effectiveness of these medical devices must be demonstrated.

FDA believes that the comments presented insufficient information on which to base special controls that could assure safety and effectiveness. The agency concludes that its proposed findings and its conclusion discussed in the preamble to the proposed rule are appropriate. Accordingly, FDA is issuing a final regulation requiring premarket approval of the CES under section 515(b)(3) of the act.

III. Final Rule

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the preamble to the proposed rule and is issuing this final rule to require premarket approval of the generic type of device, the cranial electrotherapy stimulator device, by revising § 882.5800(c).

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed with FDA within 90 days of the effective date of this regulation for any CES device that was in commercial distribution before May 28, 1976, or any device that FDA has found to be substantially equivalent to such a device on or before November 22, 1995. An approved PMA or declared completed PDP is required to be in effect for any such device on or before 180 days after FDA files the application. Any other CES device that was not in commercial distribution before May 28, 1976, or that FDA has not found, on or before November 22, 1995, to be substantially equivalent to a CES device that was in commercial distribution before May 28, 1976, is required to have an approved PMA or declared completed PDP or declared completed in effect before it may be marketed.

If a PMA or notice of completion of a PDP for a CES device is not filed on or before November 22, 1995, that device will be deemed adulterated under section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)), and commercial distribution of the device will be required to cease immediately. The device may, however, be distributed for investigational use, if the requirements of the investigational device exemption (IDE) regulations (21 CFR part 812) are met.

Under § 812.2(d) (21 CFR 812.2(d)) of the IDE regulations, FDA hereby stipulates that the exemptions from the IDE requirements in § 812.2(c)(1) and (c)(2) will no longer apply to clinical investigations of the CES device. Further, FDA concludes that investigational CES devices are significant risk devices as defined in § 812.3(m) and advises that as of the effective date of § 882.5800(c), requirements of the IDE regulations regarding significant risk devices will apply to any clinical investigation of a CES device. For any CES device that is not subject to a timely filed PMA or notice of completion of a PDP or notice of completion of a PDP, an IDE must be in effect under § 812.20 on or before November 22, 1995, or distribution of the device for investigational purposes must cease. FDA advises all persons currently sponsoring a clinical investigation involving the CES device to submit an IDE application to FDA no later than October 23, 1995, to avoid the interruption of ongoing investigations.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) and (e)(4) 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.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because PMA's for this device could have been required by FDA as early as March 4, 1982, and because firms that distributed this device prior to May 28, 1976, or whose device has been found to be substantially equivalent to the CES in commercial distribution before May 28, 1976, will be permitted to continue marketing cranial electrotherapy stimulators during FDA's review of the PMA or notice of completion of the PDP, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR Part 882

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 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 882.5800 is amended by revising paragraph (c) to read as follows:

§ 882.5800 Cranial electrotherapy stimulator.

* * * * *

(c) *Date a PMA or notice of completion of a PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 22, 1995, for any cranial electrotherapy stimulator that was in commercial distribution before May 28, 1976, or that has on or before November 22, 1995, been found to be substantially equivalent to the cranial electrotherapy stimulator that was in commercial distribution before May 28, 1976. Any other cranial electrotherapy stimulator shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: July 31, 1995.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 95–20960 Filed 8–23–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1952

Approved State Plans for Enforcement of State Standards; Approval of Supplements to the Nevada State Plan

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Approval of supplements to the Nevada State Plan.

SUMMARY: This document gives notice of Federal approval of supplements to the Nevada State occupational safety and health plan. These supplements are: Nevada's procedure for issuance of notices of violation in lieu of citations in certain situations; amendments to the Nevada Occupational Safety and Health Act enacted in 1981, 1989 and 1993; the Nevada Field Operations Manual; the Nevada Training and Consultation Section Policies and Procedures Manual; the Nevada Occupational Safety and Health Administration Technical Manual; and a regulation concerning pre-construction conferences.

EFFECTIVE DATE: August 24, 1995.

FOR FURTHER INFORMATION CONTACT: Director, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, Room N3647, 200 Constitution Avenue, N.W., Washington, D.C. 20210. Telephone: (202) 523–8148.

SUPPLEMENTARY INFORMATION:

Background

The Nevada Occupational Safety and Health Plan was approved under section 18(c) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667(c)) (hereinafter referred to as the Act) and Part 1902 of this chapter on January 4, 1974 (39 FR 1008). Part 1953 of this chapter provides procedures for the review and approval of State change supplements by the Assistant Secretary of Labor for Occupational Safety and Health (hereinafter referred to as the Assistant Secretary).

Description of Supplements

A. Notices of Violation

On October 29, 1980, the State submitted a procedure for issuing notices of violation in lieu of citations for certain other than serious violations. In order to expedite inspections and concentrate resources on serious violations, compliance officers may issue notices of violation for other than serious violations for which monetary penalties would not be proposed. If the employer agrees to abate the violation and not to file a contest, the compliance officer will issue the notice on-site. For serious, willful, repeat and/or failure to abate violations, citations continue to be issued in accordance with established procedures.

Review of the supplement raised several issues which needed to be resolved before approval of the notice of violation procedure. Because the Nevada Occupational Safety and Health Act required that citations be issued where violations were identified, statutory authority for issuance of notices was necessary. In 1981, § 618.465(1)(b) was added to the State's law, allowing for a notice in lieu of a citation for violations which are not serious and which the employer agrees to correct within a reasonable time.

There was also concern that a notice be able to serve as the basis for a future willful, repeat, or failure to abate citation, and that documentation of the violations for which the notice was issued be adequate to serve as the basis for such a citation. The State amended its enforcement regulations to provide that for future proceedings involving a repeat, willful, or failure to abate violation, the notice of violation shall have the same effect as if a citation has originally been issued and become a final order (section 618.6458(9)) and that notices of violations contain all the provisions required for citations (section 618.6458(6)). In addition, the State was asked to ensure that if it is learned following the inspection that a violation for which a notice of violation has been issued is actually a repeat violation, a citation for a repeat violation would be issued. Section 618.6458 of the State's enforcement regulations now provides that a citation may be issued even if a notice has already been issued, and the State's Field Operations Manual directs the compliance officer to check for previous violations upon returning to the office. Finally, the right of employees to contest the reasonableness of the abatement period needed to be established. The State's enforcement regulations (§ 618.6458(6)) now provide that the notice shall inform employees of their right to contest the abatement period. Based on these changes made by the State, the notice of violation procedure is now deemed approvable.

B. Amendments to Nevada Occupational Safety and Health Act

In 1981, 1989 and 1993, the State enacted amendments to its Occupational Safety and Health Act. The 1981 amendments, submitted as a plan supplement on July 10, 1981, made the following changes:

(1) As discussed above, § 618.465(1)(b) was added to allow the State to issue a notice in lieu of a citation for violations which are not serious and which the employer agrees to correct within a reasonable time.

(2) Section 618.415 was revised to delete the legislative authority for temporary variances for other than new standards. As in the Federal program, temporary variances may now only be granted from new standards.

(3) Section 618.585(2) was added to allow the Nevada Occupational Safety and Health Appeals Board to employ legal counsel.

(4) Section 618.625(3) was amended to streamline penalty collection procedures by allowing collection actions to be brought in any court of competent jurisdiction, rather than only the district court.

(5) Section 618.367 was amended to ensure confidentiality to employees making statements to the Division of Occupational Safety and Health, as well as those filing complaints. This section was extensively revised in 1989, as discussed below.

The 1989 amendments, submitted as a plan supplement on October 17, 1989, made the following changes:

(1) Section 618.336 requires the maintenance of specific logs relating to complaints received concerning occupational safety and health violations and their outcomes.

(2) Section 618.341 provides public access to records on complaints, except for confidential information.

(3) Section 618.341(3) provides confidentiality for those employees who file complaints or make statements, even when confidentiality is not specifically requested, as well as for files relating to open cases.

(4) Section 618.370 was amended to clarify that representatives of employees and former employees are entitled to access to any records in the possession of their employers or former employers which indicate their exposure to toxic materials or harmful physical agents. ''Representative of an employee or former employee'' is defined as an authorized representative of the employee bargaining unit, an attorney, a spouse, parent or child, or a person designated by a court.

(5) Section 618.425 was amended to add health care providers, and government employees whose primary duty is to ensure public safety, such as building inspectors, to those who may file complaints of hazardous working conditions.

(6) Section 618.425 was also amended to allow for oral as well as written complaints, and to require the division to respond to valid complaints of serious violations immediately and of other violations within 14 days.

(7) Section 618.435 provides that an employee who accompanies a compliance officer on the inspection is entitled to be paid for the time spent, but that only one employee may accompany the compliance officer during the inspection.

(8) Section 618.545 was amended to allow the Administrator of the Nevada Division of Occupational Safety and

Health to issue an emergency order to restrain an imminent danger situation.

(9) All maximum monetary penalties in sections 618.645 through 618.705 were doubled. At the time of their enactment, these statutory penalty levels were higher than those contained in the Federal Act. (In 1991, statutory maximum penalties for violations of the State Act were raised again. That increase was approved by OSHA on March 15, 1994 (59 FR 14556).)

The 1993 amendments, submitted on October 27, 1993, reflect a reorganization of the Nevada State government. The previous Division of Enforcement for Industrial Safety and Health and Division of Preventive Safety are now sections in the Division of Industrial Relations of the Department of Business and Industry.

C. Field Operations Manual

On December 14, 1989, Nevada submitted its Field Operations Manual in response to a revised Federal Field Operations Manual (CPL 2.45B). The State has submitted revisions to this manual on May 31, 1991, July 5, 1991, December 15, 1992 and June 13, 1994, in response to Changes 1 through 4 of the Federal manual. The Nevada Field Operations Manual is comparable to the Federal manual and has been found to be at least as effective as the Federal manual.

D. Consultation Manual

On August 12, 1987, the State submitted its Training and Consultation Section Policies and Procedures Manual. This manual includes previously approved sections of the State's Field Operations Manual on the conduct of consultation visits to employers. In addition, it incorporates chapters on safety and health program assistance and training by consultants which are nearly identical (with organization changes and adapted to the State's program structure) to Part I of the Federal Consultation Policies and Procedures Manual.

E. Industrial Hygiene Technical Manual

On March 30, 1990, the State submitted notice of its adoption of the Federal OSHA Technical Manual. The State has incorporated a cover sheet indicating that the Federal manual has been adopted for State use, how references to the Federal program in the Federal manual correspond to the State administrative structure, and how it will be applied. In addition, on March 6, 1991, June 22, 1993 and December 16, 1994, the State submitted notice of its adoption of Changes 1, 2 and 3 to the Technical Manual. These changes also incorporate updates to the Federal manual, with appropriate changes to apply to the State's organizational structure.

F. Pre-construction Conferences

On August 20, 1993, Nevada submitted a temporary regulation requiring pre-construction conferences with the Division of Industrial Relations for certain types of construction projects including high rise, structural steel erection, precast concrete erections, cast in place structures above ground level, and tilt-up wall construction. At the conference, the contractor will identify those safety measures which will be utilized to protect employees working on the project. On September 8, 1994, Nevada submitted permanent regulations covering pre-construction conferences.

G. Revised Plan

On October 2, 1992, Nevada submitted a reorganized State plan, incorporating the plan supplements approved herein as well as previously approved plan changes and other supplements still under review.

H. Other Submissions

In addition, on October 17, 1989, the State submitted legislation enacted in 1989 and implementing regulations concerning the licensing and registration of asbestos removal projects. The new procedures require any contractor engaging in asbestos removal work to be licensed by the Division of Occupational Safety and Health and to meet certain training and work practice requirements. The licensing program is administered separately from the Division's occupational safety and health enforcement program. While these provisions are not part of the State plan, and thus activities pursuant to them are not eligible for funding under section 23(g) of the Act, OSHA will monitor these activities to ensure that they do not detract from the State's ability to meet its commitments under the plan.

Location of Supplements for Inspection and Copying

A copy of the plan and the supplements may be inspected and copied during normal business hours at the following locations: Office of the Regional Administrator, Occupational Safety and Health Administration, Room 415, 71 Stevenson Street, San Francisco, California 94105; Director, Division of Occupational Safety and Health, Nevada Division of Industrial Relations, 1370 South Curry Street, Carson City, Nevada 89710; and the Office of the Director of Federal-State Operations, Room N3700, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Public Participation

A notice was published on April 3, 1981 (46 FR 20229), announcing the submission of the Nevada program for issuance of notices of violation. Interested persons were afforded 30 days to submit written comments or request a hearing concerning the supplement. One comment favoring the program was received.

With regard to the other supplements, under § 1953.2(c) of this chapter, the Assistant Secretary may prescribe alternative procedures to expedite the review process or for any other good cause which may be consistent with applicable law. The Assistant Secretary finds that the legislative amendments, Field Operations Manual, Consultation Manual, Industrial Hygiene Technical Manual and regulations concerning pre-construction conferences are consistent with Federal requirements and with commitments contained in the plan and previously made available for public comment. Good cause is therefore found for approval of these supplements, and further public participation would be unnecessary.

Decision

After careful consideration and extensive review by the Regional and National Offices, the Nevada plan supplements described above are found to be in substantial conformance with comparable Federal provisions and are hereby approved under Part 1953 of this chapter. The decision incorporates the requirements and implementing regulations applicable to State plans generally.

List of Subjects in 29 CFR Part 1952

Intergovernmental relations, Law enforcement, Occupational safety and health.

Signed at Washington, D.C., this 11th day of August, 1995.

Joseph A. Dear,

Assistant Secretary.

Accordingly, 29 CFR Part 1952 is hereby amended as follows:

PART 1952—[AMENDED]

The authority citation for Part 1952 continues to read:

Authority: Secs. 8, 18 Pub. L. 91–596, 84 Stat. 1608 Occupational Safety and Health Act of 1970 (29 U.S.C. 657, 667); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), or 9–83 (48 FR 35736), as applicable.

2. Paragraphs (b) through (h) are added to § 1952.297 of Subpart W to read as follows:

§ 1952.297 Changes to approved plans.

* * * * *

(b) *Notices of violation*. The State submitted a procedure for issuing notices of violation in lieu of citations for certain other than serious violations which the employer agrees to abate. The procedure as modified was approved by the Assistant Secretary on August 24, 1995.

(c) *Legislation*. The State submitted amendments to its Occupational Safety and Health Act, enacted in 1981, which: provide for notices of violation in lieu of citations for certain other than serious violations; delete the authority for temporary variances for other than new standards; allow the Nevada Occupational Safety and Health Appeals Board to employ legal counsel; allow penalty collection actions to be brought in any court of competent jurisdiction; and ensure confidentiality to employees making statements to the Division of Occupational Safety and Health. Further amendments, enacted in 1989: require the maintenance of specific logs relating to complaints; provide public access to records on complaints, except for confidential information; provide confidentiality for those employees who file complaints or make statements, as well as for files relating to open cases; allow representatives of employees and former employees access to any records which indicate their exposure to toxic materials or harmful physical agents; define representative of employees or former employees; allow health care providers and government employees in the field of public safety, to file complaints; allow for oral complaints; require the division to respond to valid complaints of serious violations immediately and of other violations within 14 days; provide that an employee who accompanies a compliance officer on the inspection is entitled to be paid for the time spent, but that only one employee may accompany the compliance officer during the inspection; allow the Administrator of the Division of Occupational Safety and Health to issue an emergency order to restrain an imminent danger situation; and, double maximum authorized penalty levels. Amendments enacted in 1993 reflect the new State organizational structural by designating the previous Divisions as sections in the Division of Industrial Relations of the Department of Business and Industry. The Assistant Secretary approved these amendments on August 24, 1995.

(d) *Field Operations Manual*. The State's Field Operations Manual, comparable to the Federal Field Operations Manual, through Change 4, was approved by the Assistant Secretary on August 24, 1995.

(e) *Consultation Manual*. The State's Training and Consultation Section Policies and Procedures Manual was approved by the Assistant Secretary on August 24, 1995.

(f) *Occupational Safety and Health Administration Technical Manual*. The State's adoption of the Federal OSHA Technical Manual, through Change 3, with a cover sheet adapting Federal references to the State's administrative structure, was approved by the Assistant Secretary on August 24, 1995.

(g) *Pre-construction conferences*. A State regulations requiring pre-construction conferences with the Division of Industrial Relations for certain types of construction projects was approved by the Assistant Secretary on August 24, 1995.

(h) *Reorganized Plan*. The reorganization of the Nevada plan was approved by the Assistant Secretary on August 24, 1995.

[FR Doc. 95–20863 Filed 8–23–95; 8:45 am]

BILLING CODE 4510–26–M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 925

Missouri Abandoned Mine Land (AML) State Reclamation Plan

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Missouri AML State Reclamation Plan (hereinafter referred to as the ''Missouri plan'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Missouri proposed changes to its statutes, rules, and certain sections of the Missouri plan pertaining to contractor responsibility, exclusion of certain noncoal reclamation sites, reporting requirements, creation of a future reclamation set-aside program, and general reclamation requirements. The amendment is intended to revise the Missouri plan to be consistent and in compliance with the corresponding Federal standards, and to improve operational efficiency.

EFFECTIVE DATE: August 24, 1995.

FOR FURTHER INFORMATION CONTACT: Robert L. Markey, Acting Director, Kansas City Field Office, 934 Wyandotte St., Room 500, Kansas City, Missouri 64105, Telephone: (816) 374–6405.

SUPPLEMENTARY INFORMATION:

I. Background on Title IV of SMCRA

Title IV of SMCRA established an abandoned mine land reclamation (AMLR) program for the purpose of reclaiming and restoring lands and waters adversely affected by past mining. The Secretary of the Interior adopted regulations at 30 CFR 870 through 888 that implement Title IV of SMCRA. The program is funded by a reclamation fee levied on the production of coal.

Title IV provides for State submittal to OSM of an AMLR plan. The Federal regulations at 30 CFR Part 884 specify the content requirements of a State reclamation plan and the criteria for plan approval. Under these regulations, the Secretary reviewed the plans submitted by States and solicited and considered comments of State and Federal agencies and the public. Based upon the comments received, the Secretary determined whether a State had the ability and necessary legislation to implement the provisions of Title IV. After making such a determination, the Secretary decided whether to approve the State program. Approval granted the State exclusive authority to administer its plan. Upon approval of a State plan by the Secretary, the State may submit to OSM, on an annual basis, an application for funds to be expended by that State on specific projects that are necessary to implement the approved plan. Such annual requests are reviewed and approved by OSM in accordance with the requirements of 30 CFR part 886.

The Federal regulations at 30 CFR 884.15 provide that a State may submit to OSM a proposed amendment or revision to its approved reclamation plan. If the amendment or revision changes the objective, scope, or major policies followed by the State in the conduct of its reclamation program, the Director must follow the procedures set out in 30 CFR 884.14 for approval or disapproval of an amendment or revision to the State's AML plan.

Title IV of SMCRA, as enacted in 1977, provided that lands and waters eligible for reclamation were those that were mined or affected by mining and abandoned or inadequately reclaimed prior to August 3, 1977, and for which there was no continuing reclamation responsibility under State, Federal, or