the permit by more than 10 percent.

Subsection (d) specifies the application requirements for incidental boundary revisions, including size of the area, pre- and post-mining land uses, maps, proof of the permittee's legal right to enter and conduct surface coal mining and reclamation operations on the area, necessary plans, and a statement pertaining to areas unsuitable for mining.

Subsection (e) provides that an application for an incidental boundary revision may not be approved unless the applicant demonstrates and the director finds that reclamation of the area can be accomplished and that the application complies with all requirements of Article 34.

Subsection (f) requires the director to approve or deny an incidental boundary revision of a permit within 30 days, unless the director finds that more than 30 days are needed to adequately review the application and make the findings required by subsection (e).

Subsection (g) specifies that section 14–34–5–8.6 does not alter the requirements for the submission of fees and bonds.

III. Public Comment Procedures

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

Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations.

Comments received after the time indicated under DATES or at locations other than the Indianapolis Field Office will not necessarily be considered in the final rulemaking or included in the Administrative Record.

Public Hearing

Persons wishing to speak at the public hearing should contact the person listed under FOR FURTHER INFORMATION CONTACT by 4:00 p.m., e.s.t. on June 15, 1998. The location and time of the hearing will be arranged with those persons requesting the hearing. Any

disabled individual who has need for a special accommodation to attend a public hearing should contact the individual listed under FOR FURTHER INFORMATION CONTACT. If no one requests an opportunity to speak at the public hearing, the hearing will not be held.

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

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

Public Meeting

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

IV. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 (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.

Unfunded Mandates

OSM has determined and certifies pursuant to the Unfunded Mandates Reform Act (2 U.S.C. 1502 et seq.) that this rule will not impose a cost of \$100 million or more in any given year on local, state, or tribal governments or private entities.

List of Subjects in 30 CFR Part 914

Intergovernmental relations, Surface mining, Underground mining.

Dated: May 22, 1998.

Brent Wahlquist,

Regional Director, Mid-Continent Regional Coordinating Center.

[FR Doc. 98–14272 Filed 5–28–98; 8:45 am] BILLING CODE 4310–05–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

RIN 1018-AE83

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Notice of Public Hearings and Reopening of Comment Period on Proposed Reclassification From Endangered to Threatened Status for the Mariana Fruit Bat From Guam, and Proposed Threatened Status for the Mariana Fruit Bat From the Commonwealth of the Northern Mariana Islands

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; notice of public hearing and reopening of comment period.

SUMMARY: The Fish and Wildlife Service (Service), pursuant to the Endangered Species Act of 1973, as amended (Act), provides notice of two public hearings on the proposed reclassification from endangered to threatened status for the Mariana fruit bat from Guam, and on proposed threatened status for the Mariana fruit bat from the Commonwealth of the Northern Mariana Islands. In addition, the Service has reopened the comment period. All parties are invited to submit comments on this proposal.

DATES: The comment period now closes on July 10, 1998. There will be two public hearings, one each on the islands of Saipan and Rota. The public hearing on Saipan will be held from 7:30 p.m. to 9:00 p.m. on Wednesday, June 24, 1998. The public hearing on Rota will be held from 7:30 p.m. to 9:00 p.m. on Thursday, June 25, 1998. Prior to each of the public hearings, the Service will be available from 5:00 to 6:30 p.m. to provide information and to answer questions.

ADDRESSES: On Saipan, the public hearing will be held at the Pacific Gardenia Hotel, Chalan Kanoa Beach Road. On Rota, the public hearing will be held at the Rota Resort and Country Club. Written comments and materials concerning this proposal may be submitted at the hearings or sent directly to Mr. Brooks Harper, Field