OMB under Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 3

Administrative practice and procedure, Biologics, Drugs, Medical devices.

■ Therefore, under the Federal , Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 3 is amended as follows:

PART 3—PRODUCT JURISDICTION

1. The authority citation for 21 CFR part 3 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 360gg–360ss, 371(a), 379(e), 381, 394; 42 U.S.C. 216, 262.

■ 2. Section 3.1 is amended by revising the second sentence to read as follows:

§ 3.1 Purpose.

* * * The first is to implement section 503(g) of the act, as added by section 16 of the Safe Medical Devices Act of 1990 (Public Law 101–629) and amended by section 204 of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107–250), by specifying how FDA will determine the organizational component within FDA designated to have primary jurisdiction for the premarket review and regulation of products that are comprised of any combination of a drug and a device; a device and a biological; a biological and a drug; or a drug, a device and a biological.* * *

■ 3. Section 3.2 is amended by revising paragraph (b) to read as follows:

§ 3.2 Definitions.

* * * * *

(b) *Agency component* means the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Drug Evaluation and Research, or alternative organizational component of the agency.

* * * * *

■ 4. Section 3.6 is revised to read as follows:

§ 3.6 Product jurisdiction officer.

The Office of Combination Products (HFG–3), Food and Drug Administration, 15800 Crabbs Branch Way, suite 200, Rockville, MD 20855, 301–827–9229, e-mail: *combination@fda.gov,* is the designated product jurisdiction officer.

■ 5. Section 3.7 is amended by adding a sentence to the end of paragraph (d) to read as follows:

§ 3.7 Request for designation.

* * * * *

(d) * * *Concurrent submissions of electronic copies of Requests for Designation may be addressed to *combination@fda.gov.*

■ 6. Section 3.9 is amended by revising the last sentence of paragraph (b) to read as follows:

§ 3.9 Effect of letter of designation.

* * * * *

(b) * * * A nonconsensual change in the designated agency component requires the concurrence of the Principal Associate Commissioner.

Dated: June 13, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–15698 Filed 6–20–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Part 18

RIN 1219–AA98 (Phase 10)

Alternate Locking Devices for Plug and Receptacle-Type Connectors on Mobile Battery-Powered Machines

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Final rule.

SUMMARY: MSHA is amending the existing regulation by allowing the optional use of alternative locking devices to secure battery plugs to receptacles. The final rule eliminates the need to file petitions for modification to use this alternative means of securing battery plugs to receptacles.

MSHA initially proposed using direct final rulemaking for this action because the Agency expected that there would be no significant adverse comments on the rule. However, MSHA received four comments, one of which was considered a significant adverse comment, resulting in MSHA withdrawing the direct final rule and proceeding with rulemaking based on the concurrently published proposed rule on this subject.

EFFECTIVE DATE: This regulation is effective August 22, 2003.

FOR FURTHER INFORMATION CONTACT: Marvin W. Nichols, Jr., Director, Office of Standards, Regulations, and Variances, MSHA, 1100 Wilson Boulevard, Room 2352, Arlington, Virginia 22209–3939. Mr. Nichols can be reached at *nichols-marvin@msha.gov* (Internet e-mail), 202–693–9440 (voice), or 202–693–9441 (fax). You may obtain copies of the final rule in alternative formats by calling this number. The alternative formats available are either a large print version of the final rule or the final rule in an electronic file on computer disk. The final rule also is available on the Internet at *http://www.msha.gov/REGSINFO.HTM.*

SUPPLEMENTARY INFORMATION

I. Background Information

Currently, under § 18.41 of Title 30, Code of Federal Regulations, MSHA sets forth design and construction requirements for plug and receptacle-type connectors used with permissible electric equipment approved under part 18. These technical requirements were last revised in March of 1968, which represented the latest advances in battery connector technology considered appropriate for use on mining equipment at that time.

Over the past thirty years, there have been technological improvements to the methods used for securing battery plugs to receptacles. Since the provisions of existing § 18.41(f) do not reflect the latest state-of-the-art technology, mine operators must file petitions for modification under section 101(c) of the Mine Act to take advantage of the technological advancements. Since 1980, there have been approximately 300 petitions filed and granted under section 101(c) requesting modification to 30 CFR 75.503 (Permissible electric face equipment; maintenance) and 18.41(f)(Plug and receptacle-type connectors) to allow the use of alternate locking devices. The means of securing battery connectors permitted under this final rule allow for the use of padlocks and other equally effective mechanical devices that preclude the inadvertent separation of the battery plug from the receptacle. The alternate locking devices permitted under this final rule also provide for at least the same measure of protection, as set forth in the existing regulation, and do not reduce protection to miners as required by section 101(a)(9) of the Mine Act.

In some operations, mine operators encountered difficulties with padlocks in both normal and emergency situations. The use of padlocks requires the maintenance of keys by authorized personnel. Due to the nature of mining operations, padlocks may become filled with mining debris, rendering them difficult or impossible to open with a key. Padlock keys can be misplaced, broken, or bent and may become unusable. This can go unnoticed by the operator until an emergency occurs, when the key may be unavailable or unusable. The removal of a padlock to

permit the disconnection of a battery plug in an emergency situation, such as a battery fire, requires a longer period of time and greater effort than the removal of any of the other locking devices permitted in this final rule. However, where keys are accessible and padlocks are relatively free from accumulation of dust and other materials, padlocks have proven to be effective.

In 1987, to address the problems encountered with the use of padlocks, MSHA issued a policy allowing use of an alternative to padlocks. This policy permits the use of a device that is captive and requires a special tool (*e.g.* allen wrench) to disengage and allow separation of the connector. A device is captive when a mechanical connection is made permanent by a locking device that is confined in its mounting location in a manner whereby, once installed, it cannot become inadvertently removed. The mechanical connection can only be made non-permanent by a direct and intervening action using a special tool. A special tool is one that is not normally carried by miners and is used to ensure that constant pressure, beyond that which may be achieved by hand pressure, is maintained to prevent inadvertent separation of the plug from the receptacle. Withdrawal of a battery plug from the receptacle while the machine is energized (*i.e.*, under load) can create incendive arcing and sparking that could result in a personal injury, explosion, or fire. A warning tag is also required to alert the user that the connector must not be disengaged under load.

The requirement for the warning tag, along with part 48 task training requirements, provide for appropriate hazard recognition when using alternative locking devices in lieu of a padlock. Existing § 48.7 (Training of miners assigned to a task in which they have had no previous experience; minimum courses of instruction), requires that miners be instructed in safe operating procedures applicable to new or modified machines or equipment to be installed or put into operation in the mine, which require new or different operating procedures. A padlock not only serves as a mechanical means to prevent inadvertent separation of the plug from the receptacle; it also precludes the disconnection of the battery plug from the receptacle by unauthorized persons, unfamiliar with the potential hazards associated with disconnecting the plug from the receptacle under load. The warning tag serves as a deterrent, like the padlock, for separation of the plug and receptacle under load. For the purposes of this final rule, a warning tag can be either a metal plate or a label with permanent lettering on a wear-resistant material. It must be prominently displayed on or attached to an exterior surface of the battery connector housing.

Since 1980, mine operators have also been granted permission, through the petition for modification process under section 101(c) of the Mine Act, to use a spring-loaded locking device. MSHA has determined that spring-loaded locking devices provide at least the same measure of protection as padlocks and captive locking devices. These devices maintain constant pressure on the threaded ring or equivalent mechanical fastening to prevent the plug from accidentally disengaging from the receptacle. The use of this method also requires that a warning tag be attached near the locking device to remind the user not to disengage the plug from the receptacle under load. MSHA is unaware of any adverse incidents involving alternate locking devices.

By issuing this final rule, MSHA is responding to the requirements of the Regulatory Flexibility Act and Executive Order 12866 that agencies review their regulations to determine their effectiveness and to implement any changes indicated by the review that will make the regulation more flexible and efficient for stakeholders and small businesses while maintaining needed protections for workers. The final rule will maintain the protection afforded by the existing standard.

II. Discussion of Alternative Locking Devices on Mobile Battery-Powered Machines

A. Paragraph 18.41

Section 18.41 addresses connectors used on battery and non battery-powered machines. Section 18.41(f) specifies requirements for plug and receptacle-type connectors used on permissible mobile battery-powered machines employed in underground gassy mines. This final rule modifies paragraph (f) of 30 CFR 18.41 by adding two new provisions allowing the use of devices that provide at least the same protection as that afforded by the existing standards, and does not reduce safety. The Agency recognizes that battery-powered machine designs differ from conventional machine designs employing trailing cables. The energy to battery-powered equipment is carried on-board the machine with rechargeable battery assemblies, rather than being transmitted via a trailing cable from a section power center. Because of the inherent design limitations of battery-powered machines, there is no practical way to automatically remove all electrical power from battery-powered machines. Machines powered by trailing cables have circuit-interrupting devices that can be used to de-energize them, whereas most battery-powered machines rely on a plug and receptacle for de-energization. The proper procedure for removing power from a battery-powered machine is to first open the main machine disconnect device and then to disengage the plug from the receptacle. This effectively isolates the battery power from the machine.

Another acceptable alternative to padlocked connectors, permitted under existing § 18.41(a), is the use of connectors in which the mating or separation of the male and female electrodes occurs within an explosion-proof enclosure and an electrical interlock circuit is provided to cause automatic interruption of the circuit before the male and female electrodes are separated. These types of connectors do not require a warning tag or a locking ring held captive by an external device.

Public comments have been received under the proposed rule and resulted in a change to the rule language. The change is made in §§ 18.41(f)(2) and (f)(3). An explicit statement for use on warning tags is provided in the two paragraphs. However, equivalent statements comparable to ''DO NOT DISENGAGE UNDER LOAD,'' which indicates a hazard exists when disengaging plugs from receptacles, are allowed. Judgement of an alternate statement as to the equivalency in safety will be provided by the MSHA's Approval and Certification Center during the standard approval process of equipment.

B. Section 18.41(f)(1)

30 CFR 18.41(f)(1) retains the existing provision that a plug padlocked to the receptacle is acceptable in lieu of an interlock provided the plug is held in place by a threaded ring or equivalent mechanical fastening in addition to the padlock. This paragraph also retains the provision that a connector within a padlocked enclosure is acceptable.

A padlock used on a battery plug and receptacle-type connector serves a dual purpose. It secures the threaded ring or equivalent mechanical fastening in place. A padlock is also a means to prevent the removal of the plug from the receptacle by unauthorized personnel. In this respect, only those persons having keys are considered authorized to remove the plug from the receptacle. No comments were received on § 18.41(f)(1). Therefore the final

language remains unchanged from the proposed rule.

C. Section 18.41(f)(2)

30 CFR 18.41(f)(2) is a new provision that provides for an alternate method for securing the battery plug to the receptacle. The final rule specifies that a plug which is held in place by a threaded ring or equivalent mechanical fastening will be acceptable provided that the threaded ring is secured in place with a device that is captive. It also requires a special tool to disengage the device and allows for the separation of the connector. It further requires a warning tag that states: ''DO NOT DISENGAGE UNDER LOAD,'' or an equivalent statement.

One commenter questioned the requirement for using a ''special tool'' to separate the plug from the receptacle. The commenter questioned whether a special tool is necessary and whether an allen wrench would be considered a special tool.

Under the A&CC's 1987 policy that initially permitted the use of an alternate captive locking device in lieu of a padlock, it required that a special tool be used to ensure that the alternate device was locked in place. The requirement of a special tool also prevents the removal of the plug from the receptacle by unauthorized personnel. In order for a captive locking device to provide at least the same measure of protection as the padlock, it was determined that a special tool be required to remove the plug from the receptacle. An allen wrench has been determined by MSHA to be an acceptable special tool.

A commenter expressed concern about the requirement for a clearly visible warning tag that states ''DO NOT DISENGAGE UNDER LOAD.'' The commenter alleged that it may be difficult to maintain such tags. Another commenter indicated that the language should be modified to be ''less prescriptive and more performance oriented.''

Warning tags are often used in association with safety related equipment. They are considered an acceptable means of mitigating potential hazards. It is MSHA's experience that, if good maintenance practices are followed, warning tags can be maintained with minimal difficulty.

In response to the commenter's concern about the specific warning tag language, MSHA has added language to §§ 18.41(f)(2) and 18.41(f)(3) to permit wording that is equivalent to ''DO NOT DISENGAGE UNDER LOAD.'' One example of equivalent wording that would be considered acceptable is ''DO NOT DISCONNECT UNDER LOAD.''

A commenter stated that a warning tag should not be required on each connector on a machine that could have two connectors, but that one in the ''vicinity of the battery connectors'' should be required.

MSHA does not agree with the commenter. A warning tag is only effective if it is at the location where the potential hazard exists. If the warning tag is provided on the battery connector, it would be located in the field of vision of the miner attempting to disconnect the plug from the receptacle. This would not be the case if the warning tag was provided somewhere ''in the vicinity'' of the connector.

Another commenter stated that the final rule must ''provide and maintain the same level of protection to miners as required by section 101(a)(9) of the Federal Mine Safety and Health Act of 1977.'' No specific provisions of the final rule were addressed in this comment. MSHA evaluated both alternate locking devices allowed by this final rule and determined that, as stated previously, the alternate devices do not reduce the protection afforded by the existing standard.

D. Section 18.41(f)(3)

30 CFR 18.41(f)(3) is a new provision that provides for another alternate method for securing the battery plug to the receptacle. The rule states that a plug held in place by a spring-loaded or other locking device that maintains constant pressure against a threaded ring or equivalent mechanical fastening is acceptable provided that it secures the plug and prevents accidental separation. It further requires a warning tag that states: ''DO NOT DISENGAGE UNDER LOAD,'' or an equivalent statement.

This section allows for the use of other locking devices that may become available in the future. The Agency has included this language to allow for acceptance of equally effective devices. Devices not explicitly defined in this rulemaking must be equally effective and provide at least the same measure of protection as those incorporated under this section. Innovative battery connector designs not covered by the provisions of § 18.41(f) will be evaluated for compliance under the provisions of existing § 18.20(b).

A commenter recommended a wording change to the final rule that would allow for future advancements in connector locking device technology. MSHA already had the necessary language in the proposed rule to address the commenter's concern. Section 18.41(f)(3) allows for ''other locking devices'' that are equally effective. The A&CC investigators will determine equal effectiveness during evaluations of new designs for alternate locking devices.

Neither of the alternatives in §§ 18.41(f)(2) and (f)(3) imposes additional requirements to the 1987 MSHA policy or the petitions for modification granted since 1990.

A commenter questioned the need for warning tags stating that they have battery-powered machines under several previously granted petitions for modification that did not require such warning tags. Under petitions granted prior to 1990, the conditions on the Proposed Decision and Order (PDO) emphasized training on the hazards associated with disconnecting the plug from the receptacle under load. This final rule is based on petitions granted since 1990 which all require a warning tag specifically stating ''Do Not Disengage Under Load.''

III. Petitions for Modification

On the effective date of the direct final rule, all existing petitions for modification for alternate locking devices for plug and receptacle-type connectors on mobile battery-powered machines will be superseded by this rule.

All existing mobile battery-powered machines must be in compliance with this final rule as of the effective date of the rule. All machines incorporating alternate locking devices that were accepted under petitions for modification will be considered in compliance provided that a warning tag is attached to the connector and meets the requirements of this rule. This is a change from the proposed rule (68 FR 2941) which would have allowed all equipment modified by previously granted petitions for modification to be in compliance with this rule. This change was precipitated when a commenter provided MSHA with several previously granted petitions for modification that allowed alternate locking devices but did not require warning tags. MSHA anticipates that this change will affect approximately 5% of the total granted petitions. All of these affected petitions were granted before 1990. MSHA has determined that warning tags are an essential safety requirement that must be provided when alternate locking devices for plug and receptacle-type connectors on mobile battery-powered machines are used.

IV. Executive Order 12866 (Regulatory Planning and Review and Regulatory Flexibility Act)

Introduction

MSHA is amending 30 CFR 18.41(f), concerning plug and receptacle-type connectors for mobile battery-powered equipment. The final rule revises and updates the existing regulation by allowing the use of alternate locking devices to secure battery plugs to receptacles. Two alternate locking devices are addressed in this final rule:

(1) Captive locking devices requiring use of a special tool. These devices have been accepted since 1987 under an MSHA policy allowing their usage.

(2) Spring-loaded or other locking devices. Spring-loaded locking devices have been accepted by MSHA under the 101(c) Petition for Modification process.

The final rule eliminates the need to file petitions for modification (PFM) to use spring-loaded locking devices to secure battery plugs to receptacles. It also codifies the 1987 MSHA policy of allowing acceptance of captive locking devices.

Executive Order (E.O.) 12866 requires that regulatory agencies assess both the costs and benefits of intended regulations. MSHA has fulfilled this requirement for this final rule, and based upon its economic analysis, has determined that the final rule will not have an annual effect of $100 million or more on the economy. Therefore, it will not be an economically significant regulatory action pursuant to section 3(f)(1) of E.O. 12866.

The final rule eliminates the need for mine operators of underground gassy mines, who choose to use plug and receptacle-type connectors for mobile battery-powered equipment, to file PFMs, and thereby will generate cost savings.

From 1999 to 2001, 66 petitions were filed and granted to modify the application of 30 CFR 75.503 (permissible electric face equipment; maintenance) and 30 CFR 18.41(f) (plug and receptacle-type connectors). From January 2002 through November 20, 2002, 23 petitions have been filed, for a total of 89 filed petitions from 1999 to 2002. On average, 22 petitions were filed during each of the past 4 years.

Mining Sectors Affected

The final rule applies to all underground gassy mines. All underground coal mines are considered gassy mines and are affected by this final rule. This final rule also applies to gassy metal and nonmetal (M/NM) mines. Currently there are no battery-powered machines of the type covered by the final rule in any of the gassy M/NM mines. Since these devices have not been used in M/NM mines, for purposes of this economic analysis, MSHA assumes that M/NM mines will not be affected by this rule. MSHA estimates that, on average, 22 underground coal mines per year will be affected by this rule.

Benefits

MSHA has qualitatively determined that the final rule, which will permit the use of alternate locking devices on mobile battery-powered equipment instead of using padlocks, will yield safety benefits relative to the existing rule, which does not permit use of alternate locking devices on mobile battery-powered equipment. The use of alternate locking devices in lieu of padlocks on mobile battery-powered equipment will eliminate the problems associated with difficult removal of padlocks.

Compliance Costs

Cost savings from the final rule will accrue to underground coal mines that choose to use spring-loaded locking devices on mobile battery-powered equipment since they will no longer have to file a PFM.

Gross cost savings from the final rule are estimated to be $9,747 per year.

The cost savings are based upon the elimination of the filing of an average of 22 petitions per year. The companies filing the petitions may own more than one mine. However, cost savings associated with elimination of the petition process are assumed not to depend on the number of mines at which the petitioned modification will be implemented. It is projected that of the 22 companies, 19 will employ 20 to 500 workers, and 3 will employ fewer than 20 workers. For the 3 companies that employ fewer than 20 workers these cost savings will be $1,329. For the remaining 19 companies that employ 20 to 500 workers the cost savings will be $8,418.

Mines Employing Fewer Than 20 Workers

The cost savings of $1,329 for companies employing fewer than 20 workers are derived in the following manner. On average, a mine supervisor, earning $54.92 per hour, takes 8 hours to prepare a petition (3 petitions × 8 hours × $54.92 per hour = $1,318). In addition, a clerical worker, earning $19.58 per hour, takes 0.1 hours to copy and mail a petition (3 petitions × 0.1 hours × $19.58 per hour = $6). Furthermore, MSHA estimates that, on average, each petition is 5 pages long, photocopying costs are $0.15 per page, and postage is $1 [3 petitions × ((5 pages × $0.15 per page) + $1) = $5].

Mines Employing 20 to 500 Workers

The cost savings of $8,418 for companies that employ 20 to 500 workers are derived in the following manner. On average, a mine supervisor, earning $54.92 per hour, takes 8 hours to prepare a petition (19 petitions × 8 hours × $54.92 per hour = $8,348). In addition, a clerical worker, earning $19.58 per hour, takes 0.1 hours to copy and mail a petition (19 petitions × 0.1 hours × $19.58 per hour = $37). Furthermore, MSHA estimates that, on average, each petition is 5 pages long, photocopying costs are $0.15 per page, and postage is $1 [19 petitions × ((5 pages × $0.15 per page) + $1) = $33].

Net Compliance Costs

As described below, the gross cost savings every year of $9,747 will be slightly offset by additional costs of $808 in the first year the rule takes effect. The costs are influenced by the number of mines per petition that adopt the modification. MSHA assumes that 1.4 mines per petition adopt the modification. MSHA estimates that 18 petitioners, or 25 mines (18 petitions × 1.4 mines/petition), that were approved to have alternate locking devices through the petition process but were not required to have warning tags would have to install these tags, costing $8 each, during the first year. The agency assumes that there are, on average, 1.4 mines per petition, two machines per mine, and two warning tags per machine (there are typically two connectors per machine with each requiring a warning tag). The agency estimates the total cost for warning tags would be $808 [(18 petitions × 1.4 mines/petition × 2 machines/mine × 2 warning tags/machine) or 101 tags @ $8 each]. The agency assumes that the cost for warning tags will be borne by 3 mines with fewer than 20 employees and by 22 mines with 20 to 500 employees. Thus, the cost of installing tags will be $112 for mines with fewer than 20 employees and $696 for mines with 20 to 500 employees.

Net benefits for the first year will be $8,939. Assuming that the first year cost for warning tags of $808 is annualized over the life of the alternate locking devices, the annualized costs for the warning tags will be $57 ($808 × .07, where .07 is the annualization factor for an investment with a 7 percent discount rate and an infinite life). Therefore, the yearly net benefits will be $9,690 ($9,747 − $57).

There are no substantive changes to this final rule that apply to any mine that chooses not to use alternate locking devices on mobile battery-powered equipment. Thus, these mines will not incur costs or generate cost savings as a result of the final rule.

V. Regulatory Flexibility Act Certification

Pursuant to the Regulatory Flexibility Act (RFA) of 1980 as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), MSHA has analyzed the impact of the final rule on small businesses. Further, MSHA has made a determination with respect to whether or not the Agency can certify that the final rule will not have a significant economic impact on a substantial number of small entities that are covered by these rulemakings. Under SBREFA amendments to the RFA, MSHA must include in the rule a factual basis for this certification. If the final rule will have a significant economic impact on a substantial number of small entities, then the Agency must develop an initial regulatory flexibility analysis.

Definition of a Small Mine

Under the RFA, in analyzing the impact of a rule on small entities, MSHA must use the SBA definition for a small entity or, after consultation with the SBA Office of Advocacy, establish an alternative definition for the mining industry by publishing that definition in the **Federal Register** for notice and comment. MSHA has not taken such an action, and hence is required to use the SBA definition.

The SBA defines a small entity in the mining industry as an establishment with 500 or fewer employees (13 CFR 121.201). All of the mines affected by this rulemaking fall into this category and hence can be viewed as sharing the special regulatory concerns which the RFA was designed to address.

Traditionally, the Agency has also looked at the impacts of its rules on a subset of mines with 500 or fewer employees—those with fewer than 20 employees, which the mining community refers to as ''small mines.'' These small mines differ from larger mines not only in the number of employees, but also, among other things, in economies of scale in material produced, in the type and amount of production equipment, and in supply inventory. Therefore, their costs of complying with MSHA rules and the impact of MSHA rules on them will also tend to be different. It is for this reason that ''small mines,'' as traditionally defined by the mining community, are of special concern to MSHA.

This analysis complies with the legal requirements of the RFA for an analysis of the impacts on ''small entities'' while continuing MSHA's traditional look at ''small mines.'' MSHA concludes that it can certify that the final rule will not have a significant economic impact on a substantial number of small entities that are covered by this rulemaking. The Agency has determined that this is the case both for mines covered by this rulemaking with fewer than 20 employees and for mines covered by this rulemaking with 500 or fewer employees.

Factual Basis for Certification

The Agency's analysis of impacts on ''small entities'' begins with a ''screening'' analysis. The screening compares the estimated compliance costs of a rule for small entities in the sector affected by the rule to the estimated revenues for those small entities. When estimated compliance costs are less than one percent of the estimated revenues, or they are negative (that is, they provide a cost savings), the Agency believes it is generally appropriate to conclude that there is no significant economic impact on a substantial number of small entities. When estimated compliance costs exceed one percent of revenues, it tends to indicate that further analysis may be warranted. Using either MSHA's or SBA's definition of a small mine, the final rule will result only in cost savings to affected mines. Therefore, the final rule will not have a significant economic impact on a substantial number of small entities using either MSHA's or SBA's definition of a small mine.

VI. Paperwork Reduction Act of 1995

The final amendments to 30 CFR 18.41(f) will not introduce any new paperwork requirements that are subject to OMB approval under the Paperwork Reduction Act. In addition, the third-party disclosure requirements for 30 CFR 18.41(f)(2) and (3) are not considered a ''collection of information'' because the standard provides language for warning tags (*see* 5 CFR 1320.3(c)(2)). Although MSHA is providing language to be used on the warning tag, MSHA is also providing operators some flexibility by allowing alternative language that meets the intent of the provided language.

As a result of the final rule, the number of petitions for modification filed annually related to battery plugs will be reduced. Therefore, the final rule will result in reducing burden hours and costs in the ICR 1219–0065 paperwork package, which concerns the filing of petitions for modification.

The final rule will result in 178.2 burden hour savings annually and associated annual burden cost savings of $9,709 related to the elimination of 22 petitions annually for alternate locking devices to secure battery plugs to receptacles. Of this total, for the 3 mines that employ fewer than 20 workers, there will be 24.3 burden hour savings annually and associated annual burden cost savings of $1,324. For the 19 mines that employ 20 to 500 workers, there will be 153.9 burden hour savings annually and associated annual burden cost savings of $8,385.

Mines Employing Fewer Than 20 Workers

The annual reduction of 24.3 burden hours and the $1,324 cost savings that will occur for the 3 mines that employ fewer than 20 workers are derived in the following manner. On average, a mine supervisor takes 8 hours to prepare a petition (3 petitions × 8 hours = 24 hours). In addition, on average, a clerical worker takes 0.1 hours, 6 minutes, to copy and mail a petition (3 petitions × 0.1 hours = 0.3 hours). The hourly wage rate for a mine supervisor is $54.92 ($54.92 × 24 burden hours = $1,318.10). The hourly wage rate for a clerical worker is $19.58 ($19.58 × 0.3 burden hours = $5.90).

Mines Employing 20 to 500 Workers

The annual reduction of 153.9 burden hours and the $8,385 cost savings that will occur for the 19 mines that employ 20 to 500 workers are derived in the following manner. On average, a mine supervisor takes 8 hours to prepare a petition (19 petitions × 8 hours = 152 hours). In addition, on average, a clerical worker takes 0.1 hours, 6 minutes, to copy and mail a petition (19 petitions × 0.1 hours = 1.9 hours). The hourly wage rate for a mine supervisor is $54.92 ($54.92 × 152 burden hours = $8,347.84). The hourly wage rate for a clerical worker is $19.58 ($19.58 × 1.9 burden hours = $37.20).

VII. Other Regulatory Considerations

A. Unfunded Mandates Reform Act of 1995 and Executive Order 12875 (Enhancing the Intergovernmental Partnership)

For purposes of the Unfunded Mandates Reform Act of 1995, as well as E.O. 12875, the final rule will not include any Federal mandate that might result in increased expenditures by State, local, or tribal governments, or increased expenditures by the private

sector of more than $100 million. MSHA is not aware of any State, local, or tribal government that either owns or operates underground coal mines.

B. Executive Order 12630 (Governmental Actions and Interference With Constitutionally Protected Property Rights)

The final rule is not subject to Executive Order 12630 because it does not involve implementation of a policy with takings implications.

C. Executive Order 12988 (Civil Justice Reform)

MSHA has reviewed Executive Order 12988 and determined that the final rule will not unduly burden the Federal court system. The Agency wrote the final rule to provide a clear legal standard for affected conduct and has reviewed it carefully to eliminate drafting errors and ambiguities.

D. Executive Order 13045 (Health and Safety Effect on Children)

In accordance with Executive Order 13045, MSHA has evaluated the environmental health and safety effects of the final rule on children and has determined that it will have no adverse effects on children.

E. Executive Order 13132 (Federalism)

MSHA has reviewed the final rule in accordance with Executive Order 13132 regarding federalism and has determined that it will not have federalism implications.

F. Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments)

MSHA certifies that the final rule will not impose substantial direct compliance costs on Indian tribal governments.

G. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, MSHA has reviewed the final rule and has determined that it will have no adverse effect on the production or price of coal. Consequently, it will have no significant adverse effect on the supply, distribution, or use of energy, and no reasonable alternatives to this action are necessary.

H. Executive Order 13272 (Proper Consideration of Small Entities in Agency Rulemaking)

In accordance with Executive Order 13272, MSHA has thoroughly reviewed the final rule to assess and take appropriate account of its potential impact on small businesses, small governmental jurisdictions, and small organizations. As discussed in section V in this preamble, MSHA has determined that the final rule will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 30 CFR Part 18

Mine Safety and Health, Underground mining.

Dated: June 13, 2003.

John R. Caylor,

Deputy Assistant Secretary for Mine Safety and Health.

■ For the reasons set out in the preamble, and under the authority of the Federal Mine Safety and Health Act of 1977, we are amending chapter I, subpart B, part 18 of title 30 of the Code of Federal Regulations as follows:

PART 18—ELECTRIC MOTOR-DRIVEN MINE EQUIPMENT AND ACCESSORIES

■ 1. The authority citation for part 18 continues to read as follows:

Authority: 30 U.S.C. 957, 961.

Subpart B—[AMENDED]

■ 2. Paragraph (f) of § 18.41 is revised to read as follows:

§ 18.41 Plug and receptacle-type connectors.

* * * * *

(f) For a mobile battery-powered machine, a plug and receptacle-type connector will be acceptable in lieu of an interlock provided:

(1) The plug is padlocked to the receptacle and is held in place by a threaded ring or equivalent mechanical fastening in addition to a padlock. A connector within a padlocked enclosure will be acceptable; or,

(2) The plug is held in place by a threaded ring or equivalent mechanical fastening, in addition to the use of a device that is captive and requires a special tool to disengage and allow for the separation of the connector. All connectors using this means of compliance shall have a clearly visible warning tag that states: ''DO NOT DISENGAGE UNDER LOAD,'' or an equivalent statement; or,

(3) The plug is held in place by a spring-loaded or other locking device, that maintains constant pressure against a threaded ring or equivalent mechanical fastening, to secure the plug from accidental separation. All connectors using this means of compliance shall have a clearly visible warning tag that states: ''DO NOT DISENGAGE UNDER LOAD,'' or an equivalent statement.

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DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 71 and 75

RIN 1219–AA98 (Phase 9)

Standards for Sanitary Toilets in Coal Mines

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Final rule.

SUMMARY: This final rule removes the application requirement and associated paperwork burden for approval of sanitary toilets in underground and surface coal mines. The final rule provides notice to miners, miners' representatives, mine operators, MSHA compliance specialists, and manufacturers of which sanitary toilets are approved without requiring applications for approval. The rule has no substantive effect on the sanitation standards. The types of approved toilets are drawn from the American National Standards Institute (ANSI) *American National Standard for Sanitation—Nonsewered Waste-Disposal Systems—Minimum Requirements* upon which MSHA and the National Institute for Occupational Safety and Health (NIOSH) previously based approval of applications.

DATES: This final rule is effective July 23, 2003.

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SUPPLEMENTARY INFORMATION:

I. Purpose and Scope of Rulemaking

The Office of Management and Budget's (OMB's) current approval for §§ 71.500 and 75.1712–6 under control number 1219–0101 expires on November 30, 2003. OMB approval was contingent upon MSHA initiating rulemaking ''to update and simplify this standard with the goal of eliminating unnecessary requirements and reducing the unnecessary burdens.'' In response to OMB concerns, MSHA published a direct final rule (68 FR 19347) and a companion proposed rule (68 FR 19477) on April 21, 2003 to eliminate the