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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Dexamethasone Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Veterinary Laboratories, Inc. The ANADA provides for the use of dexamethasone injectable solution for the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses.

DATES: This rule is effective October 2, 2003.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Veterinary Laboratories, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215, filed ANADA 200-324 that provides for use of Dexamethasone Injection for the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses. Veterinary Laboratories' Dexamethasone Injection is approved as a generic copy of Schering-Plough Animal Health's AZIUM (dexamethasone) Solution 2 Mg., approved under NADA 012-559. The ANADA is approved as of August 19, 2003, and the regulations are amended in § 522.540 to reflect the approval. The

basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 522.540 is amended by revising paragraph (a) to read as follows:

§ 522.540 Dexamethasone injection.

(a)(1) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) dexamethasone.

(2) *Sponsors.* See sponsors in § 510.600(c) of this chapter:

(i) Nos. 000061 and 059130 for use as in paragraph (a)(3) of this section.

(ii) No. 000857 for use as in paragraphs (a)(3)(i)(C), (a)(3)(i)(D), (a)(3)(ii)(A), and (a)(3)(iii) of this section.

(3) *Conditions of use*—(i) *Amount.* The drug is administered intravenously

or intramuscularly and dosage may be repeated if necessary, as follows:

(A) *Dogs.* 0.25 to 1 mg.

(B) *Cats.* 0.125 to 0.5 mg.

(C) *Horses.* 2.5 to 5 mg.

(D) *Cattle.* 5 to 20 mg, depending on the severity of the condition.

(ii) *Indications for use.* The drug is indicated:

(A) For the treatment of primary bovine ketosis and as an anti-inflammatory agent in cattle and horses;

(B) As an anti-inflammatory agent in dogs and cats.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

Dated: September 11, 2003.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 03-24928 Filed 10-1-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 938

[PA-135-FOR]

Pennsylvania Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: We are approving a proposed amendment to the Pennsylvania regulatory program (the "Pennsylvania program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Pennsylvania proposed revisions to its rules about surface and ground water monitoring and coal refuse disposal to satisfy required program amendments. Additionally, Pennsylvania submitted new rules concerning coal refuse disposal operations. Pennsylvania intended to revise its program to be consistent with the corresponding Federal regulations and SMCRA, clarify ambiguities, and provide additional safeguards. Finally, we are removing a regulatory program amendment where we required Pennsylvania to correct

cross-section references within the Pennsylvania Surface Mining Conservation and Reclamation Act (PA SMCRA).

EFFECTIVE DATE: October 2, 2003.

FOR FURTHER INFORMATION CONTACT:

George Rieger, Acting Field Office Director, Harrisburg Field Office, Telephone: 717-782-4036, Internet address: grieger@osmre.gov.

SUPPLEMENTARY INFORMATION:

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

I. Background on the Pennsylvania 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 the Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to the 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 Pennsylvania program on July 30, 1982. You can find background information on the Pennsylvania program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Pennsylvania program in the July 30, 1982, **Federal Register** (47 FR 33050). You can also find later actions concerning Pennsylvania program and program amendments at 30 CFR 938.11, 938.12, 938.15 and 938.16.

II. Submission of the Proposed Amendment

By two letters, both dated December 20, 2001, Pennsylvania sent us proposed

amendments to its program (Administrative Record Nos. PA 837.101 and 881.00) under SMCRA (30 U.S.C. 1201 *et seq.*). In PA 837.101, Pennsylvania revised and added regulations at 25 Pennsylvania Code (Pa. Code) Chapters 88 and 90 regarding coal refuse disposal operations to implement statutory changes made to its Coal Refuse Disposal Control Act (CRDCA). Through these revised and added regulations, Pennsylvania was also responding to required amendments codified at 30 CFR 938.16(vvv), (www), (xxx), (yyy), (zzz), (aaaa), and (bbbb). We required these amendments to the Pennsylvania program as a result of our review of Pennsylvania's amendment to the CRDCA as found in the April 22, 1998, **Federal Register** (63 FR 19802). In a May 22, 1998, letter (Administrative Record No. PA 837.72) to OSM, Pennsylvania provided clarifications in response to the required amendments. In the February 2, 2000, **Federal Register** (65 FR 4882), we responded to Pennsylvania's clarifications by indicating that we would remove the required program amendments when Pennsylvania's clarifications were incorporated into regulations and those regulations were approved by OSM. In the amendment submitted under PA 837.101, Pennsylvania has provided those regulations.

In PA 881.00, Pennsylvania submitted changes made to its regulations at 25 Pa. Code 89.59(a)(2), (3) and (b) regarding ground water monitoring. These changes were made in response to the required amendment at 30 CFR 938.16(hh) in which we required Pennsylvania to amend its program to be no less effective than 30 CFR 784.14(h)(1) regarding ground water monitoring plans. At a minimum, the plans are to contain the total dissolved solids or specific conductance, pH, total iron, total manganese, and water levels shall be monitored and data submitted to Pennsylvania at least every three months for each monitoring location.

In a third letter dated November 16, 2001 (Administrative Record No. PA 880.00), Pennsylvania sent us an explanation regarding citation of cross-references in PA SMCRA required by the program amendment at 30 CFR 938.16(kk).

We announced receipt of the proposed amendments in the January 25, 2002, **Federal Register** (67 FR 36333). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the amendment's adequacy. We did not hold a public hearing or meeting because no one requested one. The public comment period ended on February 25, 2002. We received comments on PA 837.101 from four Federal agencies, on PA 881.00 we received comments from two Federal agencies, and on PA 880.00 we received comments from one Federal agency.

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. Any revisions that we do not specifically discuss below concern nonsubstantive wording or editorial changes.

In the proposed amendment, Pennsylvania submitted regulations that implement provisions of the CRDCA. Many of these regulations are substantively the same, or have the same meaning, as portions of the CRDCA that are already in the approved Pennsylvania program. We announced our approval of these portions of the CRDCA in the April 22, 1998, **Federal Register** (63 FR 19802). The following regulations, listed in the first column of the table below, are approved because they are substantively identical to, or have the same meaning as, the corresponding State statutory provisions (shown in the second column) that we approved on April 22, 1998:

| Regulation | Corresponding CRDCA sections that were previously approved |
|--|--|
| 25 Pa. Code 88.332 | Section 30.56a(i). |
| 25 Pa. Code 90.1 definition of "operator" | Section 30.53 Definitions (8): "operator". |
| 25 Pa. Code 90.1 definition of "public recreational impoundment" | Section 30.53 Definitions (10.1): "public recreational impoundment". |
| 25 Pa. Code 90.167(d) | Section 30.56a(i). |
| 25 Pa. Code 90.201 definition of "preferred site" | Section 30.54a(a)(1)-(5). |
| 25 Pa. Code 90.202(a) | Section 30.54a(a). |
| 25 Pa. Code 90.202(b)(1) | Section 30.54a(c). |
| 25 Pa. Code 90.202(b)(2) | Section 30.54a(d). |
| 25 Pa. Code 90.202(c) | Section 30.54a(c), (d). |
| 25 Pa. Code 90.202(d) | Section 30.54a(c), (d). |
| 25 Pa. Code 90.202(e)(1)-(7) | Section 30.54a(b). |
| 25 Pa. Code 90.204(a)(1)-(3) | Section 30.54a(c), (d). |
| 25 Pa. Code 90.204(b)(1)-(3) | Section 30.54a(c), (d). |
| 25 Pa. Code 90.205 | Section 30.54a(e). |

| Regulation | Corresponding CRDCA sections that were previously approved |
|---|---|
| 25 Pa. Code 90.302 definition of "abatement plan" | Section 30.53 Definitions (1): "abatement plan". |
| 25 Pa. Code 90.302 definition of "actual improvement" | Section 30.53 Definitions (1.1) "actual improvement". |
| 25 Pa. Code 90.302 definition of "best technology" | Section 30.53 Definitions (1.4) "best technology". |
| 25 Pa. Code 90.302 definition of "pollution abatement area" | Section 30.53 Definitions (9.1) "pollution abatement area". |
| 25 Pa. Code 90.303(a)(1) | Section 30.56b(b)(1). |
| 25 Pa. Code 90.303(a)(2)(i)-(v) | Section 30.56b(b)(2)(i)-(v). |
| 25 Pa. Code 90.305(a)(1)(i)-(ii) | Section 30.56b(c)(1)(i)-(ii). |
| 25 Pa. Code 90.305(a)(2)-(4) | Section 30.56b(c)(2)-(4). |
| 25 Pa. Code 90.305(a)(6) | Section 30.56b(c)(5). |
| 25 Pa. Code 90.305(a)(7) | Section 30.56b(c)(7). |
| 25 Pa. Code 90.305(b) | Section 30.56b(d). |
| 25 Pa. Code 90.305(c) | Section 30.56b(c)(6). |

The following section contains our evaluation of regulations that do not have substantively identical corresponding sections to those in the CRDCA. Pennsylvania has made changes to its regulations at Chapter 88 covering coal refuse disposal operations in the anthracite region as well as regulations at Chapter 90 covering operations in the bituminous region.

Chapter 88 Anthracite Coal

25 Pa. Code 88.281 Requirements. This section formerly required anthracite coal operators who conduct coal refuse disposal activities to comply with the performance standards and design requirements of this subchapter. Pennsylvania added references to the new coal refuse disposal regulations to insure that anthracite operators comply with these new standards. Although these references have no direct Federal counterparts, the Director is approving them because they do not render the Pennsylvania program inconsistent with SMCRA or the Federal regulations.

25 Pa. Code 88.310 Coal refuse disposal: general requirements. Pennsylvania added subsections (j) and (k) to this section. Subsection (j) requires that the system to prevent adverse impacts to the surface and groundwater shall be constructed in accordance with design schematics, test results, descriptions, plans, maps, profiles or cross-sections approved in the permit and shall function to prevent adverse impacts to surface water and groundwater. This section is essentially the same as 25 Pa. Code 90.122(g) that the Director is approving below. This section will assure that anthracite refuse disposal operations are conducted in conjunction with the same safeguards as those in the bituminous region. Although these subsections have no direct Federal counterparts, the Director is approving them because they do not render the Pennsylvania program inconsistent with SMCRA or the Federal regulations.

Subsection (k) provides the design and installation requirements of a system designed to prevent precipitation from coming in contact with the coal refuse. These requirements are essentially the same as those that the Director is approving at 25 Pa. Code 90.122(h) (see the discussion under 25 Pa. Code 90.122(h) below for more information). The addition of these requirements to Pennsylvania's anthracite regulations will insure that anthracite coal refuse disposal operations will be carried out with the same safeguards in place as those in the bituminous region. Although this subsection has no direct Federal counterpart, the Director is approving it because it does not render the Pennsylvania program inconsistent with SMCRA or the Federal regulations.

Chapter 90 Coal Refuse Disposal

25 Pa. Code 90.1 Definition of "coal refuse disposal". Pennsylvania defines "coal refuse disposal" in section 90.1 as "the storage, placement, or disposal of coal refuse." The term includes engineered features integral to the placement of the coal refuse including relocation or diversions of stream segments contained within the proposed fill area and the construction of required systems to prevent adverse impacts to surface water and groundwater and to prevent precipitation from contacting the coal refuse." While the term "coal refuse disposal" is not defined in the Federal regulations, Pennsylvania's definition is used in its regulations for meeting the requirements of 30 CFR 816.81(a)(1) which requires waste disposal areas to minimize effects of leachate and surface water runoff on surface and ground water quality and quantity. The Director finds that the definition of "coal refuse disposal" is not inconsistent with SMCRA or the Federal regulations.

25 Pa. Code 90.5 Site selection and permitting. Subsection (a) provides that an applicant for a permit to conduct coal refuse disposal activities shall

comply with Subchapter E (relating to site selection) and shall use Pennsylvania's Technical Guidance Document number 563-2113-660, titled "Coal Refuse Disposal—Site Selection" as guidance for selecting a coal refuse disposal site. Subsection (b) provides that after Pennsylvania has approved a site in accordance with Subchapter E, the applicant may apply for a permit for coal refuse disposal activities. There is no direct Federal counterpart for this regulation. However, this section merely describes the sequence of events that an applicant must go through to secure a permit for coal refuse disposal. Because this section is not inconsistent with SMCRA or the Federal regulations, the Director is approving it.

25 Pa. Code 90.12 Geology. Pennsylvania rearranged this section and also added and deleted some language. This section describes the geologic information that an application for coal refuse disposal must include. Former subsection (a)(1) was combined into subsection (a). Pennsylvania also deleted language from former subsection (a)(1) that described the information on the specific geologic stratum that operators are required to put in their permit applications. The deleted information required stratum information that was tied to the lowest coal seam to be mined. This information was replaced with the phrase, "The description shall include the strata down to and including any aquifer that may be affected." Pennsylvania made these changes because coal refuse disposal operations typically do not require the mining of coal. If coal mining does occur in conjunction with the refuse disposal operations, it will be regulated under Pennsylvania's surface coal mining regulations.

The Federal regulation most comparable to this section is found at 30 CFR 780.22(b)(1). This section requires geologic information in applications to include the deeper of either the stratum immediately below the lowest coal seam to be mined or any aquifer below the

lowest coal seam to be mined which may be adversely impacted by mining. Since no coal mining will occur in a refuse disposal operation, Pennsylvania's revised language requiring a description of the stratum down to and including the lowest aquifer that could be affected is as effective as the Federal regulations in requiring the application to contain geologic information about strata that could be affected in a coal refuse disposal operation. The Director finds that this change is no less effective than the Federal regulations and is approving the change.

Former subsection (a)(1)(i) was moved in its entirety to (a)(1). Former subsection (a)(1)(ii) is now (a)(2) and was changed from "Depth, lithology and structure of overburden or underlying strata," to "Depth, lithology and structure of near-surface bedrock." As noted earlier, coal refuse disposal operations in Pennsylvania generally are falls that do not involve the mining of coal. Therefore, the requirement to provide the depth, lithology and structure of overburden or underlying strata, is not applicable since this requirement is tied to a coal seam to be mined. The Director finds that a description of the lithology and structure of the near-surface bedrock is no less effective than the Federal regulations requiring descriptions of the strata to be affected by refuse operations. Accordingly, the Director is approving this change.

Former subsection (a)(2) has been deleted. This section provided the geologic information to be included in an application for any portion of a permit area in which the strata will be removed. As noted earlier, this provision is not applicable to refuse disposal operations because coal mining (unless otherwise authorized under Pennsylvania's surface mining regulations) does not occur on such operations. The Director is approving this change.

Former subsection (b) has been deleted. This section provided that an applicant may request that the requirements for a statement of the results of the test borings or core samplings required under subsection (a)(2) may be waived in part or in its entirety by the Department. Since former subsection (a)(2) has been deleted there is no reason to get a waiver from its requirements, therefore, the Director is approving deletion of this section.

Pennsylvania added requirements (4) through (9) to subsection (a). These sections provide the application requirements for describing the soils,

geologic strata characteristics, aquifers, and mine workings below proposed refuse disposal areas. These additions do not correspond directly to any Federal regulations. However, they require operators to inform Pennsylvania of the conditions beneath and adjacent to the proposed coal refuse disposal area. Because they require additional descriptions of site conditions, they are not inconsistent with the Federal regulations, and the Director is approving them.

Pennsylvania added a new subsection (b) that provides that maps, cross-sections, and geologic descriptions required by this section shall be prepared and certified by a qualified registered professional geologist. The Director finds that this section is no less effective than the Federal regulations at 30 CFR 779/783.25(b), which provides that a professional geologist is among the professionals authorized to submit maps and cross-sections for permit information.

25 Pa. Code 90.13 Groundwater information. In subsection (2), Pennsylvania proposed to add the following sentence to the end of the subsection: "The application shall include a description of the groundwater flow system as it relates to the design and operation of the proposed groundwater and surface water protection system as described in § 90.50 (relating to Design criteria: groundwater and surface water protection system)." This section does not have a direct Federal counterpart. However, it is useful to provide a description of the groundwater flow system as it relates to design and operation of the groundwater and surface water protection system in the application so that Pennsylvania may evaluate the effectiveness of such systems. The information required by 25 Pa. Code 90.13(2) assists operators in meeting the requirements of, and is therefore consistent with, 30 CFR 816.81(a)(1), which requires operators to minimize adverse effects of leachate and surface water runoff on surface and ground water quality and quantity. As a result, the Director is approving this addition.

25 Pa. Code 90.45 Prime farmland The only change to this section was the addition of a reference to Subchapter E which now requires that a person who conducts or intends to conduct coal refuse disposal activities on prime farmlands historically used for cropland, in accordance with Subchapter E (relating to site selection), to submit a plan as part of the permit application for the disposal and restoration of the land. The addition of

this language clarifies that an operator must take into account the requirements of subchapter E when proposing to conduct refuse disposal on prime farmland sites. In Subchapter E, section 90.202(e)(1) provides that Pennsylvania will not approve coal refuse disposal on, or within, prime farmlands except on preferred sites. The Director finds that because this section provides protections for prime farmlands in addition to those found in 30 CFR 785.17, it is consistent with that Federal regulation and is hereby approved.

25 Pa. Code 90.49 Stream buffer zone variance This is a new section added to define the conditions when Pennsylvania will allow coal refuse disposal operations to occur within 100 feet of a stream. As such, it expands upon and clarifies the statutory provisions partially approved on April 22, 1998 (63 FR 19806). Subsection (a) provides that coal refuse disposal may not occur within 100 feet of a stream, however, the Department may grant a variance under subsection (c) if the application is consistent with Subchapter E (relating to site selection). Subsection (b) provides that surface mining operations supporting coal refuse disposal must comply with 25 Pa. Code 86.102(12) relating to areas where mining is prohibited or limited. Subsection (c) provides the procedures an operator must follow to obtain a variance for disposal of coal refuse within the 100-foot stream buffer zone (SBZ) and the circumstances under which the Department will grant such a variance.

This amendment responds to the required amendment codified at 30 CFR 938.16(www). This required amendment concerns application of the SBZ rule at 30 CFR 816/817.57. The required amendment stated:

By July 1, 1998, Pennsylvania shall amend the Pennsylvania program to authorize stream buffer zone variances for coal refuse disposal activities only where such activities will not cause or contribute to the violation of applicable State or Federal water quality standards, and will not adversely affect water quality and quantity, or other environmental resources of the stream.

Pennsylvania's submission of regulations at 25 Pa. Code 90.49(a), (b) and (c)(1), regarding coal refuse disposal activities within a SBZ, are substantially the same as the Federal regulations regarding surface mining activities within a SBZ found at 30 CFR 816/817.57. Those sections provide assurance that the activities will not cause or contribute to the violation of applicable State or Federal water quality standards, and will not adversely affect the water quantity and quality or other

environmental resources of the stream. In addition, at 25 Pa. Code 90.49(c)(2), Pennsylvania contains regulations regarding public notice of a potential variance and a method by which the public can file an exception to the proposed variance with the aim of receiving a public hearing. These sections are no less effective than the Federal regulations and we are approving them. As a result, we will remove the required amendment at 30 CFR 938.16(www).

In 25 Pa. Code 90.49(c)(3), Pennsylvania has indicated that variances to SBZs will be issued as written orders specifying the methods and techniques to be employed to prevent or mitigate adverse impacts. Mitigation can include, but is not limited to, compensatory restoration and enhancements of nearby streams or stream segments. The first sentence of this provision is essentially identical to the statutory language previously approved on April 22, 1998, which states "The variance shall be issued as a written order specifying the methods and techniques that must be employed to prevent or mitigate adverse impacts." Therefore, there is no issue in approving that language in regulation here. The second sentence merely elaborates on the scope of that mitigation concept we have previously accepted by indicating that it may include off-site restoration or enhancement. Therefore, it is also approved.

25 Pa. Code 90.50 Design criteria: groundwater and surface water protection system. This entire section was added by the amendment and provides the application requirements for the performance standards of section 30.56a(i) of the CRDCA. Subsection (a) provides that the application must include a description of the system that will be installed to prevent adverse impacts to groundwater and surface water, while subsection (b) requires the application to include a description of the system that will be installed to prevent precipitation from coming in contact with the coal refuse. Subsection (c) provides that the Department's Technical Guidance Document number 563-2112-656, titled, "Liners—Impoundments, Stockpiles and Coal Refuse Disposal Areas" shall be used as guidance for designing coal refuse disposal sites incorporating earthen, admixed, or synthetic liners or caps for preventing adverse impact to groundwater and surface water and for preventing precipitation from contacting coal refuse. Subsection (d) requires the application to include a description of the measures to be taken to ensure the long-term functionality of the systems

described in subsections (a) and (b). The description must address the site's susceptibility to mine subsidence and deterioration due to physical or chemical processes.

We approved Pennsylvania's use of a system to prevent adverse impacts to surface and ground water and to prevent precipitation from contacting the coal refuse, as described in section 30.56a(i) of the CRDCA, in the April 22, 1998, **Federal Register** (63 FR 19807). The requirements, as presented in the amendment, to describe such systems in the permit application including when and how the systems will be used and how they will be maintained are a logical extension of the requirements of their use. These permit application requirements, in conjunction with the requirements of previously approved sections 25 Pa. Code 90.35 concerning protection of the hydrologic balance, and 25 Pa. Code 90.101 concerning general requirements of the hydrologic balance, are consistent with the requirements of SMCRA section 515(b)(10) concerning protection of the hydrologic balance and 30 CFR 816.81(a) concerning coal mine waste, protection of surface and groundwater from leachate and surface water runoff. As a result, the Director is approving this section.

25 Pa. Code 90.101 Hydrologic balance: general requirements. Pennsylvania proposed only a minor change to this section. Subsection (b) previously required coal refuse disposal activities to be planned and conducted to prevent pollution of the water. In this amendment, Pennsylvania clarified that the water referred to in this section is groundwater and surface water. This clarification is consistent with the requirements of SMCRA section 515(b)(10) regarding minimizing disturbances to surface and ground water systems. As a result, the Director is approving this section.

25 Pa. Code 90.116a Hydrologic balance: water rights and replacement. This new section provides that an operator who conducts coal refuse disposal and adversely affects a water supply shall comply with 25 Pa. Code 87.119 (relating to water rights and replacement). Section 87.119 requires restoration or replacement of an affected water supply with an alternate source adequate in quantity and quality for the purpose served by the supply. While we are reviewing changes to 25 Pa. Code 87.119 as part of a different program amendment, the Director finds that the reference in 25 Pa. Code 90.116a to 25 Pa. Code 87.119 will insure that water supplies adversely affected by coal refuse disposal operation will be

restored or replaced. Therefore, the Director is approving this section.

25 Pa. Code 90.122 Coal refuse disposal. In this section, Pennsylvania deleted former subsections (e) and (g), and redesignated former subsection (f) as (e) and former subsection (h) as (f). Pennsylvania then added new subsections (g) and (h). In the former subsection (e) Pennsylvania required coal refuse disposal areas to be located on the most moderately sloping and naturally stable areas available. The section further provided that fill materials suitable for disposal are to be placed on or above a natural terrace, bench or berm to provide additional stability and prevent mass movement. Former subsection (g) required coal refuse disposal areas to be located in areas where groundwater discharge and surface water flows are minimal. These sections, which have no direct Federal counterparts, were designed to provide stability to refuse disposal fills and prevent pollution to surface and groundwater, both of which are provided for under the remaining and new subsections of 25 Pa. Code 90.122. Therefore, the Director is approving the deletion of these sections.

The new subsection (g) requires refuse disposal areas to be provided with a system to prevent adverse impacts to surface water and groundwater. New subsection (h) specifies how and when the system for preventing precipitation from coming into contact with coal refuse is to be installed. These sections are derived from, and are consistent with, section 30.56a(i) of the CRDCA that we approved in the April 22, 1998, **Federal Register** notice (63 FR 19807). Therefore, the Director is approving them.

Subchapter E. Site selection. Pennsylvania is proposing to add a new Subchapter E titled, "Site Selection" to the Chapter 90 regulations. Subchapter E will contain 25 Pa. Code 90.201 Definitions, 25 Pa. Code 90.202 General requirements, 25 Pa. Code 90.203 Proposing a preferred site, 25 Pa. Code 90.204 Proposing an alternate site, 25 Pa. Code 90.205 Alternatives analysis, 25 Pa. Code 90.206 Disapproval of a proposed site, and 25 Pa. Code 90.207 Approval of a selected site.

25 Pa. Code 90.201 Definitions. This section contains definitions of the terms "search area," and "selected site." These definitions are used to implement Pennsylvania's regulations for the selection of sites for coal refuse disposal operations.

Pennsylvania has defined the term "search area" to mean the geographic area within a 1-mile radius of an existing coal preparation facility or the

25 square mile geographic area encompassing a proposed coal preparation facility. Although these terms were not specifically used in the CRDCA, the definitions were used in section 30.54a(c) and (d) regarding criteria for selecting sites for coal refuse disposal operations. We approved the use of the 1-mile radius in identifying alternative sites for new refuse disposal areas to support an existing coal mining activity and the use of the 25 square mile geographic area for alternative sites for a proposed coal preparation facility (63 FR 19806). Accordingly, the Director is approving the definition of the term "search area" in 25 Pa. Code 90.202.

The term "selected site" is defined as a location selected by the applicant and approved by the Department for which the applicant can then apply for a permit to conduct coal refuse disposal activities. This term is not used in the CRDCA and there is no comparable term in the Federal regulations. We are approving the term because we have already approved the concept of coal refuse disposal site selection set forth in the CRDCA at 52 P.S. 30.54a(a) (63 FR 19806), and because the term is not inconsistent with SMCRA or the Federal regulations.

25 Pa. Code 90.202 General requirements. Subsection (f) provides that as part of the site selection process, an applicant may request approval for more than one site. The applicant will have the option of choosing a selected site from those approved by the Department to be used as the site for submitting an application on which to conduct coal refuse disposal operations. While there is no comparable Federal regulation for this section, there is nothing in SMCRA or the Federal regulations to prevent an operator from examining any number of sites to conduct refuse disposal operations. Any of the sites chosen must undergo the permitting process and be approved by the Department in accordance with the counterparts to SMCRA and the Federal regulations. Accordingly, the Director is approving subsection (f) of 25 Pa. Code 90.202.

25 Pa. Code 90.203 Proposing a preferred site. This section provides that if an applicant proposes to use a preferred site, the Department will approve the proposed site subject to 25 Pa. Code 90.202(c) (relating to general requirements) provided the applicant demonstrates that the attendant adverse environmental impacts will not clearly outweigh the public benefits. This section relates to section 30.54a(a) of the CRDCA, which provides that preferred sites shall be used for coal refuse disposal unless the applicant

demonstrates another site is more suitable; and that where the adverse environmental impacts of the preferred site clearly outweigh the public benefits, the site shall not be considered a preferred site. We approved section 30.54a(a) in the April 22, 1998, **Federal Register** (63 FR 19804). Because 25 Pa. Code 90.203 is consistent with the approved State statutory provision, the Director is approving it.

25 Pa. Code 90.206 Disapproval of a proposed site This section provides that if the Department disapproves the applicant's proposed site, the applicant may submit a new proposal supporting the selection of another site located within or outside the search area. There is no similar language in the CRDCA or SMCRA or the Federal regulations. However, there is no provision in SMCRA or the Federal regulations that prohibits an applicant from submitting alternative proposals if one is turned down. The Director finds this section is not inconsistent with the Federal regulations or SMCRA and is approving it.

25 Pa. Code 90.207 Approval of a selected site. This section provides that Pennsylvania's approval of a selected site does not indicate it will approve an application for coal refuse disposal activities on the selected site. The Director finds that this provision is consistent with Pennsylvania's permitting responsibilities under State counterparts to permitting requirements contained in SMCRA and the Federal regulations, and is therefore approving it.

Subchapter F. Coal Refuse Disposal Activities on Areas with Preexisting Pollutational Discharges. This is a new section added by Pennsylvania. These regulations are modeled on existing regulations regarding remining areas with preexisting pollutational discharges found in 25 Pa. Code Chapter 87, Subchapter F and approved by OSM in the February 19, 1986 **Federal Register** (51 FR 5997).

25 Pa. Code 90.301 Scope. This section gives a general overview of the sections that follow and notes that Chapter 86 (relating to surface and underground coal mining: General) and Subchapters A–D apply to authorizations to mine areas with preexisting pollutational discharges except as specifically modified by this chapter. The Director has approved, with some conditions, the concept of establishing coal refuse disposal areas on sites with preexisting pollutational discharges in the analysis of the amendment of the CRDCA in the April 22, 1998 **Federal Register** (63 FR 19802). Section 25 Pa. Code 90.301

introduces the concept in regulation; therefore the Director is approving this section.

25 Pa. Code 90.302 Definitions, Baseline Pollution Load. Pennsylvania added the definition of the term "baseline pollution load" to 25 Pa. Code 90.302. This term is defined as, "The characterization of the pollutational material being discharged from or on the pollution abatement area, described in terms of mass discharge for each parameter deemed relevant by the Department, including seasonal variations and variations in response to precipitation events. The Department will establish in each authorization the specific parameters it deems relevant for the baseline pollution load, including, at a minimum, iron and acid loadings." This term was similarly defined in the CRDCA except for the last sentence. The term, including the last sentence, was also defined in 25 Pa. Code 87.202 regarding remining on surface mining sites with pollutational discharges. We approved the definition in our evaluation of the Chapter 87 regulations in the February 19, 1986 **Federal Register** (51 FR 5997). We are approving the definition for use in coal refuse disposal operations for the same reasons.

25 Pa. Code 90.302 Definitions, Best Professional Judgment. Pennsylvania added the definition of the term "best professional judgment" to 25 Pa. Code 90.302. The term is defined to mean, "the highest quality technical opinion forming the basis for the terms and conditions of the treatment level required after consideration of all reasonably available and pertinent data. The treatment levels shall be established by the Department under sections 301 and 402 of the Federal Water Pollution Control Act (33 U.S.C.A. §§ 1311 and 1342)." This definition is identical in substance to the definition of "best professional judgment" found at 25 Pa. Code sections 87.202 and 88.502, which was approved by OSM as part of Pennsylvania's standards for treatment of preexisting discharges on remined areas in the February 19, 1986, **Federal Register** (51 FR 5997). As a result, the Director is approving the definition at 25 Pa. Code 90.302.

25 Pa. Code 90.302 Definitions, Coal Refuse Disposal Activities. The term "coal refuse disposal activities" was similarly defined in the CRDCA and in this section to mean the storage, dumping or disposal of any waste coal, rock, shale, slurry, culm, gob, boney, slate, clay, underground development wastes, coal processing wastes, excess soil and related materials, associated with or near a coal seam, that are either

brought above ground or otherwise removed from a coal mine in the process of mining coal or are separated from coal during the cleaning or preparation operations. The term does not include the removal or storage of overburden from surface mining activities. In our analysis of the term in the April 22, 1998, **Federal Register** (63 FR 19803), we required Pennsylvania to amend its program to clarify the meaning of the term "excess soil and related materials" as used in the definition. This requirement was codified at 30 CFR 938.16(vvv).

In the February 2, 2000, **Federal Register** (65 FR 4882), we noted that Pennsylvania submitted information in response to the required amendment at 30 CFR 938.16(vvv). As part of that response, Pennsylvania defined the term "excess soil and related material to mean rock, clay or other material located immediately above or below a coal seam and which are extracted from a coal mine during the process of mining coal. The term does not include topsoil or subsoil." In that **Federal Register** notice, we indicated that we would remove the required program amendment when the clarification is incorporated in Pennsylvania's regulations and those regulations are approved by OSM. Pennsylvania incorporated the definition of "excess soil and related materials" verbatim into its regulations at 25 Pa. Code 90.302. Therefore, the Director is approving the definition and removing the required amendment at 30 CFR 938.16(vvv).

25 Pa. Code 90.303 Applicability. Subsection (b) provides that:

Notwithstanding subsection (a), authorization will not be granted under this subchapter for repermitting under §§ 86.12 and 86.14 (relating to continued operation under interim permits; and permit application filing deadlines), permit renewals under § 86.55 (relating to permit renewals: general requirements) or permit transfers under § 86.56 (relating to transfer of permit).

There is no direct Federal counterpart to this provision but the Director is approving it because it acts to limit permits where coal refuse disposal activities can occur. This section does not make Pennsylvania's coal refuse disposal regulations less effective than Federal regulations.

25 Pa. Code 90.304 Application for authorization. This section provides the permit application requirements for operators seeking to obtain authorization to conduct refuse disposal operations on areas with preexisting pollutional discharges. Parts of section 6.2(e) (52 P.S. 30.56b(e)) of the CRDCA are repeated in this section. Additionally, this section copies 25 Pa.

Code 87.204, which contains the surface coal mining requirements for reining areas with pollutional discharges. As noted above, OSM approved 25 Pa. Code 87.204 in the February 19, 1986, **Federal Register** (51 FR 5997). The Director is approving this section for the same reasons.

25 Pa. Code 90.305 Application approval or denial. Subsection (a)(5) provides standards for success of revegetation on areas approved under this section. For areas previously reclaimed to the standards of Chapters 87, 88 and 90, the revegetation success standards of 25 Pa. Code 90.159 apply. OSM previously approved the revegetation standards in 25 Pa. Code 90.159. Therefore, the Director is approving this portion of the amendment.

Subsection (a)(5) also provides that for those sites not previously reclaimed to the standards of Chapters 87, 88, and 90 the standards of subsection (a)(5)(i)-(iii) apply providing the site is not a bond forfeiture. These standards are the same as those OSM approved for previously affected sites in 25 Pa. 87.205(a)(5)(i)-(iii). Therefore, the Director is approving this section.

The submission of this portion of the amendment satisfies the required amendment codified at 30 CFR 938.16(zzz). This required amendment indicates that Pennsylvania must amend its program to be no less effective than 30 CFR 816.116(b)(5), by limiting the application of the revegetation standards under subsection 6.2(k) of the CRDCA to areas that were previously disturbed by mining and that were not reclaimed to the State reclamation standards.

The submission of this portion of the amendment also allows us to remove the required amendment codified at 30 CFR 938.16(aaaa). This section required Pennsylvania to amend its program to clarify that under Subsection 6.2(l) of its Coal Refuse Disposal Act, a special authorization for coal refuse disposal operations will not be granted, when such an authorization would result in the site being reclaimed to lesser standards than could be achieved if the moneys paid into the Fund, as a result of a prior forfeiture on the area, were used to reclaim the site to the standards approved in the original permit under which the bond moneys were forfeited. Pennsylvania responded to this required amendment by including language in 25 Pa. Code 90.305(a)(5) that provides an exception to the revegetation standards for special authorization projects. The revegetation standards of that section are not applicable when such projects are conducted on bond forfeiture sites

not previously reclaimed to the standards of Chapters 87, 88 and 90, where the money paid into the fund is sufficient to reclaim the forfeited site to the applicable standards. Additionally, we find that the Pennsylvania program prohibits the issuance of a special authorization where preexisting pollutional discharges would not be adequately treated where proceeds paid into the Surface Mining Conservation and Reclamation Fund as a result of a bond forfeiture on the proposed special authorization site are sufficient to pay for such treatment. In other words, treatment of pollutional discharges will not be compromised by special authorizations. Our finding is based upon two premises. First, according to PADEP, there are no currently existing sites for which the forfeited bond would be sufficient to pay for adequate discharge treatment. Second, discharge treatment costs for any future sites will be covered either by conventional bonds, or by treatment trust funds. In the event of operator default on such sites, proceeds from the conventional bonds or treatment trust funds must be expended to accomplish discharge treatment on the sites to which they are dedicated. Thus, where those proceeds are adequate to pay for discharge treatment, they must be used to that end. For these reasons, the remaining concerns that led to the imposition of 30 CFR 938.16(aaaa) have been satisfied, and we are hereby removing this required amendment.

30 CFR 816.116(b)(5) requires that vegetative cover, for areas previously disturbed by mining that were not reclaimed to the standards of Subchapter K, shall not be less than the ground cover existing before redisturbance and shall be adequate to control erosion. In Pennsylvania's amendment, 25 Pa. Code 90.305(a)(5)(ii) and (iii) contains these requirements. As a result, Pennsylvania has satisfied the conditions of the required amendment and we are removing it.

Subsection (d) provides that the authorization allowed under this subsection is only for the pollution abatement area and does not apply to other areas of the permit. The Director is approving this portion of the regulations because it limits the areas of the permit on which coal refuse disposal activities can occur. While there is no direct Federal counterpart to this provision, it does not make this portion of the regulations less effective than the Federal regulations regarding coal refuse disposal.

25 Pa. Code 90.306 Operational requirements. This section provides that operators must comply with Chapter 86

requirements, implement the approved water monitoring program, implement the approved abatement plan and notify the Department prior to the completion of each step of the abatement plan. In addition, this section requires a progress report be sent to the Department within 30 days of completion of each step of the abatement program. We approved the statutory authority for these regulations, contained in 52 P.S. 30.56b(f)(1)–(4), on April 22, 1998 (63 FR 19808). Section 90.306 contains the same requirements as 25 Pa. Code 87.206 that OSM approved in the February 19, 1986, **Federal Register** (51 FR 5997) except that the reporting statement signed by the operator in section (a)(4) need not be notarized in 25 Pa. Code 90.306(a). The lack of a notarized seal on the operator's statement does not lessen the reporting requirements of this section. There is no comparable Federal requirement to this section so Pennsylvania's reporting requirements are more stringent than any Federal provisions. The Director is approving this section.

25 Pa. Code 90.307 Treatment of discharges. This section provides that operators shall comply with the effluent standards of 25 Pa. Code 90.102 for treating discharges, except for preexisting discharges that are not encountered during coal refuse activities or implementation of the abatement plan. For preexisting discharges that are not encountered during coal refuse activities or implementation of the abatement plan, the operator must treat the discharge to comply with the effluent limits established by best professional judgment. The effluent limitations established by best professional judgment may not be less than the baseline pollution load.

This section is the same as 25 Pa. Code 87.207. OSM approved 25 Pa. Code 87.207 in the February 19, 1986, **Federal Register** (51 FR 5997). However, both 25 Pa. Code 87.207 and 90.307 contain language that Pennsylvania added after the 1986 approval. In 1989, Pennsylvania amended 25 Pa. Code 87.207(b) by adding the following language:

If the baseline pollution load when expressed as a concentration for a specific parameter satisfies the effluent limitations at § 87.102 (relating to hydrologic balance: Effluent standards) for that parameter, the operator shall treat the preexisting discharge for that parameter to comply with either effluent limitations established by best professional judgment or the effluent limitations at § 87.102.

In our evaluation of this revision, as published in the May 31, 1991, **Federal**

Register (56 FR 24657,) we noted that while the United States Environmental Protection Agency (EPA) generally concurred with the amendment package that included the above-quoted change, we asked for a specific determination by EPA as to whether the new language in section 87.207(b) is consistent with section 301(p) of the Federal Water Pollution Act, 33 U.S.C. 1311(p). Section 301(p) authorizes the issuance of National Pollutant Discharge Elimination System permits with modified effluent limitations for pH, iron and manganese on previously mined sites with preexisting discharges. We decided to defer a decision on this provision, pending specific EPA concurrence.

While we did not receive specific concurrence from EPA on revised 25 Pa. Code 87.207(b), EPA did publish a final rule on January 23, 2002 (67 FR 3370), that addresses our questions concerning the revision. Appendix B, part I d, indicates that:

In the event that a pollutant concentration in the data used to determine baseline is lower than the daily maximum limitation established in subpart C of this part for active mine wastewater, the statistical procedures should not establish a baseline more stringent than the BPT and BAT effluent standards established in subpart C of this part.

This language, plus EPA's concurrence received for this amendment, makes 25 Pa. Code 90.307 no less effective than the Federal regulation at 30 CFR 816.42 which provides that discharges of water from areas disturbed by surface mining activities must be made in compliance with effluent limitations for coal mining promulgated by EPA.

The submission of this section also satisfies required amendments codified at 30 CFR 938.16(xxx) and (yyy) that we put into place as a result of our review of the CRDCA (63 FR 19802). The required amendment at 30 CFR 938.16(xxx) indicates that Pennsylvania shall amend its program to clarify, in regulations developed to implement the provisions of section 6.2 of the CRDCA, that preexisting discharges that are encountered must be treated to the effluent standards at 25 Pa. Code 90.102.

In the February 2, 2000, **Federal Register** (65 FR 4883), we indicated that we would remove the required amendment at 30 CFR 938.16(xxx) if Pennsylvania submitted regulations that clarified that under section 6.2 of the CRDCA, preexisting discharges that are encountered must be treated to the State effluent standards at 25 Pa. Code 90.102. In its amendment, Pennsylvania submitted section 25 Pa. Code 90.307

which indicates that in subsection (a) that all discharges, except for preexisting discharges that are not encountered during coal refuse disposal activities or the implementation of the abatement plan, must comply with 25 Pa. Code 90.102. In this regulation, Pennsylvania has satisfied the conditions of the required amendment and, as a result, we are removing it.

The required amendment at 30 CFR 938.16(yyy) indicates that Pennsylvania shall amend its program to clarify that subsection 6.2(h) of the CRDCA pertains to preexisting discharges that are not encountered. In the **Federal Register** of April 22, 1998 (63 FR 19810), we approved section 6.2(h) of the CRDCA to the extent that it provides that an operator may only discontinue treating preexisting discharges that are not encountered when the operator demonstrates that the "baseline" pollution load is no longer being exceeded. Preexisting discharges must be treated to the water quality standards of 25 Pa. Code 90.102.

In this amendment, Pennsylvania submitted 25 Pa. Code 90.307(b) which provides that preexisting discharges that are not encountered must comply with effluent limitations established by best professional judgment. The best professional judgment limitations cannot be less than the baseline pollution load. Subsection (d) in describing when an operator may discontinue treating the discharges under subsection (b), indicates that treatment may be discontinued when the preexisting discharges are meeting the effluent limits established in subsection (b). Taken together, subsections (b) and (d) satisfy the conditions of the required amendment at 30 CFR 938.16(yyy) and as a result, we are removing it.

25 Pa. Code 90.308 Request for bond release. This section is the same as 25 Pa. Code 87.208 that OSM approved on February 19, 1986. The Director is approving this section for the same reason. We note that section 90.308 states that 25 Pa. Code subsection 86.172(d) shall not apply to the release of bonds for pollution abatement areas. Subsection 86.172(d) no longer exists; however, since the now deleted provision would not have applied to bond releases under section 90.308 anyway, the cross-reference to it is a nullity.

25 Pa. Code 90.309 Criteria and schedule for release of bonds on pollution abatement areas. For the most part, this section is the same as 25 Pa. Code 87.209 that OSM approved on February 19, 1986, except for two areas. In the first, the percentage of bond

release is different. In 25 Pa. Code 87.209(a), the initial bond release can be up to 60% of the bond and the percentage of the phase II bond release in 25 Pa. Code 87.209(b) is not specified (subsection (b) specifies only that the Department will release an additional bond while retaining an amount sufficient to cover the cost of reestablishing vegetation if completed by a third party). In the regulations covering coal refuse disposal at 25 Pa. Code 90.309(a), the initial bond release is up to 50% of the bond and the phase II bond release specified in 25 Pa. Code 90.309(b) can be up to an additional 35% of the bond while retaining an amount sufficient to cover the cost of reestablishing vegetation if completed by a third party. The regulations at 25 Pa. Code 90.309(a) could result in retention of more of the bond after phase I release than the counterpart regulations at 25 Pa. Code Chapter 87. This would provide more funds available to complete reclamation if an operator defaults after phase I release. Therefore, the Director is approving this portion of the amendment.

The second area of difference is at 25 Pa. Code 90.309(b)(3)(ii)(A)(I). This section deals with one of the standards the operator must achieve to receive a bond release of up to 35%. The section provides that this portion of the bond can be released if the operator, among other things, has not caused degradation of the baseline pollution load for a period of twelve months from the date of the initial bond release under subsection (a), if backfilling, final grading, drainage control, placement of impermeable cover, topsoiling and establishment of revegetation to achieve the standard of success for revegetation in 25 Pa. Code 90.305(a)(5) have been completed. The similar section approved by OSM on February 19, 1986, for surface mines at 25 Pa. Code 87.209(b)(3)(ii)(A)(I) indicated that up to 35% of bonds could be released if the operator, among other things, had not caused degradation of the baseline pollution load for the twelve months prior to the date of application for bond release and until the bond release is approved under subsection (b), if final grading, drainage control, topsoiling and establishment of revegetation to achieve the standard of success for revegetation in 25 Pa. Code 87.205(a)(5) have been completed. The difference in the two sections amounts to the period of time for demonstrating that the site did not degrade the baseline pollution load. The proposed rules at 25 Pa. Code 90.309(b)(3)(ii)(A)(I) provide for a demonstration period of twelve months

from the date of the initial bond release, while in the previously approved regulation at 87.209(b)(3)(ii)(A)(I) the demonstration period is for twelve months prior to the date of application for bond release and until the bond release is approved. Pennsylvania indicated that the demonstration period for the bond release on coal refuse disposal sites was set by the CRDCA which is why it is different than the surface mining regulations in Chapter 87. There is no comparable Federal regulation for this provision. However, the demonstration period is not inconsistent with the Federal regulations at 30 CFR 800.40(c)(2) regarding the release of Phase II bonds. As a result, the Director is approving it.

The remaining sections of 25 Pa. Code 90.309 are the same as the sections of 25 Pa. Code 87.209 that OSM previously approved on February 19, 1986. Therefore the Director is approving them.

Subchapter G. Experimental Practices.

25 Pa. Code 90.401 General. This section provides the standards that coal refuse disposal practices must attain to be considered experimental practices. Subsection (a) is approved because it is substantively identical to, and therefore no less stringent than, the corresponding portions of section 711 of SMCRA. In addition, subsection (b) requires experimental practice permits to meet all the provisions, standards, and information requirements of 30 CFR 785.13. The Director finds that this provision will make Pennsylvania's regulations no less effective than 30 CFR 785.13 and is therefore approving it.

Submission of this portion of the amendment also satisfies the required amendment codified at 30 CFR 938.16(bbbb). This required amendment indicates that Pennsylvania must amend its program by adding implementation rules no less effective than 30 CFR 785.13 and no less stringent than SMCRA section 711. Further, Pennsylvania must clarify that experimental practices are only approved as part of the normal permit approval process and only for departures from the environmental protection performance standards, and that each experimental practice receive the approval of the Secretary. This required amendment is satisfied by subsection 90.401(a), which is substantively identical to most of section 711 of SMCRA, and by subsection (b), which requires compliance with 30 CFR 785.13, which contains the remaining applicable requirements of section 711 of SMCRA not covered by 90.401(a). Those

remaining requirements are that experimental practices be approved only as departures from the performance standards in individual cases, and that such practices must also receive the approval of the Secretary of the United States Department of the Interior, as delegated to the OSM Director. Therefore, we are removing 30 CFR 938.16(bbbb).

Removal of Required Amendments at 30 CFR 938.16(hh) and (kk)

In the required amendment codified at 938.16(hh), we required Pennsylvania to amend 25 Pa. Code 89.59(a)(1) and (2) or otherwise amend its program to be no less effective than 30 CFR 784.14(h)(1) to require the monitoring plan to specify that, at a minimum, the total dissolved solids or specific conductance, pH, total iron, total manganese, and water levels shall be monitored and data submitted to Pennsylvania at least every 3 months for each monitoring location.

In response to this required amendment, Pennsylvania submitted changes to 25 Pa. Code 89.59(a)(3). The changes include deleting the last sentence from the section that reads, "The Department will approve the nature of data, frequency of collection, reporting requirements and the duration of the monitoring programs," and adding the following two sentences to the end of the section:

Surface water shall be monitored for parameters that relate to the suitability of the surface water for current and approved postmining land uses and to the objectives for protection of the hydrologic balance as set forth in § 89.36 (relating to protection of hydrologic balance). At a minimum, total dissolved solids or specific conductance corrected to 25°C, total suspended solids, total iron, total manganese, acidity, alkalinity, pH, sulfates and flow shall be monitored and reported to the Department at least every 3 months for each monitoring location.

Pennsylvania is also proposing to change 25 Pa. Code 89.59(b) by adding a sentence to the end of the section that reads, "The Department may also require the operator to conduct monitoring and reporting more frequently than every 3 months and to monitor additional parameters beyond the minimum specified in this section."

We find that Pennsylvania's regulatory language regarding surface and groundwater monitoring is substantively identical to the corresponding portions of the Federal requirements at 30 CFR 784.14(h)(1) and therefore satisfies the required amendment at 30 CFR 938.16(hh). We are removing the required amendment at 30 CFR 938.16(hh).

The required amendment codified at 30 CFR 938.16(kk) requires Pennsylvania to correct cross-references in two sections of PA SMCRA. In section 3.1(c), the cross-reference to section 4.2(f) was to be changed to 4(b)(f). In section 3.1(d), the cross-reference to 18.6 was to be replaced with Section 24.

In response to the required amendment, Pennsylvania submitted a letter dated November 16, 2001 (Administrative Record No. PA 880.00). Pennsylvania explained that sections 3.1(c) and 3.1(d) of PA SMCRA are part of a numbering system used by the Pennsylvania Legislative Reference Bureau. Likewise the cross-referenced Sections 4.2(f) and 18.6 are also Legislative Reference Bureau numbering. Section 4b(f) is part of a numbering system used in Purdon's Pennsylvania Statutes Annotated (Purdon's). The complete number for Section 4(b)(f) in Purdon's is 52 P.S. 1396.4b(f). Purdon's 52 P.S. 1396.4b(f) is the Legislative Reference Bureau's Section 4.2(f). Section 24 was formerly a Purdon's number. The complete number for Section 24 in Purdon's was 52 P.S. 1396.24. Section 1396.24 was renumbered to 1396.18f in 1993 as a result of amendments to PA SMCRA. Purdon's section 1396.18f is the Legislative Reference Bureau's Section 18.6. Pennsylvania believes that since the cross-references in Sections 3.1(c) and 3.1(d) of SMCRA are the appropriate Legislative Reference Bureau Numbers that should be referenced, 30 CFR 938.16(kk) should be removed.

We agree with Pennsylvania's explanation regarding the cross-references and therefore, we are removing the required amendment codified at 30 CFR 938.16(kk).

IV. Summary and Disposition of Comments

Public Comments

No public comments were received.

Federal Agency Comments

Four responses were received from Federal agencies in response to Pennsylvania's submission under Administrative Record No. PA 837.101. One response was received from the United States Department of the Interior, Fish and Wildlife Service (FWS), two responses were received from the U.S. Department of Labor, Mine Safety and Health Administration's (MSHA), and one response was from the United States Department of Agriculture, Natural Resources Conservation Service (NRCS).

FWS submitted comments dated February 25, 2002 (Administrative Record No. PA 837.108). FWS indicated that 25 Pa. Code 90.49, Stream Buffer Zone Variance is inconsistent with Federal regulations. FWS indicated that the Federal regulations at 30 CFR 816.57 would prevent disturbance of a stream channel in the ephemeral portion of streams, 100 feet upstream of the intermittent zone and is therefore more protective of water quality and the stream's other environmental resources than PADEP's language. Our review of this section finds that it is similar to the stream buffer zone requirements of 25 Pa. Code 86.102(12) regarding areas not suitable for mining that we previously approved. Additionally, it appears that Pennsylvania's stream buffer zone may protect more area around streams, including the ephemeral zone upstream from an intermittent portion of a stream, because it includes areas 100 feet from an intermittent or perennial stream bank, and not just the stream itself. As a result, we have found that Pennsylvania's regulations regarding buffer zones are no less effective than the Federal regulations.

FWS further indicated that language at 25 Pa. Code 90.49(c)(1) that states that a stream buffer zone variance will only be granted if the operator demonstrates to the satisfaction of PADEP that coal refuse disposal will not adversely affect water quality or other environmental resources of the stream and will not cause or contribute to the violation of water quality standards is not as effective as the requirement of 30 CFR 816.57. FWS indicated that the Federal regulation requires that the regulatory authority must make a finding that the stream will be protected. We find that Pennsylvania's regulation does require it to make a finding that the stream will be protected because it requires that any demonstration by the operator be made to the Department's satisfaction. The Department will not be satisfied with substandard demonstrations and therefore will not allow a variance in those circumstances. We have found Pennsylvania's regulation to be no less effective than the Federal regulation.

Finally, regarding the stream buffer zone regulation at 25 Pa. Code 90.49(c)(1), FWS indicated that the words, "as a result of the variance" are also inconsistent with 30 CFR 816.57(a)(1) which states "[s]urface mining activities will not cause or contribute to * * *" We find that because both 30 CFR 816.57(a)(1) and 90.49(c)(1) are specifically written for stream buffer zones, there is no significant difference between the language of these two sections. In other

words, implicit in the language of the Federal regulation is the required finding that, as a result of the variance, there will be no adverse effects on water quality or quantity or other environmental resources of the stream nor violations of the State or Federal water quality standards. Both 25 Pa. Code 90.49(c)(1) and 30 CFR 816.57(a)(1) indicate the conditions under which a buffer zone variance will be issued and Pennsylvania's language is no less effective than the Federal regulation in communicating those conditions.

FWS's other concern was with threatened and endangered species. FWS indicated that language to ensure the protection of Federally listed threatened or endangered species was removed from the on-line version of PADEP's Technical Guidance Document 563-2113-660 titled, "Coal Refuse Disposal—Site Selection." PADEP indicated that a footnote containing the referenced language was inadvertently removed from the on-line version of the Technical Guidance Document. The footnote has subsequently been restored to the on-line version of the document. The footnote, as it now appears on page 4, reads:

PADEP's Section 4.1 (b) of CRDCA prohibits coal refuse disposal on non-preferred sites that contain federally listed threatened or endangered species. With respect to preferred sites, the Department will not approve (via the site selection process) or permit (via the permitting process) a site that is known or likely to contain Federally listed threatened or endangered species, unless the Department concludes and the U.S. Fish and Wildlife Service concurs that the proposed activity is not likely to adversely affect Federally listed threatened or endangered species or result in the "take" of federally listed threatened or endangered species in violation of Section 9 of the Endangered Species Act.

In our final rule of April 22, 1998 (63 FR 19802), we indicated that the proposed site selection provision at subsection 4.1(b) of the CRDCA was approved to the extent of the provisions contained in the above language. Consequently, we find that FWS's concern has been answered.

MSHA's Wilkes-Barre Office replied on January 14, 2002, (Administrative Record No. PA 837.104) that the amendment did not conflict with existing MSHA regulations. On January 23, 2002, MSHA's New Stanton Office (Administrative Record No. PA 837.105) replied that the amendment did not conflict with its refuse pile regulations.

NRCS replied on January 29, 2002, (Administrative Record No. PA 837.106) that it found no inadequacies with the proposed amendment.

In regard to Pennsylvania's submission under Administrative Record No. PA 881.00, there were three responses from Federal agencies: two from MSHA and one from NRCS. MSHA's New Stanton Office replied on January 11, 2002, (Administrative Record No. PA 881.03) that the amendment did not conflict with any of MSHA's regulations under 30 CFR parts 75 and 77. MSHA's Wilkes-Barre Office replied on January 14, 2002, (Administrative Record No. PA 881.04) that nothing in the amendment conflicted with existing MSHA regulations. NRCS replied on January 29, 2002, (Administrative Record No. PA 881.05) that it found no inadequacies with the proposed change.

In regard to Pennsylvania's submission under Administrative Record No. PA 880.00, we received a response from MSHA's Wilkes-Barre office on September 6, 2002 (Administrative Record No. PA 880.04), indicating that it had no comments on the amendment.

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.*). On February 25, 2002 (Administrative Record No. PA 837.107), EPA informed us that there are no apparent inconsistencies with the Clean Water Act or other statutes or regulations under EPA's jurisdiction regarding Pennsylvania's submission under Administrative Record No. PA 837.101. EPA had three additional comments:

(1) EPA commended the portion of the amendment requiring the use of previously impacted areas for refuse disposal because of the environmental benefits of reclamation of previously impacted areas and because it would spare non-impacted areas that would otherwise be designated as refuse disposal sites.

OSM accepts the comments and also recognizes the environmental benefits of Pennsylvania's refuse disposal regulations.

(2) EPA indicated that it is apparent that some refuse disposal fills will be in headwater areas and pointed out that filling of waters of the United States requires proper authorization under Section 404 of the Clean Water Act, administered by the U.S. Army Corps of Engineers.

This comment is similar to one EPA made during its review of the changes to the CRDCA that precipitated this amendment. For a detailed discussion of OSM's response to the comment, see the final rule of April 22, 1998 (63 FR 19816–19819).

(3) Discharges from refuse disposal sites into waters of the United States require National Pollutant Discharge Elimination System (NPDES) permits from the Pennsylvania Department of Environmental Protection. NPDES permits for refuse disposal discharges must meet the more stringent of effluent guideline regulations under 40 CFR part 434 or those effluent limits necessary to comply with Pennsylvania's water quality standards for the receiving stream.

We note that one of the conditions of EPA's concurrence with the CRDCA involved the relationship between discharges and NPDES permits. For a full discussion of the Director's concurrence with this condition, see the final rule of April 22, 1998 (63 FR 19818–19819).

On September 5, 2002 (Administrative Record No. PA 880.05), EPA also responded to our request for comments on Pennsylvania's submission under Administrative Record No. PA 880.00. After reviewing Pennsylvania's submission, EPA determined that there were no apparent inconsistencies with the Clean Water Act or other statutes and regulations under its jurisdiction.

V. OSM's Decision

Based on the above findings, we approve the amendment Pennsylvania sent us on December 20, 2001. In addition, we are removing the required amendments codified at 30 CFR 938.16(hh), (kk), (vvv), (www), (xxx), (yyy), (zzz), (aaaa), and (bbbb).

To implement this decision, we are amending the Federal regulations at 30 CFR Part 938, which codify decisions concerning the Pennsylvania 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 regulation effective immediately will expedite that process. SMCRA requires consistency of State and Federal standards.

VI. Procedural Determinations

Executive Order 12630—Takings

This rule does not have takings implications. This determination is

based on the analysis performed for the counterpart Federal regulation.

Executive Order 12866—Regulatory Planning and Review

This rule is exempted from review by the Office of Management and Budget 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. The basis for this determination is that our decision is on a State regulatory program and does not involve a Federal program involving Indian lands.

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 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. 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.

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 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

regulation was not considered a major rule.

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 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 regulation did not impose an unfunded mandate.

List of Subjects in 30 CFR Part 938

Intergovernmental relations, Surface mining, Underground mining.

Dated: September 8, 2003.

Brent Wahlquist,

Regional Director, Appalachian Regional Coordinating Center.

■ For the reasons set out in the preamble, 30 CFR part 938 is amended as set forth below:

PART 938—PENNSYLVANIA

■ 1. The authority citation for part 938 continues to read as follows:

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

■ 2. Section 938.15 is amended in the table by adding a new entry in chronological order by “*Date of final publication*” to read as follows:

§ 938.15 Approval of Pennsylvania regulatory program amendments.

* * * * *

| Original amendment submission date | Date of final publication | Citation/description |
|------------------------------------|---------------------------|---|
| * * * * * | * * * * * | * * * * * |
| December 20, 2001 | October 2, 2003 | 25 Pa. Code 88.281, 88.310, 88.332, 89.59, 90.1, 90.5, 90.12, 90.13, 90.34, 90.45, 90.49, 90.50, 90.101, 90.116a, 90.122, 90.167, 90.201–207, 90.301–309, and 90.401. |

§ 938.16 [Amended]

■ 3. Section 938.16 is amended by removing and reserving paragraphs (hh), (kk), (vvv), (www), (xxx), (yyy), (zzz), (aaa), and (bbb).

[FR Doc. 03–24945 Filed 10–1–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 80

[FRL–7566–3]

Regulation of Fuel and Fuel Additives: Gasoline and Diesel Fuel Test Method Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking action to make certain fuel testing requirements more consistent and up-to-date by having refiners and laboratories use the most current version of an American Society of Testing and Materials (ASTM) analytical test method.

Specifically, we are updating an ASTM designated analytical test method, ASTM D 1319 to the most recent 2002a version which when adopted will supersede earlier versions of this method in EPA’s motor vehicle