E.O. 11514; Pub. L. 100–202; 49 U.S.C 106(g) (Revised Pub. L. 97–449, January 12, 1983).

2. By adding Special Federal Aviation Regulation No. 55 to read as follows:

SFAR No. 55—Flight Restrictions in the Vicinity of Prince William Sound, Alaska

1. *Applicability.* This rule applies to all aircraft operations in the vicinity of Prince William Sound, Alaska, and other areas affected by the oil spill on March 24, 1989, within airspace and at times specifically described by NOTAM.

2. *Special flight restrictions.* No person may operate an aircraft or initiate a flight in the area of applicability except in accordance with the provisions of this special rule.

3. *Definition.* For the purposes of this special rule:

"Responsible agency" shall mean the U.S. Coast Guard, Valdez, Alaska, or other office or person designated by the Director, Air Traffic Operations Service, Federal Aviation Administration, as responsible for approval and monitoring of aircraft operations in an area designated by NOTAM under this special rule. The responsible agency is not an air traffic control facility and will not provide separation of aircraft.

4. *Operating procedures.*

A. No person may operate an aircraft contrary to the requirements and terms of any Notice to Airmen issued under this special rule by the Director, Air Traffic Operations Service or his designee.

B. No person may operate an aircraft in any area designated by NOTAM without receiving prior approval from the responsible agency, if the NOTAM establishes a prior approval requirement for that area.

C. No person may operate an aircraft within any area designated by NOTAM unless all of the following conditions are met:

(1) The operator complies with all instructions and special identification procedures issued by the responsible agency, including by NOTAM or by radio through the designated communications facility;

(2) The operator establishes and maintains 2-way radio communications with the Coast Guard Cutter Rush or other communications facility designated by the responsible agency;

(3) The operation is conducted under VFR at all times while in the area.

D. Operating procedures to and from established landing areas within the designated areas in support of communities (such as Ellamar, Tatitler, and Perry Island) and/or existing commercial interests will be provided by the responsible agency.

5. *Expiration.* This special rule expires July 1, 1989.

Issued in Washington, DC, on March 30, 1989.

Robert E. Whittington,

Acting Administrator.

[FR Doc. 89–7998 Filed 3–31–89; 10:39 am]

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Wednesday
April 5, 1989

Part III

Department of the Interior

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 701 et al.

Surface Coal Mining and Reclamation Operations; Final Rule

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 701, 740, 750, 773, 774, 800 and 843

Surface Coal Mining and Reclamation Operations

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

ACTION: Final rule.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSMRE) of the Department of the Interior (DOI) is amending its rules to provide for specific situations where a coal mine operator may not be required to renew a permit to conduct reclamation activities on a location where no coal extraction is taking place. This action is necessary to establish a consistent policy with respect to permit requirements for reclamation activities. The intended effect of this action is to remove requirements to renew a permit for which the permit term has expired when only reclamation activities must be performed.

EFFECTIVE DATE: May 5, 1989.

FOR FURTHER INFORMATION CONTACT: Dr. Fred Block, Branch of Federal and Indian Programs, OSMRE, 1951 Constitution Avenue, NW., Washington, DC 20240; Telephone (202) 343–1864.

SUPPLEMENTARY INFORMATION:

I. Background

The Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act), establishes a regulatory framework under which persons may obtain the right to surface mine coal. However, the right to mine carries with it the obligation to restore the land after mining has ceased. The link between mining and reclamation is one of the basic underlying themes of the Act. In section 101, Congress finds that regulation of surface coal mining operations in accordance with the requirements of SMCRA is an appropriate and necessary measure to minimize the adverse effects of mining. SMCRA made it clear that mining must be followed by efforts to ameliorate the disturbances it causes. Section 102, which sets forth the basic purposes of the Act, again ties mining and reclamation together. Paragraph (c) provides that the Act will assure that mining will not take place where reclamation is not possible. Paragraph (e) indicates that the Act will assure that procedures to reclaim will be undertaken as contemporaneously as possible with mining operations.

Section 502 of SMCRA, which establishes the initial regulatory program, repeats the concept that surface coal mining operations can only take place when accompanied by reclamation. Paragraph (c) provides that all surface coal mining operations regulated by a State under the initial regulatory program conform to certain performance standards in section 515 of the Act, including the requirement for restoring the land affected to a condition capable of supporting premining or higher or better uses. Similarly, section 506, which establishes the permitting requirements for the permanent regulatory program, provides that no one may engage in "surface coal mining operations" in a State without first obtaining a permit issued pursuant to an approved State program or a Federal program. The State program requirements of sections 503 and 515(a) of SMCRA provide that the State must have a law that regulates mining in accordance with the requirements of SMCRA, one of which is, as noted above, the requirement to restore the land to a condition capable of supporting premining or higher or better uses. Thus, it is evident that SMCRA requires reclamation to accompany mining and that the regulatory framework can only allow mining if the obligation to reclaim is also assumed.

In its previous public positions, OSMRE has required that the permit to conduct surface coal mining operations be renewed for the duration of all mining *and reclamation* activities (emphasis added). The September 28, 1983, preamble to OSMRE's final rule at 30 CFR 773.19(d) addressed rights of renewal under an approved permit application (48 FR 44374). In discussing the relationship between the area covered by the permit and the area comprising the life-of-mine operation, a commenter expressed the belief that a permit cannot properly contain within its boundaries more area than can be mined and reclaimed during the permit term. Implicit in this statement is the belief that reclamation must be completed within the initial permit term of five years. OSMRE disagreed with the commenter, but affirmed the implied assumption that a permit is necessary for reclamation by stating, "A permit is required for reclamation activities until final bond release. Since bond release cannot occur until after the 5- or 10-year period for establishing revegetation, no permit could have only one 5-year term without renewal" (48 FR 44374). The 1983 preamble did not contain an explanation of the requirement nor did it provide any reference or citations where an explanation of the requirement could be found.

OSMRE has also argued before the Interior Board of Land Appeals that permanent program reclamation activities must be permitted. In a case concerning whether a permanent program permit is required for the reclamation of an operation that extracted coal only during the initial regulatory program (81 IBLA 209, June 5, 1984), OSMRE argued that "when surface coal mining occurs, it triggers the requirement of reclamation" and "reclamation activities which follow coal extraction which occurs during the permanent program must be permitted until they are completed and the bond release occurs."

However, at the same time that OSMRE argued that a permit was required for solely reclamation activity, OSMRE recognized specific circumstances where reclamation may be ordered in the absence of a permit. Both the initial program regulations and the permanent program regulations provide for the suspension or revocation of a permit without affecting the obligation to reclaim (30 CFR 722.16(d) and 843.13(c) respectively). During the revision of the permanent program regulations in 1982, OSMRE re-emphasized that the obligation to reclaim continues in cases where the permit has been suspended or revoked. In the preamble to the final Federal enforcement rules OSMRE stated, "[t]he permit issued under the Act is a permit to mine coal under specified conditions. Suspension of the right to mine does not suspend the obligation to reclaim under the Act." This statement in the 1982 preamble implicitly recognized that a distinction exists between the authority to conduct coal extraction activities, specified in section 701(28), and the obligation to reclaim. (47 FR 35631, August 16, 1982)

OSMRE recognizes that it is inconsistent to require on the one hand that an operator renew a permit for only reclamation activities and, on the other, to require reclamation even in the absence of a permit. OSMRE also recognizes that, whether or not a permit is renewed by a permittee for purposes of extracting coal or otherwise disturbing land for the purposes of coal extraction, the reclamation obligations as described in the permit's reclamation plan remain incumbent upon the permittee until final bond release. OSMRE is promulgating this final rule to

recognize that requiring permit renewal when only reclamation activities remain has been inconsistent with other instances where OSMRE required reclamation activities in the absence of a section 506 permit; and, to avoid needless consumption of resources for permit renewal where only reclamation activities remain.

A permit is sought and granted to authorize an activity of benefit to the permittee, i.e., the activities associated with the extraction of coal. The exercising of that authorization creates the obligation to reclaim any resulting disturbance. While the authorization (or permit) to extract coal may expire or be revoked or suspended, the obligation to reclaim in accordance with the approved plan cannot expire or be revoked or suspended but remains in full force until all reclamation work is completed. Therefore, there is no need to renew that which does not expire.

The proposed rule was published in the **Federal Register** on September 19, 1988 (53 FR 36404–8). A public hearing was scheduled for October 27, 1988, in Washington, DC. Since no one requested to testify at the hearing, it was not held. The period for public comment on the proposed rule closed on November 3, 1988. OSMRE received comments from five sources, the State regulatory authority for Ohio, two public interest groups, a coal company and a coal mining industry association. The public interest groups opposed the proposal. The other commenters generally supported it, although two suggested modifications.

II. Discussion of Final Rule and Response to Comments

The final rule adopted today establishes a consistent policy with respect to permit requirements when reclamation activities are conducted where no coal extraction or other activities described in the definition of "surface coal mining operations" at section 701(28) of SMCRA are taking place. Based on an analysis of the issues involved, the legislative history of SMCRA, the statutory language, applicable court decisions, and the administrative record of this rulemaking, including comments received, this final rule is a proper and reasonable interpretation of section 506 of SMCRA.

This final rule, while having an identical effect, clarifies the rule as proposed. As pointed out by some commenters, labeling a permit that had not been renewed when only reclamation remained, an "expired" permit, may cause uncertainties about the validity of the permit. In particular, some commenters questioned whether OSMRE could enforce conditions and reclamation requirements of an "expired" permit. Therefore, OSMRE is making clear in this final rule that the only thing which expires is the authorization to conduct surface coal mining operations, while the obligation to complete reclamation in accordance with the approved reclamation plan of the permit does not expire until completed and, therefore, need not be renewed. OSMRE in this final rule rightly recognizes that a permit need only be renewed for purposes of coal extraction or other activities specified in the definition of "surface coal mining operations" at section 701(28) of SMCRA. Although a permittee may choose not to renew the permit for these activities, the permit and all reclamation obligations under the regulatory program remain in full force and effect for all reclamation requirements until final bond release.

OSMRE is amending its rules at 30 CFR 701.11, 740.13, 750.11, 773.11, 800.60 and 843.11 to implement a consistent policy with respect to permit requirements when reclamation activities would be conducted where no coal extraction or other surface coal mining operations specified in SMCRA section 701(28) would be taking place.

In accordance with OSMRE's determination that a permit is required to conduct "surface coal mining operations" and that reclamation is an obligation that must follow *any* surface coal mining operations, 30 CFR 701.11 (a), (b), (c) and (d); 740.13(a) (1) and (3); 750.11 (a) and (c); 773.11(a) and 843.11(a)(2) are revised by replacing the term "surface coal mining and reclamation operations" with the term "surface coal mining operations." OSMRE is adding language to 30 CFR 773.11(a) to clarify that a permit need not be renewed if solely reclamation obligations exist under the permit and that the obligations under a permit continue regardless of whether the permit has been renewed or the permit has been terminated, revoked or suspended. OSMRE is modifying 30 CFR 774.10 to reflect the reduced information collection requirements attendant to this final rule. Also, OSMRE is modifying 30 CFR 800.60(b) to clarify that liability insurance must be maintained through the completion of the surface coal mining and reclamation operation even though the permit which authorizes the coal extraction activities may not have been renewed.

General Comments

Three commenters expressed support for the proposal. Two commenters felt that the proposal would remove burdensome and unnecessary requirements to obtain a permit where only reclamation activities are being conducted. One said the proposal would not sacrifice protection of the environment. One said that the requirement to renew a permit after coal extraction is completed and only reclamation remains is wasteful of the manpower and resources of the regulatory authority and the permittee. Another commenter strongly supported the proposal because it would clarify that reclamation is required even in the absence of a permit. In the commenter's view, the reclamation obligation is derived from disturbances to the land surface resulting from mining. Another commenter shared this view because "[w]hile reclamation obligations attend the mining which occurs pursuant to a permit, the requirements to obtain and renew a permit attach only to the removal of coal."

One commenter stated that based on sections 509 and 511 of the Act, the regulatory authority's ability to enforce the provisions of the permit are in no way tied to the permit term; enforcement authority exists until the time at which the bond is fully released. Another commenter referred to sections 506, 507, and 508 of SMCRA to support the view that the determination of a reclamation plan's compliance with the Act is not affected by the expiration of the permit term.

Two commenters characterized the proposal as "unnecessary, ill-considered and illegal" in providing that the permit need not be renewed for completion of reclamation. The commenters said that the proposal would "illegally, irrationally and unnecessarily delete the term 'reclamation' from the phrase 'surface coal mining and reclamation operations.' " One commenter said that the proposal would violate SMCRA by dividing the link between mining and reclamation and conveying the notion that the latter does not necessarily follow the former. The commenter said the proposal would cause confusion and have deleterious and illegal side effects. The commenter also suggested that the proposal was "at least partially motivated by a hidden agenda" and said the motivations for the proposal should be fully discussed. The other commenter charged OSMRE with "sophistry unparalleled in recent rulemakings" and with "tinkering unnecessarily and dangerously with the rules" while being "oblivious to the legal constraints in which it must operate and the practical ramifications of its actions."

This rulemaking has discussed the factors leading to the proposal to adopt

a consistent policy concerning permit requirements where only reclamation activities remain to be completed. The rulemaking is based on the priniciple that the right to mine coal conveyed by the approval of a permit application is firmly and unalterably joined to the obligation to reclaim the disturbed land. All of the commenters indicated agreement with this principle. The desagreement concerns whether the permit must be renewed for the reclamation obligation to be fulfilled. OSMRE's view is that the reclamation obligation persists regardless of whether the permit is renewed to authorize SMCRA section 701(28) activities. This final rule is intended to implement this view in all its facets and ramifications.

The Act's requirement to obtain a permit in section 506 specifies the permit requirement for surface coal mining operations, which is defined in section 701(28), not the additional reclamation activities specified in the definition of surface coal mining and reclamation operations defined in section 701(27). Section 506(a) provides that: "no person shall engage in or carry out on lands within a State any *surface coal mining operations* unless such person has first obtained a permit issued by such State pursuant to an approved State program or by the Secretary pursuant to a Federal program." (emphasis added) A permit under SMCRA authorizes the mining of coal and other attendant operations specified in section 701(28) and sets forth the planned and required reclamation. Section 506(d) specifies that any valid permit carries with it the right to successive renewal and that the permit holder may apply for renewal.

It does not require the permit holder to apply for renewal. To require renewal of the authorization to mine coal, solely to reclaim the land, make little sense. Indeed, the last 5 or 10 years of many surface coal mining and reclamation operations entail a period of inactivity while growth of vegetation is monitored.

A permittee who has finished mining coal, or other section 701(28) activities, and who has only reclamation obligations remaining to complete operations need not obtain a renewal of the 5-year permit term to conduct "surface coal mining operations," because section 506 does not require such an authorization. Whether a permit is renewed affects a person's authority to conduct surface coal mining operations, but has no bearing on the person's responsibility to complete reclamation which continues until satisfied. The 5-year limit on permit terms specified in section 506(b) is not intended to curtail reclamation activities required under the permit. In other words, the permit requirements, including the reclamation plan, continue in force after the authorization to conduct section 701(28) activities lapses.

One commenter said that SMCRA mandates that the permit for a mining operation be maintained in active status through the mining and reclamation activity and until final bond release for the permitted operation. The commenter cited a number of provisions of SMCRA that the commenter believed support this view. The commenter pointed out the following statement in paragraph (a) of section 507 of SMCRA, which describes permit application requirements: "[E]ach application for a surface coal mining *and reclamation* permit * * *." (Emphasis added by the commenter.) The commenter also noted that the bonding provisions of the Act in section 509 describe the permit as a surface coal mining and reclamation permit. In the commenter's opinion, by identifying the permit as one for surface coal mining and reclamation, Congress envisioned a "live" permit authorizing both active mining and subsequent reclamation.

OSMRE does not agree with the commenter's narrow assessment of the language of section 507(a) and 509 of the Act. OSMRE fully recognizes that the permit which authorizes the extraction of coal also specifies the nature of the reclamation obligation that goes with exercising that authorization. Therefore, the use of "surface coal mining and reclamation permit" in these provisions is simply intended to recognize and emphasize that the permit must contain information related to both the mining and reclamation phases of the operation. These sections do not directly pertain to the requirement to obtain a permit. In the section of SMCRA addressing the need to obtain a permit, section 506(a), the activity is described as "surface coal mining operations," in other words those activities defined in section 701(28), not the reclamation component contained in section 701(27). OSMRE interprets this usage to mean that the mining operation is required to be permitted, but the reclamation obligation described in the permit exists and must be fulfilled independently of the renewed authorization to conduct section 701(28) activities. OSMRE notes that the Act uses the term "surface coal mining operations" in section 515(a) when referring to a permit to conduct operations and requires that such operations comply with all applicable performance standards, which includes those for reclamation. This again supports the view that the permit is for section 701(28) activities and that reclamation is an obligation assumed by exercising that authorization.

The commenter also said the following provision of section 507(f) of the Act, which creates the obligation on the part of the permittee to obtain liability insurance for the operation, demonstrates that the permit term includes relcamation activities: "Such [insurance] policy shall be maintained in full force and effect during the term of the permit or any renewal, *including the length of all reclamation operations.*" (Emphasis added by the commenter.)

OSMRE interprets the cited provision to require that liability insurance shall remain in effect throughout the duration of all mining and any reclamation operations irrespective of whether or not a permit is renewed, and has clarified this point in the final rule. However, OSMRE contends that if Congress meant the permit term renewals to include reclamation periods, the last clause of the cited provision would have been redundant and unnecessary.

Accordingly, OSMRE is also amending 30 CFR 800.60(b) of the permanent program regulations to state that the liability insurance policy shall be maintained in full force during the life of the permit or any renewal thereof *and* the liability period necessary to complete all reclamation operations (emphasis added). This change clarifies that the liability period extends through the completion of reclamation regardless of whether the permit was renewed for authorization to conduct section 701(28) activities.

The commenter also cites section 515(c)(6) of SMCRA, which requires a permit review not more than three years from issuance of the permit unless the applicant demonstrates that the proposed development is proceeding in accordance with the approved schedule and reclamation plan. In the commenter's view, this provision demonstrates the intent of Congress that the permit remain active and be reviewed throughout implementation of the reclamation plan.

As stated above, guidance on the requirement for a permit and any renewals is found in section 506(a) of SMCRA. The cited provision merely recognizes Congress' concern about closely monitoring certain 701(28) activities as they develop. However, development will be occurring only in connection with surface coal mining operations. Once development has ceased only reclamation work remains. Therefore, this section does not support the commenter's assertion.

The commenter also argued that the statement in section 511(a)(1) of SMCRA, that "[d]uring the term of the permit the permittee may submit an application for a revision of the permit, together with a revised reclamation plan, to the regulatory authority," indicates that revisions to permits can only occur during the term of the permit. The commenter further argued that SMCRA contains no provision for revising the reclamation plan portion of an expired permit.

OSMRE believes that this final rule is consistent with section 511. Section 511(a)(1) is a permissive provision, that is, use of the term "may submit" indicates that revision is allowed during the life of the permit. Such language does not necessarily exclude revision at other times. Since obligations under the reclamation plan do not expire at the end of the permit term but remain in effect until completed, it is consistent with the intent of section 511 to allow for these revisions. Any revisions to the reclamation plan following expiration of the permit term must comply with the requirements of 30 CFR 774.11 and 774.13 or the State program counterparts thereof.

The commenter also said that the reporting, recordkeeping and monitoring requirements of section 517(b)(1), as well as many other obligations under Title V of the Act, apply to the "permittee," i.e., one holding a permit, not to one who once held a now-expired permit.

OSMRE agrees that section 517(b)(1) applies to surface coal mining and reclamation operations and that such obligations assumed by a permittee when he initiates mining remain in effect until completed. However, this is irrespective of whether or not the permittee renewed his authorization to extract coal. The rule language has been modified to make this point clear.

Finally, the commenter cited a portion of the legislative history of SMCRA that, in the commenter's opinion, supported the proposition that the permit must remain active through reclamation. Specifically, the commenter cited portions of House Report No. 95–218, 95th Congress, 1st Session (1977), that (1) described the permitting program as a permit system for surface mining and reclamation operations, (2) indicated the reclamation plan is a portion of the permit application, (3) identified the reclamation plan as the basis by which the regulatory authority determines the feasibility and adequacy of the proposed reclamation, (4) described a permit as a permit for surface mining and reclamation operations, and (5) indicated that liability insurance must be maintained during the term of the permit and all renewals until reclamation is complete.

OSMRE agrees that the permit describes the reclamation obligation that will be assumed by exercising the authorization granted under the permit. OSMRE does not agree that these statements all support the idea that the permit must be renewed until the completion of those reclamation activities. The commenter may have failed to grasp the concept that the reclamation obligation is assumed when the surface is disturbed and does not expire should the permit authorizing section 701(28) activities not be renewed. When SMCRA or the legislative history describe a permit or its components, they refer to both mining and reclamation because they are both described in the permit. However, when SMCRA specifies the *need* to obtain a permit, in section 506(a) and 515(a) for example, the term surface coal mining operations is used.

The reclamation plan does not expire because it is an obligation assumed by the "permittee" when the permit to mine is approved. The reclamation and other obligations remain in full force and effect until regulatory jurisdiction over the site of a completed surface coal mining and reclamation operations is terminated according to 30 CFR 700.11(d). See 53 FR 44356–63, November 2, 1988.

One commenter suggested that alternative approaches, such as streamlining or expediting the permitting process in a manner tailored to the specific areas of concern, could be a better method to achieve the desired benefits. One said that SMCRA provided for an expedited renewal process so that the permit would remain active through completion of the reclamation plan.

OSMRE considered, but did not adopt, the approach of modifying permitting procedures because such an approach would not be consistent with its interpretation of SMCRA. Since section 506 of SMCRA requires a permit only for the mining portion of a mining and reclamation operation, to continue to require that a permit be renewed, regardless of how streamlined the process, only to explicitly authorize the completion of an already defined and existing reclamation obligation would be unnecessary and unjustified and would not achieve an increased degree of environmental protection.

Two commenters challenged OSMRE's conclusion that it is inconsistent to argue on one hand that reclamation activities must be permitted and on the other hand that reclamation may be required in the absence of a permit. One commenter argued that there is no inconsistency between SMCRA's permitting and enforcement provisions and that although ordering reclamation to abate a violation is not contingent on an area being permitted, it does not follow that areas once permitted may be allowed to be reclaimed under a lapsed permit. One said if the rule was to resolve a perceived inconsistency it should be clarified to a much greater degree.

OSMRE has a responsibility to provide clear and coherent guidelines for the effective implementation of SMCRA. A significant amount of confusion exists concerning whether a permit is required to perform reclamation activities. OSMRE is concerned above all that successful reclamation be performed and thus is modifying its regulations to reflect the paramount importance of fulfillment of the reclamation obligation. OSMRE believes that this final rule clarifies the objectives of the Act; that is, to recognize that a permit is required to authorize surface coal mining operations as defined in section 701(28) of SMCRA, but that the absence or expiration of such authorization does not affect the obligation to reclaim in accordance with the applicable program and a non-renewed permit.

One commenter was concerned about a possible adverse effect of the proposal on the Applicant/Violator System. The commenter suggested that in the absence of a permit, "the source of information for updating the necessary ownership and control information would be cut off."

The Applicant/Violator System contains information about certain violators, those who own or control such violators and those owned or controlled by such violators to be used by regulatory authorities in the process of approving or denying permit applications. The collection of updated information on permittees is addressed in the permit rules. The absence or non-renewal of a permit does not preclude the inclusion of violation information in the system.

The commenter asserted that all the implications of the proposal have not been addressed by OSMRE, and thus all possible side effects are not clear. Another commenter was concerned that a lack of discussion of the proposal's relationship to existing relevant provisions of the Act and the regulations creates confusion. This final rule preamble sets forth the policy being adopted, explains its statutory basis, and sets forth the responsibilities and

obligations incumbent on operators to comply with the Act's provisions. All reclamation and permit obligations continue as before under the permanent program regulations. All enforcement policies continue as before. The only change is that a careful reading of section 506 reveals that a permit need not be renewed when all surface coal mining operations have been completed and solely reclamation obligations remain.

Section 701.11 Applicability

Section 701.11 describes the applicability of the permanent regulatory program. Final paragraphs (a), (b), and (c) are identical to the proposal and require that persons conducting surface coal mining operations on or after 8 months from approval of a State program or implementation of a Federal program, shall have a permit issued pursuant to the applicable program. The final rule substitutes "surface coal mining operations" where "surface coal mining and reclamation operations" appeared previously. Final paragraph (d) has been changed to clarify the proposal. It applies the requirements of Subchapter K to "each surface coal mining and reclamation operation for which the surface coal mining operation is required to obtain a permit under the Act," rather than to "each surface coal mining and reclamation operation which is required to obtain a permit under the Act."

Section 740.13 Permits

Section 740.13(a) contains the general requirements for permits on Federal lands. Final paragraph (a)(1) is identical to the proposal and provides that no person shall conduct surface coal mining operations on lands subject to Part 740 unless that person has first obtained a permit issued pursuant to the regulatory program and Part 740. Final paragraph (a)(3) is identical to the proposal and provides that surface coal mining operations authorized under the initial regulatory program or 43 CFR Parts 3480–3487 may be conducted beyond the eight-month period prescribed in the applicable regulatory program under certain conditions. The previous language included the words "and reclamation".

Section 750.11 Permits

Section 750.11 contains permit requirements under the Federal program for Indian lands. Final paragraph (a) is identical to the proposal and provides that no person shall conduct surface coal mining operations on Indian lands after eight months following the effective date of Subchapter E (Indian Lands Program) unless that person has first obtained a permit pursuant to Part 750. Final paragraph (c) is identical to the proposal and provides that surface coal mining operations authorized prior to the effective date of Subchapter E may be conducted beyond the specified eight month period under certain conditions. The previous language included the words "and reclamation."

Section 773.11 Requirements to Obtain Permits

Final § 773.11(a) in the first sentence states that "* * * no person shall engage in or carry out any surface coal mining operations, unless such person has first obtained a permit * * *." Previously § 773.11(a) stated that "* * * no person shall engage in or carry out any surface coal mining and reclamation operations, unless such person has first obtained a permit * * *." This sentence is adopted as proposed.

The second sentence of proposed § 773.11(a) stated that, "Obligations established under a permit continue until satisfied, regardless of whether the permit has expired or has been terminated, revoked or rescinded." In the final rule this is the third sentence of the paragraph and it states that obligations established under a permit continue until completion of surface coal mining and reclamation operations pursuant to 30 CFR 700.11(d), regardless of whether the authorization to conduct surface coal mining operations has expired or has been terminated, revoked, or suspended.

In response to a commenter who indicated that section 521(a)(4) of the Act authorizes suspension or revocation of a permit, but not rescission, OSMRE deleted the word "rescinded" and substituted "suspended" in its place in the final rule. The same commenter suggested a change to the proposal to read, "Obligations established under a permit continue until bond release * * *." The commenter argued that bond release reflects the regulatory authority's decision that the permittee has satisfied the requirements under the Act. In response to the comment, OSMRE inserted the phrase "completion of surface coal mining and reclamation operations" in place of the word "satisfied" in the proposal. The final rule adopted today establishes a consistent policy with regard to the permit requirements for reclamation activities, and does not address the issue of when a permittee's liability for a reclaimed site terminates. And finally, the last part of the sentence was revised to clarify that it is the authorization to conduct surface coal mining operations that may expire.

The third sentence of proposed § 773.11(a) stated that any person conducting reclamation activities pursuant to the requirements of a permit, even if the permit is no longer extant, must comply with all applicable provisions as a permittee. This sentence is not adopted. OSMRE has recognized in this final rule that the reclamation obligations of the permit do not expire, even though the permit is not renewed, therefore, it is not necessary to reiterate that the person conducting reclamation must comply with all applicable provisions as a permittee. One new sentence has been added to make more explicit that a permittee need not renew the permit if no surface coal mining operations will be conducted under the permit and solely reclamation activities remain to be done.

Section 774.10 Information Collection

Final § 774.10 states that the collections of information contained in §§ 774.11, 774.13, 774.15 and 774.17 have been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.* and assigned clearance number 1029–0088. The information will be used to determine if the applicant meets the requirement for revision, renewal, transfer, sale, or assignment of permit rights. Response is mandatory in accordance with sections 102, 511, 506, and 507 of the Act. This section is modified by the final rule adopted today to reflect the anticipated reduction in information collection burden imposed by Part 774 due to elimination of the requirement to renew a permit where only reclamation activities remain to be completed. This final provision was not included in the proposal, but was added to the final rule at the suggestion of the Office of Management and Budget.

Section 800.60 Terms and Conditions for Liability Insurance

Final § 800.60(b) provides that a liability insurance policy shall be maintained in full force during the life of the permit or any renewal thereof and the liability period necessary to complete all required reclamation operations. The previous language stated that the policy was to be maintained during the life of the permit or any renewal, *including* the liability period for completing reclamation (emphasis added.) The word "including" is replaced by "and" in this final rule; no other change is made. OSMRE made this change, which was not included in the proposal, in response to a comment, to clarify and make explicit that the

insurance policy must be maintained through the period necessary to complete reclamation even if the permit is not renewed. The final rule adopted today, recognizes that reclamation must be completed irrespective of whether or not the permit is renewed. OSMRE does not intend any substantive change to the liability insurance provisions.

Section 843.11 Cessation Orders

Final § 843.11(a)(2) is identical to the proposal and states that "surface coal mining operations conducted by any person without a valid surface coal mining permit constitute a * * * significant imminent environmental harm * * *." Previously, § 843.11(a)(2) stated that "surface coal mining and reclamation operations conducted by any person without a valid surface coal mining permit constitute a * * * significant imminent environmental harm * * *."

No new substantive requirements are contained in this rulemaking action. Rather, the final rule clarifies and makes consistent OSMRE's interpretation of SMCRA requirements concerning a permit to conduct reclamation operations where no coal extraction is taking place, and removes the requirement to renew a permit solely to conduct reclamation activities.

Effect of Final Rule

In keeping with OSMRE's determination that the obligation to reclaim continues in the absence of a permit, the final rule makes it unnecessary for a person to renew a permit where only reclamation activity is required. A permit is required for surface coal mining operations, i.e., the extraction of coal, an activity of benefit to the permittee, but the reclamation obligations associated with that mining are assumed by the permittee irrespective of whether a permit was issued or the permit is renewed or expired. Thus, the permit, including any conditions, defines the nature of the reclamation obligation that will be assumed by the permittee should he conduct any mining activities under the permit. Those obligations are unaffected by suspension, revocation or expiration of the authorization for further coal extraction or other section 701(28) activities under the permit. The person conducting reclamation activities alone, i.e., in the absence of coal extraction or other section 701(28) activities, is a "permittee," even though he no longer has the authority to conduct the 701(28) activities under a permit.

One commenter was concerned that the proposal would allow excess spoil to be dumped on an unpermitted site under the pretext of reclaiming the site. The commenter interpreted the statement in the proposal that, "it would not be necessary for an operator to obtain a permit where only reclamation activity is required," as legalizing unregulated dumping in the name of reclamation.

This final rule does not affect the requirements contained in 30 CFR 780.35 to provide permit information and receive approval for proposed excess spoil disposal sites and designs of spoil disposal structures. Neither does this rulemaking affect the recently proposed changes to 30 CFR 816.74 governing the disposal of excess spoil on pre-existing benches (53 FR 43970, October 31, 1988). These sites used to dispose of excess spoil must be permitted.

The final rule also provides an economic benefit insofar as permittees and regulatory authorities will realize reductions in time and cost expenditures on permit renewals no longer necessary. Because this final rule will affect the number of permit renewal applications required to be submitted by permittees in accordance with section 506(d) of the Act and 30 CFR Part 774, the information collection burden imposed by Part 774 will be reduced. To document the reduction, OSMRE has included in this final rule a modification to § 774.10, which describes the information collection requirements of Part 774.

Permit Renewal—In cases where coal extraction, processing and handling have been completed under a valid permit, the final rule provides that the permit need not be renewed simply for the completion of reclamation since there are no longer any SMCRA section 701(28) activities the permittee wishes to perform and the only remaining activities are those associated with reclamation obligations assumed with the prior mining activities. The permittee assumed the obligation to complete reclamation when mining occurred. The ongoing obligation to reclaim in accordance with the permit and any permit conditions exists whether or not the permit is renewed. Regardless of whether a permit is in existence or has been renewed, section 509(b) of SMCRA provides that liability under the performance bond posted to guarantee faithful performance of all requirements of SMCRA and the permit, shall extend for the duration of the surface coal mining and reclamation operation and for a period coincident with the operator's responsibility for the revegetation requirements of section 515 of SMCRA, a period that is independent of permit renewals. In addition, section 506(d) of the Act does not mandate permit renewal. It provides that permit holders *may* apply for renewal.

Reclamation must be achieved according to the approved reclamation plan, and that obligation is unaffected by the renewal or non-renewal under section 506, of the permit. The reclamation obligations under the applicable State or Federal program, the permit, and the performance bond remain in effect and are enforceable regardless of whether the 5-year permit term has lapsed. In cases where mining or other section 701(28) activities have been completed under a valid permit and reclamation work remains to be completed or the period of extended liability has not expired, permit renewal is not a prerequisite for completion of the reclamation phase of the operation according to the approved permit. The permittee whose authorization to conduct surface coal mining operations has expired but who still has reclamation obligations to complete according to the permit must conduct those reclamation activities as the "permittee." Any revisions to the reclamation plan following expiration of the permit must comply with the requirements of 30 CFR 774.11 and 774.13 or the State or Federal program counterparts thereof.

One commenter said that OSMRE's stated assurances in the proposed rule preamble that reclamation and performance bond liability would extend until successful completion of reclamation, and that any obligation for reclamation is unaffected by expiration of the permit, "* * * appear to be limited to situations where the operator received a permit and the reclamation work is confined to the area permitted to the particular operator performing the work." The commenter said the rule language changes however, "are not limited to these situations, nor does the preamble indicate that they are so limited * * *" OSMRE does not agree that the rule language changes are in any way limited with respect to reclamation and bonding requirements. A permittee is required to complete reclamation without the need to renew the permit when a permit term lapses. The permittee is not released from his responsibilities until reclamation has been successfully completed.

One commenter suggested that OSMRE clarify the proposal in three aspects: First, permits need not be renewed when only reclamation activities remain to be completed or the extended period of liability has not ended. Second, renewal of a permit within its term, even if reclamation is the only remaining activity, remains an option for the permittee. And, third,

revision of the reclamation plan is not authorized following permit expiration.

OSMRE agrees with the first two statements, but disagrees with the third. The first statement expresses a concept that is basic to this rulemaking. Since section 506(a) of SMCRA requires a permit only for "surface coal mining operations," there is no need to renew a permit after mining has ceased simply to cover the completion of reclamation. The second statement correctly interprets section 506(d) of SMCRA, which requires submittal of an application for permit renewal prior to the expiration of the permit term. Permittees should be aware that not renewing a permit after mining has ceased, but before reclamation has been completed is an option, not a requirement. The third statement is an unnecessarily strict interpretation of section 511(a)(1) of the Act. As discussed earlier in this preamble in response to another comment, section 511(a)(1) allows submittal of a permit revision application during the term of the permit, but does not preclude such submittal at another time, e.g., after the term of the permit for section 701(28) activities. Since the reclamation obligation specified in the permit does not expire until reclamation is completed, revisions to that reclamation plan may be appropriate even if the authorization to extract coal was not renewed.

One commenter suggested an alternate way of addressing the issue of permit renewals. This commenter advocated making a distinction between "permit term" and "permit" to the effect that the "permit term" would expire, but the "permit" carrying the reclamation and other ongoing obligations would continue to be in effect until bond release.

OSMRE considered, and partially agrees with the concept of this suggestion. The commenter's suggested distinction between the permit term and the permit is, in effect, the same distinction (although with a different characterization) between the section 506 permit and renewal requirements, for section 701(28) activities and areas, and the non-renewed permit, for reclamation only activities. The distinction exists in the statutory language of sections 506 and 701, regardless of how the distinctions are characterized.

Surface Disturbance Off the Permit Area—Surface disturbances off the permit can occur either (1) from mining activities conducted within the permit or (2) from extension of mining operations beyond the permitted boundaries. In the first case, off-permit disturbances such as those caused by flyrock, landslides, subsidence, or sedimentation typically result from a violation of a performance standard and are usually confined to small areas. Under this final rule, it is not necessary to require a permit since only reclamation activities will be conducted to correct these disturbances, because the permittee is required to return the land to its previous condition through abatement measures described and ordered in an enforcement action issued by the regulatory authority.

In the second case, the permittee will be ordered to cease surface coal mining operations on the unauthorized areas and to take necessary measures to prevent any short term environmental damage. The regulatory authority may require either immediate full reclamation of the area or submission and diligent pursual of approval of a new permit or permit revision if the permittee desires to continue surface coal mining operations and the regulatory authority agrees that immediate full reclamation would interfere with the resumption of mining upon issuance of the permit.

This final rule does not affect the requirements contained in 30 CFR 780.35 to provide permit information and receive approval for proposed excess spoil disposal sites and designs of spoil disposal structures. Neither does this rulemaking affect the recently proposed changes to 30 CFR 816.74 governing the disposal of excess spoil or preexisting benches (53 FR 43970, October 31, 1988). Those sites used to dispose of excess spoil must be permitted.

One commenter said that when an off-permit disturbance occurs, the regulatory authority's only appropriate response is "immediate issuance of appropriate enforcement action" requiring immediate action necessary to abate the adverse environmental effects of the disturbance. The commenter agreed that abatement measures need not be permitted depending on the circumstances involved. However, the commenter argued that when mining "or other more substantial land damage" occurs the requirement to permit the disturbed area should be one of the remedial measures. In the commenter's opinion, permitting should not be optional in these cases. The commenter believed that the structure of SMCRA's environmental standards presupposes disturbances will be permitted and bonded to "assure that the area is reclaimed, revegetated and restored to the standards of the Act."

OSMRE agrees that when an off-permit disturbance occurs, the regulatory authority should initiate enforcement action requiring immediate abatement of the disturbance. However, OSMRE does not agree that permitting the disturbance is a panacea or the only way to handle such a situation. In many cases, by requiring abatement to specified standards, such as those found in Subchapter K of this chapter or in the State program counterparts thereto with such details as necessary specified in the required abatement measures, rather than requiring the area be permitted, the ability to require and achieve reclamation is expedited. The reclamation burden on the permittee is not lessened by requiring reclamation without requiring the area to be permitted under section 506. Also, there may be circumstances under which the disturbed area cannot be permitted, such as areas protected under section 522(e) of SMCRA or where the operator is unable to obtain bond. This does not release the obligation to reclaim disturbances which have already occurred.

Further, the ability of the regulatory authority to require an approved reclamation plan through the permitting process for the disturbed area is not precluded by the adoption of this final rule. The regulatory authority may require an approved reclamation plan and additional bond if the facts and circumstances of a particular off-permit disturbance warrant one. Since 1979, OSMRE has publicly recognized that permitting of off-permit disturbances is not always warranted. In the preamble to its initial bonding regulations, OSMRE stated, "It is the intent of [OSMRE] that the initial bond amount, the amount retained after partial releases * * * and amounts forfeited * * * be adequate to not only allow the regulatory authority to complete the backfilling, grading, topsoiling and revegetation program contained in the approved reclamation plan, but also to restore any property damaged outside the permit area * * *. In addition, the amount must be adequate to abate any pollution or hazards to life or property which exist within or outside the permit area * * *." (44 FR 15111, March 13, 1979) It is clear that the 1979 rules anticipated abatement of *off-permit* pollution and property damage (emphasis added). The final rule adopted today codifies this policy in a consistent manner.

The commenter also argued that the proposal would create a "free-bite mentality" and a strong incentive for "straying" off the permit area "since such areas could be mined without bonding and extended reclamation obligations."

OSMRE does not agree. The operation is still subject to the same enforcement actions and interruption of operations. The regulatory authority is also free to require additional bond to be posted for the additional cost of compliance with pertinent performance standards. The policy simply recognizes that permitting is not always necessary or appropriate.

The commenter also raised four specific concerns related to off-permit disturbances required to be reclaimed, but not permitted: First, when a permit is transferred, would the transferee assume liability for a nonpermitted, off-permit disturbance? Second, would the requirement to minimize additional contributions of suspended solids apply to such areas? Third, if such an area is prime farmland, how will success of revegetation and soil handling be mandated and monitored? And, fourth, would any violations occurring in such areas be counted for a pattern of violations finding under section 521(a)(4) of the Act?

Concerning permit transfers, all obligations associated with a permitted surface coal mining operation including required reclamation of any off-permit impacts, accrue to the transferee. Indeed, 30 CFR 774.17 (d) and (f) and State program counterparts to them allow the regulatory authority not to transfer a permit under the circumstances described in the first concern. In regard to the second and third concerns, which relate to performance standards, again the reclamation standards contained in Subchapter K of this chapter or the State program counterparts thereof apply to all surface coal mining and reclamation operations irrespective of whether or not they occur within a permit area. Finally, any enforcement actions related to an off-permit disturbance must be considered when determining whether a pattern of violations exists under 30 CFR 843.13.

Unauthorized (Illegal) Mining—When mining is conducted without the required permit (wildcat mining), the wildcatter nevertheless incurs the obligation to reclaim. However, there are difficulties with requiring wildcatters to obtain a permit for reclamation only. They are often reluctant to cooperate, unable to obtain the financing necessary to conduct the required studies, or unable to obtain a performance bond or liability insurance. Also, environmental harm may result during the time (six to nine months) required to prepare and process a permit application.

Therefore, in lieu of always requiring a permit in cases of mining without a permit, it has been OSMRE's policy to order the immediate cessation of mining and direct the person to backfill, grade and revegetate in accordance with applicable regulations. This final rule continues that policy by requiring immediate reclamation pursuant to the applicable standards of Subchapter K, 30 CFR Chapter VII, or the State or Federal program counterpart, in the absence of an approved reclamation plan, in accordance with any enforcement action citing performance standard violations. The cessation order or a notice of violation written for each performance standard violation would specify the standards and remedial measures necessary to assure proper reclamation. These could include a requirement to prepare a reclamation plan or do monitoring or analysis, if appropriate, and posting a bond.

One commenter said that a requirement to permit all wildcat operations for reclamation may not be feasible, and that such permitting should be on a case-by-case basis, depending on the nature of the disturbance. Another commenter said that while immediate reclamation of the wildcat operation is actively pursued, the area should also be brought under permit.

This final rule does not restrict regulatory authorities from requiring that wildcat operators obtain an approved reclamation plan through the permitting process including posting a bond and obtaining liability insurance. However, reclamation as contemporaneously as practicable of any illegally mined areas must be required upon discovery of such areas. OSMRE does not anticipate that requiring an approved reclamation plan through the permitting process will be necessary to ensure compliance with applicable reclamation standards under the applicable regulatory program prior to ordering reclamation work to proceed in many, if not most, cases.

Applicable Regulatory Programs

In accordance with the interpretation of the requirements for permits for surface coal mining operations provided in this rulemaking and the obligations associated with such permits, this final rule is primarily applicable to mining operations conducted pursuant to a Federal program for a State (30 CFR Part 736), the Federal lands program (30 CFR Part 740), and the Indian lands program (30 CFR Part 750). Under the rule adopted today, a State could amend its program not to require renewal of a permit on which coal extraction, processing, and handling have been completed but where reclamation work remains or the period of extended liability has not expired. In such circumstances, the State program would be considered no less effective than Federal requirements if the reclamation plan, permit conditions, and related permit provisions remain in effect until the operation has met all applicable performance standards and the appropriate operator liability period has expired. Any revisions to the reclamation plan following expiration of the permit term would have to comply with the requirements of the State program counterparts to 30 CFR 774.11 and 774.13. With respect to the other situations discussed in the preamble to the final rule, State performance will be evaluated in terms of the policy set forth herein unless the approved State program contains specific differing requirements.

Effect in Federal Program States and on Indian Lands

The final rule applies through cross-referencing in those States with Federal programs and on Indian lands. The States with Federal programs include California, Georgia, Idaho, Massachusetts, Michigan, North Carolina, Oregon, Rhode Island, South Dakota, Tennessee, and Washington. The Federal programs for these States appear at 30 CFR Parts 905, 910, 912, 921, 922, 933, 937, 939, 941, 942, and 947, respectively. The rule will also apply through cross-referencing in 30 CFR Part 750 to surface mining and reclamation operations on Indian lands.

Effect of the Rule on State Programs

Following promulgation of this rule, OSMRE will evaluate State programs to determine whether any changes in these programs will be necessary. If the Director determines that any State program provisions should be amended to be made no less effective than the revised Federal rules, the individual States will be notified in accordance with the provisions of 30 CFR 732.17.

III. Procedural Matters

Federal Paperwork Reduction Act

The collection of information contained in this rule has been submitted to the Office of Management and Budget (OMB) for approval as required by 44 U.S.C. 3501 *et seq.* The collection of this information will not be required until it has been approved by OMB. Public reporting burden for this collection of information is estimated to average 11 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send

comments regarding this burden estimate or other aspect of this collection of information, including suggestions for reducing the burden, to Information Collection Clearance Officer, OSMRE, Washington, DC 20240; and to OMB, Paperwork Reduction Project (1029–0088), Washington, DC 20503.

Executive Order 12291 and Regulatory Flexibility Act

The DOI has determined that this document is not a major rule under the criteria of Executive Order 12291 (February 17, 1981) and certifies that it will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* The final rule does not distinguish between small and large entities. The economic effects of the proposed rule are estimated to be minor and no incremental economic effects are anticipated as a result of this rule.

National Environmental Policy Act

The DOI has also determined that the final rule does not constitute a major Federal action significantly affecting the quality of the human environment within the meaning of section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C).

Authors

The authors of this rule are Dr. Fred Block and Patrick W. Boyd, Branch of Federal and Indian Programs, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Avenue, NW., Washington, DC 20240; Telephone: (202) 343–1864.

List of Subjects

30 CFR Part 701

Law enforcement, Surface mining, Underground mining.

30 CFR Part 740

Public lands-mineral resources, Reporting and recordkeeping requirements, Surety bonds, Surface mining, Underground mining.

30 CFR Part 750

Indians-lands, Reporting and recordkeeping requirements, Surface mining.

30 CFR Part 773

Reporting and recordkeeping requirements, Surface mining, Underground mining.

30 CFR Part 774

Reporting and recordkeeping requirements, Surface mining, Underground mining.

30 CFR Part 800

Insurance, Reporting and recordkeeping requirements, Surety bonds, Surface mining, Underground mining.

30 CFR Part 843

Administrative practice and procedure, Law enforcement, Reporting and recordkeeping requirements, Surface mining, Underground mining.

Accordingly, Title 30, Chapter VII, Parts 701, 740, 750, 773, 774, 800 and 843 are amended as set forth below.

Dated: January 19, 1989.

James E. Cason,

Deputy Assistant Secretary—Land and Minerals Management.

PART 701—PERMANENT REGULATORY PROGRAM

1. The authority citation for Part 701 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended, and Pub. L. 100–34.

2. Section 701.11 is amended by revising the first sentence of paragraphs (a) and (b), paragraph (c) introductory text and paragraph (d) to read as follows:

§ 701.11 Applicability.

(a) Any person who conducts surface coal mining operations on non-Indian or non-Federal lands on or after 8 months from the date of approval of a State program or implementation of a Federal program shall have a permit issued pursuant to the applicable State or Federal program. * * *

(b) Any person who conducts surface coal mining operations on Federal lands on or after 8 months from the date of approval of a State program or implementation of a Federal program for the State in which the Federal lands are located shall have a permit issued pursuant to Part 740 of this chapter. * * *

(c) Any person who conducts surface coal mining operations on Indian lands on or after eight months from the effective date of the Federal program for Indian lands shall have a permit issued pursuant to Part 750 of this chapter. However, a person who is authorized to conduct surface coal mining operations may continue to conduct those operations beyond eight months from the effective date of the Federal program for Indian lands if the following conditions are met: * * *

(d) The requirements of Subchapter K of this chapter shall be effective and shall apply to each surface coal mining and reclamation operation for which the surface coal mining operation is required to obtain a permit under the Act, on the earliest date upon which the Act and this chapter require a permit to be obtained, except as provided in paragraph (e) of this section.

* * * * *

PART 740—GENERAL REQUIREMENTS FOR SURFACE COAL MINING AND RECLAMATION OPERATIONS ON FEDERAL LANDS

3. The authority citation for Part 740 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended; 30 U.S.C. 181 *et seq.*; and Pub. L. 100–34.

4. Section 740.13 is amended by revising paragraph (a)(1) and paragraph (a)(3) introductory text to read as follows:

§ 740.13 Permits.

(a) *General requirements.* (1) No person shall conduct surface coal mining operations on lands subject to this Part unless that person has first obtained a permit issued pursuant to the regulatory program and this Part.

* * * * *

(3) Surface coal mining operations authorized under the initial regulatory program or 43 CFR Parts 3480–3487, as applicable, may be conducted beyond the eight-month period prescribed in the applicable regulatory program if all of the following conditions are present:

* * * * *

PART 750—REQUIREMENTS FOR SURFACE COAL MINING AND RECLAMATION OPERATIONS ON INDIAN LANDS

5. The authority citation for Part 750 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended; 5 U.S.C. 301; and Pub. L. 100–34.

6. Section 750.11 is amended by revising paragraph (a) and paragraph (c) introductory text to read as follows:

§ 750.11 Permits.

(a) No person shall conduct surface coal mining operations on Indian lands after eight months following the effective date of this Subchapter unless that person has first obtained a permit pursuant to this Part.

* * * * *

(c) Surface coal mining operations authorized prior to the effective date of this subchapter may be conducted

beyond the eight-month period specified in paragraph (a) of this section if the following conditions are present:

* * * * *

PART 773—REQUIREMENTS FOR PERMITS AND PERMIT PROCESSING

7. The authority citation for Part 773 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended; 16 U.S.C. 470 *et seq.;* 16 U.S.C. 1531 *et seq.;* 16 U.S.C. 661 *et seq.;* 16 U.S.C. 703 *et seq.;* 16 U.S.C. 668a; 16 U.S.C. 469 *et seq.;* 16 U.S.C. 470aa *et seq.;* and Pub. L. 100–34.

8. Section 773.11 is amended by revising paragraph (a) to read as follows:

§ 773.11 Requirements to obtain permits.

(a) *All operations.* On and after 8 months from the effective date of a permanent regulatory program within a State, no person shall engage in or carry out any surface coal mining operations, unless such person has first obtained a permit issued by the regulatory authority except as provided for in paragraph (b) of this section. A permittee need not renew the permit if no surface coal mining operations will be conducted under the permit and solely reclamation activities remain to be done. Obligations established under a permit continue until completion of surface coal mining and reclamation operations, regardless of whether the authorization to conduct surface coal mining operations has expired or has been terminated, revoked, or suspended.

* * * * *

PART 774—REVISION; RENEWAL; AND TRANSFER, ASSIGNMENT, OR SALE OF PERMIT RIGHTS

9. The authority citation for Part 774 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended; and Pub. L. 100–34.

10. Section 774.10 is revised to read as follows:

§ 774.10 Information collection.

The collections of information contained in §§ 774.11, 774.13, 774.15 and 774.17 have been approved by the Office of Management and Budget under 44 U.S.C. 3501 *et seq.* and assigned clearance number 1029–0088. The information will be used to determine if the applicant meets the requirement for revision, renewal, transfer, sale, or assignment of permit rights. Response is mandatory in accordance with sections 102, 511, 506, and 507 of the Act.

PART 800—BOND AND INSURANCE REQUIREMENTS FOR SURFACE COAL MINING AND RECLAMATION OPERATIONS UNDER REGULATORY PROGRAMS

11. The authority citation for Part 800 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended; and Pub. L. 100–34.

12. Section 800.60 is amended by revising paragraph (b) to read as follows:

§ 800.60 Terms and conditions for liability insurance.

* * * * *

(b) The policy shall be maintained in full force during the life of the permit or any renewal thereof and the liability period necessary to complete all reclamation operations under this Chapter.

* * * * *

PART 843—FEDERAL ENFORCEMENT

13. The authority citation for Part 843 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*, as amended; and Pub. L. 100–34.

14. Section 843.11 is amended by revising paragraph (a)(2) introductory text to read as follows:

§ 843.11 Cessation orders.

(a) * * *

(2) Surface coal mining operations conducted by any person without a valid surface coal mining permit constitute a condition or practice which causes or can reasonably be expected to cause significant imminent environmental harm to land, air, or water resources unless such operations:

* * * * *

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Wednesday
April 5, 1989

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 878

General and Plastic Surgery Devices; Exemptions From Premarket Notification; Final Rule

21 CFR Parts 878 and 892

Dental and Radiology Devices; Exemptions From Premarket Notification; Final Rule and Withdrawal of Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 86N-0011]

General and Plastic Surgery Devices; Exemptions From Premarket Notification

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is exempting from the requirement of premarket notification, with limitations, eight generic types of class I general and plastic surgery devices. For the exempted devices, FDA has determined that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that review of such notifications by the agency will not advance FDA's public health mission. Granting the exemptions will allow the agency to make better use of its resources and thus better serve the public.

EFFECTIVE DATE: May 5, 1989.

FOR FURTHER INFORMATION CONTACT: Thomas J. Callahan, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION: The Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of safety and effectiveness: class I (general controls), class II (performance standards), and class III (premarket approval).

Section 513(d)(2)(A) of the act (21 U.S.C. 360c(d)(2)(A)) authorizes FDA to exempt, by regulation, a generic type of class I device from the requirement of, among other things, premarket notification in section 510(k) of the act (21 U.S.C. 360(k)) and Subpart E of 21 CFR Part 807. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting to FDA a premarket notification. When FDA was publishing its proposed classification regulations for preamendments devices, the agency did not routinely evaluate whether it should grant to manufacturers of devices placed in class I an exemption from the requirement of premarket notification. Generally, FDA considered such exemptions only when the advisory panels specifically included them in recommendations made to the agency. Recently, FDA developed criteria for exempting certain class I devices from the requirement of premarket notification to reduce the number of unnecessary permarket notifications, thereby freeing agency resources for the review of more important notifications.

FDA believes that exempting certain devices from premarket notification will allow the agency to make better use of its resources and thus better serve the public. In other words, the process of exempting devices from the premarket notification program of section 510(k) of the act (21 U.S.C. 360(k)), where premarket notification will not advance FDA's public health mission, will free additional resources to address pressing regulatory concerns and will make the agency more efficient. The development of exemption criteria and the issuance of proposed and final rules exempting appropriate devices from the requirement of premarket notification will help implement a goal in FDA's May 1987 "A Plan for Action Phase II" (Ref. 1).

On June 24, 1988 (53 FR 23856), FDA published a final regulation classifying general and plastic surgery devices. Also on June 24, 1988 (53 FR 23880), FDA proposed to exempt from the requirement of premarket notification, with limitations, eight of those class I general and plastic surgery devices. Interested persons were given until August 23, 1988, to comment. One comment was received, and the comment supported FDA's proposal. Accordingly, FDA is adopting the regulation as proposed. The final classification regulation exempted one of the eight devices, the noninflatable extremity splint (§ 878.7910), from certain current good manufacturing practice regulations (53 FR 23856). The amendment to § 878.7910(b) reflects that exemption.

Criteria for 510(k) Exemptions

FDA is exempting a generic type of class I device from the requirement of premarket notification, with the limitations described below, if the agency determines that premarket notification is unnecessary for the protection of the public health. FDA is granting an exemption if both of the following criteria are met:

1. FDA has determined that the device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials. When making these determinations, FDA may consider the frequency, persistence, cause, or seriousness of such claims or risks, or other factors.

2. FDA has determined that: (a) Characteristics of the device necessary for its safe and effective performance are well established; (b) anticipated changes in the device that are of the type that could affect safety and effectiveness will (i) be readily detectable by users by visual examination or other means, such as routine testing, e.g., testing of a clinical laboratory reagent with positive and negative controls, before causing harm; or (ii) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (c) ensure that any changes in the device will not be likely to result in a change in the device's classification.

FDA will make the determinations above based on its knowledge of the device, including past experience and relevant reports or studies on device performance. FDA may, if it has concerns only about certain types of changes in a class I device, grant a limited exemption from premarket notification for the generic type of device. A limited exemption will specify what types of changes manufacturers must continue to report to FDA in the context of premarket notification. For example, FDA may exempt a device except when a manufacturer intends to use a different material.

FDA's decision to grant an exemption from the requirement of premarket notification for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic of a device that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(1) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use

of a preamendments device to which it had been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care prefessionals only; or

(2) The modified device operates using a different fundamental scientific technology than that in use for the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

Reference

The following information has been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Food and Drug Administration—A Plan for Action Phase II," Public Health Service, Department of Health and Human Services, May 1987, p. 19.

Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) 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.

Economic Impact

FDA has carefully analysed the economic effects of this final rule and has determined that the final rule would not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive Order 12291, the impact of this final rule has been carefully analyzed, and it has been determined that the final rule does not constitute a major rule as defined in section 1(b) of the Executive Order.

The devices subject to this final rule are now subject only to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j), with certain exemptions.

List of Subjects in 21 CFR Part 878

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 878 is amended as follows:

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

1. The authority citation for 21 CFR Part 878 continues to read as follows:

Authority: Secs. 501(f), 510, 513, 515, 520, 701(a), 52 Stat. 1055, 76 Stat. 794–795 as amended, 90 Stat. 540–546, 552–559, 565–574, 576–577 (21 U.S.C. 351(f), 360, 360c, 360e, 360j, 371(a)); 21 CFR 5.10.

2. New § 878.9 is added to Subpart A to read as follows:

§ 878.9 Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

The Food and Drug Administration's (FDA's) decision to grant an exemption from the requirement of premarket notification (section 510(k) of the act) for a generic type of class I device is based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change in intended use or characteristic that could significantly affect a device's safety or effectiveness, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification must still submit a premarket notification to FDA before introducing or delivering for introduction into interstate commerce for commercial distribution the device when:

(a) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device to which it has been determined to be substantially equivalent; e.g., the device is intended for a different medical purpose, or the device is intended for lay use where the former intended use was by health care professionals only; or

(b) The modified device operates using a different fundamental scientific technology than that in use in the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in virto diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than calture or immunoassay technology.

3. Section 878.1800 is amended by revising paragraph (b) to read as follows:

§ 878.1800 Speculum and accessories.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

4. Section 878.3250 is amended by revising paragraph (b) to read as follows:

§ 878.3250 External facial fracture fixation appliance.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

5. Section 878.3910 is amended by revising paragraph (b) to read as follows:

§ 878.3910 Noninflatable extremity splint.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in Part 820 of this chapter, with the exception of § 820.180, with respect to the general requirements concerning records, and § 820.198, with respect to complaint files.

6. Section 878.3925 is amended by revising paragraph (b) to read as follows:

§ 878.3925 Plastic surgery kit and accessories.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

7. Section 878.4160 is amended by revising paragraph (b) to read as follows:

§ 878.4160 Surgical camera and accessories.

* * * * *

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

8. Section 878.4800 is amended by revising paragraph (b) to read as follows:

§ 878.4800 Manual surgical instrument for general use.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

9. Section 878.4950 is amended by revising paragraph (b) to read as follows:

§ 878.4950 Manual operating table and accessories and manual operating chair and accessories.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

10. Section 878.5900 is amended by revising paragraph (b) to read as follows:

§ 878.5900 Nonpneumatic tourniquet.

* * * * *

(b) *Classification.* Class I. If the device is made of the same materials that were used in the device before May 28, 1976, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

Dated: February 22, 1989.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 89-8052 Filed 4-4-89; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 872 and 892

[Docket Nos. 86N-0007 and 86N-0014]

Dental and Radiology Devices; Exemptions From Premarket Notification

AGENCY: Food and Drug Adminsitration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is exempting from the requirement of premarket notification, with limitations, 22 generic types of class I dental devices and 4 generic types of class I radiology devices. For the exempted devices, FDA has determined that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that review of such notifications by the agency will not advance FDA's public health mission. Granting the exemptions will allow the agency to make better use of its resources and thus better serve the public. Elsewhere in this issue of the Federal Register, FDA is withdrawing its proposed rules to exempt one dental device and one radiology device.

EFFECTIVE DATE: May 5, 1989.

FOR FURTHER INFORMATION CONTACT

For dental devices: Gregory Singleton, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 8757 Georgia Avenue, Silver Spring, MD 20910, 301-427-7555

For radiology devices: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4874

SUPPLEMENTARY INFORMATION: The Medical Device Amendments of 1976 (the amendments) (Pub. L. 94-295) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance and safety and effectiveness: class I (general controls), class II (performance standards), and class III (premarket approval).

Section 513(d)(2)(A) of the act (21 U.S.C. 360c(d)(2)(A)) authorizes FDA to exempt, by regulation, a generic type of class I device from the requirement of, among other things, premarket notification in section 510(k) of the act (21 U.S.C. 360(k)) and Subpart E of 21 CFR Part 807. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting to FDA a premarket notification. When FDA was publishing its proposed classification regulations for preamendments devices, the agency did not routinely evaluate whether it should grant to manufacturers of devices placed in class I an exemption from the requirement of premarket notification. Generally, FDA considered such exemptions only when the advisory panels specifically included them in recommendations made to the agency. Recently, FDA developed criteria for exempting certain class I devices from the requirement of premarket notification, to reduce the number of unnecessary premarket notifications, thereby freeing agency resources for the review of more important notifications.

FDA believes that exempting certain devices from premarket notification will allow the agency to make better use of its resources and thus better serve the public. In other words, the process of exempting devices from the premarket notification program of section 510(k) of the act (21 U.S.C. 360(k)), where premarket notification will not advance FDA's public health mission, will free additional resources to address pressing regulatory concerns and will make the agency more efficient. The development of exemption criteria and the issuance of proposed and final rules exempting appropriate devices from the requirement of premarket notification will help implement a goal in FDA's May 1987 "A Plan for Action Phase II" (Ref. 1).

On August 12, 1987 (52 FR 30082), FDA published a final regulation classifying 110 dental devices. Also on August 12, 1987 (52 FR 30120), FDA proposed to exempt from the requirement of premarket notification, with limitations, 23 of those devices classified into class I. Interested persons were given until October 13, 1987, to submit comments on the proposal.

On January 20, 1988 (53 FR 1554), FDA published a final regulation classifying 59 radiology devices. Also on January 20, 1988 (52 FR 1588), FDA proposed to exempt from the requirement of premarket notification, with limitations, six of those devices. Interested persons were given until March 21, 1988, to submit comments on the proposal.

One comment was received on the dental proposal and one comment was received on the radiology proposal. Both comments supported the agency's policy of exempting certain class I devices from the requirement of premarket notification. Accordingly, FDA is adopting the regulations as proposed for 22 dental devices and 4 radiology devices.

Elsewhere in this issue of the Federal Register, FDA is publishing a notice withdrawing the proposed rules to exempt from the requirement of premarket notification one dental device, rubber dam and accessories (§ 872.6300), and one radiology device, wall-mounted radiographic cassette holder (§ 892.1880). After publishing the dental proposal of August 12, 1988, FDA determined that the rubber dam and accessories did not meet its criteria justifying the agency's proposal to exempt the device from premarket notification.

After publishing the radiology proposal, FDA found that it had inadvertently proposed to exempt the wall-mounted radiographic cassette holder, a class II device. Thus, FDA is